The assessment and treatment of sub-acute hand oedema after trauma or surgery.

A thesis submitted for the degree of Doctor of Philosophy (PhD)

by

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March 2019

Word count: 67,224

Declaration

I certify that the work contained in this thesis, for the degree of Doctor of Philosophy, is my original work except where due reference is made to other authors, and has not been previously submitted for a degree, diploma or other qualification at any university or institution.

This thesis does not exceed the work limit as stated in the UEA regulations for the degree of Doctor of Philosophy

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March 2019

Abstract

Background: Hand oedema (swelling) is a common consequence of hand trauma or surgery. However, there is no consensus on the best practice for assessment or management and a lack of high quality evidence. This programme of research aims to address this knowledge gap.

Methods: Systematic reviews were conducted on methods of assessing and treating hand oedema. An online survey established current practice of UK-based hand therapists. A subsequent Delphi with eight hand therapy experts led to consensus on a standardised oedema management programme. The relative responsiveness of two clinical and two patient-rated outcome measures were evaluated in an observational study. Finally, an assessor-blind pilot randomised controlled trial of kinesiology tape for sub-acute hand oedema tested the feasibility of methods, recruitment, adherence and acceptability of interventions.

Results: There was limited, low to moderate quality evidence to support the use of one of 16 oedema interventions described in the literature. The survey of current practice identified ‘standard care’ as comprising compression, elevation and massage. The Delphi established consensus on the dose, method and instructions for interventions. The volumeter was identified as the most responsive method of measuring hand oedema. Finally, the pilot RCT identified issues with recruitment and retention.

Conclusion: There is wide variation in the type and application of oedema treatments, and actual practice does not concur with best evidence. Manual oedema mobilisation may be applied in addition to conventional therapies in problematic oedema. However, this technique requires more consistent description. The volumeter is the most responsive measure for hand oedema, but the figure-of-eight tape should be considered as an alternative where immersion in water is not practical. The pilot trial confirmed that a definitive trial is warranted. However, strategies to maximise recruitment and retention in a full study need to be considered.

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Acknowledgements

With very special thanks to the NIHR, for seeing potential in me and this project and for agreeing to fund my fellowship. I feel heavily indebted to them for all the amazing opportunities that this fellowship has allowed me.

Despite having written over 60,000 in this thesis, I struggle to find the words to express my gratitude to my primary supervisor, Professor Christina Jerosch-Herold, for all her personal and professional support and guidance over the years. I aspire to be as knowledgeable, respected and internationally renowned as you one day. You truly are an inspiration to me and an incredible asset to the UEA, the profession of Occupational Therapy, and the specialism of hand therapy. I have learnt so much from you, and have felt extremely privileged to work for you, and with you over the past 10 years. Your faith in me has enabled me grow and develop, and I firmly believe that you have played a major role in shaping my future career. I only hope that I can pass on some of the knowledge and skills I have gained from you to other aspiring clinical researchers.

I would also like to thanks Professor Lee Shepstone, my secondary supervisor, for his expert advice on statistics. It has only taken me 4 years to finally be able to hold my own in a conversation with you about the stats in this thesis, and I cannot tell you how much of a buzz I got from that! Thank you both for your honesty and constructive feedback which has transformed this thesis over many iterations.

I would like to acknowledge the Norfolk and Norwich University Hospital and all the staff in the hand therapy department for helping to recruit patients to my studies, and for supporting me as I try to juggle a clinical career with a PhD. I hope I can ‘pay it forward’ when I start my new role as operation lead. Thank you also to colleagues in the Queen’s Building for their words of support over the years.

To my mum, for your unconditional love and belief in me. To my sister, Shelly for your support when my motivation was low and to Alexis and Indi, who, without even realising it, have spurred me on to achieve this goal. Finally, to my fiancé Ben, for your patience and your support as I selfishly pursue this academic dream.

Relevant publications and presentations

Conference oral presentations

Miller L, Jerosch-Herold, Shepstone L. Does kinesiology tape reduce oedema after injury or surgery*? Annual Conference of the British Association of Hand Therapists, Birmingham, UK, November 2018*

Miller L, Jerosch-Herold, Shepstone L. Methods for clinically assessing hand oedema: a systematic review. *Annual Conference of the British Association of Hand Therapists, Norwich, UK, November 2017*

Miller L, Jerosch-Herold C, Shepstone L. Effectiveness of Edema Management Techniques for Sub-Acute Hand Edema: A Systematic review**.** *Annual Conference of the British Association of Hand Therapists, Liverpool, UK, November 2015*

Conference poster presentations

Miller L, Jerosch-Herold C, Shepstone L. Does kinesiology tape reduce oedema after injury or surgery*?11th Triennial Congress of the International Federation for Societies of Hand Therapy (IFSHT)& 14th Congress of the International Federation of Societies for Surgery of the Hand (IFSSH), Berlin, Germany; June 2019*

Miller L, Jerosch-Herold C, Shepstone L. The Management of sub-acute hand oedema post trauma- an online survey and Delphi Consensus Method.*10th Triennial Congress of the International Federation of Societies for Hand Therapy (IFSHT)& 13th Congress of the International Federation of Societies for Surgery of the Hand (IFSSH), Buenos Aires, Argentina; October 2016*

Peer reviewed publications

Miller L, Jerosch-Herold C and Shepstone L. 2017. Effectiveness of edema management techniques for subacute hand edema: a systematic review. *Journal of Hand Therapy, 20, 432-446.*

Miller, L, Jerosch-Herold C and Shepstone L. 2017. Methods for clinically assesing hand oedema: a systematic review. *Hand Therapy, 22, 153-164.*

Abbreviations

AROM	Active Range of Motion
BAHT	British Association of Hand Therapists
CEC	Clinical Evidence Committee
CI	Chief Investigator
CI (95%)	Confidence Interval (95%)
CJH	Christina Jerosch-Herold- primary supervisor
CONSORT	Consolidated Standards of Reporting Trials
COSMIN	Consensus-based Standards for the Selection of Health Measurements Instruments
CPM	Continuous Passive Motion
CRN	Clinical Research Nurse
CVA	Cerebral Vascular Accident
CVI	Chronic Venous Insufficiency
DASH	Disabilities of the Arm, Shoulder and Hand
DNA	Did Not Attend
EBP	Evidence Based Practice
ES	Effect Size
EQ-5D-5L	EuroQol- 5 Dimensions
Fo8	Figure of Eight
GRADE	Grading of Recommendations, Assessment, Development and Evaluations
HR-PRO	Health Related- Patient Rated Outcome
HT	Hand Therapist
HVPC	High Velocity Pulsed Current
IRAS	Integrated Research Application System
ICC	Intraclass Correlation Coefficient
IPC	Intermittent Pulsed Current

ITT	Intention to Treat
IQR	Interquartile Range
LM	Leanne Miller
LS	Lee Shepstone- medical statistician and secondary supervisor
MHQ	Michigan Hand Questionnaire
MEM	Manual Edema Mobilisation (US spelling)
MOM	Manual Oedema Mobilisation (English spelling)
MLD	Manual Lymph Drainage
NIHR	National Institute for Health Research
NMS	Neuro Muscular Stimulation
HEP	Home Exercise Programme
ORIF	Open Reduction Internal Fixation
ORS	Oedema Rating Scale
OT	Occupational Therapist
PEM	Patient Evaluation Measure
PI	Principal Investigator
PIS	Participant Information Sheet
POP	Plaster of Paris
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analysis
PROM	Patient Rated Outcome Measure
PRWHE	Patient Rated Wrist and Hand Evaluation
PT	Physiotherapist
RCT	Randomized Controlled Trial
REC	Research Ethics Committee
RICE	Rest Ice Compression Elevation
SAE	Serious Adverse Events
SD	Standard Deviation
SDC	Smallest Detectable Difference

SEM	Standard Error of Mean
SEQES	Structured Effectiveness Quality Evaluation Scale
SR	Systematic Review
SRM	Standardised Response Mean
TAU	Treatment as Usual
TIDieR	Template for Intervention Description and Replication
TT	Trial Treatment
UK	United Kingdom
VAS	Visual Analogue Scale

Chapter 1 Introduction

This chapter will describe what oedema is and when it is likely to occur. It will introduce some of the key concepts surrounding hand oedema, and will discuss the multiple and complex challenges associated with research into this area. It will also set out the approach taken to this programme of research.

A hand which has reduced mobility and functional capacity following acute injury or post-surgery is likely to develop oedema. It is an abnormally large accumulation of interstitial fluid (Schmidt, 1989) which collects at the site of injury in the healing phase and can be slow to dissipate. In healthy tissue there is a balance between the vascular and lymphatic systems, therefore excessive tissue fluid is rare because arm movements create a force pushing fluid towards the axilla.

Following hand trauma or surgery, however, there is increased capillary filtration and reduced lymphatic drainage. Lack of normal limb movement and inactivity result in impaired venous return, which increases hydrostatic and capillary pressures. Whilst oedema is part of the normal inflammatory response (Villeco, 2012), its form alters over time, which has implications for how it is treated. In the primary inflammatory phase oedema is made up of water and dissolvable electrolytes, and it is soft and easy to mobilise. This type of oedema rarely causes adhesions, but can restrict range of motion. Basic first aid principles (RICE - rest-ice-compression-elevation) are sufficient to reduce this type of swelling (Newman, 1988, Pedretti and Zoltan, 1996). As swelling progresses to a sub-acute phase, the fluid is depleted in nutrients and has increased protein content, making it more viscous and resulting in inelasticity and thickening of the tissues. Clinically, this is where issues can arise and this is the focus of this research programme. To maximise restitution of the hand following trauma, it is paramount to control oedema effectively (Saunders, 1989).

From clinical experience, an oedematous hand loses flexibility, strength and precision with dexterous tasks, as the increased fluid can compress peripheral nerves, which act as the hand's sensory and motor communication channels. Oedema can be

aesthetically unsightly, distorting features of the hand. Prolonged oedema can cause fixed joint contractures, leading to loss of function and long-term disability. Where hand oedema is prolonged, a patient's recovery is delayed. This requires more frequent outpatient appointments, delays the patient's return to work and results in difficulties with daily activities, which have negative psychosocial and economic consequences.

There is no published data which highlights the extent of this problem. As the oedema is a secondary consequence to primary trauma, patients are categorised according to their presenting injury or surgery. This means that it is impossible to know the exact number of patients being treated for hand oedema. However, from clinical experience, the treatment of oedema is a core component of the hand therapist's management of patients with hand conditions.

Hand therapists need to establish the type and degree of oedema, the current status of oedema and decide on what assessment procedures to use (Palmada et al., 1998). This evaluation of the oedema helps to guide therapists to the most appropriate treatments, in order to reduce or prevent the potentially disabling secondary complications of oedema. No standardised diagnostic criteria or established grading scale exists for oedema, which leads to uncertainties regarding how clinicians identify, rate and document the presence and severity of hand oedema.

Furthermore, there is no consensus on specific timeframes for classifying oedema as acute, sub-acute or chronic. Some authors report the sub-acute phase starts at 2 weeks (Artzberger, 2002), others suggests it starts at day 3 post-injury or trauma (Villeco, 2011). If oedema persists after 2 weeks it is generally considered sub-acute (Artzberger, 2002). The point at which 'sub-acute' oedema becomes chronic, however, is also a contentious issue. Some authors state that oedema present beyond 12 weeks is classified as chronic (Artzberger, 2002), whereas others report timeframes in keeping with tissue healing and suggest the sub-acute phase lasts only until around the 6-week mark post- injury, depending on the extent of the wound (Flowers, 1995, Smith, 1995). Tissue healing is a complex process that can be divided into at least three continuous and overlapping phases. Whilst there will be some individual factors which influence the

healing process (comorbidities, smoking etc), it is impossible to put definitive time points on when one phase stops and the next starts (Li et al., 2007). It is useful to view phases of oedema in the same way as stages of tissue or wound healing, as it highlights that phases occur on a continuum, so timeframes are estimations and not absolute. The sub-acute phase of oedema would be akin to the fibroplastic or proliferation phase of tissue healing.

There are numerous methods employed to reduce oedema. These include traditional methods such as compression, elevation and massage, but also newer methods such as adherent elasticated tape (kinesiology tape). Whilst these may appear to be effective in a clinical setting, outcomes are often obtained from trial and error as there are currently no clinical practice guidelines, and little empirical evidence to support the use of oedema treatments currently utilised.

Interestingly, the proposed mode of action for kinesiology tape is in contrast to traditional methods, such as compression and massage. Traditional methods such as compression or massage generally use pressure, where the fluid is pushed proximally into the venous and lymphatic system (Palmada et al., 1998). Kinesiology tape does the opposite, lifting the skin to allow greater interstitial space and encouraging lymphatic drainage. The proposed skin drag and lifting mechanism of the tape would support the theory that pressure, via compression or massage, may be contraindicated when trying to assist lymphatic flow in the delicate superficial vessels. However, studies which have attempted to support the lifting action and skin drag of the tape have been unsuccessful (Parreira and Costa et al., 2014 and Yang and Lee 2018). Kinesiology tape has received much media coverage since the 2008 Beijing Olympic Games, where each participating country was issued with samples to use on their athletes. Since then it has been seen on high-profile sports people, and has been adopted for use in the NHS and private sector for a multitude of functions, including joint support, pain relief and lymphatic drainage. Its link with the sporting world has glamourised its use for medical or rehabilitation purposes. The tape’s bright colours and patterns have increased its

popularity amongst patients and clinicians, despite the limited evidence of its effectiveness.

Oedema treatments, which in clinical practice are often prescribed in conjunction with each other, have different proposed modes of action, for example gravity (elevation) (Villecoo 2012), stimulation of lymphatic system and mobilization of fluid (massage) (Artzberger and Priganc, 2011), tissue mobilisation (lift/drag) and stimulation of lymphatic vessels (kinesiology tape) (Kase et al., 2003). There is a lack of scientific corroboration of these proposed mechanisms of action, therefore comparing treatments in clinical trials, when the treatments themselves are not fully understood creates further uncertainties.

Another potential issue with oedema treatments is the variation in methods and how they are implemented. Furthermore, some methods may be contraindicated due to the primary trauma or surgery, which makes standardisation of oedema treatment problematic.

For these reasons, it is feasible to classify oedema management as a complex intervention. A complex intervention has been defined as an intervention which has several interacting components (Craig et al., 2008). Therapists often use a combination of modalities, including patient education, advice, physical therapies and medical devices, such as compression gloves, employed together in order to reduce hand oedema. In contrast, simple interventions are seen as having simple linear pathways linking the intervention with the outcome (Petticrew, 2011). However, so-called ‘simple interventions’ may have components or interactions which are not fully understood or even known, and this puts into question how accurate or helpful the term ‘simple’ is. When relating this to oedema management, it could mean simplistically viewing event A (using an oedema glove, for example) as causing effect B (a reduction in oedema). As an oedema glove is often prescribed alongside limb elevation and/or massage, it may be difficult to establish causality, as ‘event A’ is made up of multiple components, such as adherence and ‘doses’ (frequency, method, duration depending on severity and acuteness of oedema), each causing a different outcome. The Medical Research

Council (MRC) (Craig, 2008) acknowledges that complexity may have multiple dimensions, including the number and variability of outcomes from the complex interventions and the degree of flexibility and tailoring of the intervention permitted. From clinical observation it has become apparent that practices vary from department to department, as do the outcomes seen from implementing various oedema treatments (i.e. no change, oedema reduction, worsened oedema), and even those with 'standardised guidelines' require an element of personalisation, depending on multiple patient factors such as presence of comorbidities and type of injury/condition. As Campbell et al., (2000) acknowledge, "The evaluation of complex intervention is difficult because of problems developing, identifying, documenting, and reproducing the intervention." They suggest a phased approach to evaluating complex interventions to help researchers define clearly where they are in the research process.

Despite the uncertainty surrounding the most effective oedema treatment, it is widely acknowledged that oedema prevention and early intervention are important, ensuring that the recovery process is more complete and restitution more rapid, with fewer complications such as pain, stiffness and contractures (Airaksinen et al., 1988, Byron and Muntzer et al., 1986, Moberg, 1984).

The management of oedema is an area of hand rehabilitation where patients can take responsibility for their care with an active role in implementing oedema treatments as home therapy, following education and training from a hand therapist, which is a key priority for the health service (Department of Health, 2013).

The overall aims of the research were to:

- identify the most relevant and responsive patient-rated and clinician-derived measure for hand oedema
- to define and agree on a standardised manual for delivering oedema interventions
- begin to test the feasibility, effectiveness and acceptability of two oedema interventions.

These aims were addressed through four projects which are covered in the six chapters of this thesis.

Work package 1: A systematic review to examine the effectiveness of current oedema assessments and treatment techniques in the hand (Chapters 2 and 3).

Work package 2: A cross-sectional survey and Delphi consensus method to describe and agree on current best practice in assessing and treating hand oedema among hand therapy experts (Chapters 4 and 5).

Work package 3: An observational study to assess the responsiveness of two clinician-derived and two patient-reported outcome measures for hand oedema (Chapter 6).

Work package 4: A pilot randomised, single blind, controlled trial to compare kinesiology tape and traditional oedema management techniques with compression and traditional oedema management techniques in reducing post-traumatic/surgical hand oedema (Chapter 7).

Before embarking on a programme of research which seeks to address these aims it is important to consider the overarching approach taken to this field of research. As the research focuses on questions surrounding evidence of effectiveness of different methods to treat oedema and how it should be assessed a quantitative approach was taken, a perspective which implies a positivist research paradigm. Bryman (2004) identifies a paradigm as a cluster of believes and dictates which, for scientists in a particular discipline influence what should be studied, how research should be done [and] how results should be interpreted. A positivist approach relies on two assumptions; that the universal laws can be studied and understood (ontology), and that the world can be investigated objectively through experiment (epistemology) Carson et al (2001). However, as an early career researcher with over a decade of experience in clinical practice, and given the restrictions (time, experience and resources) of this fellowship, it was acknowledged that taking a purist approach may but counterproductive. For these reasons the philosophical stance was modified and a pragmatic approach was adopted. Pragmatists recognise there are many different ways of interpreting the world and undertaking research, that no single point of view can ever give the entire picture, and that there may be multiple realities (Saunders et al 2012). This approach allows for greater flexibility in choosing the ontological and

epistemological stance and research design best suited to the research topic. It also acknowledges that research is conducted in a real world environment (i.e a clinical setting) in spite of its many limitations, in order to generate useful knowledge for practice. Multiple methodologies were chosen in order to address the aims of the research project. This programme of research culminates in a pilot randomized controlled trial which looks at clinical effectiveness (amongst other things) of oedema treatments. Clinical effectiveness refers to a pragmatic approach to measure the degree of beneficial effect under “real world” clinical setting (Godwin et al., 2003).

This chapter has introduced some of the complexities surrounding oedema, a condition which is not static but which alters over time, and researching a condition which lacks a standardised diagnostic criteria, or established grading criteria. The lack of scientific evidence to support the mechanism of action of treatments proposed to reduce hand oedema further confounds these complexities, and highlights the many challenges of research into oedema. It has also set out the overarching approach taken to this programme of research. The next chapter will review the quality and quantity of existing literature on the effectiveness of oedema treatments.

Chapter 2 Treatment of hand oedema - systematic review

2.1 Introduction

This chapter will examine the quantity and quality of published evidence of effectiveness of a range of hand oedema treatments and provide a synthesis of their methodological quality, statistical conclusions and recommendations for clinical practice.

The management of oedema after hand injury or surgery is a constant challenge for hand therapists. The objective is to reduce oedema as quickly and effectively as possible in order to focus therapy on more functionally related goals, such as return to usual activity. “Oedema is glue” (Watson-Jones, 1955) highlights the challenges of balancing the physiological healing process after injury with the need to maintain and restore soft tissue length, function and joint motion.

Prolonged swelling can have a negative impact on joint range of motion, soft tissue mobility, quality of scar tissue formation, function, strength and aesthetics of the hand. These factors may delay a patient's recovery, meaning frequent and increased outpatient appointments, delayed return to work, and difficulties with activities of daily living and meaningful participation in functional roles.

Hunter and Mackin (1995) advocate a comprehensive treatment programme to manage oedema, tailored to the individual needs of the patient and comprising a combination of evidenced-based interventions. “The prevention and treatment of edema [sic] are of paramount importance during all phases of management of the injured hand”. (Hunter and Mackin, 1995)

Conventional treatment techniques used in this phase include massage, exercises and compression. Compression for hand oedema is usually achieved through Lycra gloves (Figure 2.1).

Figure 2.1 Lycra compression glove

The garment acts as an external counter pressure (Zuther, 2009) which compensates for the inelasticity of oedematous tissues and therefore improves circulatory efficiency by facilitating venous and lymphatic flow (Zuther, 2009).

Elevation permits gravity to assist with the drainage of oedema from the distal limb (Villeco, 2012). Elevation alone (Fagen, 2004) is not effective in reducing oedema, but is recommended in combination with other modalities.

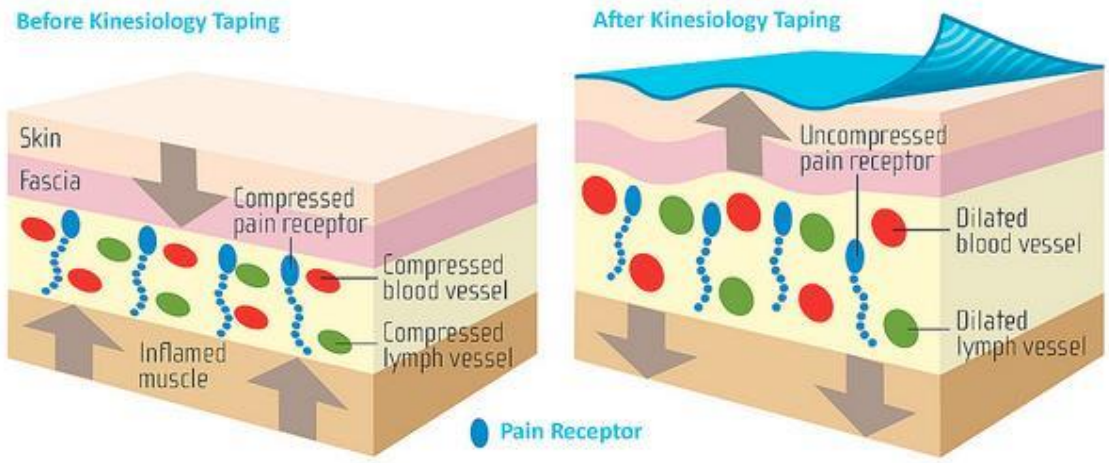
There are different styles of massage described for oedema. The more traditional style involves ‘retrograde’ (distal to proximal) massaging. This effleurage technique uses a firm ‘milking’ action, but has been questioned as potentially being too aggressive for the lymphatic system to cope with (Villeco, 2012). Recent evidence suggests that lighter massage may be preferable, with only minimal pressure in order to traction the skin (Artzberger, 2011) (Artzberger and Priganc, 2011) This style of massage should start and end proximally in order to clear lymph channels proximally, and make way for fluid distributed distally. It is also referred to as manual oedema mobilisation (MOM) (Artzberger and Priganc, 2011) and is complemented by deep diaphragmatic breathing. MOM massage does not involve pressure and in effect is more of a stroking action, where the therapist brushes the hand across the skin with only enough force to gently drag on the skin to the point at which it creases. Active exercises, which enable tendon gliding and muscular contractions, can act as a pump which will assist with the flow of oedema away from the periphery. Exercises can be completed in conjunction with other techniques to maximise the benefit.

However, in certain circumstances, depending on the nature of the injury and/or surgery, the patient's hand movements may be restricted based on healing timeframes, and if it is not possible to use other techniques, this immobilisation or restricted movement phase can have a detrimental effect on oedema control.

Traditional methods (elevation, compression, massage) remain the mainstay of standard therapy. However, the more recent introduction of kinesiology tape could offer an alternative method to oedema management. Whereas in compression the fluid is pushed proximally into the venous and lymphatic system (Palmada et al., 1998), kinesiology tape, which is designed to mimic the elastic properties of the skin, does the opposite, lifting the skin to allow greater interstitial space and encourage lymphatic drainage.

The wave-like grain of the tape provides a pulling force to the skin and creates more space by lifting the fascia and soft tissues under the areas where it is applied (Kase et al., 2003). See Figure 2.2.

Figure 2.2. Effect of kinesiology on skin and sub-cutaneous structures



https://pivotalphysio.com/kinesiology-tape-what-is-it-and-how-do-we-use-it/

Although available since the 1970s, kinesiology tape has primarily been used with elite athletes for muscle recovery, joint stability, proprioception and pain relief, but there is little evidence to support its use (Williams et al., 2012). When it was originally developed for use on sumo wrestlers, one of its initial functions was to

decrease congestion of lymphatic fluid under the skin through increasing lymphatic motility.
This multi-functional tape can be applied anywhere on the face or body.
The benefit of using it on the hand, unlike an oedema glove, is that it leaves the majority of the skin surface free for sensory feedback, which is essential for functional use. It can also be worn in water.

As the tape is elastic and stretches up to 55-60% of its length, it allows for unrestricted movement (Kase et al., 2003, Chang et al., 2010). Kinesiology tape is becoming more popular for hand oedema management and is already widely used in NHS clinical practice, despite a lack of empirical evidence regarding its effectiveness (Thelen et al., 2008) and limited understanding of its mechanism of action (Stupik et al., 2007).

The evidence on effectiveness of kinesiology tape in the management of sub-acute oedema is very limited. Three studies have evaluated the effect of kinesiology taping in sub-acute oedema. Only one paper focused on hand oedema and will be discussed in this systematic review (Bell and Muller, 2013). The other two were studies that used kinesiology tape to reduce acute/sub-acute oedema following leg-lengthening surgery (Bialoszewski et al., 2009) and after open reduction internal fixation (ORIF) of mandibular fractures (Ristow et al., 2014). Bialoszewski et al (2009) found that both kinesiology tape and lymphatic massage reduced lower limb oedema in patients post leg-lengthening surgery. However, the use of kinesiology tape resulted in a statistically significantly (thigh lengthening $p=0.02$, calf lengthening $p=0.03$, no mean difference or confidence intervals were presented) faster reduction of the oedema compared to standard lymphatic massage. The authors of this study concluded that due to the paucity of trials evaluating the effectiveness of kinesiology taping in the treatment of oedema of the limbs, further prospective studies are required. Ristow et al., (2014) found a statistically significant difference in the kinesiology tape group ($p< 0.001$), but no confidence intervals were given. Both studies had methodological weaknesses, including small, underpowered sample sizes, lack of blinded assessors, lack of a sham application of tape in the control arm, and unconventional application of tape for the management of swelling. Lack of

detail in the reporting of the studies, such as method of randomisation, raises further doubts about the quality.

Other controlled studies have been conducted which investigate the effectiveness of kinesiology tape versus placebo or sham application or alternative (manual lymph drainage or bandaging) in patients with acute oedema post-trauma (Nunes et al., 2015), chronic venous insufficiency (CVI) (Aguilar-Ferrandiz et al., 2014) and lymphoedema (Tsai et al., 2009, Smykla et al., 2013, Pekyavas et al., 2014, Malicka, 2014). Nunes et al's., (2015) study found that kinesiology tape, when compared to sham application, was ineffective (mean difference -2ml, 95% CI -28 to 32) in reducing acute lateral ankle oedema. Nunes et al., (2015) recommend the application of kinesiology tape for more than three days, and at different phases of the inflammatory process.

In contrast, Aguilar-Ferrandiz et al., (2014) found a statistically significant reduction in lower limb foot and ankle oedema in the kinesiology taping group in women with chronic oedema from CVI (right foot mean difference 0.76cm p=0.02 95% CI 0.56-0.92, left foot mean difference 0.68cm p=004 95% CI 0.14-1.28, right ankle mean difference 1.07cm p=0.01 95% CI 0.04-2.1, left ankle mean difference 1.29cm p=0.01 95% CI 0.31-2.29). However, a second study with a similar group showed no effects of kinesiology tape. Studies investigating kinesiology tape with lymphoedema (Morris et al., 2013) reported conflicting results regarding its effectiveness. However, three of these studies (Tsai et al., 2009, Smykla et al., 2013, Malicka, 2014) were pilot trials, and therefore not powered to detect superiority of treatments. Smykla et al (2013) reported no statistically significant difference between kinesiology tape and decongestive bandaging (p=>0.05). Malicka (2014) reported a statistically significant difference in favour of kinesiology tape (p=<0.01) however did not report confidence intervals. Tsai et al (2009) found no statistically significant difference between kinesiology and decongestive bandaging (p>0.05) at any time point in their study but report that limb circumference (forearm) and water composition was "significant" at the p=<0.05 level in both groups. They present mean and standard deviations but no confidence intervals or precise p values. They also report acceptance of K-tape was better than the bandage, benefits included longer wearing time during the day, less difficulty in usage, and increased comfort and convenience (p<0.01), however

kinesiology tape caused more wounds than the bandage (p=0.01). Again, no confidence intervals were presented.

The above studies included participants with oedema of varying aetiology and/or type (acute, sub-acute, chronic). Therefore, due to this heterogeneity, it is not possible to extrapolate the effects of kinesiology taping to sub-acute hand oedema after trauma or surgery. The sub-acute phase of oedema offers a window of opportunity where potentially problematic oedema can be treated before it progresses into the chronic phase. In contrast, lymphoedema and CVI are conditions of a chronic nature that are characterised by irreversible overloading or damage to the lymphatic system. The conflicting results could indicate that kinesiology tape may not be universally effective at facilitating lymphatic drainage across all phases. Other possible explanations for these results could lie in the variation and responsiveness of methods used to measure the change in oedema, which makes comparison or pooling of results difficult. A further reason is that kinesiology tape may only be effective in changes at a cellular level, and not the volume of the limb itself. Poor methodological quality of these studies must also be considered and could account for the results obtained.

This is the first systematic review examining the effectiveness of hand oedema treatments which aims to address a knowledge gap in the current literature.

2.2 Methods

A systematic review using PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-analysis) recommendations (http://www.prisma-statement.org/index.htm) (Moher et al., 2009) was carried out.

The review protocol was prospectively registered (CRD42015026836) on the international Prospective Register of Systematic Reviews (PROSPERO) website http://www.crd.york.ac.uk/PROSPERO .

2.2.1 Search strategy

The electronic databases: The Cochrane Library (Wiley InterScience), MEDLINE (via Ovid), EMBASE (via Ovid), AMED (via Ovid), CINAHL (via EBSCO), SPORTDiscus (via EBSCO), PEDro (Physiotherapy Evidence Database)- Allied Health Evidence, Trial registers – Cochrane Central Register of Controlled Trials (CENTRAL) and the WHO International Clinical Trials Registry Platform from inception to August 2015 were searched using the following search terms: *EDEMA THERAPY/, exp EDEMA/TH [TH=Therapy], (hand ADJ edema).ti,ab, (oedematous ADJ hand).ti,ab, *CRYOTHERAPY/, *RADIUS FRACTURES/, *FINGERS/, *HAND/, *WRIST/ OR *WRIST JOINT/, [Limit to: (Language English) and (Age group Adult) and Humans] Additional references were searched for by examining the reference list of retrieved studies.

2.2.2 Eligibility criteria

Criteria for inclusion were: English language, randomised controlled or controlled trials with adult participants where sub-acute* swelling, following a recent upper limb musculoskeletal or neurological injury (including hemiplegic stroke** if all other criteria were met) or post-surgery (i.e. orthopaedic, plastic), was treated. Active treatment had to have occurred during the sub-acute phase and included: compression, rest, cryotherapy, ultrasound, elevation, manual lymph drainage techniques, massage, CPM (continual passive motion), kinesiology taping or any other method deemed appropriate. The control group had to have received placebo treatment**,** sham application of tape or compression, different styles of massage or any other intervention as a comparator to that of the intervention group. Primary outcome had to be assessed using any clinician-derived tool or method and/or patient-reported method of assessing oedema to express swelling as a measurement of volume in cm or ml or a severity scale.

*sub-acute refers to swelling that is present after the initial acute inflammatory phase of ~3-5 days and which persists into the fibroplastic phase between 2-6 weeks.

**In contrast to lymphedema, in hemiplegia the lymph vessels of the hand are intact and functional and theoretically, there should be no obstruction to the removal of oedema fluid. It is a complication of stroke and can often subside spontaneously which matches the characteristics of oedema post-surgery or hand trauma.

Studies were excluded if: i) they used animals or human populations where oedema was at an organ or cellular level; ii) studies using participants with oedema due exclusively to pregnancy; or iii) studies which only measured acute oedema (day 0-14 post-surgery or trauma) or chronic oedema (around 3 months post-surgery or trauma). Studies which only used a medicinal product or invasive methods to treat the oedema (such as cortisone injection and anti-inflammatory drugs) were also excluded.

2.2.3 Screening

One reviewer (LM) read the titles of all citations retrieved from electronic database searches and removed all citations which were not related to the treatment of oedema. Abstracts of the remaining articles were screened to check for eligibility by one reviewer (LM). Full text articles were obtained for all abstracts meeting the inclusion criteria.

2.2.4 Eligibility

After reading the full text article, if the eligibility was uncertain, a second reviewer (CJH) reviewed the article to determine its eligibility using the agreed inclusion and exclusion criteria.

2.2.5 Inclusion in analysis

All articles passing the screening and eligibility check were included in the systematic review and subsequent analysis.

2.2.6 Data extraction

Data extraction from the included studies was done by the lead author (LM) using a purposely designed standardised data extraction form. This form summarised details on study design, sample, interventions, outcomes and results. See Appendix A for a copy of the data extraction form.

On occasions when there was doubt over the interpretation of the data being extracted, a second reviewer (CJH) completed the data extraction independently, using the same form, to verify understanding and clarity of extracted data.

Each included study was assessed for quality, using the guidelines developed by MacDermid in the Structured Effectiveness Quality Evaluation Tool (MacDermid, 2004). See Appendix B for a copy of the SEQES. The scale consists of 24 items covering study question, design, subjects, interventions, outcomes, analysis and recommendations, and uses a 0-2 ordinal rating scale with 48 points maximum. A score of 2 means that the criterion was fully met, 1 = partially met and 0 = criterion not met. To assess for risk of bias, two reviewers independently rated each paper at study level in accordance with the evaluation guidelines recommended by MacDermid (2004). This 24-question checklist covers seven key components of risk of bias, including adequacy of randomisation and concealment of allocation, blinding of patients, healthcare providers and outcome assessors, extent of loss to follow-up, and analysis. Each of the 24 items has detailed descriptors, and scores can be summed into an overall score of methodological quality. Any disagreements between the reviewers were resolved by discussion.

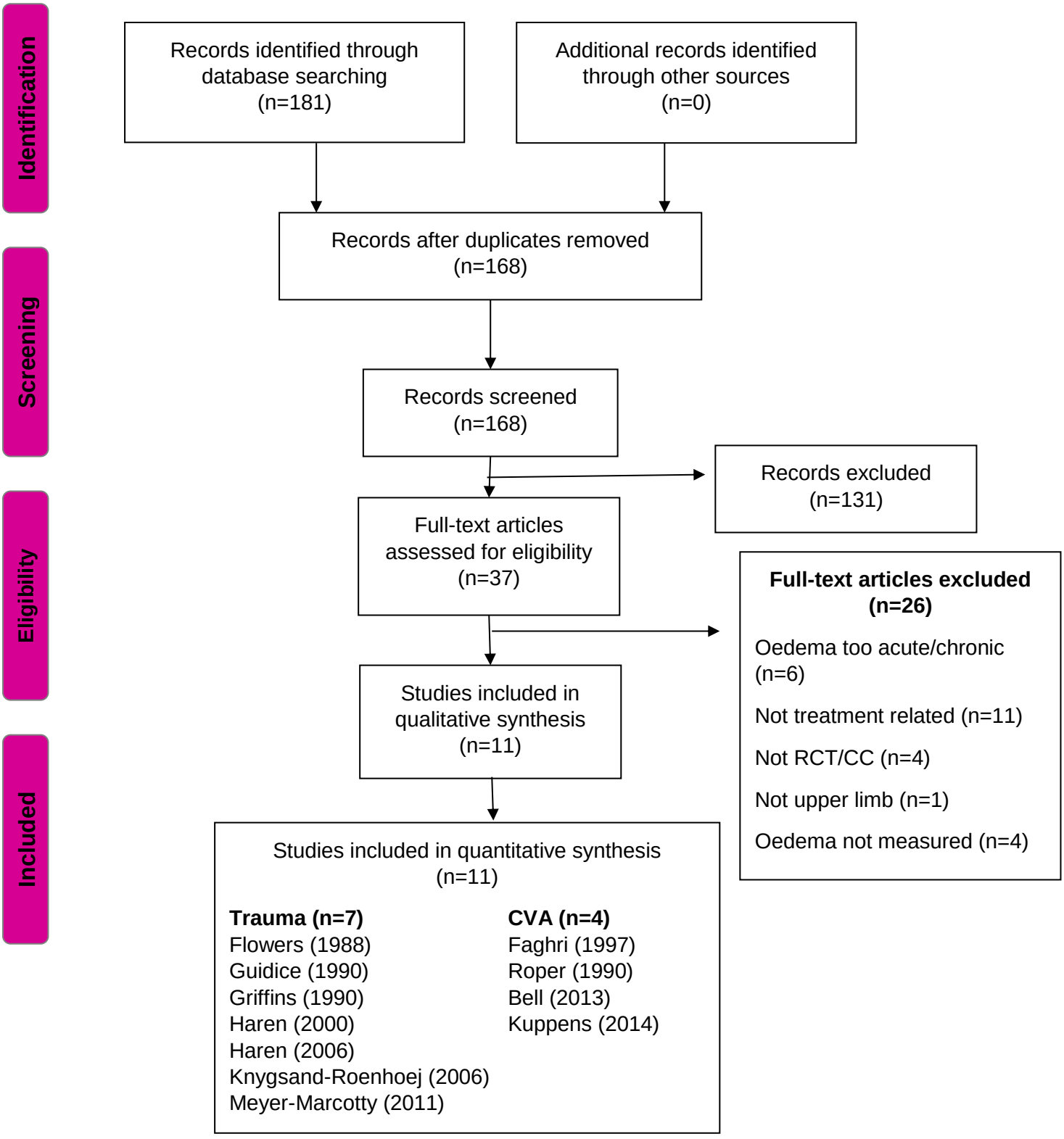
2.2.7 Grading of evidence

The strength of the body of evidence was assessed using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) guidelines (Meader et al., 2014), which assesses the risk of bias, publication bias, imprecision (random error), inconsistency and indirectness. This final score is based on scores from four categories of evidence: quality, consistency, directness and effect size. High = at least 4 points overall, moderate = 3 points, low = 2 points and very low = 1 point or less. Low and very low categories can be combined, and were done so in this systematic review.

2.2.8 Evidence synthesis

The 11 included studies were grouped according to patient population: patients with sub-acute oedema as a result of a musculoskeletal trauma or surgery, and patients with sub-acute oedema as a result of a hemiplegic stroke. This formed the basis of how we analysed and reported our results in this systematic review. However, the combination or transformation of results for meta-analysis was not possible because of differences in the methods of reporting results or heterogeneity of interventions and outcomes assessed.

Figure 2.3 PRISMA 2009 flow diagram



2.3 Results

The initial search identified 168 articles for which titles and abstracts were screened. A total of 11 studies met the inclusion criteria and were included in the review. See Figure 2.3 for PRISMA flow diagram. The study characteristics of all 11 studies are summarised in Table 2.1.

Quality scores ranged from 23 to 41 points out of 48 on the MacDermid Evaluation tool (2004). Flowers (1988) scored the lowest and Knygsand-Roenhoej and Maribo (2011) scored the highest (see Table 2.2 Quality assessment scores table). When these studies were assessed using the GRADE system (Meader et al., 2004), the scores ranged from 0 to 3. In keeping with the scored for SEQES (MacDermid 2004), Flowers (1988) (along with Kuppens et al., (2014) and Bell and Muller (2013)) scored zero points and Knygsand-Roenhoej and Maribo (2011) scored the highest of all 11 studies, again with 3 points. Sample sizes ranged from 8 to 128 patients. There were a total of 489 participants across the 11 studies, whose ages ranged from 18 to 85 years.

A total of 16 interventions were described, including kinesiology taping, massage (retrograde and intermittent), normal functional use, strengthening, manual lymph drainage, elevation, high-voltage pulsed ultrasound, cryotherapy, neuromuscular stimulation, positioning/splinting, active/passive exercises, and compression which was administered in numerous forms: string wrapping, Isotoner glove, intermittent pneumatic compression or Coban™.

All studies used either circumferential measurements (in cm or mm) or volumetry (ml) to express volume. Two studies (Guidice, 1990, Faghri,1997) used both; two studies (Flowers, 1988, Bell and Muller, 2013) used circumferential measurements alone; the other seven studies (Knygsand-Roenhoej and Maribo, 2011, Kuppens et al., 2014, Griffin et al., 1990, Haren et al., 2000, Haren and Wilberg, 2006, Meyer-Marcotty et al., 2011, Roper et al., 1999) used volumetry.

Four studies (Knygsand-Roenhoej and Maribo, 2011, Griffin et al., 1990, Meyer-Marcotty et al., 2011, Roper et al., 1999) used the same method of analysis: mean volume of oedema (ml). Some authors (Flowers, 1988, Guidice, 1990, Faghri, 1997) used percentage change (ml and mm), others used a variety of mean difference,

median decrease, median circumference and presence of oedema duration in weeks.

Only three of the 11 studies examined similar intervention (Knygsand-Roenhoej and Maribo, 2011, Haren et al., 2000, Haren and Wilberg, 2006). They assessed the effectiveness of manual lymph drainage (MLD)/ manual oedema mobilisation (MOM) versus standard treatment. Although these interventions use different terminology, they essentially comprise very similar techniques and clinically the terms are often used interchangeably, including light massage (in a proximal to distal direction), some form of compression (low stretch bandages or a glove), elevation, exercises, and breathing techniques; this is why they have been grouped together during analysis.

These studies (Knygsand-Roenhoej and Maribo, 2011, Haren et al., 2000, Haren and Wilberg, 2006) used the same outcome measure, the volumeter (ml), but different methods of analysis (mean difference, median decrease and mean volume) when expressing their outcomes, which means we are unable to pool their results for meta-analysis.

2.3.1 Trauma/surgery

Retrograde massage vs string wrapping vs continuous massage and string wrappings vs intermittent massage and string wrapping (Flowers, 1988)

This study scored the lowest mark on both the SEQES (MacDermid, 2004) (23/48) and the GRADE (Meader et al., 2014) (0/4) quality assessment tools.

A combination of string wrapping with massage is consistently more effective in reducing circumferential digit oedema than either massage or string wrapping alone. Continuous massage (with string wrapping) was shown to be superior to continuous massage (with string wrapping), as this gave the greatest average circumferential reduction in oedema (3.46%) compared to other methods. A Wilcoxon test demonstrated a statistically significant difference between the two types of massage with string wrapping ($p= 0.05$). There was no statistically significant difference between string wrapping and retrograde massage when done in isolation, both techniques showing the smallest average circumferential reductions of 1.35% and 1.74% respectively.

Elevation and continual passive motion (CPM) vs elevation alone (Guidice, 1990)

Continuous passive motion with elevation resulted in a significantly greater reduction of hand oedema than elevation alone, authors did not qualify whether this was clinical or statistical significance. However, the reduction in oedema in this group generally returned to pre-treatment levels within 24 hours. This was the only study which had a mixed group of patients, whose oedema was from either a trauma/injury or paresis. Findings for the total group were similar to a subgroup analysis of the cerebrovascular accident (CVA) group (n=11), and whilst the author suggests that CPM and elevation is an effective treatment to reduce hand oedema for patients with hemiplegia after CVA, the results do not support this, given the short-term and reversible reduction in hand oedema. The authors also found that the greater the amount of pre-treatment oedema and time after the onset of the oedema, the greater the treatment effect. This study had a low quality rating with a score of 26/48 on the SEQES (MacDermid, 2004) and 1/4 on the GRADE system (Meader et al., 2014).

High-voltage pulsed current (HVPC) vs intermittent pneumatic compression (IPC) vs placebo HVPC (Griffin et al., 1990)

In this study of moderate quality (SEQES (MacDermid, 2004) 29/48, GRADE 1/4 (Meader et al., 2014)), volume measures were taken before and after a 10-minute rest period and after a 30-minute treatment of either HVPC, IPC or placebo HVPC (an identical machine was switched off without the participant being aware). There was no statistically significant difference between the pre and post-rest hand volume (mean change 0.13ml -3 to 8ml range) in 30 subjects (p=0.7). Therefore, the authors conclude that patient activity prior to the treatment session did not affect the measurement. There was a statistically significant difference between IPC and placebo HVPC in favour of the IPC treatment (p=0.004). No significant difference was found between IPC and HVPC (p=0.4). The difference between HVPC and placebo HVPC did not reach statistical significance (p=0.036), but the authors report this finding as clinically significant. Overall, IPC gave the best result, with a 2-3% reduction in oedema from post-rest values.

Manual lymph drainage (MLD) + conventional therapy vs conventional therapy alone (Haren et al., 2000, Haren and Wilberg, 2006)

Both studies were by the same lead author with similar cohorts who had distal radius fractures requiring external fixator (Haren et al., 2000) or plaster and/or external fixation (Haren and Wilberg, 2006). The latter study also specified at least a 40ml difference between the volume of the injured and uninjured hand in order for the patient to be eligible for the study. Both studies were of moderate quality, with Haren (2006) scoring the second highest SEQES (MacDermid, 2004) score of all 11 studies (34/48) and 2/4 on the GRADE (Meader et al., 2014). Haren et al., (2000) scored slightly lower on both tools (SEQES (MacDermid, 2004) 28/48 and GRADE (Meader et al., 2014 1/4).

In the Haren et al., (2000) study a statistically significant difference in hand volume was seen, with a lesser degree of oedema in the group treated with MLD at the first two measurements (day 3 and 17 after removal of external fixator). They recommend that oedema treatment should be initiated during early fracture healing, as patients in the MLD group will have less oedema at an earlier post-traumatic stage compared with the conventional treatment, which reduces the risk of oedema-associated complications. Patients in the MLD group were seen a mean of three more times than the control group. The authors defend this as being necessary as they were adding MLD to conventional therapy and not trying to replace it, which may explain why they do not recommend MLD for all patients after fracture distal radius, but as complementary to conventional treatment when oedema is troublesome.

In the Haren and Wilberg (2006) study, both groups had a reduction in oedema after treatment. A statistically significant difference in oedema reduction was seen, with a large overall reduction in the experimental group at the first measurement ($p=0.005$). At the second measurement a greater reduction was observed in the experimental group, but this was not statistically significant. The authors concluded that MLD should be used as complementary to conventional therapy when there is excessive oedema. However, as the sample size was relatively small (n= 51), the confidence intervals were very wide, indicating poor precision in their estimates.

Manual oedema mobilisation (MOM) + conventional therapy vs conventional therapy (Knygsand-Roenhoej and Maribo, 2011)

This study scored the highest on both quality assessment tools (SEQES (MacDermid, 2004) 41/48, GRADE (Meader et al., 2014) 3/4). Despite these scores, the study is still classed as being of moderate quality, as the authors did not fulfil important criteria to score maximal points in the quality assessment questions. Both groups had a statistically significant difference in oedema reduction between inclusion in the study and penultimate follow-up (9 weeks). However, there was no statistically significant difference in any outcome between groups. Therefore, the authors conclude that using conventional therapy with or without the addition of manual oedema mobilisation is satisfactory in treating oedema. However, as the MOM group had 20% fewer sessions (not statistically significant p=0.13) compared to the control group who had conventional therapy alone, this is recommended for sub-acute oedema. At no other time point was the volume difference between the groups statistically significant.

Table 2.3 compares the content of MOM as described by Knygsand-Roenhoej and Maribo (2011), and MLD as described by Haren et al., (2000, 2006).

Cooling compression vs cryotherapy (Meyer-Marcotty et al., 2011)

In this study of low quality (SEQES (MacDermid, 2004) 27/48, GRADE (Meader et al., 2014) 1/4), there was no statistically significant difference between groups in terms of volume change over time. However, the authors do not report p-values. Volume of the wrist and forearm tended to be lower in the experimental group from pre-op to day 1 post-arthroscopy; however, this reduction (35ml) was not statistically significant. The control group had a small but not statistically significant increase in volume during the same time period (22ml). In both groups, volume remained relatively unchanged from pre-op to day 21 post-arthroscopy, with a reduction of just 13ml in the experimental group and a 15ml increase in the control group.

2.3.2 Cerebrovascular accident (CVA)

Neuromuscular stimulation (NMS) and usual activities vs elevation and usual activities (Faghri, 1997)

In a group of eight post-CVA patients with visible hand oedema, 30 minutes of NMS was found to be more effective at reducing oedema than 30 minutes of elevation. Both groups were also instructed to carry out their usual activities, which included treating oedema. No details were given on these 'other' oedema treatments and whether they were standardised across both arms of the trial. It is therefore difficult to ascertain whether the reduction in oedema was purely due to the NMS. This factor, amongst others, contributed to a moderate quality rating (SEQES (MacDermid, 2004) 30/48, GRADE (Meader et al., 2014) 1/4). Hand and arm volumes, using a volumeter and circumferential measures of hand and arm girth, were taken immediately after 30 minutes of experimental and control interventions. However, the reduction seen after NMS had returned to pre-treatment levels within 24 hours. The investigators confirm there was no carry-over effect of the sequence of treatments or days of treatment for either intervention.

Intermittent pneumatic compression and standard physiotherapy vs standard physiotherapy (Roper et al., 1999)

This study of moderate quality scored 29/48 on the SEQES (MacDermid, 2004) and 1/4 on the GRADE (Meader et al., 2014) quality assessment tools. In the experimental group, the addition of intermittent pneumatic compression to the standard physiotherapy brought about no change in mean hand volume after treatment. In the control group a decrease of 3.2 ml was seen after treatment; however; this was not statistically significant (p=0.69). The authors indicate that IPC at this pressure and duration cannot be recommended. They advocate that oedema can resolve spontaneously without any active intervention, which was highlighted in n=17 participants who failed to reach the volume criteria after the second week of assessment (<20ml between unaffected and affected hand volume), and therefore became ineligible to take part for the study as their oedema had resolved.

Kinesiology tape and standard OT and PT vs standard OT and PT (Bell and Muller, 2013)

This study had a low quality rating, scoring 26/48 (SEQES (MacDermid, 2004)) and 0/4 (GRADE (Meader et al., 2014)). Eight of the nine (88%) patients in the experimental group had a reduction in oedema, with one patient having an increase in oedema. The reductions at both the MCPJ and wrist level were small and there was no statistically significant difference between the two groups. In the control group, a median negative change indicated oedema worsened over the 6-day trial, despite the patients receiving therapy which included positioning, active and passive exercises.

Preventative measures and progressive treatment vs standard care (Kuppens et al., 2014)

This is the only study which did not present oedema as a volume (difference/mean/change) or circumference. The authors measured both of the patient's hands and obtained the difference in overflow using a volumeter between the paretic and non-paretic hand. This percentage was adjusted for mean differences in right and left hand volumes in healthy people before being converted, using an arbitrary cut-off point of 2 SD of the population score, into the presence/absence and duration of oedema. The presence of oedema was then further categorised into hospital-acquired oedema; oedema present at first measurement; and rehab centre-acquired oedema (oedema which first presented itself after admission, and therefore assumed as rehab centre-acquired). The incidence of hand oedema and hospital-acquired oedema was statistically significant between groups ($p<0.01$). Also, the incidence of rehab-centre acquired oedema was statistically significant between groups ($p<0.05$). The duration of hand oedema between groups and in those with hospital and rehab centre-acquired oedema was also statistically significant ($p<0.01$). These results may have been attributed to the fact there was a statistically significant baseline difference between the groups in terms of age. The longer duration of oedema could be caused by the fact the experimental group had the worse prognosis (hand function/age/duration of oedema). This study had a low quality rating, scoring only half of the available 48

points on the SEQES (MacDermid, 2004) and 0/4 on the GRADE (Meader et al., 2014) tools.

Table 2.1 Summary of studies

Author/ Date	Study Design	Patients	Outcomes Measured	Experimental Intervention	Control	Timing of follow-up	Results	Conclusion
Trauma/Surgery								
Flowers (1988)	Cross over trial	Patients with generalised hand oedema due to: hand or wrist injury, surgery, pregnancy or venous stenosis (n=14)	Circumferential measurement at the middle level of the PIPJ using a Jobst tape measure. PIPJs were marked with a fine-tip pen before each treatment. Proximal edge of tape measure placed over pen mark. PIPJs held in comfortable end of range extension.	*A).Traditional retrograde massage* Stroke distal to proximal over entire length of affected digit with a firm milking action using baby powder as lubricant. Continuous strokes for 5 minutes. B*).String wrapping* Coiling #36 ball twine around digit from nail bed to web space. Each successive loop placed directly next to preceding loop with no gaps for 5 minutes. Snug but not tight. *C).String wrapping with continuous superimposed retrograde massage* Apply string wrapping as in (B) with (A) performed over the string for 5 minute. *D).String wrapping with intermittent superimposed retrograde massage.* Massaging the string wrapped digit for 20 strokes. String wrapping removed rapidly and reapplied immediately and		Immediately after treatment.	**Average circumferential reductions (%)** (A)Retrograde massage 1.35% (B)String wrapping 1.74% (C)Continuous massage with string-wrapped digits for 5 mins 3.46% (D)Intermittent massage of string wrapped digit for 5 mins 2.95% No significant difference between string wrapping and retrograde massage. ANOVA showed a significant difference existed between treatments (P= <.001) Wilcoxon test significant differences between the 4 techniques, except between A and B. C>A (P = .01) D>B (P = .01) C>D (P = .05) 1st digit treated showed greatest circumferential reduction. Order of digit treated had no significant bearing on outcome.	A combination of string wrapping with intermittent retrograde massage is consistently more effective in reducing circumferential oedema in digits than either massage or wrapping alone.

Author/ Date	Study Design	Patients	Outcomes Measured	Experimental Intervention	Control	Timing of follow-up	Results			Conclusion
				followed by another 20 strokes for 5 minutes.						
Guidice (1990)	Cross over trial	Patients with upper extremity injury/surgery more than 4 weeks ago or 4/52 after onset of upper extremity paresis (n=16)	1). Circumferential measures (mm) of proximal phalanx of most visibly oedematous finger 2). Finger stiffness determined by PROM of MCPJ flexion using goniometer and 200g constant force gauge applied for 5 seconds 3). Volumeter (mL) Average of 2 successive volumetric measures of affected hand	Elevation and 30 minutes of continual passive motion. Extension and flexion of D2-5. Wrists supported with universal wrist splint provided with CPM machine during treatment.	Elevation alone (30 minutes) supine on flat surface, limb maintained on stand at 30° shoulder abduction, 30 ° shoulder flexion and 70° elbow flexion. Wrists supported with universal wrist splint provided with CPM machine during treatment.	Immediately after treatment.	**Elevation alone** Change Score (SD)/ % change(SD) *Circum* 0.6mm (0.6) / 0.8mm (0.8) *Volumeter* 6.1ml (9.5) / 1.1ml (1.8)	**CPM with elevation** Change score (SD)/% Change (SD) *Circum* 1.4mm (0.9) / 1.9ml (1.2) *Volumeter* 14.5ml (8.4) / 27.ml (1.6)		Measures of oedema that were reduced following CPM and elevation generally returned to pre-treatment level within 24 hours. The greater the time after onset the greater treatment effect. The greater the amount of pre-treatment oedema, the greater the treatment effect. 30 minutes of CPM with limb elevation resulted in a significantly greater reduction in hand oedema than 30 minutes of elevation alone. Findings for total group similar to sub group analysis of CVA (N=11) group suggests CPM with elevation is an effective treatment to reduce hand oedema for patients with hemiplegia after CVA.
							CPM with elevation resulted in a significantly greater reduction of hand oedema than elevation alone. Sequence effects were not significant for measures of hand volume and finger circumference. Small to moderate (.2 and .3) +ve relationship (between treatment outcome and time after onset) for reduction in hand volume following elevation alone. Almost no relationship was found for hand volume and finger circumference following CPM with elevation or finger circumference following elevation alone.			
Griffin (1990)	RCT	Patients with trauma to 1 upper extremity at	Volumeter (mL) Measured affected and unaffected side	High Voltage Pulsed Current (HVPC) n=10.	Placebo HVPC. Dispersive electrode	Post rest (10 minutes) and post treatment	**Pre- rest** **Placebo- HVPC**	**Post rest** **Placebo-HVPC**	**Post Rx** **Placebo-HVPC**	No change occurred after rest period therefore concluded that patient activity prior to session

Author/ Date	Study Design	Patients	Outcomes Measured	Experimental Intervention	Control	Timing of follow-up	Results			Conclusion
		least 2/52 before study participation and with clinically significant (visually detectable swelling of sufficient magnitude to be considered a problem) hand oedema judged by 1 PT. (n=30)	pre-rest. 10 minutes rest with arm at heart level and patient seated, 2nd measurement. 30 minutes treatment then 3rd volumetric measurement of affected hand.	1 electrode over MN, other over UN, dispersive electrode dorsolumbar region of back. Intensity adjusted to produce observable and maintainable muscle contracture of FLP/FPB and dorsal lumbricals) 8 (twin) pulses per second alternating between 5 seconds UN and 5 seconds MN.	was disconnecte d without the subject's knowledge.	(30 minutes) measure-ments	Unaffected hand 512.2 (SD 104.1) Affected hand 573.1 (SD 111.2) **HVPC** Unaffected hand 507.3 (SD 54.2) Affected hand 553.7 (SD 75.0) **IPC** Unaffected hand 503.8 (SD 82.9) Affected hand 557.4 (SD 92.4)	572.1 (SD 109.9) **HVPC** 553.3 (SD 73.8) **IPC** 558.4 (SD 92.1)	570.8 (SD 109.5) **HVPC** 547.0 (SD 73.0) **IPC** 550.7 (SD 92.1)	did not affect measurement. Wide variability in HVPC and IPC in amount of post treatment change 0-15ml Hypothesis rejected. Pre-rest and post-rest hand volumes in 30 subjects not significantly different (Wilcoxon test P=.761) Mean change between pre-rest and post-rest= 0.13ml (-3 to 8ml) Post-treatment volume: KW test significant difference between IPC, placebo and HVPC groups (P .011)Wilcoxon rank sum significant difference between IPC and placebo (P=0.004) No significant difference between placebo and HVPC (P= 0.446) Difference between HVPC and placebo HVPC did not reach statistical significance (P= .036)
Haren (2000)	RCT	Patients with distal radius fractures requiring an	Volumeter (4 measurements) difference in volume	10 MLD treatments- light surface massage	Elevation, active, passive exercises	3, 17, 33, 68 days after removal of external fixator.	**Experimental Group Mean (SD) differences between volume measures**	**Control Group Mean (SD) differences between volume measures**		Oedema treatment should be initiated during early fracture healing

Author/ Date	Study Design	Patients	Outcomes Measured	Experimental Intervention	Control	Timing of follow-up	Results		Conclusion
		external fixator (n=26)	calculated in mL between uninjured and injured. Water of room temperature.	proximal to distal + Elevation, active, passive exercises and compression with elastic bandages (Elastomull) during ex-fix period then tubigrip or isotoner glove after removal of ex.fix. Use of hand encouraged as much as possible, verbal instructions and written programme for HEP.	and compression with elastic bandages (Elastomull) during ex-fix period then tubigrip or isotoner glove after removal of ex.fix. Use of hand encouraged as much as possible, verbal instructions and written programme for HEP.		**(ml) of injured and uninjured hand** Day 3 39 (SD 12) Day 17 27 (SD 9) Day 33 19 (SD 9) Day 68 12 (SD 11) 95 % CI of mean differences between group: Day 3: 0.6-49.5 Day 17: 2.2-43.4 Day 33: -0.3-31.5 Day 68: -1.0-24.2 A significant difference in hand volume, with a lesser degree of oedema in the group treated with MLD, was recorded at the first 2 measurements. Probability at first measurement P = 0.04 (n=26) 2nd measurement P = 0.1 and 4th measurement P= 0.2	**(ml) of injured and uninjured hand** Day 3 64 (SD 41) Day 17 50 (SD 35) Day 33 35 (SD 26) Day 68 24 (SD 20)	Patients in MLD group will have less oedema at an earlier post traumatic stage compared with conventional treatment, which reduces risks of oedema associated complications. MLD not proposed for all patients with hand oedema after # DR but as complementary to conventional treatment when oedema is troublesome.
Haren (2006)	RCT	Patients with distal radius fracture treated with plaster or	Volumeter with water heated to room temperature. Uninjured hand	First 6 treatments included 40 minutes of MLD in	Conventional treatment of: elevation, active and resistive	2nd measurement 60 days after inclusion (49-71) for Experimental	**Pre Treatment Experimental** Median normal size before trauma 545ml (95% CI 372- 595)	**Post treatment Experimental 1st measurement** Median decrease injured hand	Study supports the use of MLD as complimentary to conventional therapy when there is excessive oedema.

Author/ Date	Study Design	Patients	Outcomes Measured	Experimental Intervention	Control	Timing of follow-up	Results		Conclusion
		external fixation with oedema of hand and wrist of more than 40mL difference between volume of uninjured and injured hand (using volumeter) (n=51)	measured first. Hand dominance estimated to be 3.43% larger than non-dom hand according to standard techniques. All other oedema measurements were made on injured hand and compared to pre-treatment volume of injured hand.	additional to conventional treatment of: elevation, active and resistive exercises (hand and wrist) and compression (oedema glove- night and day until 1st measurement) Verbal and written instructions (HEP) Encouraged to use hand as much as possible.	exercises (hand and wrist) and compression (oedema glove- night and day until 1st measurement) Verbal and written instructions (HEP) Encouraged to use hand as much as possible.	group and 56 days (32-63) after inclusion for control group.	**Control** Median normal size before trauma 453ml (95% CI 343-637)	30ml (95% CI 10-55**)** **Control** Median decrease injured hand 20ml (95% CI -10-45) **2nd measurement Experimental** Median decrease injured hand 40ml (95% CI 10-90) **Control** Median decrease injured hand 35ml (95% CI 15-80)	
							Statistically significant difference in oedema reduction with a large overall reduction in the experimental group at 1st measurement (P= 0.005) At 2nd measurement a greater reduction was seen in the experimental group but this was not statistically significant.		
Knygsand-Roehoej (2011)	RCT	Patients with unilateral post distal radius fracture,	1). Volumeter. Standardized volumeter protocol recommended by the ASHT	Isotoner glove (25- 35mmHg pressure) full time (except for hygiene and massage),	Elevation Compression: Coban (digits to proximal wrist)	1,3,6,9 and 26 weeks after inclusion in study.	**Pre treatment** **Modified MOM group** (n=14) Mean (95% CI)	**Post treatment (9 weeks)** **Modified MOM group** 12.1 (0.2, 24.1)	Tendency for MOM group to receive 20% fewer OT session (oedema and other treatments) than the control group, however not S.S (P= 0.13)

Author/ Date	Study Design	Patients	Outcomes Measured	Experimental Intervention	Control	Timing of follow-up	Results		Conclusion
		treated with POP/ internal or external fixation with subacute oedema 4-10 weeks after trauma/ surgery and with a 60mL+ in volume difference between the upper extremities (n=30)	with 2 modifications: water temperature 23-24° and patients were standing. 2). AROM- PV distance (average of D2-D5) and thumb opposition3). Pain using VAS 4). ADL's using custom designed bilateral activity questionnaire (QBA) and structured interviews 5). Perceived performance and satisfaction using the COPM (2+ change= clinically important)	regular therapy : ROM/strengthening HEP. MOM: deep diaphragmatic breathing, exercises (proximal to distal), terminus stimulation, axillary stimulation (uninvolved side 1st), MPP stimulation to involved upper extremity, light skin traction in 'U' shape massage, low stretch bandage system (if needed), exercising and exercising during massage.	Functional retraining- solitaire in elevation for 10 minutes + regular therapy (ROM/Strengthening) + Flowtron intermittent compression system for 20 minutes. Isotoner glove (open fingers) night only (25-35mmHg pressure)		86.8 (73.0, 100.6) **Control Group (n=15)** 96.3 (83.0, 109.7)	**Control group** 28.3 (16.8, 39.8)	Either approach is satisfactory (statistically significant difference in oedema reduction between inclusion and last follow up in both groups) however as the MOM group had fewer sessions, this is recommended for sub-acute oedema.
Meyer-Marcotty (2011)	RCT	Patients undergoing elective wrist	1). Pain- VAS (0-10) + pain diary	10 minutes of cooling-compression	Apply cryotherapy of either	Day 1, 8 and 21 after arthroscopy.	Volume of wrist and forearm tended to be lower in experimental group from pre-op to Day 1: 967 +/- 24ml to 932 +/- 34 ml (Not S.S)		No difference between both study groups in

Author/ Date	Study Design	Patients	Outcomes Measured	Experimental Intervention	Control	Timing of follow-up	Results		Conclusion
		arthroscopy for TFCC lesions, intra-carpal ligament ruptures and or damage to the wrist cartilage (n=54)	2). ROM- Extension, flexion, radial and ulnar deviation and pro/supination) using goniometer. Overall global ROM = summation of 3 different directions of motion measured from dorsum of wrist. 3).Water displacement with volumeter. Displaced water collected and expressed in mL. Water temperature 28˚. 4). DASH 0-100 score.	period prior to sterile prepping of arm. Cryo-cuff applied to operated wrist. 30mmHg pressure. 3 x 10 minutes for 22 days (at least twice daily)	mode (cool packs or crushed ice) wrapped in towel to operated wrists. No time interval or frequency given just PRN.		The control group had slight but not significant increase in volume: 890 +/- 36ml to 912 +/- 38ml Volume unchanged from pre-op to Day 21 (Not S.S): **Experimental:** 967 +/- 24ml Vs 954 +/- 25ml **Control:** 890 +/- 36ml Vs 905 +/- 33ml		terms of volume change over time. No significant effect on hand volume, pain, ROM or DASH scores between groups over a 3 week period.
CVA									
Faghri (1997)	CT	Patients with visible hand oedema following CVA (less	1). Volumeter. Average of 3 successive measures (mL) of affected hand/forearm,	Neuromuscular Stimulation+ usual activities including treating oedema.	Elevation + usual activities including treating oedema.	Immediately after treatment.	**Mean change scores** **NMS:** Hand volume (ml) -13.38 (SD 2.03)	**% change scores** **NMS:** 2.64% (SD 0.53)	In 8 subjects, 30 minutes of NMS is more effective than 30 minutes of elevation.

Author/ Date	Study Design	Patients	Outcomes Measured	Experimental Intervention	Control	Timing of follow-up	Results		Conclusion
		than 6/12 ago) (n=8)	2). Circumferential girth measures of upper arm and lower arm using flexible tape measure.	Frequency 35Hz to create reciprocal activity of flexors and extensors of lower arm. 10 seconds action of wrist and finger flexors, 10 seconds action of wrist and finger extensors, 10 seconds rest. Total treatment time 30 minutes.	30 mins of elevation in standardized position previously recommended by other investigators as most effective and comfortable: lay supine, 30° shoulder abduction, 30° shoulder flexion, 70° elbow flexion.		Arm volume (ml) -32.63 (5.83) Lower arm girth (mm) -8.75 (1.26) Upper arm girth (mm) -7.50 (1.65) **Elevation:** Hand volume (ml) 1.88 (3.90) Arm volume (ml) 26.5 (9.81) Lower arm girth (mm) 1.30 (2.29) Upper arm girth (mm) 1.25 (2.29)	1.97% (0.45) 3.88 (0.58) 2.63 (0.64) **Elevation:** 1.89 (0.67) 1.35 (0.51) 0.63 (0.95) 0.35 (0.77)	Measures of oedema that were reduces following 30 mins of NMS returned to pre-treatment levels within 24 hours. No carry over effect (sequences/days of treatment (for NMS/elevation.
Roper (1990)	RCT	Patients with a first ever hemisphere stroke (WHO criteria) and oedema of hemiparetic hand (>20mL volume in stroke hand	1). Volumeter (device made for study- not a standardized tool) average of 3 measurements taken from both hands. 2). Motricity Index	Intermittent pneumatic compression + standard physiotherapy 50mmHg applied with a 30 second inflation and 20 seconds deflation cycle.	Standard Physio-therapy (pragmatic) included: positioning and passive movements.	Weekly during 4 week treatment period.	**Pre Treatment** Mean volume (affected hand – unaffected hand) **Experimental:** 52.7ml (SD 27.2) **Control:** 63.7ml (SD 23.7)	**Post Treatment** Mean volume (affected hand – unaffected hand) **Experimental:** 52.7ml (SD 36.9) **Control:** 60.5ml (SD 32.7)	Standard physio had a non SS decrease in oedema Oedema can resolve spontaneously (n=17 not eligible) ? Parameters of the compression machine were inadequate.

Author/ Date	Study Design	Patients	Outcomes Measured	Experimental Intervention	Control	Timing of follow-up	Results		Conclusion
		compared with unaffected hand after 2 readings, 1 week apart) (n=37)		2 sessions of 2 hours a day for 1 month.				No change in experimental group in mean hand volume after treatment (P=1.0) No statistically significant decrease in mean hand volume of 3.2ml (SD 33.3) (P=0.69) No statistically significant difference I between two groups (P< 0.65)	IPC cannot be recommended at this pressure/duration.
Bell (2013)	RCT	Patients with hemiplegic stroke within last 3/12 and presence of oedema by visual inspection (n=17)	1). Circumferential measurements of wrist and MCPJs using spring loaded Gulick anthropometric measuring tape 2). Upper limb portion of Fugl-Meyer Assessment (FMA). Total 66 points (higher score = better function)	Kinesiology tape with 20% stretch. Dorsal and volar application with buttonhole technique covering 2/3 of forearm for 6 days (replaced as/when needed) + standard OT, PT and SLT.	Standard physical, occupational and speech and language therapy. Including: positioning, active and passive range of motion.	6 days after baseline.	**Pre Treatment Experimental:** Median MCPJ circumference (cm) 21.4 (SD 2.0) Median wrist circumference (cm) 18.0 (SD 1.7) **Control:** Median MCPJ circumference (cm) 20.7 (SD1.7) Median wrist circumference (cm)	**Post Treatment Experimental:** Median MCPJ circumference (cm) 0.5 (SD 0.65) -0.1 t0 2.2 Median wrist circumference (cm) 0.2 (SD 0.4) 0 to 1.1 **Control:** Median MCPJ circumference (cm) -0.3 (SD 0.91) =1.0 to 1.6	8/9 patients (88%) had oedema reduced in experimental group: 1 pts had increased oedema. Median negative change in control group indicated oedema worsened over the 6 day trial. ES of KT are smaller than those reported with NMES, CPM and lycra garments however KT cheaper and quicker to apply.

Author/ Date	Study Design	Patients	Outcomes Measured	Experimental Intervention	Control	Timing of follow-up	Results		Conclusion
							17.8 (SD1.5)	Median wrist circumference (cm) -0.1 (SD 0.57) -0.5 to 0.8 Experimental group showed a small reduction in MCP and wrist circumference measurements, greater results at MCPJ. Control group showed an increase in both areas. No statistical difference between the 2 groups for change at MCPJs (P= .111) or change at the wrist (P= .189) A large effect size was seen at the MCPJ (0.8) and a medium ES at the wrist (0.7)	
Kuppens (2014)	CT	First stroke patients with hand oedema (n=128)	1). Volumeter score- difference in overflow between paretic and non-paretic hand (% adjusted for mean difference in right and left hand volumes in healthy people) Overflow weighted with electronic scale.	1). Preventative measures 2). Progressive treatment steps (minimum of 2/52 per step) orthosis (night/increasing duration), cryotherapy for 3/7, compression	"As usual" care, not standardized. Offered on basis of trial and error and therapists preferences. Intervention strategies not adapted based on volumeter results.	One or two weeks after admission then measured weekly or fortnightly (depending on oedema) until D/C (~3/12 later). UAT assessed at D/C and 8/52 after D/C.	**Experimental** Oedema present 64/129 (50%) Hospital acquired 43/129 (33%) Rehab centre acquired oedema 21/129 (16%) Duration of mean hand oedema 6.5 weeks (SD 5.5)	**Control** Oedema present 27/77 (35%) Hospital acquired oedema 11/77 (14%) Rehab centre acquired oedema 16/77 (21%) Duration of mean hand oedema 3.1 weeks (SD 2.5)	Statistically significant baseline differences (age) P < 0.01 Oedema incidence and duration did not correlate significantly with sex, type of stroke or hemisphere of stroke. Preventative measures can a difference in oedema incidence rates. Further investigations needed.

Author/ Date	Study Design	Patients	Outcomes Measured	Experimental Intervention	Control	Timing of follow-up	Results		Conclusion
			Incidence and duration of hand oedema. 2). Hand Function (UAT). Scores 0-7. 0 = complete paralysis, 7= clumsy hand.	tape (Coban) 1.5 hours minimum, elastic glove.	Examples of interventions : sling, compression tape, splinting.		Rehab centre acquired oedema duration 4.9 weeks (4.6) Hospital acquired oedema duration 7.3 weeks (5.8)	Rehab centre acquired oedema duration 1.8 weeks (1.6) Hospital acquired oedema duration 5.0 weeks (2.4)	Longer duration of oedema could be caused by the fact the treatment group/centre had the worse prognosis (hand function/age/duration of oedema)
							Incidence of hand oedema and hospital acquired oedema statistically significant between groups: P <0.01 Incidence of rehab centre acquired oedema statistically significant between groups: P < 0.05 Duration of hand oedema between groups and in those with hospital and rehab centre acquired oedema was also statistically significant: P < 0.01		

D/C = discharge, ROM= range of motion, HEP= home exercise programme, PV= pulpa vola distance, OT= occupational therapy, PT= physiotherapy, SLT= speech and language therapy, COPM= Canadian Occupational Performance Measure, PIPJs= proximal interphalangeal joints, MCPs= metacarpal interphalangeal joints, ASHT= American Society of Hand Therapy.

Table 2.2 Quality assessment scores

	Study question	Study design							Subjects				Intervention			Outcomes			Analysis					Recommendations	Total (48)	GRADE score
Study/question no.	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**	**21**	**22**	**23**	**24**		**(4)**
Knygsand-Roenhoej (2011)	2	2	2	2	1	1	1	2	1	2	2	2	2	1	2	2	2	2	2	1	2	2	1	2	**41**	**3**
Haren(2006)	2	1	2	2	1	1	1	1	2	2	2	2	1	1	2	2	0	2	1	0	1	2	1	2	**34**	**2**
Faghri (1997)	2	2	2	2	0	1	1	0	1	2	0	2	2	2	2	1	0	1	2	0	1	2	1	2	**30**	**1**
Griffin (1990)	2	2	2	2	1	1	1	0	1	1	0	2	2	1	1	2	0	1	2	0	1	1	1	2	**29**	**1**
Roper (1999)	2	2	2	2	1	1	1	2	2	2	0	1	1	1	1	1	2	1	1	0	1	0	1	1	**29**	**1**
Haren (2000)	2	2	1	2	1	1	1	1	2	1	0	0	2	1	1	2	0	2	0	0	2	1	0	2	**28**	**1**
Meyer-Marcotty (2011)	1	1	2	2	1	1	1	0	0	1	2	2	1	1	1	1	1	2	2	2	1	0	0	1	**27**	**1**
Guidice (1990)	2	2	2	2	1	1	1	0	0	1	0	2	1	1	1	2	1	0	1	0	1	1	1	2	**26**	**1**
Bell (2013)	2	2	2	2	2	0	1	2	2	2	0	0	1	0	1	1	1	1	1	0	1	0	1	2	**26**	**0**
Kuppens (2014)	2	1	2	2	0	1	1	0	1	2	0	0	1	0	1	2	2	2	1	0	1	0	1	1	**24**	**0**
Flowers (1988)	2	2	2	1	1	1	1	0	0	0	0	1	1	1	2	2	0	1	2	0	0	1	1	1	**23**	**0**

GRADE score: High= 4/4, Moderate 3/4 , Low 0-2/4

Study question

1. Was the relevant background work cited to establish a foundation for the research question?

Study design

2. Was a comparison group used?
3. Was patient status at more than one time point considered?
4. Was data collection performed prospectively?
5. Were patients randomised to groups?
6. Were patients blinded to the extent possible?
7. Were treatment providers blinded to extent possible?
8. Was an independent evaluator used to administer outcome measures?

Subjects

9. Did sampling procedures minimise sample/selection biases?
10. Were inclusion/exclusion criteria defined?
11. Was an appropriate enrolment obtained?
12. Was appropriate retention/follow-up obtained?

Intervention

13. Was the intervention applied according to established principles?
14. Were biases due to the treatment provider minimized (i.e. attention, training)?
15. Was the intervention compared with the appropriate comparator?

Outcomes

16. Was an appropriate primary outcome defined?
17. Were appropriate secondary outcomes considered?
18. Was an appropriate follow-up period incorporated?

Analysis

19. Was an appropriate statistical test(s) performed to indicate differences related to the intervention?
20. Was it established that the study had significant power to identify treatment effects?
21. Was the size and significance of the effects reported?
22. Were missing data accounted for and considered in analyses?
23. Were clinical and practical significance considered in interpreting results?

Recommendations

24. Were the conclusion/clinical recommendations supported by the study objectives, analysis and results?

Total quality score (sum of above/48)

Table 2.3 Comparison of descriptions of manual lymph drainage (MLD) and manual oedema mobilisation (MOM)

Author/ intervention	Haren et al., (2000)	Haren and Wilberg, (2006)	Knygsand-Roenhoej and Maribo, (2011)
Name of intervention	Manual lymph drainage (MLD)	Manual lymph drainage (MLD)	Modified manual oedema mobilisation (MOM)
Quality assessment score: SEQES GRADE	28/48 1/4	34/48 2/4	41/48 3/4
Intervention	• Light surface massage (proximal – distal) In addition to "conventional treatment" as per control group. • Elevation • Compression (elastic bandage/Tubigrip/glove) • Active/passive/resistive exercises • Normal function use of hand		• Light skin traction massage (proximal-distal) • Deep diaphragmatic breathing • Compression (low-stretch bandage and Isotoner glove) • Active exercises (+/- massage) and strengthening • Terminus stimulation • Axillary stimulation (uninvolved side first)
Control	• Elevation • Active and passive exercises • Compression with elastic bandages or Tubigrip or Isotoner glove • Use of hand	• Elevation • Active and resistive exercises • Compression with glove • Use of hand	• Elevation • Compression with Coban • Functional retraining (solitare in elevation for 10 minutes) • Range of motion and strengthening

Author/ intervention	Haren et al., (2000)	Haren and Wilberg, (2006)	Knygsand-Roenhoej and Maribo, (2011)
			• Flowtron intermittent compression for 20 minutes • Isotoner glove overnight
Outcome measure	Volumeter (ml)		Volumeter (ml)
Protocol	• Water at room temperature • Difference in volume calculated in ml between uninjured and injured hand	• Water at room temperature • Uninjured hand measured first • Hand dominance estimated to be 3.43% larger than non-dominant hand according to standard techniques • All other oedema measurements were made on injured hand and compared to pre-treatment volume of injured hand.	• Standardised protocol recommended by ASHT with 2 modifications: • Water temperature 23-24° • Patients standing during assessment
Method of analysis	Mean difference (ml)	Median decrease (ml)	Mean volume (ml)

2.4 Discussion

The aim of this systematic review was to review the current quantity and quality of evidence on the effectiveness of conservative treatments for sub-acute hand oedema in patients following a recent upper limb musculoskeletal trauma, hemiplegic stroke or post-hand surgery.

2.4.1 Methodological quality

The overall quality of the 11 studies was low to moderate, with the majority of studies scoring consistently poor marks on four particular questions on the SEQES (MacDermid, 2004). These were: a lack of an independent evaluator to perform outcome measures; lack of appropriate enrolment process; appropriateness of secondary outcomes; and lack of sufficient power to identify treatment effects. The same therapist administered all the treatment and conducted all assessments in studies by Griffin (1990) and Flowers (1998). Meyer-Marcotty (2014) reported it was not possible to blind assessors in their trial; however ,all patients would have had an arthroscopy scar and could have removed the Cryo-cuff or ice pack before follow-up assessments. Unblinded assessment has been associated with inflated treatment effects compared to blinded outcome assessments (Poolman et al., 2007). Pre-treatment measures were not conducted in Haren et al's., (2000) study, nor were secondary outcome measures considered in this, or their 2006 study. Post-hoc analyses were performed in Haren and Wilberg (2006) and Flowers' (1998) studies. In the case of Flowers' (1998) study, this showed a statistically significant difference ($t= 20$, $p=0.05$) between continuous and intermittent massage (along with string wrapping), but the size and significance of the treatments effects were not reported. Despite randomisation in Roper et al's., (1990) study, limited details were given on the precise method. Possible baseline differences were not adjusted for in their analysis, as the mean time since stroke was nearly twice as long in the control arm, and this group had more pre-treatment oedema (t-test $p=0.59$). This could be a meaningful difference which may have confounded the results. Inappropriate statistical tests were performed in Haren et al's., (2000) study, which assumed a normal distribution. Poor retention, unaccounted missing data and the lack of sham or placebo application of kinesiology tape were limitations of Bell and Muller's (2014)

study. Low scores were given when the study did not meet the criteria or where there was insufficient detail to make a judgement on that particular question. A lack of reported detail was a particular issue in five of the 11 studies (Meyer-Marcotty, 2011, Haren et al., 2000, Flowers, 1998, Guidice, 1990 and Faghiri, 1997). Table 2.3 gives the quality assessment scores (SEQES and GRADE) for all studies.

2.4.2 Reporting quality

A lack of detail in the reporting is a limitation of all the included studies. The level of detail recommended in the CONSORT 2010 (Schulz et al., 2010) statement's 25-point checklist was not adhered to by most of the included studies. Hoffmann et al., (2014) went on to develop an extension to the CONSORT checklist, specifically focused on the amount of detail required to describe the interventions in randomised controlled trials. The Template for the Intervention Description and Replication (TIDieR) (Hoffmann et al., 2014) was devised as a response to a lack of comprehensive guidance on how to report interventions, with a view to improving the replicability and completeness of reporting of interventions. The structured checklist is designed to prompt the researcher to document the minimum recommended items for describing an intervention. A lack of transparency in the reporting of the reviewed studies affected the present study's ability to adequately assess the validity of the results. In some cases neither the experimental nor the control interventions were described in enough detail for them to be reproduced. This is a common issue with therapy research. Many interventions are anecdotally passed between clinicians, completed out of routine, trial and error or a subjective belief in its effectiveness. Sufficient published details of therapy interventions are rare, and different terminology for the same intervention and interchangeable terminology for different treatments can add to the confusion on what constitutes the exact 'ingredients' of therapy programmes.

Many authors discuss the issues surrounding the 'black box' of rehabilitation in relation to stroke research (DeJong et al., 2004 and 2005, Ballinger et al., 1999]. Ballinger et al., (1999) report the lack of documented detail on the components of treatment as one of the main methodological limitations of research studies in rehabilitation. They go on to point out that the description of therapy treatment has

had scant attention and that this needs to be understood first before outcomes can be truly interpreted and measured. Pomeroy et al., (2001) and Ballinger et al., (1999) refer to “unpacking the black box” of therapy practice.

DeJong (2004) states: “We are yet to disassemble the black box of rehabilitation” and this was very much representative of the studies included in this systematic review. “Standard therapy” (Roper et al., 1999) and “usual activities” (Faghri, 1997) were not described in sufficient detail to allow the reader to adequately understand the specific treatments that were being implemented or to differentiate between the experimental intervention and the control.

Kuppens et al., (2014) used “preventative measures” in the first stage of the experimental group but failed to describe exactly what these measures entailed. They also state that the experimental group interventions are representative of “standard care”; however, the control group is also described as getting “usual” care. Without a clear definition of these terms it is difficult to ascertain how the groups differ, and there is no justification for the assumption of the “standard care” terminology.

The experimental intervention in Haren et al’s study (2000) was called “manual lymphatic drainage”. However, only massage was described, which makes the use of this term misleading.

Many of the reviewed studies pre-date the TIDieR and CONSORT checklists, but these could be useful tools to use in future studies to enhance replicability and comparison of interventions across studies

2.4.3 Variations in same interventions across studies

Across the included studies, the details given of the interventions highlighted conflicting theories, particularly relating to massage.

For example, Haren et al., (2000) and Flowers (1988) both used massage as part of their experimental intervention; however, Flowers (1988) used a one-off 5-minute treatment whereas Haren et al., (2000) used 10 sessions but didn’t comment on the duration. In the Meyer-Marcotty (2011) study the control group used cryotherapy, either with cool packs or crushed ice to operated wrists; however, unlike the structured experimental group who were instructed to apply the Cryo-cuff twice daily

for 10 minutes, the control group had no stipulated frequency or duration. Whilst this 'per required need' (PRN) approach may reflect real life, for the purposes of the research it would have been useful to document the control group's use of cryotherapy in order to establish the effect of adding the regular compression element in the intervention group.

Flowers (1988) describes a "firm milking action" in a distal to proximal direction, whereas Haren et al., (2000) use a "light surface massage" in a proximal to distal direction and Knygsand-Roenhoej (2011) complete "light traction massage" in a 'U' shape from proximal to distal. This difference may be due to advances in clinical practice since the 1980s when Flowers conducted his study, and whilst 'retrograde massage' is still used in clinical practice, it has been adapted to use a lighter action as opposed to a firm milking one, which is thought to be too aggressive on the delicate lymphatic system (Jackson et al., 2012).

Bell and Muller (2013) used kinesiology tape in the experimental group; this was applied with 20% stretch using a dorsal and volar buttonhole technique. They state this application method is described by the manufacturer (Shushter and Murray, 2005). However, according to Kenzo Kase, the founder of kinesiology tape and as documented in his instruction manuals (Kase et al., 2003), the tape should be cut into fan or fork shape. See Figure 2.4.

Figure 2.4 Kinesiology tape cut into fan shape with proximal anchor

This is designed to mirror the lymphatic system vessels and is anchored by a 2-inch solid piece of tape at the closest lymphatic duct. A study by Nunes (2015) examined

the effectiveness of kinesiology tape (fan shape) versus sham application (solid strip along the tibia) for acute lateral ankle sprain in athletes. The fan application, as described by its creator (Kase et al., 2003), did not show any benefit on oedema reduction compared with sham application in this population. As there were other limitations in this study and no other study has compared the recommended application (fan) with other alternatives, there is no evidence to suggest one method is superior to another and therefore we are unable to criticise Bell and Muller's' (2013) study for the method used when applying kinesiology tape.

2.4.4 Patient group/inclusion criteria

The heterogeneity of patients across the 11 studies may also be a limitation. Flowers (1988) included pregnant women alongside patients with venous stenosis and post-hand/wrist surgery. The differing aetiology indicates that conditions such as water retention during pregnancy may be temporary, transient and fluctuating, whereas patients with venous stenosis may have this condition due to a chronic thickening of the blood vessels secondary to trauma or external compression of the musculoskeletal system, and that this may require surgical or pharmacological interventions. No inclusion or exclusion criteria were reported in Haren et al's., (2000) study. Haren et al., (2000, 2006) used patients with external fixators (ex-fix) following distal radius fractures, which makes any oedema management technique difficult to apply around protruding metal work. Haren et al., (2000) adapted their technique by using elastic bandages during the external fixator period, then Tubigrip or a glove after the ex-fix period. Whilst both techniques are classed as compression, we are unsure of the mmHg pressure difference between them, which involve clinician or patient self-tensioning elastic bandages as opposed to the pre-set tension of oedema gloves and Tubigrip. Haren and Wilberg (2006) included those patients with an external fixator 3-5 days after it had been removed. Patients with external fixators were left a mean of 47 days (experimental group) and 43 days (control group), and while the external fixator was in place there was no oedema management in place. Patients treated with external fixators had this fixation on for an average of 13 days longer than patients treated with plaster of Paris (PoP), which meant the time from fracture to treatment start date was delayed by this length of time. Whilst there was an equal number of PoP to external fixators in both the experimental and control groups, patients with external fixators may have had more

longstanding and untreated oedema which could have impacted on the success of the intervention.

2.4.5 Type II errors

Eight of the 11 included studies did not document their sample size calculations, so we are unable to establish if these studies had sufficient power to identify treatment effects. This may have increased the likelihood of type II errors occurring. Although three studies did include sample size calculations (Meyer-Marcotty et al., 2011, Knygsand-Roenhoej and Maribo, 2011, Haren and Wilberg, 2006), in some cases these had flaws which also contributed to the degree of caution needed when interpreting the results. Only two studies had reported or established significant power to identify treatment effects (Meyer-Marcotty, 2011 and Knygsand-Roenhoej and Maribo, 2011). Meyer-Marcotty (2011) specified that 25 participants were required in each arm of the trial to obtain a 20% difference in the primary outcome: pain levels. As there was no effect size, P value or confidence intervals, we were unable to assess if the study was adequately powered to identify treatment effects for secondary outcomes of oedema reduction, range of motion and function. Haren et al (2006) needed a sample size of 82 to detect a 12ml difference in volume with 90% power. They estimated it would take two years to recruit 82 participants; however, by the third year they had under-recruited and stopped with 51 participants. Because of this they adapted the power calculation to 73%; thus the study was under-powered, increasing the risk of type II error: that is, not detecting a treatment effect if one existed.

Knygsand-Roenhoej's (2011) sample size calculation was based on Haren and Wilberg's (2006); however, they used 80% power to detect a difference greater than 12ml in hand volume. Allowing for a 10% drop-out rate, their sample size was 15 participants in each group.

2.4.6 Length of follow-up

Follow-up ranged from immediately after treatment to day 68 post-treatment (~ 9 weeks). Four of the 11 studies assessed oedema immediately after the intervention (Faghri, 1997, Haren et al., 2000, Flowers, 1988, Griffin, 1990), and whilst some showed a statistically significant reduction in oedema, this returned to pre-treatment

levels within 24 hours, indicating a longer term follow-up was required to see if the effects of the intervention could be maintained over time.

2.4.7 Strengths and limitations of the review

The strengths of this review include the publication of a protocol on the PROSPERO website. This attempts to “avoid duplication of work and reduces opportunity for reporting bias by enabling comparison of the completed review with what was planned in the protocol” (https://www.crd.york.ac.uk/PROSPERO/) This review also adhered to PRISMA recommendations (Moher, 2009), which ensures transparency and consistency when reporting in systematic reviews. However, this review also had a number of limitations. Due to the lack of RCTs and CTs of oedema management techniques in this population, it meant older studies were incorporated with more recent ones using more current interventions. Therefore, comparison between some interventions, which have changed over time, may be a limitation of the inclusion criteria of this systematic review to include studies of any age. This review focused on hand oedema, as this is the primary area of interest. The narrow inclusion criteria helped focus the review, its results and implications for practice to a specific clinical speciality of hand therapy. However, interventions and evidence of the effectiveness to reduce oedema in other areas of the body which could also be used on the hand were included. Narrowing the focus of this review could be viewed as both a strength and limitation. Greater breadth of inclusion criteria may have identified additional studies, although extrapolating from evidence in other conditions or body parts to sub-acute oedema in the hand may not be appropriate.

The inclusion of stroke patients alongside post-trauma/surgery patients may be seen as a limitation. Broadening criteria to include this condition was done due to the similarities in the aetiology and physiology of the sub-acute oedema. Hand oedema as a result of post-hemiplegic stroke involves the lymph vessels remaining intact and functional, and theoretically there should have been no obstruction to the removal of the fluid. Oedema is a complication of stroke and can often subside spontaneously, which matches the characteristics of oedema post-surgery or hand trauma. However, this does not take into consideration potential chronic vascular issues which could contribute to the stroke or delay oedema reduction post-stroke.

2.5 Future research

Using the TIDieR checklist to ensure adequate description of treatments would enable reproducibility in clinical practice and research. Further preliminary work is required, to reduce the variations seen in oedema treatments and to establish agreement on “standard treatment”, which could be used as the control arm in future trials. Additional development work is needed to identify treatment dose and parameters (frequency, duration and method) for more novel oedema treatments. There is a need for further high quality primary studies to assess the effectiveness of therapy interventions in the management of sub-acute hand oedema**.**

2.6 Conclusions

The review found limited low to moderate quality evidence to support the use of a combination of interventions (in addition to standard care), known as manual edema mobilisation or modified manual lymph drainage, when treating problematic sub-acute hand oedema compared to standard treatment alone. The results need to be interpreted with caution due to numerous limitations associated with the included studies.

This chapter has presented a systematic review of evidence of effectiveness of hand oedema treatments. It identified and graded methodological issues at the study and outcome level and discussed the implications of these on the conclusions for research and clinical practice. The next chapter will present a synthesis of the methodological quality and psychometric properties of methods of assessing hand oedema.

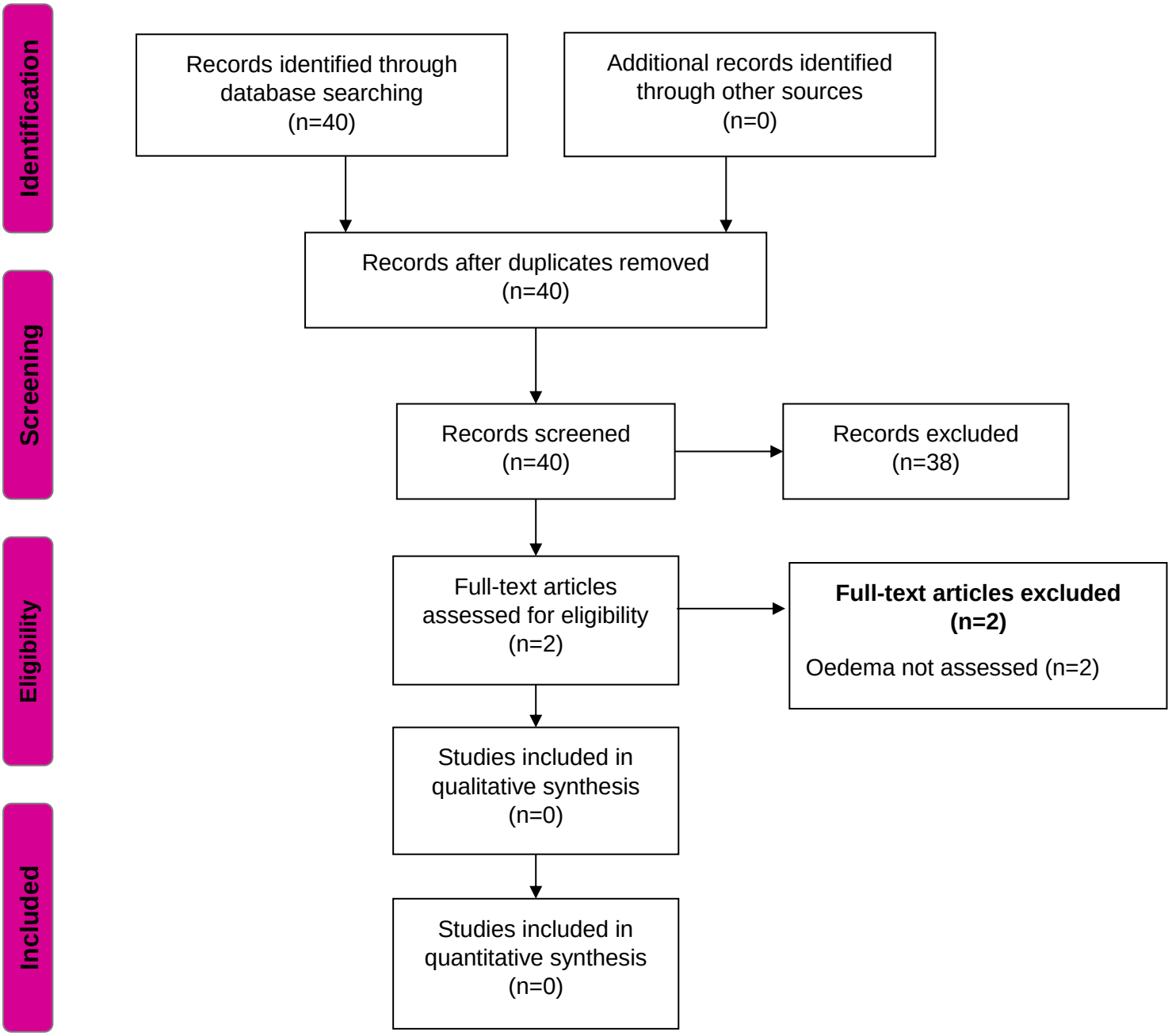
2.7 Addendum

A repeated database search was conducted to identify any studies published since the initial search (between August 2015 and November 2018). Titles were screened and abstracts reviewed using the same eligibility criteria. Full-text articles were obtained in order to confirm inclusion or exclusion.

An updated PRISMA flow diagram is presented in Figure 2.5.No additional studies met the inclusion criteria. The results and conclusion remain unchanged.

See Appendix C for a copy of the published systematic review**.**

Figure 2.5 PRISMA 2009 flow diagram (updated)



3.1 Introduction

This chapter will focus on methods used to measure hand volume in the assessment of hand oedema. It will provide an overview of methods highlighted in the literature, and will introduce and define the properties being assessed before evaluating the evidence of their psychometrics and implications on their use in clinical practice.

Assessing oedema is a core part of the clinician's assessment of the hand following a hand injury or surgery. Accurate and timely assessment of oedema is paramount in order to evaluate the effectiveness of any interventions given and to track change over time. Numerous methods of measuring hand oedema have been evaluated in the literature. However, a synthesis of the methodological quality and psychometric properties of these studies has not yet been conducted. This review aims to bridge this gap and will underpin further work in this programme of research.

3.2 Psychometric properties

Reliability, validity and responsiveness domains and psychometric properties will be discussed throughout this chapter. A definition for each (Mokkink, Terwee and Patrick et al., 2010) is presented along with the statistics which are generally used (and were reported by studies in this review).

Domain:

Reliability is the degree to which the measurement is free from measurement error.

Validity is the degree to which an instrument measures the construct(s) it purports to measure.

Responsiveness is the ability of an instrument to detect change over time in the construct to be measured.

Psychometric property:

Reliability: The proportion of the total variance in the measurement which is because of "true" differences among patients. Inter class correlation coefficients (ICC) are measures of reliability which report the degree of between (inter) and within (intra) measure or assessor variance. There are no standard values for acceptable

reliability and various scales are available to interpret the ICC. An ICC is a numeric index of reliability reported between zero and one with an ICC of one indicating excellent reliability. There are no standard values for acceptable reliability and various scales are available to interpret the ICC, however these are arbitrary and there is no universally accepted grading (Portney and Watkins, 1993). Cohen's Kappa (Cohen, 1960) is often used to grade inter rater reliability.

Measurement error: The systematic and random error of a patient's score that is not attributed to true changes in the construct to be measured. The standard error of the mean (SEM) is an indication of how well the mean of a sample of estimates is representative of the mean of the population it is drawn from. The SEM gives an absolute index of reliability, rather than a relative measure of reliability given with an ICC and is reported in the units of the measure being investigated (Curran-Everett, 2008).

Criterion or concurrent validity: the degree to which the scores of an instrument are an adequate reflection of a 'gold standard'. Concordance correlation, which measures agreement between two variable and is similar to an ICC and how this is graded, are presented by papers in this chapters. Sensitivity and specificity, reported as a percentage of proportion, are also measures of concurrent validity. Sensitivity refers to the ability of the test to correctly identify those with the condition (oedema) i.e a true positive. Specificity refers to the ability of the test to correctly identify those without the condition (oedema) i.e a true negative (Altman, 1991)

Responsiveness: (as above domain definition). Effect size (ES) and standardised response mean (SRM) are often used to report responsiveness. The effect size, is calculated by dividing the mean change over time by the baseline standard deviation (SD) (Sullivan and Feinn 2012). The Standardised Response Mean (SRM) is calculated by dividing the mean change by the standard deviation of change. The results can be compared across measures because they are unit free as neither one carries the original units of measurement. According to Cohen's criteria (Cohen 1988) an effect size of <0.3 is considered small, 0.5 is moderate and >0.8 large.

3.3 Methods of assessing oedema

Multiple methods of measuring hand oedema exist, including volumetry, figure-of-eight tape measure, circumferential tape measure, ring gauge, opto-electric device (perometer), 3D scanners and cameras, and visual grading of severity by a hand therapist.

3.3.1 Objective methods

Water volumeter (see Figure 3.1)

Volumetry, which uses Archimedes' principle of water displacement, works on the basis that the volume of the displaced water is equal to the volume of the hand immersed in the water container. This is often referred to as the ‘gold standard’ method of measuring hand size, and has excellent inter (>0.95) and intra-rater (0.99) reliability (Farrell et al., 2003) according to Portney and Watkins (1993) interpretation. However, volumetry is not always a practical or feasible method to use where immersion of the hand in water is contraindicated, such as the presence of wounds, dressings or skin conditions. The volumeter kit is also expensive at approximately £300, and requires a lengthy set-up to ensure the water in the volumeter is completely level before proceeding and a constant water temperature is maintained. This is often an impractical technique to use in busy clinic settings with limited space and where frequent hand oedema assessments need to be performed.

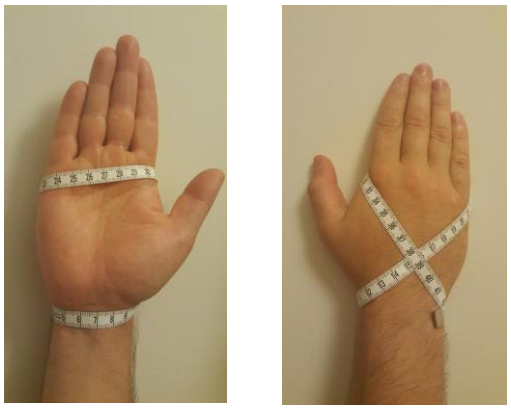
Figure 3.1 Water volumeter set

Figure-of-eight tape measure (see Figure 3.2)

The figure-of-eight tape measurement has been found to be as reliable as the volumeter. The figure-of-eight method is more time and cost-efficient, and if used

with precise landmarks it has very good reproducibility (Pellechia, 2003). Research has shown that a single measure, as opposed to the average of three trials using the figure-of-eight method, is sufficient and also more time-efficient (Leard et al., 2004). In the hand, Maihafer et al., (2003) argued that the figure-of-eight method is better able to capture hand volume than single-joint circumferential measures. However, this study, like others (Pellachia, 2003), used a healthy cohort who had no hand oedema. Studies that have compared circumferential measures with the volumeter in lymphoedema patients with upper limb oedema have not included circumferential measurements of the hand (Deltombe et al., 2007, Chen et al., 2008, Gjorup et al., 2010). The limitation with this method is its exclusion of the digits, and so it cannot be used in cases of isolated digital swelling.

Figure 3.2 Figure-of-eight tape measure method



Circumferential tape measure (see Figure 3.3)

This method can be used for isolated digit oedema (Lewis, 2010) and although the reliability of this method has been tested, its responsiveness has not. This study also used a healthy population. Despite the simplicity and cost-effectiveness of this method, the placement and tension on the tape can affect inter and intra-rater reliability of the measurement (Bear-Lehman and Abreu, 1989). The American Society of Hand Therapists (Lavelle and Stanton, 2013) states that circumferential measures are not recommended for routine use unless constant tension is applied (King, 1993) and specific landmarks are noted. Jansen et al (2010) has shown a weighted tape measure to be reliable, when used with a protocol, on patients with oedematous digits with intraclass correlation coefficients (ICC) of 0.9 for inter and intra-rater reliability. However, the responsiveness of this method is yet to be

assessed. It requires the digit to be positioned so the tape measure is perpendicular to the part being measured and that the tape is in contact with the skin at all times. This may discount its use on patients with tendon repairs in the early stages (i.e. first four weeks whilst in a splint).

Figure 3.3 Circumferential tape measure method

Ring gauge (see Figure 3.4)

A ring gauge system, like ones used by jewellers to measure the diameter of digits for ring sizes, has been suggested by Suzuki et al (2017). The diameter of the finger is recorded numerically from 1-30 or 40. It was tested on uninjured little fingers and the study compared its inter and intra-rater reliability to the figure-of-eight tape measure. Results showed interclass correlation coefficients (ICC) for inter-rater reliability of 0.95 (95% CI 0.93-0.96) and intra-rater reliability ICCs of 0.75 (95% CI 0.67-0.81). Furthermore, the authors of this paper identify an advantage to using the ring gauge method, as the skill of the examiner does not affect the results, whereas the circumference measurement techniques relies on the assessor's accurate placement of the tape and the amount of tension applied to it (Bednarczyk et al., 1992). However, despite its reliability and validity in healthy participants, in a symptomatic cohort bony prominences such as Heberden's and Bouchard's nodes on the distal and proximal interphalangeal joints, joint contractures, tissue thickening post-injury or scar tissue following surgery are all factors which could lead to overestimation of digit size using the ring gauge system. It would also be an unsuitable method to use on digits with open wounds, as the shearing forces of the ring passing up and down the digit may disrupt wound healing. The potential of the

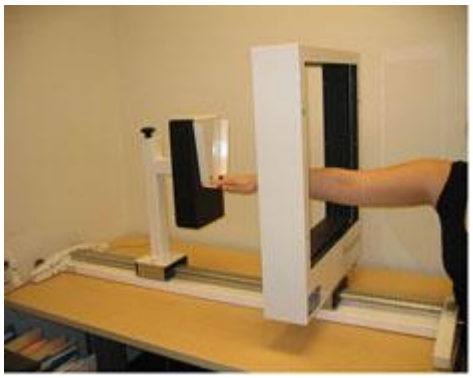
gauge getting stuck on oedematous digits may also pose a risk of harm to the patient.

Figure 3.4 Example of ring gauge system

Perometer (see Figure 3.5)

The perometer is an opto-electric limb volumeter. Originally designed and used in Germany for measuring pressure garments, it was adapted by US designers to measure limb volume. The arm is positioned with the shoulder at 90 degrees abduction, with the hand and arm independently held in pronation, the digits straight and thumb adjacent to index finger and the middle finger touching the tip of the metal plate on the hand rest. The perometer frame then moves distal to proximal and back to its starting position in front of the hand, whilst the hand and arm remain in the centre of the square moving frame.

Figure 3.5 Perometer



3D scanners, 3D cameras and ultrasound

These methods are not routinely used by hand therapists to measure oedema, but information on their application and psychometric properties could be transferable to use in clinical practice on the hand. The hand presents a unique challenge when measuring volume due to its shape and structure, and this may mean some methods are not suitable to use. To date, no systematic reviews exist of methods of assessment of hand oedema in a trauma (orthopaedic, plastic or neurological, lymphatic) or post-surgical cohort.

3.3.2 Subjective methods

Visual grading

In clinical practice therapists use terminology such as mild, moderate and severe to describe the severity of oedema. This is based on visual inspection of hand volume; the colour and tautness of the skin; and appearance of, or lack of, defined anatomical landmarks when compared to the unaffected hand. Due to varying perceptions of severity between clinicians, and difficulties with recall between sessions with the same clinician, visual inspection alone may not be sufficient to give an accurate measurement of hand volume, and an objective measurement of oedema should be performed.

This systematic review will examine the practicalities of using different oedema assessment techniques in a variety of hand conditions and after surgery or injury. This population has been chosen to be representative of those patients who may be seen and treated by a hand therapist. However, this systematic review focuses on the assessment of the oedema, regardless of any interventions given, and the underlying cause for the oedema.

3.4 Objectives

To review the current quantity and quality of evidence on tools designed to assess oedema. Specifically, this review will:

1. Identify methods of assessment for hand oedema
2. Review the psychometric properties of the identified hand oedema assessment tools

3. Identify factors influencing/affecting the standardisation of assessment tools.

3.5 Methods

This systematic review was conducted and reported using PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-analysis) recommendations (Moher et al., 2009) (http://www.prismastatement.org/index.htm).

3.5.1 Database search

The electronic bibliographic databases Cochrane Library (Wiley InterScience), MEDLINE (via Ovid), EMBASE (via Ovid), AMED (via Ovid), CINAHL (via EBSCO), SPORTDiscus (via EBSCO), PEDro (Physiotherapy Evidence Database)- Allied Health Evidence Trial registers – Cochrane Central Register of Controlled Trials (CENTRAL) and the WHO International Clinical Trials Registry Platform from inception to March 2017 were searched, using the terms: Hand/, Edema/, Hand adj size, hand adj volume, perometer. A further search was conducted to November 2018 to check for any additional publications since the original search.
Additional studies were searched for by examining the reference list of retrieved studies.

3.5.2 Eligibility criteria

Criteria for inclusion were: any English language study which reports any aspect of psychometric evaluation of an assessment to measure hand oedema in an adult population with hand swelling after surgery or trauma, or from a disease or condition affecting the hand, irrespective of any treatment given, where hand oedema measurements are expressed as volume (ml), measurement (cm/mm) or as a severity description.

3.5.3 Exclusion criteria

Studies were excluded if the psychometric evaluation was completed on normal/healthy participants only who had no swelling; animal studies; studies which assessed upper limb and forearm in addition to hand oedema; and studies where oedema at an organ or cellular level was investigated.

3.5.4 Screening

One reviewer (LM) read the titles of all citations retrieved from electronic database searches and removed all citations which were not related to the assessment of hand oedema. Abstracts of the remaining articles were screened to check for eligibility by one reviewer (LM). Full text articles were obtained for all abstracts meeting the inclusion criteria.

After reading the full text article, if the eligibility was uncertain, a second reviewer (CJH) reviewed the article to determine its eligibility using the agreed inclusion and exclusion criteria.

3.5.5 Inclusion in analysis

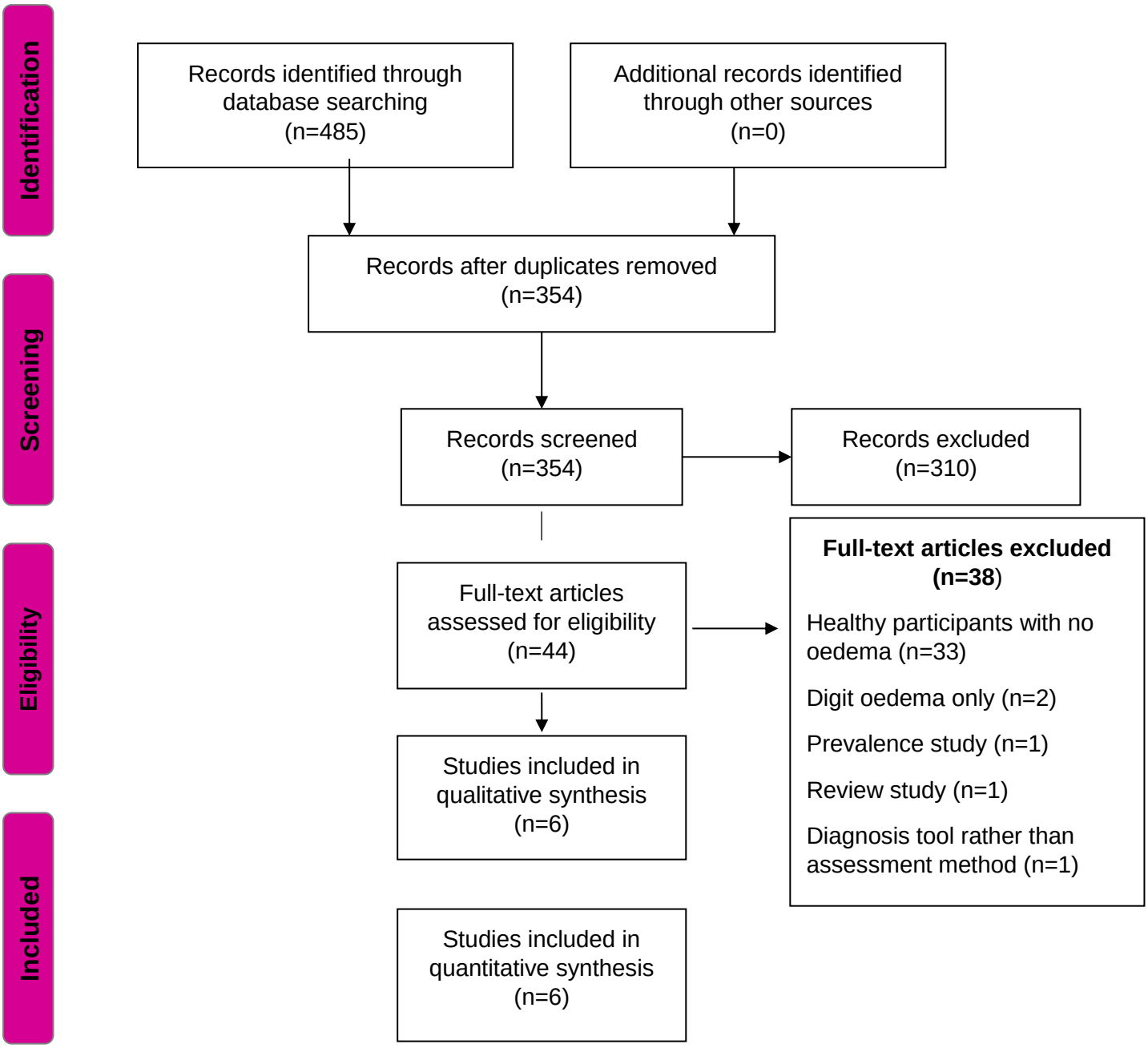
All articles passing the screening and eligibility check were included in the systematic review and subsequent analysis.

3.5.6 Data extraction

Extracting data from the included studies was done by the lead author (LM), using a purposely designed standardised data-extraction form. This form summarised details on study design, sample, assessment methods, outcomes and results. See Appendix D for a copy of the data extraction form.

On occasions where there was doubt over the interpretation of the data being extracted, there was opportunity for discussion with the second reviewer (CJH).

Figure 3.6 PRISMA 2009 flow diagram



3.5.7 Assessment of methodological quality

The Consensus-based Standards for the selection of health Measurement Instruments (COSMIN) Risk of Bias checklist version 9 January 2012 (Mokkink et al., 2012) was used to evaluate the methodological quality of the studies. Each study was assessed using the relevant domain for the psychometric property being evaluated, i.e. reliability, validity or responsiveness by the primary reviewer (LM). The second reviewer (CJH) completed the checklist on two of the six included studies and the agreement between the reviewers was checked to ensure consistent grading across each domain for each study. There was 86% agreement between primary and secondary reviewers on the selected two studies; the inconsistencies in scores were settled with discussion and resulted in 100% agreement. Each domain has between 7-14 questions which are graded ‘excellent’, ‘good’, ‘fair’ or ‘poor’ according to the descriptors given under each category. The ‘lowest score counts’ method is recommended to provide an overall quality judgement. An updated version v17 (July 2018) of the COSMIN Risk of Bias checklist has now replaced the earlier version. The 2018 version has removed some of the questions from the previous version and has a different grading structure: very good, adequate, doubtful and inadequate. The lowest rating in the property being assessed is still taken as the overall rating, i.e. a ‘worst score counts’ principle.

3.5.8 Evidence synthesis

The six studies were grouped according to the assessment tool used: i) figure-of-eight tape, ii) perometer, iii) visual inspection. This formed the basis of how results were analysed and reported. Meta-analysis was not possible because of differences in the methods of reporting results or heterogeneity of assessment tools and/or methods used.

3.6 Results

Six studies met the inclusion criteria and were included in this review. See Figure 3.6 for a PRISMA flow diagram.

A total of 243 participants were included in the six studies, with sample sizes ranging from 24 to 88. Participants had a range of musculoskeletal injuries, burns, lymphoedema, post-orthopaedic surgery or CVA. Only one study (Lee et al., 2011) used a healthy comparison group when assessing the reliability of the perometer in women with and without lymphoedema.

A total of four methods of assessing oedema were used: water volumetry, figure-of-eight tape measure, perometer and visual observations by clinicians.

Water volumetry was used as the ‘gold standard’ method in all studies, as this has excellent intra and inter-rater reliability (ICC 0.99 respectively) according to Portney and Watkins (1993) interpretation (Farrell et al., 2003).

Four studies (Leard et al., 2004, Dewey et al., 2007, Borthwick et al., 2013, Leard et al., 2008] assessed the reliability of the figure-of-eight comparing it to the volumeter. However, not all statistical results were reported. Leard et al., (2008) also assessed the responsiveness of these two methods of assessing oedema.

One study (Post et al., 2003) assessed the reliability of using visual inspection versus volumeter, and the final study (Lee et al., 2011) evaluated the reliability of the perometer versus the volumeter.

Four studies (Lee et al., 2011, Leard et al., 2004, Dewey et al., 2007, Borthwick et al., 2013) assessed criterion validity and, along with Leard et al., (2008) also investigated measurement error of their respective oedema assessment tools. See Table 3.1 for an overview of the studies and the psychometric properties they assessed.

Table 3.1: Overview of included studies, cohort, assessment method and psychometric properties assessed.

Author	Patient type	Methods assessed (and compared to the volumeter)	Psychometric properties assessed
Post 2003	88 hands after first CVA	Visual inspection	Reliability
Leard 2004	33 hands after trauma or surgery	Figure-of-eight tape measure	Reliability, criterion validity, measurement error.
Dewey 2007	33 burned hands	Figure-of-eight tape measure	Reliability, criterion validity, measurement error.
Leard 2008	25 hands after trauma or surgery	Figure-of-eight tape measure	Reliability, responsiveness, measurement error.
Lee 2011	20 hands with and 20 hands without lymphoedema	Perometer	Reliability, criterion validity, measurement error.
Borthwick 2011	24 hands with lymphoedema	Figure-of-eight tape measure	Reliability, criterion validity, measurement error.

3.6.1 Figure-of-eight method

There were slight variations in the methods used to administer the figure-of-eight assessment between the four studies (Leard et al., 2004, Dewey et al., 2007,

Borthwick et al., 2013, Leard et al., 2008) and often some detail was not adequately documented. See Appendix E for full details and comparison of the methods of administration between these studies.

Leard et al's (2008) paper reports completing intra-rater reliability assessment for the figure-of-eight; however, it only documents inter-rater reliability results.

Intraclass correlation coefficients (ICC) for intra-rater reliability ranged between 0.89 and 0.99 across three of the studies (Leard et al., 2008 did not report intra-rater reliability), demonstrating excellent levels of intra-rater reliability with the figure-of-eight method according to Portney and Watkins (1993) ICC interpretation. Standard error of the mean (SEM) ranged between 0.28-0.70cm across the three studies (Leard et al., 2004, Dewey et al., 2007, Borthwick et al., 2013) which documented this.

High inter-rater reliability was also demonstrated across all four studies with an ICC of 0.84-0.99, and SEM range of 0.28-0.71cm. The study which reported the highest ICC of 0.99 (Leard et al., 2004) also reported the smallest SEM of 0.28, and the same was true for the reverse of this, 0.86 ICC and 0.71 SEM (Borthwick et al., 2013, Leard et al., 2008).

Leard et al., (2008) also assessed the responsiveness of the figure-of-eight (Fo8) versus the volumeter, which demonstrated similarly small effect sizes (ES) (0.26 for Fo8 and 0.19 for volumeter), highlighting that the ability of the tools to detect changes in hand volume over time is comparable but slightly favours the figure-of-eight. When reporting the standardised response mean (SRM), however, the figure-of-eight had a slightly lower value (0.87) than the volumeter (1.04), which contradicts the ES. As no summary statistics were given, it is not possible to replicate the analysis to verify these results.

Of the four studies which used the figure-of-eight, two scored 'poor' (Borthwick et al., 2013, Leard et al., 2008) and two 'fair' (Leard et al., 2004, Dewey et al., 2007) in the COSMIN quality evaluation tool.

3.6.2 Perometer

Lee et al (2011) assessed 20 women with and 20 women without lymphoedema of the hand and reported reliability data both for subgroups and the whole group.

Excellent inter and intra-rater reliability, according to Portney and Watkins (1993) ICC interpretation, was demonstrated for the perometer, ICC= 0.99, 95% CI 0.98-0.99, ICC= 0.99, 95% CI 0.99-1.0, respectively. Similarly, excellent inter and intra-rater reliability (ICC > 0.99) was observed for the two subgroups. There was no statistically significant difference between measurements taken by different raters or between the two measurements taken by tester 1. Whilst Lee et al (2011) gave confidence intervals with their ICCs, they did not report the SEM. The SEM may be a more relevant measure, particularly for clinicians, to interpret the typical within-subject variation of a measurement tool in the units of the assessment method.

Lee et al (2011) also assessed the concurrent validity of the perometer in relation to the volumeter. The concordance correlation, which is a measure of agreement between two continuous variables, showed good levels of agreement (Portney and Watkins, 1993) between the two assessment techniques for the group as a whole (0.88) and the 20 patients with lymphoedema (0.87). However, the group of 20 patients without lymphoedema showed a correlation of 0.71. The slightly lower correlation in this subgroup is also reflected in the intra and inter-rater reliability (ICC) of the perometer. Although there is not a substantial difference between subgroups, it is surprising as one may expect a higher level of agreement in those with no oedema.

The correlation was lower in the subgroup of patients with no lymphoedema and may be due to the fact that the hand had more concave and convex surfaces which the infrared beam may not be able to distinguish.

The perometer systematically overestimated hand volume by a mean of 24ml compared with the volumeter. This overestimation was observed to a greater extent in the subgroup of patients with lymphoedema, as seen in the wider limits of agreement (-11.97 to 68.27). Mean hand volume (n=20 women without lymphoedema) was 380ml, which equates to a 6% overestimation in volume. Whilst the perometer has inter and intra-rater reliability comparable to the gold standard volumeter and very good concordance correlation, calibration issues led to a 6% overestimation and therefore the two methods for measuring hand volume should not be used interchangeably.

Lee et al (201) commented that a potential issue of the perometer is its inability to discriminate interdigital spaces, and therefore it interprets this space as volume and includes it in the overall volume measurement. This may account for the overestimations seen, and for the lower correlation in the subgroup with no lymphoedema. It may also be difficult for some patients to maintain a static position over the period required to complete the assessment, and therefore a slight shift of the hand may result in an overestimation of the actual volume.

Lee et al's study (2011) scored 'fair' overall across absolute error, reliability and criterion validity categories of the COSMIN quality assessment.

3.6.3 Visual Inspection

Visual observations were carried out by experienced therapists during a 1-hour consultation for post-stroke arm/hand problems. The therapists classified the amount of hand swelling observed during visual inspection as being nil, minor or severe. Post et al (2003) assessed 88 hands after the patients' first stroke. Whilst the authors claim there was "a clear relationship between the assessment by the physical therapists and the 'adjusted volume scores'", the results actually indicated a lack of agreement between clinical and volumetric assessment of oedema. A 67% agreement was found between classification of oedema by therapists and the volumeter. A Kappa value of 0.34 is considered a fair level of agreement (Cohen, 1960). However, no confidence intervals were provided.

The authors did not report sensitivity or specificity values, but these have been calculated from the data provided. Sensitivity of visual inspection by therapists was 74%, indicating that in 24% of cases, therapists missed oedema using this technique. In 76% (22/29) of cases when the therapist reported oedema, the volumeter also agreed. Therapists' clinical judgement classified only 4.5% (n=4) of the group as having major oedema, when the volumeter results show that actually 18.5% of the group were in this category.

Specificity of visual inspection was 63%, meaning that in 63% (37/44) of cases the therapist reported no swelling and the volumeter also agreed. Therapists' clinical judgement classified 40% of the population (n=44) as having no oedema, whereas the volumeter results indicate only 2.2% of the group had no oedema.

Visual estimations by therapists will miss some patients with oedema and wrongly diagnose some patients as having oedema.

This study scored ‘fair’ on the COSMIN quality assessment in both criterion validity and reliability categories (see Table 3.2 for quality rating, showing number of items scoring each grade). See Appendix F for quality assessment tables for each psychometric property assessed.

Across the two categories, scores of ‘fair’, ‘good’ or ‘excellent’ were given for each question. However, in light of the lack of sensitivity and specificity calculations, this brought the overall rating down to ‘poor’.

Table 3.2 COSMIN scores for each study and domain

Study	Domain assessed	Excellent	Good	Fair	Poor	'Lowest score counts'
Post et al (2003)	Reliability	5	3	3	0	**Fair**
Leard et al (2008)	Reliability	5	0	3	1	**Poor**
	Responsiveness	7	0	4	1	**Poor**
	Measurement error	6	1	1	1	**Poor**
Dewey et al (2007)	Reliability	4	0	5	0	**Fair**
	Criterion validity	2	0	2	0	**Fair**
	Measurement error	6	1	2	0	**Fair**
Borthwick et al (2011)	Reliability	6	1	1	1	**Poor**
	Criterion validity	2	0	1	1	**Poor**
	Measurement error	6	1	1	1	**Poor**
Lee et al (2011)	Reliability	2	3	4	0	**Fair**
	Criterion validity	2	0	2	0	**Fair**
	Measurement error	6	1	2	0	**Fair**
Leard et al (2004)	Reliability	6	1	2	0	**Fair**
	Criterion validity	2	0	2	0	**Fair**
	Measurement error	6	1	2	0	**Fair**

3.7 Discussion

The aim of this systematic review was to review the quality and quantity of current evidence on the psychometric properties of methods for assessing hand oedema, and identify factors which may affect the standardisation of these methods when used on the hand.

The review found limited, low quality evidence to support the use of the figure-of-eight tape measure to assess hand volume in patients with acute or chronic oedema from a traumatic, lymphatic or neurological cause. Differences, or lack of documented detail, on the administration of the assessment highlighted a need for standardisation of this assessment method.

Whilst the perometer had similar levels of reliability to that of the ‘gold standard’ volumeter, it showed a systematic overestimation that equated to 6% of total hand volume, highlighting its incompatibility to be used interchangeably with the volumeter. Issues around hand position and accuracy of the infrared beam to discriminate hand volume and space contributed to the overestimation of hand volume. While a lightweight and portable version of the perometer exists, the standard version would require a permanent space in a clinical setting and costs between £10,000 and £15,000, depending on the model.

Visual inspection had a fair level of agreement with the volumeter. However, it showed that this method may miss some patients with oedema and wrongly diagnose some patients as having oedema.

3.7.1 Methodological quality

The Consensus based Standards for the selection health Measurement Instruments v9 2012 (COSMIN) (Mokkink et al., 2012) was used to assess the methodological quality of the studies. COSMIN was developed specifically to assess health-related patient-rated outcome measures (HR-PRO) the latter are often made up of several items designed to measure a latent construct. Therefore some sections and questions of the checklist are not appropriate when evaluating measures of a single domain, such as hand volume. For example, the first two questions of the 10-item checklist, "Was the percentage of missing items given?” and “Was there a descriptor of how missing items were handled?” are not relevant.

The current scoring system works on a 4-point rating scale: excellent, good, fair and poor. This was adapted from a dichotomous response option (yes/no) and accounts for some of the issues with scoring. In the majority of questions there are descriptors under each rating, which qualify what the paper must report in order to achieve that rating. However, in some cases, descriptors were not included. For example, for internal consistency (question 7) only 'excellent' and 'poor' descriptions are given and for question 10 the descriptor for 'good' was not given.

In some cases the missing 'good' and 'fair' descriptions were appropriate, as the question related to the completion of statistical tests that warrant only a 'yes' (excellent) or 'no' (poor) answer. However, in some instances the gap or difference between descriptors seemed arbitrary, and often it is difficult to find the most appropriate score based on the descriptions given to accurately reflect the quality of the paper. The working group who developed the 4-point rating scale report that for some questions it was not possible to define four different response options (Mokkink et al., 2012).

A 'worst score counts' method is used to give an overall quality rating for each measurement property. A poor score on any one item is thus considered to represent a fatal flaw (Terwee et al., 2012). Other methods of scoring were considered. Firstly, the method of rating the overall methodological score as being good when most, but not all, items are considered 'adequate' and 'poor' when more than a set number of items are inadequate. This flexible approach to scoring quality was inconsistent with the results of the Delphi study (Mokkink et al., 2010) which developed the tool, as the expert panel considered all items to be important whereas this scoring method would give greater weight to certain items. Secondly, a 3-point rating scale (good, fair and poor) was considered, but the inclusion of 'excellent' was felt necessary to differentiate between studies which scored adequate in all items, rather than in most. A third approach is to take the mean score per measurement property. Each response is given a score (poor=0, fair=1, good=2 and excellent=3), and the total score is divided by the number of items completed. This method can be used even if some items are not applicable and therefore not scored, and it is not affected by different numbers of items per measurement property. Whilst the overall score is often lower than the subjective judgement of the marker, this method was agreed, following a Delphi consensus study (Mokkink et al., 2010), to be the most

appropriate. The scoring method, however, is based on arguments and not evidence, and the validity and reliability of the current recommended scoring system has not been investigated (Terwee et al., 2012). Despite the limitations of this critical evaluation tool, it is the only standardised rating tool which can be applied to health-related clinician-derived measurement instruments.

Four studies (Leard et al., 2004, Dewey et al., 2007, Lee et al., 2011, Post et al., 2003) scored 'fair' in all measurement properties assessed. Leard et al (2008) and Borthwick et al (2013) scored 'poor' across all three measurement properties assessed (reliability, criterion validity and measurement error). Both studies scored 'poor' based on a single item: adequate sample size. Sample size numbers are given as a guide for each response option based on 'rule of thumb' (Terwee et al., 2012). However, authors report that definitions of an 'adequate' sample size may differ depending on the situation, and that markers should have the flexibility to adapt the scoring system based on their own application. This explains why certain items do not have specified guides, such as the time between assessments in test-retest evaluation. Whilst this flexibility is useful to ensure the scoring system is representative of a particular instrument and its setting, it may cause issues regarding the standardisation of the checklist scoring system and comparison between markers' scores and across studies (i.e. updating of a systematic review), unless the guides have been pre-specified, clearly documented and remain consistent during any comparison.

3.7.2 Minimal detectable change in hand volume

Three studies (Leard et al., 2004, Dewey et al., 2007, Borthwick et al., 2013) documented inter-rater reliability of the figure-of-eight tape measure method. ICCs ranged from 0.84-0.99 across the three studies with an SEM range of 0.28-0.60cm. Whilst it is important to be using the most reliable, feasible, valid and responsive tool, it is also important to know what would be considered the smallest detectable change (SDC) (Van Kampen et al., 2013) or smallest real difference (Beckerman et al., 2001) using that tool. SDC refers to the minimal within-subject change which cannot be attributed to measurement error but rather indicates real change in the measured ability (Serbetar, 2014). Dewey et al (2011) highlights that 95% of the time the true value of hand size (based on the cohort of 33 burned hands) should be

within 1.16 cm of the measured value (Portney and Watkins, 1993). As the ICC is higher in the Leard et al (2004) study (0.99), and therefore the SEM is smaller (0.28cm), an SDC of 0.56cm would indicate a real change in hand size. However, this is less than half of the value of the Dewey et al (2007) study. Practice, experience and clear standardised guidelines should increase inter-rater reliability, which will reduce the SEM and SDC values, giving clinicians' greater confidence in the tool, its inter-rater reliability and its ability to reflect a true and clinically relevant change in hand volume.

3.7.3 Level of experience

Assessors with a variety of experience levels were included across the six studies. Post et al., (2003) used experienced physical therapists, whereas Borthwick et al., (2013) used two novice practitioners (one newly qualified physiotherapist and one final-year nursing student). They received a 1-hour training session on how to use the figure-of-eight and the volumeter. Borthwick et al., (2013) suggests the slightly lower reliability values seen in this study (inter-rater reliability 0.84, intra-rater reliability 0.88-0.92) in comparison to others (Leard et al., 2004, Borthwick et al., 2013, Leard et al., 2008), may be due to the inexperience of the assessors. They propose that novice testers may have difficulty tensioning the tape measure accurately on swollen hands. Leard et al., (2004) also used two inexperienced assessors, who were students in the final year of a physical therapy master's degree. Testers received four practice sessions held on separate days, totalling 2 hours of practice, measuring seven healthy participants and seven participants with recent hand trauma. The testers were encouraged to discuss and compare their results during the practice session with a senior investigator, and to develop strategies to standardise the administration procedure. Despite having slightly longer to practise than the assessors in the Borthwick et al study (2013), they were still classified as novice testers. However, the ICC values obtained in this study (0.98-0.99 inter and intra-rater reliability) contradict Borthwick's study (2013), which claimed inexperienced testers contributed to lower reliability. The five assessors in Leard's (2008) study were all certified hand specialists with an average of 18.6 years of experience (13-25 years). The five assessors completed a pre-study training session to ensure experimental procedures would be followed. Leard et al., (2008) suggests that experienced hand therapists may affect the generalisability of the

results to other examiners, who may not have as much skill or familiarity with hand anatomy. Dewey et al., (2007) used three licensed occupational or physical therapists. They had two practice sessions on separate days, using healthy individuals, and also discussed the most effective methods of standardising the procedure. They gave no details on the level of their experience.

These results suggest that level of experience does not seem to have a statistically significant effect on reliability using the figure-of-eight method on patients with hand swelling. This is consistent with evidence suggesting years of practice and hand therapy experience has no influence on the reliability of hand goniometry (Ellis and Bruton., 2002).

3.7.4 Measurement error

Incorrect limb position has been described as the main reason for the poor accuracy of the volume measurement obtained by the perometer. This has been previously documented (Stanton et al., 1997, Hebeda et al., 1993, Louisy et al., 1995). Stanton et al., (1997) reports that large measurement errors occurred when the limb was not perpendicular to the laser beam; for example, if a segment/section of the limb was slightly rotated within the device. Lee et al., (2011) attempted to reduce measurement error arising from limb position by ensuring all patients held their digits tightly together, including the thumb close against the index finger. The perometer, however, viewed the hand as an elliptical object and included interdigital air spaces as tissue, and therefore this was included in the overall volume.

Inter and inter-rater reliability ICC was lower (0.96 intra-rater and 0.95 inter-rater reliability) for the subgroup of 20 women without lymphoedema in this study. When a hand is swollen (such as in lymphoedema), it takes on more of a triaxial ellipsoid shape and thus the laser beams cannot detect the diminished or absent interdigital air spaces, resulting in greater reliability measures for patients with swelling than those without.

Lee et al., (2011) highlights that the perometer has advantages to the water displacement method in that it can be used on patients with skin conditions and open wounds, where using the volumeter may not be feasible. It is much quicker to administer and requires less set-up time. However, the measurement errors described above are not isolated to the hand. Man et al., (2003) reports that angle of

the knee could affect the volume measure by up to 11% using the perometer. It is possible that even with a standardised protocol and limb position, the unique position of the thumb in a frontal plane makes opto-electric imaging unsuitable for use on the hand when assessing volume.

Post et al., (2003) highlight a limitation of their study, which was the time between assessments. Median time between clinical evaluation and volumetric assessment was seven days. They report that time between assessments did not influence results; however, it was shown that visual inspection may underestimate the number of patients with oedema and overestimate the number of patients without oedema. As the clinical evaluation was performed first, the oedema could have improved spontaneously or worsened by the time the volumetric assessment took place seven days later. The authors do not report what, if any, therapy interventions took place during the seven days which may account for a change in volume. A higher level of agreement with clinical evaluation could have been observed if the volumetric assessments were completed at a more appropriate time, i.e. on the same day as the clinical evaluation.

The type of tape measure may also affect the accuracy of the measurements obtained. Retractable measures may have more ‘give’ to them and can be pulled tighter. Particularly in oedematous hands, the danger is that whilst a therapist is concentrating on locating anatomical landmarks to achieve accurate tape placement, the tension being applied can squash the puffy tissues. Education, practice and standardised protocols for administration may reduce this risk.

3.7.5 Limitations of the review

This systematic review has a number of limitations. Firstly, the included studies focus on hand oedema, and whilst methods such as the volumeter, perometer and visual inspection will take into account swelling of the digits as well as the hand, the figure-of-eight method neglects the digits and therefore could not be used in isolated finger swelling. The circumferential measurement of digits which is routinely used when assessing isolated digit swelling was not a method described in the selected papers.

The volumeter is also likely to include volume of the wrist and possibly part of the forearm along with the hand and digits, whereas the figure-of-eight focuses purely on the hand. The inclusion criteria for this systematic review specified hand oedema

only. However, as the volumeter was used as the comparator in all studies, it is feasible, particularly in patients with lymphoedema, (Lee et al., 2011, Borthwick et al., 2013), stroke (Post et al., 2003) and burns (Dewey et al., 2007), that the swelling extended into the arm and that this may have been included in volumetric assessment but not in the figure-of-eight measurements. It is also unclear of the exact cut-off point for the perimeter's laser beams and the clinician's visual evaluation.

The inclusion criteria specified oedema of the hand and excluded studies where oedema of the entire upper limb, including the hand, was assessed. However, it was not made explicit whether studies which only assessed digital oedema would be included or not. For the purposes of this study the two studies which focused on digit oedema (Jansen et al., 2010, Lewis, 2010) were not included. Future reviews may benefit from their inclusion, to compare the psychometric properties of method to assess oedema in the digits and hand.

Another limitation could be the generalisability of the results. Whilst it appears the results are general sable to therapists with varying levels of experience, due to the limited number of papers meeting the inclusion criteria, the results may not be generalisable to patients with different hand conditions, or in different settings, such as chronic, rehabilitation or the very acute phase of oedema.

3.8 Future research

To the best of the authors' knowledge there are no patient-rated outcome measures currently being used which assess or grade swelling from the patient's perception. Although oedema is often an observable condition which can be measured by the clinician using a tape measure or volumeter, it is also a subjective condition, like pain, where a patient may feel that their hand is swollen even if this swelling is not detectable to the eye. It would be useful to establish the relationship between a clinician-derived outcome, such as a tape measure or volumeter, and a patient-rated outcome measure which grades their perception of the swelling: for example, mild, moderate, severe or extreme. This could be a useful and quick method of evaluating treatment effectiveness from the patient's perception.

3.9 Conclusion

There is low-quality evidence supporting the use of the figure-of-eight tape measure to assess hand volume. This method should be considered as the best alternative to the volumeter. Benefits include reduced cost and time, and comparable reliability to the ‘gold standard’ volumeter. Visual estimation of hand oedema is not to be recommended**.**

This chapter has synthesised the evidence of psychometric properties of measures to assess hand oedema. Each paper was graded using the COSMIN quality assessment criteria, with issues affecting methodological quality and feasibility of use in clinical practice being discussed before providing recommendations regarding measuring hand oedema in a clinical setting. The next chapter will present a cross-sectional survey of current hand therapy practice on the assessment and treatment of hand oedema.

3.10 Addendum

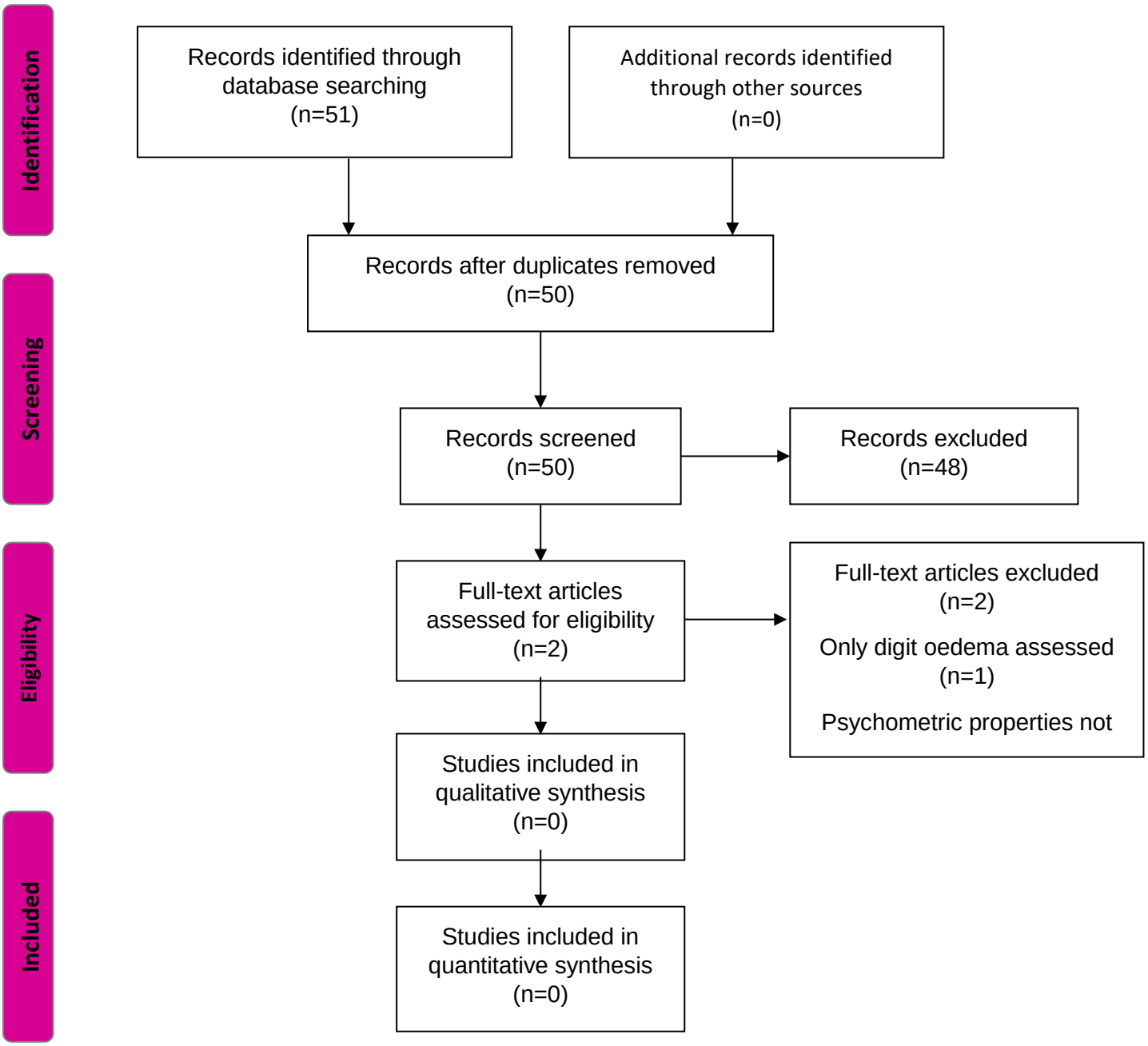
A repeated database search was conducted from March 2017 to November 2018. Article titles were screened and abstracts reviewed in accordance with the eligibility criteria. Full-text articles were obtained in order to confirm inclusion or exclusion.

An updated PRISMA flow diagram is presented in Figure 3.7.

No additional papers met the inclusion criteria. The results and conclusion remain unchanged.

Please refer to Appendix G for a copy of the published systematic review.

Figure 3.7 PRISMA 2009 flow diagram (updated)



4.1 Introduction

The previous chapters reviewed the published evidence regarding the assessment and treatment of sub-acute hand oedema. The systematic review of assessment methods found that the figure-of-eight tape measure was the best alternative to volumetry. Other assessment methods included in the review were found to systematically overestimate volume (perometer), whereas visual estimation had poor sensitivity and specificity and was therefore not recommended in clinical practice. However, the quality of the included studies was low. The systematic review of treatments for sub-acute hand oedema found low to moderate quality evidence for the use of manual edema mobilisation in conjunction with conventional therapies. This review identified 16 treatments to reduce hand oedema, with little consensus on the most effective method or dose. Some treatments described were dated and are no longer used in clinical practice. Therefore it was necessary to establish what current UK practice is and to compare this to the evidence from published studies.

This chapter focuses on a survey which aimed to establish how hand therapists in the UK assess and treat sub-acute hand oedema. This chapter describes and discusses the methods and results of an online survey designed to identify current assessment and treatment methods of hand oedema among hand therapists in the UK

4.2 Methods

4.2.1 Study design

A cross-sectional study was conducted using an electronic survey. This method was chosen over interviews or observation of practice for its cost and time-saving benefits, and the ability to capture a more representative sample of a larger population. Drawbacks of using an online survey were also considered, such as non-completion, need for incentives and the potential difficulty in capturing detail or in-depth explanation from respondents (Fischbacher and Chappel et al., 2000, Shih and Xitao 2008) . However, this was balanced with the potential for higher response rates to an online survey compared to arranging Skype, telephone or face-to-face

interviews, which would require planning, travel time and costs, room booking and interviewer training. Observations of practice may not have elicited reliable data, as clinicians would have been aware they were being observed and may have altered their practice. It is likely that some questions would not be answered through observations of practice alone, and therefore would be needed to be supplemented with an interview or survey.

4.2.2 Sampling and recruitment

This survey focused on UK practice, and therefore the British Association of Hand Therapists (BAHT) was the most appropriate special interest group to approach to gain access to hand therapists working in the UK. BAHT membership involves an annual paid subscription available to any occupational therapist or physiotherapist working in, or with a special interest in, hand therapy.

4.2.3 Eligibility criteria

Therapists (occupational or physiotherapist), assistant practitioners and therapy assistants who were members of the British Association of Hand Therapists (BAHT) and held a clinical case load that includes treating patients with hand oedema were eligible to participate in the online survey.

4.2.4 Exclusion criteria

Therapists were excluded if they were not current members of the British Association of Hand Therapists (BAHT) or did not regularly treat (at least 2 per week) patients with sub-acute hand oedema. As this survey was distributed via BAHT social media and oedema is commonly treated by hand therapists, it was anticipated that few therapists would be excluded from the survey.

4.2.5 Data collection and questionnaire design

The web-based questionnaire was designed and administered using a premier package of SurveyMonkey®. UK practising hand therapists were recruited through a special interest group, the British Association of Hand Therapists (BAHT), comprising circa 800 members (occupational therapists and physiotherapists specialising in the rehabilitation of the hand).

Basic demographic information was collected to establish the profession, grade and experience levels of the cohort.

The questionnaire comprised 10 sections pertaining to 10 different treatments for hand oedema. These were established from the systematic review completed in work package 1. Initially respondents were asked to state if they used the treatment. If they did not, the questionnaire skipped to the next intervention and the respondent was asked the same question regarding their use of that treatment. When respondents indicated they did use a particular treatment, this populated a series of questions designed to ascertain their exact prescription of that treatment in terms of advice to patients, precautions or contraindications, length and frequency of use and equipment.

Further questions asked respondents to rank in order the 10 treatments that they perceived to be most effective, regardless of whether they were qualified to perform these techniques or not. It was acknowledged that some respondents may not have received training to use all of the treatments, therefore the next question asked them to rank the same 10 treatments into order of the perceived effectiveness of the methods they are currently trained to administer. These two questions were asked in order to establish if respondents felt a particular treatment was superior, regardless of whether they could use this in their clinical practice.

Continuing on from this, respondents were asked to state the level of training or qualification they have received in order to perform each technique. Possible responses included: formal and informal training, specific qualifications or no training received.

The final set of questions asked respondents to identify which measure/s they used to assess the effectiveness of their treatment. A range of objective and patient-rated measures were listed, and specific details were requested from respondents who identified using the volumeter, tape measure or patient-rated outcome measures, as this information linked to the observational study in work package 3.

4.2.6 Piloting

The online questionnaire was piloted by the principal investigator's supervisor to ensure the question-skip logic and functions of the survey directed respondents to the appropriate page/section of the survey. Following further refinement, the survey was piloted by two members of the local hand therapy team, who recorded the length of time it took to complete and any technical issues they encountered. These were then rectified before the survey link was opened to hand therapists.

4.2.7 Advertising

A quarterly e-bulletin, sent to all BAHT members, was used to advertise the survey and invite members to participate. Members had already agreed to receive these e-bulletins and relevant emails regarding research activity as part of their BAHT membership. Members are able to unsubscribe to these emails at any time. The principal investigator (PI) of this study was not given access to individual members' email addresses, but she is a member of BAHT. The survey web link was forwarded to the secretary of BAHT, who then included this in the quarterly e-bulletin.

The BAHT annual conference (November 2015) and regional group contacts were also used to raise awareness of the study and maximise response rates.

The web-based questionnaire was designed using open and closed questions to obtain data on respondents' current practice with regards to assessing and treating hand oedema. At the end of the survey, respondents were asked to contact the principal investigator if they considered themselves suitably qualified and experienced to take part in the next phase: the Delphi consensus method.

The survey opened on 21 December 2015 and was accessible for 14 weeks, closing on 31 March 2016. Email reminders were sent to regional therapy leads to encourage their team members to take part. Social media was used, in the form of the BAHT's Facebook and Twitter accounts, to post reminders and the e-bulletin also featured a reminder message in order to try and increase the response rate.

4.2.8 Software

A premier package of SurveyMonkey® was used. This is an online survey development, cloud-based, 'software as a service' company. The premier package is a paid back-end program that includes data analysis, sample selection, bias elimination, and a data representation tool.

4.2.9 Confidentiality

SurveyMonkey® is password-protected software which only the PI had access to. The survey responses were submitted anonymously with no personal identifiable information required from the respondent. The PI had no way of tracing the Internet Protocol (IP) address of the device used to complete and submit the survey.

4.2.10 Ethics and consent

The Chair of the BAHT Clinical Evidence Committee (CEC) approved the project and use of BAHT social media and e-bulletin to advertise the survey link in October 2015. Ethics approval was gained from the Faculty of Medicine and Health Research Ethics Committee on 16 December 2015 (see Appendix G for approval letters) Participants were not able to access the start of the survey until they had read the participant information sheet (PIS) and completed a consent form (see Appendix H for PIS and Appendix I for consent form).

4.2.11 Analysis

The SurveyMonkey® package used collated survey data and presented the data for each question in proportions (percentage and number of respondents answering and number of respondents who skipped the question). Questionnaire data was presented in bar charts when response options were specified. Free-text data was listed according to respondent number.

The survey data were analysed using summary statistics for closed questions and content analysis for open questions. The results helped to describe UK current oedema treatment and assessment methods and assisted in the development of the first round of the Delphi Consensus study.

4.3 Results

4.3.1 Response rate

The online survey (see Appendix J for survey questions) was available for 14 weeks, between 21 December 2015 and 31 March 2016. During this time 156 respondents accessed the online survey link. At the time of conducting the survey BAHT had 730 current members, of which 612 subscribed to the e-bulletin. Twenty-six e-bulletins bounced back, indicated either an incorrect e-mail address or the member had opted out of receiving the e-bulletin. Five hundred and eighty-six members received the e-bulletin, giving a 27% (n=156) response rate. As it is not possible to identify the number of members who accessed the link via social media, the response rate was based on the members who accessed the e-bulletin link.

One hundred and fifty six participants confirmed they were members of BAHT in the first screening question. However, only 130 participants confirmed they regularly treat hand oedema (at least 2 patients per week) in the second screening question. One hundred and eighteen participants completed the consent process. At this point three participants left the survey, leaving 115 active respondents by the start of the questionnaire, giving a 20% response rate. A 70% (n=80) completion rate was calculated, based on the proportion of respondents who passed screening and started the survey. Thirty-five respondents did not complete the full questionnaire.

4.3.2 Demographics

Seventy percent (n=81) of respondents were occupational therapists (OT), which is representative of the BAHT membership (459 (63%) OT members, 271 physiotherapist members)**.** No assistant practitioners or therapy assistants completed the survey, which accounts for the lack of NHS Agenda for Change Band 3 and 4s. One respondent chose the ‘Other’ option and commented that her job title was Clinical Specialist in Hand Therapy. See Table 4.1 for details on banding of respondents.

Table 4.1 Banding of respondents

Years of hand therapy experience	%	N=
Under 2 years	2%	2
2-5 years	10%	11
6-10 years	29%	33
11-15 years	28%	32
16- 20 years	17%	19
More than 20 years	16%	18
Total	**100%**	**115**

Of the 6 respondents who chose 'Other', 3 stated they were specialist hand therapist in private practice, 1 was a supervisor OT, 1 a senior and 1 working in the Republic of Ireland, which does not adhere to the Agenda for Change banding structure. See Table 4.2 for a summary of the level of experience of respondents. Table 4.3 shows the number of patients with hand oedema treated per week by respondents.

Table 4.2 Experience of respondents

Banding level	%	N=
Band 3	0%	0
Band 4	0%	0
Band 5	2%	2
Band 6	26%	30
Band 7	49%	56
Band 8	18%	21
Other	5%	6
Total	**100%**	**115**

Table 4.3 Frequency of treating patient with oedema

Patients with sub-acute oedema per week	%	N=
Less than 2*	3%	3
3-5	30%	35
6-10	20%	23
11-20	30%	35
More than 20	17%	19
Total	**100%**	**115**

***This question screened out any participants who did not meet the eligibility criteria.

4.3.3 Treatments

The survey inquired about 10 treatments. Table 4.4 gives the number of respondents for each treatment, along with the proportion of respondents who reported using the treatment. The treatments are listed in order of most frequently used, based on absolute number order, i.e. n=. Respondents could select as many options as was relevant to their clinical practice. The final column summarises descriptive data on the implementation of treatments.

Table 4.4 Absolute number order of treatments most frequently used, with details on the implementation of treatment

Absolute number order	Treatment	Number of respondents	Percentage of respondents using	Description * See table 4.5 for more details.
1	Compression	n=112	93% (n=104)	Isotoner or oedema glove*
2	Compression	n=104	95% (n=99)	Coban™ wrap*
3	Elevation	n=90	100% (n=90)	Elevate above the level of the heart (98%, n=86) Exercise with arm in elevation (91%, n=80) Sling or collar and cuff not advised (53% n=47) Elevate when practical/ during rest (n=14), until oedema subsides (n=18). Precautions include; numbness, increased pain or stiffness or compromised vascularity.
4	Massage	n=90	94% (n=85)	Distal to proximal direction (88%, n=75) using light pressure with cream/oil (91%, n=77), for approximately 10-15 minutes (n=17), 3 times a day (n=11) until oedema resolved (n=26).
5	Exercise	n=86	94% (n=81)	Active exercises (98%, n=78) With elevation (85%, n=68) With contrast bathing (69%, n=55)
6	Compression	n=97	72% (n=70)	Lycra sleeve*
7	Kinesiology tape	n=93	41% (n=38)	Fan shape (n=23) Beige tape (71% n=25) Colour of tape not influencing effect (77% n=27) Use on clean dry skin no creams/oils, shave area if needed (n=38) Tension: paper off (n=8), 0- 20% (n=8). Wear until tape comes off (n=7), 3-5 days (n=4).
8	Manual lymph drainage	n=88	23% (n=20)	"As per Artzberger 2004 programme" (n=3). Breathing and massage performed by n=6, three times a day (n=5)
9	Breathing exercises	n=86	16% (n=14)	Deep diaphragmatic in sitting (n=6) or standing (n=5). Three breaths (n=5) 3-6 times daily (n=5)
10	Electrotherapy	n=86	9% (n=8)	Ultrasound 75% (n=6) Administered twice weekly 50% (n=4)

Respondents who identified using a particular treatment were directed to further questions to find out what recommendations they gave to patients. These have been summarised under the description column of Table 4.4.

Compression (glove, sleeve or wrap) was the treatment used by most of the respondents, and larger variations were observed in responses relating to the frequency, duration and precautions advised to patients. Table 4.5 summarises the number of distinct response categories for each question for compression and gives further details on the top three responses received, where appropriate

Table 4.5 Details on implementing treatment- compression.

Treatment	n=	When to wear	When to remove	Frequency (minutes/hours)	Duration (days/weeks)	Precautions	Other methods used
Oedema glove	n=96	16 distinct response categories; 1. Day time n=23 2. 24 hours a day n=20 3. 23 hours a day n=10	12 distinct response categories; 1. Hygiene n=57 2. Function n=24 3. Scar massage n=10	20 distinct response categories; 1. As much as possible n=14 2. 23 hours a day n=14 3. Patient dependent n=13	11 distinct response categories; 1. Until stop seeing benefits n=31 2. Review at each appointment n=15 3. As required n=13	2 distinct response categories; 1. If capillary refill or sensation affected, if pain increases, or if skin damage/allergies occur 2. None issued n=8	Coban™ Lycra sleeve Tubigrip Flowtron 'Chippy' bag Massage
Coban™ Wrap	n=94	2 methods of application described- spiral and tubular. Tubular- with single layer of 3-inch Coban™ using pinch technique to secure on dorsum of digit. Spiral-with 1-inch Coban™ wrapping distal to proximal. The amount of stretch required was described in 9 different ways; not full, gentle, minimal, slight, light, 50-75% stretch, no stretch, 30%, 0-20% stretch. The proportion of the tape which should overlap was described in 3 different ways: ½, 50%, or 1/3 overlap.	Responses for when to wear ranged from 5-10 minutes every hour to 24 hours a day. Remove for hygiene, skin check/normal sensory input and during exercises if restrictive.	Responses ranged from 5-15 minutes to 24 hours a day.	Most respondents stated use as needed, as long as required, or until oedema had resolved. Specific timeframes varied from 7 days to 6 weeks.	As above for oedema glove.	N/A

Treatment	n=	When to wear	When to remove	Frequency (minutes/hours)	Duration (days/weeks)	Precautions	Other methods used
Lycra digi sleeve	n=70	Gently pull sleeve on ensuring no wrinkles with seams on outside. Location of seam; responses varied from central dorsal to palmar.	Responses were split into those who recommended just day time use, those who recommended for day and night those who states wear as needed. Removal as per Coban™.	Responses ranged from 30 minutes to 25 hours a day.	As above responses for Coban™.	As above responses for Coban™ and glove.	N/A

4.3.4 Likelihood of using treatment

Respondents were asked to rank the 10 oedema treatments according to the likeliness of using these in their clinical practice. The difference between this question and the previous one was to highlight which were the most commonly implemented treatments, as opposed to which treatments were used in general. Table 4.6 displays the results.

Treatments in bold appeared in the same rank order as in the previous question, which ranked the treatments most frequently used.

Table 4.6 Rank order and score of treatment most likely to be used to treat hand oedema for n=80 respondents.

Rank order	Treatment	Score 1-10 1=least likely, 10-most likely
1	Elevation	8.6
2	Exercises	7.9
3	Coban™ wrap	7.4
4	**Massage**	7.2
5	Compression glove	7.0
6	**Lycra digi sleeve**	5.7
7	**Kinesiology tape**	5.2
8	Breathing techniques	4.0
9	Manual lymph drainage	3.8
10	**Electrotherapy**	3.0

4.3.5 Perceived effectiveness of treatments

Respondents were then asked to rank the 10 treatments according to their perceived effectiveness irrespective of whether they were trained to use, or used, the method in their clinical practice. Results are shown in table 4.7. Two treatments (in bold) appeared in the same rank order as the previous two questions.

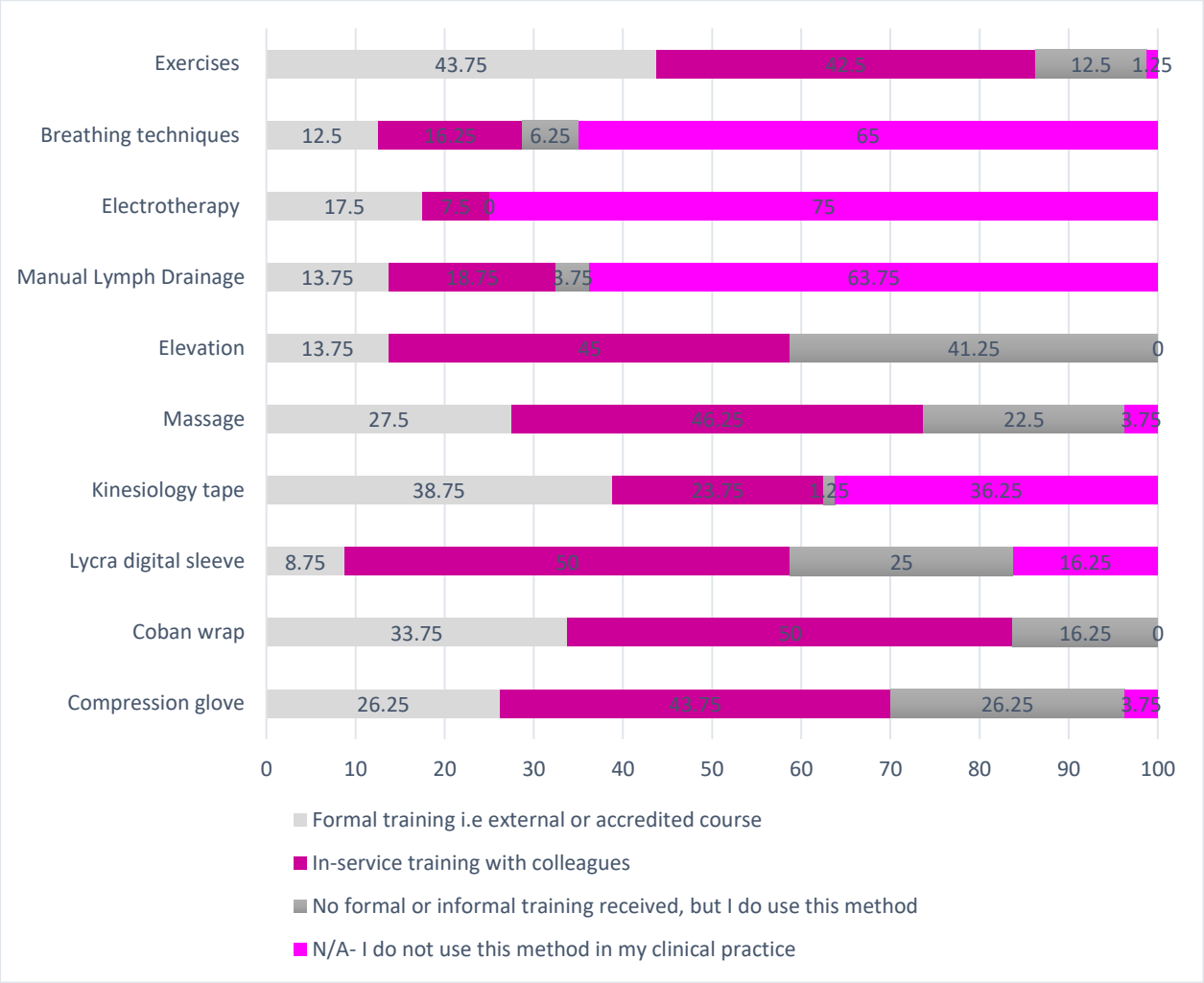
Table 4.7: Rank order and score of treatment according to their perceived effectiveness for n=80 respondents

Rank order	Treatment	Score 1=least likely, 10=most likely
1	Elevation	8.2
2	Coban™ wrap	7.3
3	Compression glove	7.2
4	Exercises	7.1
5	Massage	6.5
6	**Lycra digital sleeve**	5.4
7	Manual lymph drainage	4.6
	Kinesiology tape	
9	Breathing techniques	2.2
10	**Electrotherapy**	2.0

4.3.6 Level of training

Question 40 asked respondents to identify which of the 10 treatments they had received training for and to describe the style of that training (for example, formal or informal), and whether they used the treatment in their current practice. The results show that of the 80 respondents who completed this section, and used the technique in question, formal training (through external or accredited courses) was obtained for treatments such as exercise prescription (44%), kinesiology taping (39%) and Coban™ wrapping (34%). The number of respondents receiving informal training in the form of in-service teaching with colleagues was generally higher across the majority of modalities than formal training. With the exception of electrotherapy, some respondents used modalities without any formal or informal training. For example, over 50% used some form of compression, 22% used massage and 4% used manual or modified manual lymph drainage. See Figure 4.1 for full details.

Figure 4.1: Stacked bar chart of level of training received for each treatment



4.3.7 Evaluating effectiveness of treatment

Respondents were asked to identify how they would evaluate the effectiveness of their oedema treatment from a list of 10 options, including subjective and objective measures (question 41: of the following options, how would you evaluate the effectiveness of your chosen oedema treatment/s? Please tick all that apply). These methods are presented (Table 4.8) in order of those most likely to be used by therapists. Multiple options could be chosen by respondents.

Table 4.8 Rank order of outcome measures used by therapists to evaluate effectiveness of oedema treatments from n=80 respondents

Rank Order	Measure	%	N=
1	Visual inspection	94	75
2	Goniometry	85	68
	Patient subjective account	85	68
3	Functional assessment	54	43
4	Strength	25	20
	Return to work	25	20
5	Patient-rated outcome measure (PROM)	0	0
	Measuring tape	0	0
	Volumetry	0	0

Questions 42, 44 and 46 then asked respondents if they used volumetry, tape measures or patient-rated outcome measures to assess oedema in clinical practice. The results are summarised in Table 4.9. If a respondent identified that they did use one of the above assessments, they were directed to a further question to gather more details.

Despite the results in Table 4.8 (question 41), which suggests that volumetry, tape measures and PROMs were not used to evaluate the effectiveness of oedema treatment, responses to subsequent questions (Table 4.9) indicate they were used to assess oedema. This may imply that questions in this section were not fully understood. These particular three methods were chosen for further questioning in order to feed into the subsequent observational study, which compared the relative responsiveness of two assessment and two patient-rated outcome measures in a cohort with hand oedema.

Table 4.9 Details on volumetry, tape measuring and PROMs assessment methods

Method	% (n) using method	Description
Tape measure	93% (n=74)	38% (n=28) use Fo8 96% (n=71) use circumferential 3% (n=2) report 'other' -Fo8 for hand oedema and circumferential for digit oedema
Volumetry	16% (n=13)	100% (n=13) use the commercially available upper limb volumeter 18% (n=2) reported using a 'standardised protocol', however 38% (n=5) gave unspecific details about the protocol they used. 31% (n=4) correctly stated the hand was lowered into the volumeter until the positioning bar was in the 3rd webspace, whereas 1 respondent (8%) stated the first webspace. One respondent stated calculating volume increase of affected hand based on volume of unaffected hand. 54% stated they would not use the volumeter in the presence of wounds, whilst 46% (n=6) said they would use a tape measure instead of the volumeter in these circumstances.
Patient-rated outcome measures	23% (n=18)	QuickDASH 88% (n=15) Other 47% (n=8) Patient Specific Function Scale (n=3), EQ-5D (n=2) DASH 41% (n=7)

Method	% (n) using method	Description
		PRWHE 24% (n=4) PEM 19% (n=3) MHQ 12% (N=2)

Legend: Fo8= Figure-of-eight tape measure, DASH- Disabilities of Arm, Shoulder and Hand, PRWHE= Patient Rated Wrist and Hand Evaluation, PEM= patient evaluation measure, MHQ, Michigan Hand Questionnaire, EQ-5D=EuroQol 5 dimensions

The final question asked if respondents had any further comments to make on anything relating to oedema management, which had not been captured in the survey. Sixteen respondents added comments. Table 4.9.1 summarises these comments.

Table 4.9.1 Comments received from respondents

Topic	Comment
Treatment for oedema not mentioned in survey	*"The survey did not give me a chance to rate Flowtron as a treatment intervention."* *"At times we use POSI* splints in conjunction with 'chippy bags'"* *"I sometimes use 'chip bags' with oedema gloves"* *"It is important to note that oedema does settle over time, as long as the patient is using his hand as normally as possible."* *"I use splinting….."*
Tailoring oedema treatments	*"I do not work with strict rules and protocols that the patient has to follow rigidly"* *"In reality techniques are used in combination rather than isolation so this may be a factor in their effectiveness"* *"Difficult to answer so [sic] questions because is all based on clinical findings and clinical reasoning"*

Topic	Comment
	"What is right for one patient could be harmful for another depends on comorbidities." Factors to consider when tailoring an oedema programme included: presence of wounds, severity of oedema, type of injury, pain, patient's expectations, engagement in therapy, *"What they believe will work (given the limited evidence for most of the treatments)";* frequency/dose depends on responsiveness to treatment, patient's lifestyle.
Assessment of oedema	*"Don't measure oedema very often unless patient not improving then do [sic] do it more formally"* *"Also, I have answered no to the use of some assessment tools and treatment modalities simply because I do not have them available rather than selecting not to use them."* *"All our treatment decisions are based on assessment, to evaluate intervention."*
Survey topic	*"Much more formal training required in this field"* *"Oedema is one area that requires the practice to be standardised and I hope this study will help."* *"I look forward to a definitive algorithm for treatment decision making…."*
Standard oedema treatment	*"Baseline is compression, elevation, massage and movement in some combination……"* *"Usually start with basic techniques of elevation, exercise and some form of compression."*

*POSI=position of safe immobilisation splint

4.3.8 Summary of results

Results suggest the most common treatment for sub-acute hand oedema used by the respondents is compression, closely followed by elevation and massage. Electrotherapy was the treatment least used for sub-acute hand oedema. In seventh place, with 41% (n=38) of respondents using this treatment, was kinesiology tape.

Manual lymphatic drainage (MLD) was the eighth most popular treatment. In contrast, the treatments most likely to be used in clinical practice were elevation, exercise and Coban™ wrap. The treatments perceived to be the most effective were elevation, Coban™ wrap and compression (glove). Large variations were seen in the frequency and duration of all the treatments. Responses were more consistent for the precautions when using each treatment.

Electrotherapy was the only treatment not used unless training had been received. However, some treatments were still used in clinical practice despite respondents receiving no formal or informal training, such as MLD (4%) and kinesiology tape (1%). Whilst these were used by only a very small number of respondents, it highlights that some treatments are implemented without training (which should include some guidance on parameters of use), and this could contribute to the number of variations seen in treatment delivery.

MLD, breathing techniques and electrotherapy were amongst the treatments that therapists were least likely to receive training for (formal or informal). Exercise (43.75%) and kinesiology tape (38.75%) were the treatments in which most respondents had received formal training, whereas Coban™ and Lycra sleeves (both 50%) received the most informal training.

With regards to assessment of oedema, visual inspection was the most commonly used method (94%, n=75). Of the 93% (n=74) of respondents who used a tape measure to assess oedema, 38% (n=28) used the figure-of-eight method. Only 13 of the 80 therapists who responded to this question reported using a volumeter to assess oedema. The QuickDASH was used by the majority (n=15) of respondents who reported using a patient-rated outcome measure to assess oedema (23%, n=18).

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4.4 Discussion

The aim of this survey was to establish current UK practice for the treatment of hand oedema. The results highlighted large variations in practice and the potential challenges to standardising oedema treatments in clinical practice. However, there is

a need to develop an oedema management manual that would provide some parameters in terms of modality, frequency and dose, for use in clinical trials.

4.4.1 Comparing survey results to published systematic reviews

The results of this survey are not consistent with those of the previous systematic reviews (Miller et al., 2017[a], Miller et al., 2017[b]). Despite published evidence of its poor reliability, this survey found that visual inspection was the method used by the vast majority of respondents (94%, n=75), with the volumeter being the least used method to assess oedema. This may be because some units do not have a volumeter, or practical issues such as time to complete volumetry set-up and assessment, cost of purchasing a volumeter, the presence of wounds or large caseloads, which seemingly limit the use of volumetry. The diverse responses received on how the volumeter was used by the 13 respondents suggest that some clinicians are not aware of the standardised protocol.

In this survey MLD was rated the 8th (out of 10) most commonly used method of treating hand oedema, and 9th most likely treatment to be used. Given that the highest level of evidence for the treatment of hand oedema supports the use of MLD in addition to standard therapy only in cases of problematic or stubborn oedema, the rank position of MLD in these questions reflects that it is not a treatment which should be used in every case of hand oedema. As 64% of respondents are also not trained to use MLD, these survey results are unsurprising. However, the most unexpected results from this survey are that MLD is in 7th place (out of 10) for perceived effectiveness. This highlights that therapists are not aware of the best available evidence for the most effective methods of treating hand oedema.
The discrepancies between current clinical practice and best available evidence may indicate that oedema management is not viewed as a priority by clinicians, and may not have received enough attention to date. This could have resulted in anecdotal evidence and perpetuated practice, as opposed to consulting and critically appraising the literature. A lack of time and critical appraisal skills could also account for discrepancies between practice and research findings. Although it is an expectation, in reality, clinicians often have very little, if any, dedicated time to read research papers and evaluate the literature during clinical practice. Accredited courses attempt to offer a best-evidence synthesis of current treatment techniques;

however, such courses rely on the skills of the educator to have critically appraised the research in order to incorporate the most reliable and effective treatments into their teaching. Anecdotal evidence of treatment effectiveness is included in accredited courses and in-service training, which has the potential to perpetuate existing practice without being challenged. The ability to challenge practice may become easier with experience and knowledge; therefore some inexperienced clinicians may simply accept treatments without considering their effectiveness. Equally, some highly experienced clinicians may be unwilling to consider new treatments if they have used a treatment for many years and believe it to be effective.

Interestingly, although kinesiology tape was the treatment for which respondents had received the second highest level of formal training, it was the 7th (out of 10) most likely to be used. This may indicate that despite paying, or receiving funding, to attend an external or accredited course to learn about it, respondents rarely used it. In keeping with this, kinesiology tape was ranked 7th in the perceived effectiveness question. Breathing techniques, which form part of MLD, were the second least likely (after electrotherapy) to be used in clinical practice.

4.4.2 Defining ‘standard treatment’

‘Standard treatment’ was not defined by the researcher in this study, nor were respondents specifically asked to describe what they believed to be standard oedema treatment. Additional comments from recipients (Table 4.9.1) mentioned “baseline” or “usual” treatments, which could be viewed as ‘standard treatment’. The responses that emerged identified the most frequently used, and most likely used, treatments that could also indicate standard treatment. However, even these had large variations in how they were prescribed to patients.

‘Standard treatment’, as mentioned by numerous papers in the previous systematic review of oedema treatments, was not defined in sufficient detail to be replicated in practice or research, but included compression, elevation and exercise. These treatments featured in the top five mostly frequently used treatments, which lends support for these being the standard ‘go-to’ treatments for the majority of therapists treating oedema. The additional details obtained during this survey regarding the

prescribed ‘dose’ highlighted there was no consensus. Many hand conditions and surgeries have local or regional treatment protocols or guidelines, based on best available evidence; examples of these include flexor and extensor tendon injuries. There is no accepted oedema management guideline. This may be due to the unpredictable nature of oedema in the hand, or uncertainty regarding the most effective treatment. Some respondents stated there was ‘no recipe’ to oedema management. Clinical guidelines have been blamed for being anti-intellectual, standardising practice around the average, preventing discretion in individual cases, cost-cutting, limiting innovation and clinical freedom, and encouraging litigation (Deutsch et al., 1998). As many respondents commented, there is a need to tailor treatment to the individual’s requirements (patient, condition, type of oedema). However, consensus is needed to establish parameters for treatments whilst allowing a degree of flexibility and clinical reasoning.

4.4.3 Oedema management as a complex intervention

This survey, along with results of the systematic review of treatment, highlight the numerous complexities associated with oedema management. Treatment are used in combination with each other to treat hand oedema, each with their own (questionable) mode of action, however the interactions between these treatment have not been identified nor understood, and there is potential that one treatment could cancel another out. Campbell et al., 2000 suggest a phased approach to evaluating complex interventions to help researchers clearly define where they are in the research process. This programme of research has attempted to break the process down by i) identifying the evidence on oedema management from published research; ii) defining current practice in the UK; iii) establishing agreement on an oedema management programme to be used in a clinical research trial; and iv) comparing treatment as usual to trial treatment in a pilot RCT. Due to the challenging and multi-faceted nature of complex interventions, the ‘active components’ of the intervention may be difficult to identify. The previous systematic review, in conjunction with this survey, has assisted in identifying and describing the possible active components of oedema management. However, establishing if they are active components, and how they may work, is beyond the scope of this programme of research and would require further investigation. The wide variation in practice demonstrates the need for further work to establish consensus on the active

components of oedema management as a complex intervention, which will inform the control and intervention arms of a pilot randomised controlled trial.

4.4.4 Limitations

The response rate for this survey was poor at only 20%. A high response rate is generally seen as the key to legitimising a survey's results (Wiebe et al., 2012). In the US and Canada a number of medical journals recommend a survey response of at least 60% to ensure that non-response bias does not threaten the validity of the findings (JAMA Network, 2012, Burns et al., 2008).

A meta-analysis, comparing response rates for web and mail surveys, found that web surveys have a lower response rate than mail surveys in general (Shih and Fan, 2008), with population type and follow-up reminders playing a statistically significant role in the differences in response rates. They report that students tend to prefer web surveys, whereas professionals such as doctors and teachers prefer mail surveys. Follow-up reminders appeared to be less effective for web-based surveys. Their meta-analysis was published 10 years ago, however, and trends may have changed since then. Using a web-based survey was time and cost-efficient. Adding the survey link to the e-bulletin and social media pages meant that individual BAHT members' addresses were not required. The limitations of this, along with anonymous responses, meant that reminders were generic to all members receiving the e-bulletin and not personalised to those who had not responded.

Based on the total BAHT membership at the time of the survey (730), only 16% of members were involved in this survey and therefore the results may not represent current UK practice. It is recognised (from clinical experience) that oedema management is commonly encountered by hand therapists, therefore this response rate is likely to under-represent the number of BAHT members who treat oedema in clinical practice. Very low response rates increase the risk of selection bias (Fischbacher et al., 2000). Members who chose not to respond may have been systematically different to those who responded. Reasons for non-response may relate to using an internet-mediated survey. However, it was assumed that BAHT members had easy electronic access in their professional organisation or at home, as they had already signed up to receive the electronic bulletin. An issue may have

arisen on computers with old operating systems or stringent NHS firewalls that block access to external websites. This may have caused issues with the speed, layout and functionality of loading the lengthy questionnaire. Offering to post paper-based questionnaires to those who requested this method may have increased the response rate, particularly in those who had reduced access to a computer. Thirty-two respondents started but did not complete the questionnaire, further lowering the response rate for some questions. This could indicate responder fatigue and that the questionnaire was too long.

The wording of question 41: “Of the following options, how would you evaluate the effectiveness of your chosen oedema management treatment/s?” appears to have confused some respondents. Results for this question contradict those obtained for subsequent questions that asked respondents if they used a certain method to assess hand oedema. The original question (Q41) was trying to establish which method/s were most frequently used to assess hand oedema, whereas subsequent questions were specifically designed to obtain more detail on the methods of three particular assessments. This confusion may reduce the validity of the responses obtained in this section. Clearer wording may have reduced this issue.
The series of questions which asked for further details on how a treatment was implemented (frequency/duration/when to wear and remove) received similar, or in some cases, the same responses across the questions. The respondents often indicated for the researcher to look at their comments for the previous question. This may indicate a lack of clarity in the instructions, or potentially repetitive questioning. These issues were not highlighted during piloting.

4.5 Conclusion

Current practice for oedema management amongst UK hand therapists is not consistent with the results of systematic reviews of the assessment and treatment of hand oedema. The survey results formed part of a staged process in identifying and describing current oedema treatments and establishing consensus on a standardised oedema management programme, which informed subsequent work packages.

This chapter has attempted to collate and organise information on how hand therapists currently assess and treat hand oedema. It highlighted the large variation in clinical practice, a lack of standardisation in oedema treatment and further confirmed the level of uncertainty regarding this topic. The next chapter will try to address the variation of responses by using a consensus development method with hand therapy experts to gain agreement on a standardised manual of oedema management which will inform the intervention and control arm of a subsequent pilot randomised controlled trial. .

5.1 Introduction

This chapter presents the method and results of a consensus development study with hand therapy experts which aimed to establish agreement on treatments to manage oedema.

There are numerous techniques to reduce hand oedema. It is often a 'multi-modal' approach, meaning multiple methods are used in conjunction with each other; for example, elevation and compression, or elevation, compression and massage. A recent systematic review of the existing literature identified 16 different oedema management interventions (Miller et al., 2017a)]. There was no standardisation of interventions across studies, with variations observed in terminology, frequency, duration and technique. There was little consensus in this literature regarding the most appropriate methods of even so-called 'standard' interventions (Miller et al., 2017[a]).

This lack of standardisation and consensus was also reflected in the results of the previous online survey, with disparities between clinicians in the advice they give to patients on managing their oedema. In addition, the limited research evidence to support one treatment over another indicated a need to develop consensus on the content and implementation of oedema management. A standardised 'one size fits all' approach to oedema management may not be feasible, or desirable by clinicians. The variation in how these are implemented in practice needs addressing in order to manualise the interventions so they can be replicated in the context of a clinical trial.

The purpose of this study was to engage a group of self-identified hand therapy experts to discuss and develop consensus on specific components of an oedema management package which could be used in a subsequent pilot randomised controlled trial.

The objectives of this study were to:

i) develop consensus on best practice for hand oedema interventions, including frequency, duration, safety and contraindications.

ii) define treatment as usual and trial treatment to be administered in the pilot randomised controlled trial in work package 4.

5.2 Methods

5.2.1 Consensus development

Two consensus development methods, commonly adopted in healthcare research, are the Delphi process and the nominal group technique (also known as the expert panel).

The nominal group process was developed in the United States in the 1960s and has been used in a variety of settings, including social services, education, industry and healthcare. It involves a highly structured physical meeting of 9-12 experts about a specific issue, facilitated by an expert on the topic. Participants have time to consolidate their own views on a topic before contributing one idea to the facilitator, who records this visibly for the whole group to see. Similar suggestions are grouped together and the panel of experts discuss each idea. Each expert privately ranks each idea: this is classed as round 1. The results are then tabulated and presented to the group, and in round 2 the panel discuss the overall ranking and can alter their rankings from the first round (Delbecq and Van, 1971, Jones and Hunter, 1995).

The Delphi consensus method was originally developed by the RAND Corporation (www.rand.org) in the 1950s to forecast the impact of technology on warfare. Since then its use in solving problems in healthcare settings is well recognised (Fink et al., 1991). It has been widely used in nursing and midwifery research (Linderman, 1975, Bond and Bond, 1982, Goodman, 1986, Broome et al., 1996, Schmidt et al., 1997, Sleep, 1999), and is a useful technique for situations where individual judgements must be tapped and combined in order to address a lack of agreement or incomplete state of knowledge (Delbecq et al., 1975, Van de Ven et al., 1972). The Delphi survey is a group facilitation technique, which is an iterative multistage process designed to transform opinion into group consensus (Hasson et al., 2000, 2011, McKenna et al., 1994, Lynn et al., 1998).

An internet mediated Delphi technique was chosen for this study due to its benefits in terms of cost, convenience and anonymity of experts (Delbecq et al., 1975) in contrast with other methods such as the nominal group process, focus groups or general survey of practice.

5.2.2 Definition of consensus

Dictionary definitions of 'consensus' have changed over the years, with the 1969 Oxford Dictionary (Oxford University Press) defining it as "an agreement in opinion on the part of all concerned". In 1984 the updated version of the Oxford Dictionary (Oxford University Press) defines it as "an agreement in opinion: a majority view". A more recent version (www.en.oxforddictionaries.com) defines it as "a general agreement". Previous consensus studies have been criticised for not adequately defining consensus *a priori* and there is no standardised acceptable level of agreement (Williams and Webb, 1994). In a recent systematic review of defining consensus in Delphi methods, the most common definition of consensus was based on percent agreement. Bassoon et al (2000) highlights that as the Delphi technique is used in a diverse range of topics, there is no way of ascertaining the validity of any specific definition of consensus. Authors suggest varying levels of consensus, with some reporting a minimum of 51% level of agreement should be adopted (McKenna, 1994, Loughlin and Moore, 1979), while Sumison (1988) recommends at least 70% and Green et al., (1999) suggest 90% or more. Others state that a percentage measure is not a reliable indicator of consensus (Campbell et al., 1999) and that more attention should be paid to the stability of the responses throughout the rounds. A 75% agreement level was set *a priori* for this study to ensure a definite majority agreement.

5.2.3 Sampling and recruitment

This Delphi method focused on UK practice and therefore the British Association of Hand Therapists (BAHT) appeared to be the most appropriate special interest group to approach for experts. BAHT membership involves an annual paid subscription, available to any occupational therapist or physiotherapist working in hand therapy within the UK. Members who completed the online survey were informed of the planned Delphi consensus study and were invited to contact the PI via email if they wished to take part.

One hundred and fifty six members accessed the online survey link, giving a 6% (n=9) response rate for the Delphi.

5.2.4 Inclusion criteria

Criteria for therapists to be included as an expert were: at least 10 years' working in hand therapy and/or upper limb neurology services (regardless of their banding/grade); working currently as a hand therapist (full or part-time, NHS, primary care, community or private sector); treating at least five patients per week with sub-acute oedema post-trauma. Eligible participants also had to feel confident to discuss and justify oedema management interventions and share their clinical reasoning for these interventions. Research suggests that the composition of the panel influences ratings (Campbell et al., 1999). In this study experts were either occupational therapists or physiotherapists specialising in hand therapy, but came from a range of clinical settings and had varying levels of experience (10+) and experience of using oedema interventions. Black et al., (1999) comments that in Delphi methods, heterogeneity is preferred to homogeneity, in order to encompass all relevant aspects of the topic from different viewpoints. Delbecq et al., (1975, 1971) go on to say that panel members with widely varying personalities and substantially different perspectives on a problem produce a higher proportion of high quality, highly acceptable solutions than homogeneous groups. Rowe (1994) suggests drawing experts from varied backgrounds in order to guarantee a wide base of knowledge. Hong et al., (2010) discussed the need for the full range of stakeholders to be included in the panel, as their differing opinions will enrich the procedure. In this case, differences in professional background, clinical setting, years of experience and place of work were all factors which could create differences in opinion within the group. However, their shared specialty in hand therapy could increase the likelihood of homogeneity. The authors defined 'stakeholders' as being clinicians with relevant skills and knowledge who regularly use oedema treatments. Jones and Hunter (1995) recommend that studies that are concerned with clinical interventions should use specialists in that area. As noted by Powell (2003), representative samples are not required for statistical purposes.

5.2.5 Panel size

A group of 10 to 20 experts were invited via purposive sampling from among those who had completed the web-based survey and expressed an interest to participate in the subsequent Delphi study. Whilst this non-representative sample relied upon therapists volunteering to take part, only those who met the pre-set eligibility criteria were invited to complete the Delphi, thus reducing any self-selection bias (Williams, 1994). Purposive sampling is based on the assumption that a researcher's knowledge about the population can be used to select the cases to be included in the sample (Polit and Hungler, 1997). This 'handpicking' suggests an arbitrary selection which could give rise to researcher and subject bias; however; this was reduced by using specific inclusion criteria. Allowing therapists to volunteer to take part could also increase the response rate, given that the therapist has entered the process of their own volition. A pragmatic sample size was set *a priori*, based on the estimated response rate of the survey and as a manageable panel size for the PI to facilitate. Evidence suggests there is no agreement regarding the size of the panel or the sampling techniques used to obtain a panel (Loughlin and Moore, 1979). Murphy et al., (1998) believe the more participants there are, the better; suggesting a positive correlation between the number of experts and the reliability of their composite judgements. However, they also admit that very little empirical evidence exists on the effect of the number of participants on the reliability or validity of consensus processes. Reid (1988) critiqued 13 Delphi studies and found panel sizes ranging from 10 to 1685; only one of these studies selected a truly random sample. More recently, Okali and Pawlowski (2004) report the literature recommends 10-18 experts on a Delphi panel.

5.2.6 Attrition and response rate

A low attrition and high response rate were anticipated in this study, given that participants had volunteered to take part with a relatively short timeframe of involvement. Okali and Pawlowski (2004) highlight that attrition tends to be low in Delphi studies, similar to non-response, and that facilitators can easily ascertain the cause by liaising with the drop-outs. Several authors (Crisp et al., 1997, Walker and Selfe, 1996) have stated that in order to maintain rigour when using a Delphi method, a 70%

minimum response rate should be achieved in each round. Although the identities of the experts were known to the facilitator, she was unable to identify which experts had submitted which responses and was therefore unable to send direct reminders or liaise with those who dropped out.

5.2.7 Procedure

An internet-mediated Delphi technique was used to allow geographically dispersed experts the opportunity of participating. All experts were known to the facilitator (PI), but remained anonymous to each other. This not only encourages honesty within the group but avoids bias through status, which is often compounded by the hierarchical structure of the health service (Williams and Webb 1994), or dominant personalities (Hoogvliet et al., 2013) where members may feel pressured into changing their opinion. The Delphi technique was deemed an appropriate method for this study, as the topic lacks certainty and empirical evidence (Delbecq et al., 1971).

A gold package of SurveyMonkey® was used at a cost of £300 for a one-year subscription. This package was also used for the preceding online survey, and was therefore a cost-effective tool to use, as opposed to sending mailed paper surveys to each expert with stamped addressed return envelopes, which would have had the added disadvantage of being more time-consuming. Everett (1993) and Jones and Hunter (1992) describe the Delphi method as quick, cheap and efficient. Internet-based questionnaires are becoming increasingly popular to save time and increase dissemination (Colucci et al., 2010). However, Leece et al., (2004) showed statistically significantly lower response rates (absolute difference 13% $p<0.01$, CI 4-22) with internet-based questionnaires than mailed questionnaires.

Williams and Webb (1994) and Jairath and Weinstein (1994) contradict Jones et al., (1992), and Everett (1993) argues that extensive time commitment is required to complete a Delphi. A four-month period was set aside for this study, with all participants being informed prospectively of the timeframe and the deadline for responses in each round, in an attempt to ensure fully informed consent, increase the response rate and reduce the attrition rate.

A communication log was set up to record names and professions of the expert panel, dates when the consent forms were emailed and returned, dates when the link to each round was emailed, and dates of any reminder emails.

5.2.8 Ethics and consent

Ethics approval was gained from the Faculty of Medicine and Health Research Ethics Committee on 16 December 2015 (see Appendix K for approval letters). All clinicians volunteering to take part in the Delphi were emailed with a participant information sheet (PIS) (see Appendix L for PIS), eligibility criteria of an 'expert' and the consent form. The consent form (refer to Appendix M) requested the participant to initial each statement to confirm they had read the PIS, met the inclusion criteria and understood that they had the opportunity to ask questions. They were required to complete the consent form electronically, saving the consent form as a pdf, to ensure the document could not be edited. Consent forms were then emailed back to the facilitator, requesting a delivery receipt (if able), or posted back to the facilitator.

5.2.9 Piloting

Each round of the Delphi was piloted by the PI's supervisor to check for any errors and to ensure the question-skip logic and functions of the survey directed respondents to the appropriate page/section of the survey. Following any amendments, a final check was made before the link was emailed to participants. Okali and Pawlowski (2004) supports the use of pre-testing, stating it is an important reliability assurance for the Delphi. However, piloting test-retest reliability is not relevant in a Delphi process, since researchers expect the respondents to revise their responses. Therefore, piloting the questions with the same test audience on different occasions is likely to give different responses. Hasson et al., (2000, 2011) support the use of Lincoln and Guba's (1985) criteria for qualitative studies (truthfulness, applicability, consistency and confirmability), which focus more on the credibility of the results and the interpretations which arise from them, as opposed to the reliability of the Delphi method itself, which has no evidence (McKenna, 1994).

5.2.10 Confidentiality and anonymity

Anonymity of Delphi participants is viewed as both a benefit and a limitation of this technique. Sackman (1975) argues that anonymity may lead to a lack of accountability of views expressed, which encourages hasty decisions. In contrast, maintaining anonymity mitigates hierarchy or perceived power imbalance among the participants and is likely to produce greater honesty amongst participants (Loughlin and Moore, 1979). The term ‘quasi-anonymity’ has been used to refer to respondents who are known to the researcher and possibly even to one another, but their judgements and opinions remain strictly anonymous (Lynn et al., 1998). In this study, participants were known to the researcher but not to each other. The experts’ responses, which were submitted electronically, did not identify them to the researcher. During feedback of results the comments were labelled “Expert #1, Expert #2 etc” to allow the respondent who submitted them to identify their own views but to ensure that anonymity of opinions was maintained.

5.2.11 Number of rounds

The recommended number of rounds is two or three, according to a systematic review of using and reporting the Delphi methods for selecting healthcare quality indicators (Boulkedid et al., 2011).However, there is little scientific rationale guiding the optimal number of rounds. Whilst two or more rounds are likely to result in convergence of individual judgements, it is unclear whether this increases the accuracy of the group’s decision making (Murphy et al., 1998). Young and Hogben (1978) report that the literature states a classic Delphi technique has four rounds. However, in order to reduce responder fatigue, more recent evidence has shown either two or three rounds are preferred (Campbell et al., 1999, Proctor and Hunt, 1994, Beech, 1997). The number of rounds may also depend on what criterion has been used to define ‘consensus.’ It was anticipated that at least two rounds would be used to seek consensus on standardised oedema management, due to the complexity of the topic (modality, mode of delivery, duration and frequency). It is recommended that feedback given in subsequent rounds should include qualitative comments and statistical measures (Powell, 2003).

5.2.12 Reliability and validity

Some argue that the Delphi method fails to meet the standards normally set for scientific methods (Sackman, 1975), in particular with poor questionnaire design and the defining and selection of experts. Sackman (1975) claims that the Delphi method forces consensus and is limited by the inability of the panel to discuss the issues amongst themselves as they might during a nominal group technique. Although experts are not able to directly correspond with each other either via the internet or face-to-face (an aspect which contradicts one of the basic rules of Delphi methods), multiple free-text boxes were included in the questionnaire to allow experts to retract, alter or add to their view with the benefit of considered thought (Williams and Webb, 1994). This does, however, rely heavily on the interpretation of the facilitator in the absence of face-to-face contact with and between experts. The Delphi method lacks the benefit of seeking clarification on reasons for disagreement (Walker and Selfe, 1996). For this reason, questions in rounds 2 and 3 enabled the experts to agree, partly agree or disagree. When choosing to partly agree or disagree, the experts were prompted to provide alternative wording or to rewrite the statement which gave an insight into their reasons for disagreeing with the original statement. Forced consensus in a Delphi has been criticised, as it is thought to be weakened by not allowing participants to discuss the issues raised and there is no opportunity for participants to elaborate on their views (Goodman, 1986, Walker and Selfe, 1996). The structure of this Delphi was such that it allowed the experts to see the results of the previous rounds, before being presented with a new or adapted question in which they were asked to offer their opinion on and justify their responses, thereby giving the experts the opportunity to elaborate on their views.

Hassoon et al., (2000) discussed the reliability of Delphi methods and, as previously stated, there is no evidence which supports the reliability of the technique, as groups with different members are likely to arrive at different decisions. Hassoon et al (2000) go on to state that the Delphi is based on the assumption that several people are less likely to arrive at a wrong decision than a single individual. However, the results are not

intended to produce the only, or correct, answer. This would need testing with empirical evidence or compared to observed data, but the use of averages produced by multiple experts in the field has been shown to be superior to the average of an individual response (Okali and Pawlowski, 2004). During the Delphi process, decisions are strengthened by reasoned arguments where assumptions are challenged, which helps to enhance validity (Hill and Fowles, 1975). However, the claim that one group represents valid expert opinion has been criticised as scientifically untenable and overstated (Strauss and Ziegler, 1975). Goodman (1986) states that the use of participants with an interest and knowledge of the topic may help to increase the content validity of the method, with the use of successive rounds assisting to increase the concurrent validity. Lincoln and Gruba (1985) propose that whilst participants should be experts who reflect current knowledge and perceptions, they should be relatively impartial to the findings. In this study the justification for conducting a Delphi method was to gain consensus on oedema, which would be used for a future pilot randomised controlled trial being conducted at the PI's workplace. The included experts were not employed by the same trust as the PI and therefore the results would not have had direct relevance to the experts.

5.2.13 Analysis

Consensus for this study was set *a priori* as a level of agreement of at least 75%. Some authors (Goodman, 1986, Walker and Selfe, 1996) have commented that there is a danger with Delphi methods for greater reliance to be placed on the results than might be warranted. This Delphi study had very clear and pre-set aims and did not seek to go beyond the scope originally planned. Agreement with statements was obtained by asking the experts to: i) rank the importance of an item; ii) rate their level of agreement with a statement; and iii) add additional comments or justification. Wording used by the experts was used verbatim as much as possible when analysing and feeding back the results, as recommended by Hasson et al (2000). The results from the Delphi were designed to inform the standardisation of the interventions administered in a subsequent pilot randomised controlled trial (RCT).

5.2.14 Reporting procedure and results

There is no consistent method for reporting the results of Delphi studies (Schmidt et al., 1997). Diamond et al., (2014) state there are no validated quality indicators for Delphi studies. Hasson et al., (2000) highlight that reporting on each round separately illustrates clearly the array of themes generated and gives an indication of the strength of support for each round. Boulkedid et al., (2011) and Diamond et al., (2014) have made recommendations for the reporting of Delphi studies which have been used for the reporting of this Delphi study.

5.3 Results

The Delphi method consisted of three internet-mediated rounds held between 3 May and 15 July 2016. Nine clinicians identified themselves to the principal investigator (PI) via email (after completing the online survey), expressing their interest in taking part. All nine clinicians met the pre-defined 'expert' eligibility criteria. There were four occupational therapists (OT) and five physiotherapists (PT). Eight experts (4 OT/ 4 PT) returned their consent forms and were sent the link to the first round. The experts were geographically dispersed across England and Scotland. Seven of the eight experts were based in secondary care or private practice, with one expert being primarily based in hand therapy research. The response rate in round 1 was 100% (n=8); in rounds 2 and 3 it reduced to 87.5%, with seven of the eight enrolled experts completing these rounds.

The results of the Delphi study are presented according to four treatment modalities. Within each modality the number of items on which consensus was reached and relative to the number of items discussed in each round is reported in Table 5.1. A copy of the full Delphi questionnaire and results obtained in each round can be found in Appendix N.

The total number of items discussed was 26. This ranged from 23 in round 1 to three in round 3. In round 1, consensus was reached on 7/23 (30%) items. The required 75% consensus was reached on 14 items in round 2; the final three items achieved (direction and pressure of massage only achieved 71% agreement) agreement in round 3.

Massage was the only treatment which required a third round (see Table 5.1). Consensus was reached on general recommendations for performing a standardised oedema management programme for four treatments. Table 5.1 shows the round in which consensus was achieved and for each treatment.

Table 5.1 Number of items on which consensus was achieved in relation to number of items discussed in each round

Treatment	Round 1	Round 2	Round 3
Compression	1/4	3/4	N/A
Elevation	2/6	4/6	N/A
Massage	0/4	2/4	3/3
Kinesiology tape	4/9	5/9	N/A
Total	**7/23**	**14/23**	**3/3**

Table 5.2. Round in which consensus was achieved for each item.

Topic	Round 1	Round 2	Round 3
Compression			
When to wear an oedema glove	Consensus not achieved	75% (n=6)	N/A
When to remove an oedema glove	75% (n=6)	N/A	N/A
Duration of wearing oedema glove	Consensus not achieved	75% (n=6)	N/A
Precaution of wearing an oedema glove	Consensus not achieved	75% (n=6)	N/A
Elevation			
Method of limb elevation in day	75% (n=6)	N/A	N/A
Method of limb elevation at night	Consensus not achieved	85.7% (n=6)	N/A
Level of limb elevation	Consensus not achieved	100% (n=7)	N/A
Dose of hand elevation	Consensus not achieved	100% (n=7)	N/A
Duration of hand elevation	Consensus not achieved	100% (n=7)	N/A
Stopping or amending hand elevation	100% (n=3)*	N/A	N/A
Massage			
Method of massage	Consensus not achieved	Consensus not achieved	N/A
Direction of massage	Consensus not achieved	Consensus not achieved	71.4% (n=5)**
Frequency of massage	Consensus not achieved	85.71% (n=6)	N/A
Duration of massage	Consensus not achieved	100% (N=7)	N/A
Pressure of massage	N/A	N/A	71.4% (n=5)**
Style of massage	N/A	N/A	85.7% (n=6)
Kinesiology tape			
Shape of tape	Consensus not achieved	100% (n=6)	N/A

Topic	Round 1	Round 2	Round 3
Preparation of skin	100% (n=6)	N/A	N/A
Colour of tape	100% (n=6)	N/A	N/A
Tension of tape at anchor point	100% (n=6)	N/A	N/A
Tension of central portion of tape	Consensus not achieved	80% (n=4)	N/A
Duration of wearing tape	Consensus not achieved	100% (n=8)	N/A
Rest day between applications of tape	Consensus not achieved	100% (n=6)	N/A
Reasons to discontinue tape	Consensus not achieved	100% (n=6)	N/A
Contraindications of kinesiology tape	88.33% (n=5)	N/A	N/A

*items with question-skip logic meant some respondents skipped questions which they should have answered.

**75% consensus level not met as one expert reported she was not trained in manual oedema mobilisation (a technique which includes a specific style and direction of massage and requires post-graduate training), therefore a majority accepted.

N/A Not discussed

5.4 Discussion

The aims of this Delphi study were to develop consensus on best practice for hand oedema interventions, including the frequency, duration and instructions given to patients, in order to formulate a standardised package of interventions to be administered in a pilot randomised controlled trial in work package 4.

The *a priori* level of consensus (75%) was met over two rounds, for three of the four sections: compression, elevation and kinesiology taping. Questions relating to massage required three rounds and did not reach the set level of consensus by the end of the third round, therefore a majority was accepted.

Eight experts agreed on the frequency, duration, instructions and potential methods of delivering these interventions to reduce sub-acute oedema.

A previous systematic review (Miller et al., 2017a) highlighted the lack of consensus surrounding oedema management, with 16 interventions being described in the literature, none of which have high quality evidence of effectiveness. The benefits of using the Delphi methodology, as opposed to a face-to-face focus group or postal survey, include cost and time. It enabled geographically dispersed therapists to participate via an online link in their own time. This eliminated the need for travel, booking venues and arranging a suitably convenient time and date for all participants to attend. The Delphi technique has its limitations, however. The virtual nature of the online method precludes discussion, clarification of arguments and greater depth of debating contentious issues.

5.4.1 Comparing results to the literature

Transferability, a form of trustworthiness that some believe (Cornick 2006, Holloway and Wheeler, 1996, Day and Bobeva, 2005) is more important than reliability and validity, should be used to assess the effectiveness and appropriateness of the Delphi study. Delphi findings should be compared with other relevant evidence in the field and verified with further research, to enable findings to be tested against observed data to enhance confidence (Hasson et al., 2000, 2011). As no previous Delphi studies have looked at the management of sub-acute hand oedema, it may be appropriate to compare the

Delphi findings to results of published literature. Some of the findings on massage were in keeping with results of the systematic review, which found low to moderate quality evidence to support the use of manual oedema mobilisation (MOM) massage for stubborn oedema only, and that it should not be used routinely (Miller et al., 2017a, Haren et al., 2000, 2006). Other oedema interventions discussed in the Delphi (compression, elevation and kinesiology taping) do not have such a formally prescribed method (frequency, method, duration etc) or detailed description in the literature, and have limited high quality evidence to support their effectiveness (Miller et al., 2017a). Despite the Delphi relying on expert opinion or judgement to form consensus, the experts in this study may have been aware of, or revisited, the existing literature when completing the Delphi questionnaire to ensure their responses were consistent with published literature. There was limited evidence of this from this Delphi, as the results were only marginally consistent with the published literature.

5.4.2 Methodological rigour

Each round of questions underwent pilot testing by an academic supervisor prior to disseminating to check for grammatical errors and ease of navigating the online functionality, in particular the 'question skip logic' which forwarded the respondent on to different questions depending on their response. During the formal Delphi study, however, an issue with questions 4 and 5 of the compression section and 9 to 11 of the elevation section of round 1 meant that five respondents did not answer questions which they should have done. This did not happen in rounds 2 or 3. This issue potentially delayed consensus being achieved, as this question had to be taken into a second round, where 100% (n=7) consensus was achieved. This also posed a threat to the methodological rigour of this study (Hasson et al., 2000, 2011), as errors which occurred due to using an online approach may have contributed to inaccuracies in the results/level of agreement in round 1.

5.4.3 Modified Delphi

Hasson et al (2000, 2011) identify 10 different Delphi designs, including classic, modified, real-time, policy and online. These designs are not necessarily mutually exclusive; for example, a modified Delphi could also be an e-Delphi, as was the case in

this study. It has been identified that few researchers use a uniform method (Hasson et al., 2011). However, modified versions of the Delphi may pose a threat to the credibility of the technique, and have the potential to lead to further confusion (Hasson et al., 2000, 2011), as the term 'modified' hides the complexity and diversity of the design. The unconventional nature of the first round of this Delphi lends itself to a modified design, as the results of the online survey and previous systematic reviews helped to develop the first round (Hasson et al., 2001, 2011). The amount of variation within each Delphi design (number of rounds, level of anonymity, inclusion criteria, sampling approach etc) raises potential problems when comparing results of Delphi studies. Woudenberg (1991) viewed these variances as hampering the evaluation of reliability and accuracy of a Delphi. However, others may view these variances as flexibility, which could be seen as a strength of this technique.

5.4.4 Anonymity

Anonymity is one of the advantages of the Delphi method. It eliminates participant bias, as panelists are not known to each other. (Delbecq et al., 1975, Van de Ven et al., 1972). However, in the case of a small Delphi study such as this, where panel members from a special interest group contacted the facilitator to take part, some of the panel members were known to the facilitator and vice versa. In this respect, it is thought to be quasi-anonymous. The facilitator was not able to identify panel members' responses. However, lack of anonymity may have influenced the responses obtained in an attempt to help the facilitator with her PhD. This will be discussed in more detail under 5.4.6: influence of the facilitator on the Delphi process. . Complete anonymity between panelists may lead to a lack of accountability for the views expressed (Sackman, 1975, Powell, 2003) and could potentially give rise to ill-considered judgements. One expert stated: "There is no published evidence to suggest that K tape [sic] is effective…", yet reported they used kinesiology tape for oedema and agreed with the majority of statements relating to its application without offering further comments.

5.4.5 Defining panelists as 'experts'

Pre-specified inclusion criteria were set which identified eligible panelists as those who: had practised for at least 10 years in hand therapy or upper limb neurology services,

were currently working as a therapist (occupational therapist or physiotherapist); and were treating at least five patients per week with sub-acute hand oedema post-trauma. It was also specified that panelists must feel confident to discuss and rationalise their opinions and share their clinical reasoning. Jones and Hunter (1995) suggest that for studies concerned with clinical interventions, such as this one, specialists in that area would be appropriate. Those meeting the above eligibility criteria were classed as 'experts'. Experts have been defined as 'informed individuals' (McKenna, 1994), 'specialists' (Goodman, 1986), and those with knowledge about a specific subject (Green et al., 1999). This term has been criticised as it implies knowledge and expertise, which may not be assumed purely by years of clinical practice. Conversely, the terminology may assist in motivating panelists, as their membership gains them access to an 'excusive' group. The term 'expert' was justified in this study with clearly defined, specific and measurable criteria based on years of clinical practice in the specialist area, and frequency of assessing and treating patients with oedema. However, this term may have deterred some therapists from taking part, as they may not have perceived themselves as an expert in this topic, despite meeting the necessary criteria.

5.4.6 Influence of the facilitator on the Delphi process

The role of the facilitator in a Delphi process is often overlooked, and there is little documented in the Delphi method literature on the impact of the facilitator on the process. Whether the facilitator is well-known in the topic area, influential, respected or even liked could influence not only the number of potential experts volunteering to take part, but also the responses of the experts throughout the Delphi process. Respondents may wish to please the facilitator or feel intimidated by them, and will therefore agree with their proposed statements without offering further improvements or suggestions. The level of knowledge that the experts perceive the facilitator to have on the topic could also influence their judgements, as although anonymity addresses the power balance between respondents, it does not address the potential power imbalance between the facilitator and the respondents. Respondents may feel that the facilitator is actually the 'expert' in the subject, and therefore their responses are inferior.

From experience of the facilitation process, a great deal of reliance is placed on the facilitator to interpret the experts' comments. In a Delphi, there is no option for the facilitator to liaise directly with individuals to aid clarification of their responses, and therefore the facilitator summarises and presents comments back to the group for further discussion in subsequent rounds. As the facilitator is likely to be heavily invested in the subject, this could bias the consensus development. If the facilitator drives the first round of initial statements and questions, these could be loaded, opinion-based statements that could influence the experts. This Delphi could be viewed as a modified version of a classic Delphi method, where the first round is unstructured, allowing the respondents to identify the issues themselves, instead of the facilitator imposing a set of structured questions with little flexibility. Using a structured first round implies that the facilitator has already completed the problem identification process. This could be seen as a flaw of the modified Delphi method used in this study, as facilitator bias (of the issues requiring consensus) could inadvertently affect the results obtained. The facilitator may not have identified potentially important problems requiring discussion. This could result in researcher bias. Campbell et al., (1999) argue, however, that a traditional first round may create ambiguous, broad statements which could also lead to bias from the outset. Campbell et al., (1999) and Hsu and Sandford (2007) recommend using a modified Delphi (close ended) in order to verify content and face validity. In this Delphi, the problem identification list arose from findings of two systematic reviews and a survey of practice undertaken previously, which identified the need for consensus.

5.4.7 Panel members

Panel members were not a randomly sampled but instead 'experts' were purposively sought, from the British Association of Hand Therapists, specifically for their specialist interest, knowledge and skills on the topic. The relationship of the panel members to the larger population of potential experts is an interesting concept, as different panel members can affect the results obtained, and the generalisability of these results. By only sampling from BAHT membership, this potentially discounted non-BAHT members who may have classed themselves as 'experts'. The experts in this study may have been motivated and committed to be involved due to a vested interest in the topic of this

study, and therefore it may not have been a truly representative sample. Conventional Delphi studies require a heterogeneous sample (Powell 2003) in order to attract the broadest spectrum of opinions. Large samples may also increase generalisability of results. However, there are the potential logistical issues which arise from synthesising data from large groups (Hasson et al., 2000 and 2011, McKenna, 1994, Martino, 1983). The aim of this study was to gain consensus on the content and implementation of a standardised oedema management programme that would be used in a pilot randomised controlled trial. Although it was important to gain a wide range of opinions, it was anticipated that panelists who met the eligibility criteria might not offer widely diverse opinions due to similarities in their postgraduate training. Other potential stakeholders, such as patients, nurses or hand surgeons, were not invited to take part. This was due, in part, to issues understanding therapy terminology (in the case of patients), but also because the inclusion of other stakeholders would not have assisted in gaining consensus on this topic, as it is hand therapists who assess and treat hand oedema. However, the inclusion of non-hand therapists could have provided insight into the acceptability of treatments. In light of this, a smaller sample size of 10 to 20 consisting purely of hand therapists was proposed. The Delphi recruited nine experts, with eight completing the process. Sample sizes of 10 to 18 have been recommended in the literature (Okali and Pawlowski, 2004) However, for Delphi studies which require a more homogenous group, 10 to 15 experts have been recommended (Delbecq et al 1975, Van de Ven and Delbecq, 1972) or as few as 5 to 10 have been cited (Hsu and Sandford, 2007).

Based on the number of BAHT members who accessed the online survey (n=156), nine members volunteered for the Delphi, which represents a 6% response rate.

5.4.8 Limitations

Potential limitations of this study include the number of topics covered in each round of the Delphi. Traditionally, in the first round, open questions are used to generate ideas to uncover the issues pertaining to the topic under study (Loo, 2002); subsequent rounds are then designed around the analysed responses. Oedema management is a multi-faceted approach and often encompasses a series of interventions used in conjunction

with each other, and therefore a series of questions was required to cover all aspects of oedema management. In the first round of this Delphi study the questions were specific and focused on different oedema interventions (as highlighted from the previous online survey) with pre-specified response options and the ability for free-text comments to be added.

Schmidt et al., (1997) and Okali and Pawlowski (2004) suggest that the researcher's interpretation and categorisation of round 1 findings should be fed back to the experts for checks to be undertaken. As the first round did not follow a classic Delphi design (categories had been developed by the facilitator based on the results of the previous online survey and were presented to the panel members for refining), these checks were not done and could have resulted in researcher bias, with the facilitator assuming understanding of the comments received in round 1. However, respondents were able to disagree and suggest amendments to the new statements in round 2 as part of the Delphi process; therefore misunderstandings in the facilitator's interpretation of the results in round 1 could have been rectified.

Conducting a pilot test may have identified technical issues as well as the need for further questions regarding massage as an intervention. Massage was the only topic which required discussion in a third round. This could indicate that it was a potentially contentious topic, or there was a lack of knowledge amongst the experts. This topic elicited further questions in round 2, which the facilitator had not previously considered. This topic did not achieve consensus to the *a priori* level, even after round 3, and therefore a majority decision was accepted. This may indicate that massage is difficult to standardise or to achieve consensus on. Alternatively, consensus may not have been achieved due to one expert reporting she had not received post-graduate training in manual oedema mobilisation which was featured in round 3. In hindsight, a fourth round should have been conducted to establish agreement on the direction and pressure of different styles of massage.

The experts could have been used to rate the study protocol (to be used in the pilot RCT) after completion of the Delphi. However, this was not stated in the original aims of this study and clear guidance would have been required on how to deal with comments

from the experts. It was felt this would be more appropriate to be done by the clinical team involved in providing the interventions in the pilot randomised controlled trial. The practicalities of implementing the study protocol in clinical practice were discussed with the recruiting team prior to the trial commencing.

5.5 Conclusion

A three-round Delphi has established consensus on the frequency, duration, method, precautions and advice to patients on four types of interventions used to manage oedema. The findings informed the content and prescription given to patients in the intervention and control arm of a subsequent pilot randomised controlled trial, comparing kinesiology tape (combined with massage and elevation) with compression (combined with massage and elevation). The findings were also used to produce the patient information leaflets issued to all trial participants to support their home therapy programme for oedema management.

This chapter has described the process of conducting a Delphi method with hand therapy experts. Additional topics (relating to massage) which had not previously been considered by the facilitator were identified in round two and required further discussion. The process highlighted that even amongst “experts” oedema management is a complex condition to standardise.

Chapter 6 An observational study to compare the relative responsiveness of clinician-derived and patient-rated outcome measures to assess hand oedema

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6.1 Introduction

This chapter focuses on the psychometric property of responsiveness, and compares the relative responsiveness of objective and subjective measures to assess hand oedema with an observational study design. It also investigates whether the location of oedema affects the responsiveness of the measure. It includes the development of an oedema specific patient rated outcome measure and its comparison to an existing validated patient rated outcome measure. Identification of factors affecting responsiveness are also discussed.

A previous systematic review (Miller et al., 2017[b]) provided evidence to support the use of the figure-of-eight tape measure as the best alternative to the volumeter. However, the quality of this evidence was low and the results were inconsistent with how hand therapists currently assess oedema clinical practice, with only 38% (n=28) of respondents reportedly using the figure-of-eight tape measure and 16% (n=13) using a volumeter to assess oedema. Twenty-three percent (n=18) reported using a patient-rated outcome measure (PROM) when assessing oedema, none of which were oedema-specific. Patient rated outcome measures exist for pain (Freyd, 1923) and scars (Draaijers and Tempelman et al 2004) however there are currently no PROMs that focus solely on oedema. Nor do any of the existing generic or condition-specific PROMs contain questions explicitly related to oedema. No previous studies have incorporated patient-rated outcome measures when assessing responsiveness of methods to assess oedema. This could indicate that an important concept is neglected in the assessment of hand oedema. The development of a oedema specific PROM could help to gather important information which is currently missed from oedema assessment. For the purposes of clinical practice and testing effectiveness in clinical trials there is a need to establish the most responsive objective and subjective outcome measures to assess hand oedema. Based on the limitations of a previous

responsiveness study (Leard et al., 2008), there is also the need for studies with large sample sizes and including patients with a broad range of pathologies, whilst also incorporating a longer follow-up period.

6.2 Aims and objectives

The purpose of this study was to compare the relative responsiveness of two clinician-derived and two patient-rated measures. The findings of this study will be used to inform the choice of outcome measures in a pilot randomised controlled trial comparing standard care (compression with elevation and massage) with trial treatment (kinesiology tape with elevation and massage).

The objectives of this study were therefore to:

i) compare the relative responsiveness of two methods of assessing hand volume: the volumeter and the figure-of-eight tape measure method, in relation to location of the oedema

ii) compare the relative responsiveness of two patient-rated methods to assess hand oedema, the patient evaluation measure (PEM) and a new single item patient-rated oedema severity scale, in relation to the location of oedema

iii) calculate the correlation between clinician-derived measures of oedema and patient-rated outcome measures

iv) investigate patient preference across all four measures.

6.3 Methods

6.3.1 Study design

A prospective observational study of clinician-assessed and patient-reported measures was undertaken. Responsiveness can be assessed with a single group repeated-measures design. This takes one group of participants (who are expected to change over time), assesses them at pre-specified time points, and observes how hand oedema changes over time without altering any aspects of their standard therapy treatment.

There are two types of responsiveness: internal and external. Internal responsiveness is defined as “the instrument’s ability to detect change over time in the construct to be measured” (Mokkink et al., 2012). External responsiveness is “the extent to which changes in a measure over a specified time frame relate to corresponding changes in a reference measure of health status” (Husted et al., 2000).This study focused on internal responsiveness.

Whilst there undoubtedly were variations between and potentially within each participant’s treatment during the study period, which may have included different methods of reducing hand oedema, this reflects standard current practice. There is currently no consensus on how best to treat oedema (Miller et al., 2017[a]). Given the short-term follow-up (2 and 4 weeks) we anticipated that variations within the same subject, in terms of changes made to the prescribed method of oedema management, would be minimal or negligible. This study assessed change in hand volume before and after treatment, and the participants’ own judgements of the severity of their hand oedema rated on a numerical scale. Obtaining patient-rated data on hand oedema has not been included in previous responsiveness studies that compared volume assessments.

6.3.2 Setting

This single-centre study was conducted in a regional hand therapy department at the Norfolk and Norwich University Hospital between January and April 2017. Recruitment commenced on 3 January 2017 and continued for 10 weeks in order to recruit 100 participants. All follow-up assessments were completed by April 2017.

Ethics and local research governance approvals were obtained from the East of England - Cambridgeshire and Hertfordshire Research Ethics Committee, the Health Research Authority and Research Governance Department of the local NHS hospital (REC Ref: 16/EE/0365, IRAS ID: 209952) See Appendix O for copies of approval letters. All participants gave written informed consent to participate in the study.

6.3.3 Participants

Eligible participants were those over 18 years old referred to hand therapy at the Norfolk and Norwich University Hospital after elective hand surgery or hand trauma (with or without surgery) with hand oedema confirmed by a hand therapist, requiring treatment. Participants were recruited via their treating therapist during a routine hand therapy appointment. Interventions were not recorded for the purpose of this study. The duration of oedema was not listed as part of the inclusion/exclusion criteria, as the assessment methods used in the study were not time-specific nor dependent on a particular type of oedema; for example, acute, sub-acute or chronic.

Patients were excluded if they were unable to give valid consent or could not speak and read English. Patients with wounds and/or dressings were not eligible to take part until they were free of dressings and able to submerse their hand into water for the purposes of the volumeter. (See Appendix P for a copy of the Patient Information Sheet).

One experienced hand therapist (LM), who was not involved in the patients' treatment, assessed all participants, at baseline, two and four weeks later. The order in which assessments and patient-rated measures were administered was alternated between participants, ensuring that patient-rated outcome measures were completed first to avoid the clinician-derived measures potentially influencing the patient's estimation of swelling.

6.3.4 Assessment interval

Previous studies assessing responsiveness of the volumeter compared to the figure-of-eight tape measure used a 2-week follow-up (mean 19 days from baseline to follow-up assessment) (Leard et al., 2008). Given that the previous responsiveness study (Leard et al., 2008) only used one follow-up at 2 weeks, a longer follow-up period of 4 weeks was also incorporated in this study. This is particularly relevant for those chronically oedematous hands, which may be slower to respond to treatment.

It was anticipated that short-term follow-up (such as two and four weeks) would minimise loss to follow-up, which may be associated with prolonged study involvement (Herbert, 2018). From clinical experience, failure to return for follow-up is common in hand therapy, particularly with self-employed patients who cannot justify unpaid time away from work and therefore (if their injury allows them to return to work) factors such as oedema may not be limiting them enough to return for follow-up. By combining study follow-up with the patient's routine hand therapy appointment, we hoped this would maximise retention by reducing the burden on the participant to attend additional appointments for the purposes of the study. Based on observation of physiological response, we anticipated a change in oedema within a 4-week timeframe, particularly if oedema treatment had commenced and the oedema was in the acute or sub-acute phase.

6.3.5 Outcome measures (all assessed by LM)

Objective measures of hand volume

i) A single measure of the affected hand using a volumeter was completed. Water displacement was recorded in ml. Water temperature was maintained between 18 and 24 degrees Celsius as has been recommended (King, 1993[b]). This method has been referred to as the 'gold-standard' method of measuring hand volume, as it has excellent inter and intra-rater reliability (ICC 0.99) (Farrell et al., 2003). Its usage, however, is thought to have diminished in hand therapy departments over the years due to time and space constraints, increased patient load and the absence of volumeters in clinical practice. A volumeter was purchased for the purpose of this study.

ii) A single measure of the affected hand with a ¼ inch-wide fibreglass, retractable, non-stretch tape measure in a figure-of-eight method was completed following a standardised protocol described by Pellecchia (2003). Measurements were recorded in cm and mm to 1 decimal point. This method

has comparable reliability (Pellecchia, 2003) to the volumeter and has benefits in terms of portability, time to administer and low cost.

Subjective patient-rated measures

As well as direct measures of hand volume, it may also be desirable to obtain patient-reported outcome measures (PROMs). These are defined as “any report of the status of a patient’s health condition that comes directly from the patient, without interpretation of the patient’s response by a clinician or anyone else” (FDA Guidance for Industry, 2009). Collecting patient-reported outcome measures (PROMs) has been a mandatory requirement for all providers treating NHS patients in elective surgery (hip, knee, hernia and varicose vein surgery) since 2009 (Black, 2013). According to Kyte et al., (2015) PROMs have the potential to empower patients, support clinical decision-making and drive forward quality improvement.

Currently available validated hand and upper limb specific PROMs include the Disabilities of the Arm, Shoulder and Hand (DASH) (Hudak et al., 1996), the Michigan Hand Questionnaire (MHQ) (Chung et al., 1998) and the patient evaluation measure (PEM) (Dias et al., 2001). Whilst the hand health profile of the PEM includes items on the ‘feel’ and ‘appearance’ of the hand, which may address hand swelling, it could also relate to scarring and sensation. None of the existing PROMS include any question directly related to swelling. There is no existing patient-rated oedema severity scale. Numerical rating scales for pain severity are widely used and the principle of asking patients to rate severity using a simple numerical scale can be applied to other symptoms or impairments. There was a need to develop such a scale specifically for hand oedema, and to assess how well it correlates with other measures and how responsive it is in detecting change over time.

i) The hand health profile of the patient evaluation measure (PEM) (see Appendix Q) is an 11-question standardised region-specific patient-rated outcome measure (Dias et al., 2001,Dias et al., 2008). It is scored on a 0-7 Likert scale, with a total score being expressed as a percentage disability ranging from zero to 100. The higher the percentage, the greater the perceived disability. The PEM, unlike other commonly used patient-rated outcome measures in hand therapy, includes items on the 'feel' and 'appearance' of the hand ,which may relate to hand swelling but could also relate to scarring and sensation. This, combined with the evidence on its speed and ease of completion (Dias et al., 2008), made the PEM the most appropriate patient-rated outcome measure (PROM) to use in this study.

ii) The oedema rating scale (ORS) is a single-item self-reported severity-of-swelling scale, where the patient is asked "Please rate the swelling in your hand today" using a 7-point ordinal scale (none=0, extreme=6) (Figure 6.1). This scale was devised in collaboration with a patient advisory group (PAG), made up of current and previous hand therapy patients, who co-designed the format and descriptors for each point.

Figure 6.1 Oedema rating scale (ORS)

Please rate the swelling in your hand today?

Please tick the box which best describes your hand swelling.

☐	☐	☐	☐	☐	☐	☐
None	**Minimal**	**Mild**	**Moderate**	**Severe**	**Very Severe**	**Extreme**
(0)	**(1)**	**(2)**	**(3)**	**(4)**	**(5)**	**(6)**

On the final assessment at 4 weeks, participants were also asked which assessment they preferred overall and why. Additional relevant data also collected at baseline included: age, sex, time since injury or operation, medication and past medical history. The location of oedema was recorded as either global (affecting the whole hand +/- digits) or isolated to a digit.

Participants' involvement in the study ended after their 4-week follow-up assessment. Participants were asked if they would like to receive a report of the results of the study once it had been completed and results analysed. Participants still undergoing hand therapy assessment and treatment continued as per departmental guidelines.

6.3.6 Sample size

The Consensus-based Standards for the selection of health Measurement Instruments (COSMIN) (Terwee et al., 2012) suggest that sample sizes of, or exceeding, n=100 are

classed as excellent for responsiveness studies. This formed part of the rationale for the sample size, alongside a pragmatic approach based on average throughput in the department and available time for recruiting. We anticipated approximately 20 patients per week would meet the inclusion criteria. Using a conservative estimate that 30% of patients would consent provided 7 participants per week. Over a 4 to 6-month recruitment period this would result in112 to 168 participants. Due to delays in Health Research Authority (HRA) and local NHS approvals, the study commenced later than planned and therefore a revised target sample size was set at 100, over a 3-month period.

6.3.7 Statistical analysis

The internal responsiveness for each measure was quantified using effect size (ES) and standardised response mean statistics. Effect size is calculated by dividing the mean change over time by the baseline standard deviation (SD) (Sullivan and Feinn, 2012). The standardised response mean (SRM) is calculated by dividing the mean change by the standard deviation of change. These statistics can be compared across measures because they are unit-free. According to Cohen's criteria (Cohen, 1988), an effect size of <0.3 is considered small, 0.5 is moderate and >0.8 large.

The relative responsiveness of the two assessments (volumeter and figure-of-eight) were compared. Similarly, the relative responsiveness of the patient-rated PEM and global oedema rating scale were compared. Subgroup analyses were performed, based on the location of oedema, i.e. either global or isolated digit. Previous studies comparing the responsiveness of oedema assessment methods (Leard et al., 2008) have neglected to record and analyse by location of oedema. It was an important factor to include in this study, given the variations in the area of the hand taken into account by the placement of the figure-of-eight tape compared to the volumeter, where the whole hand is immersed.

The data distribution was assessed using histograms. Scattergraphs were used to assess the type of relationship between the independent variable (oedema rating scale or patient evaluation measure) and dependent variables (figure-of-eight tape measure

and volumeter). A Pearson's product-moment correlation was used to test the direction and strength of the relationship between the subjective and objectives measures over four weeks. Data on patient preference were summarised in counts and percentages.

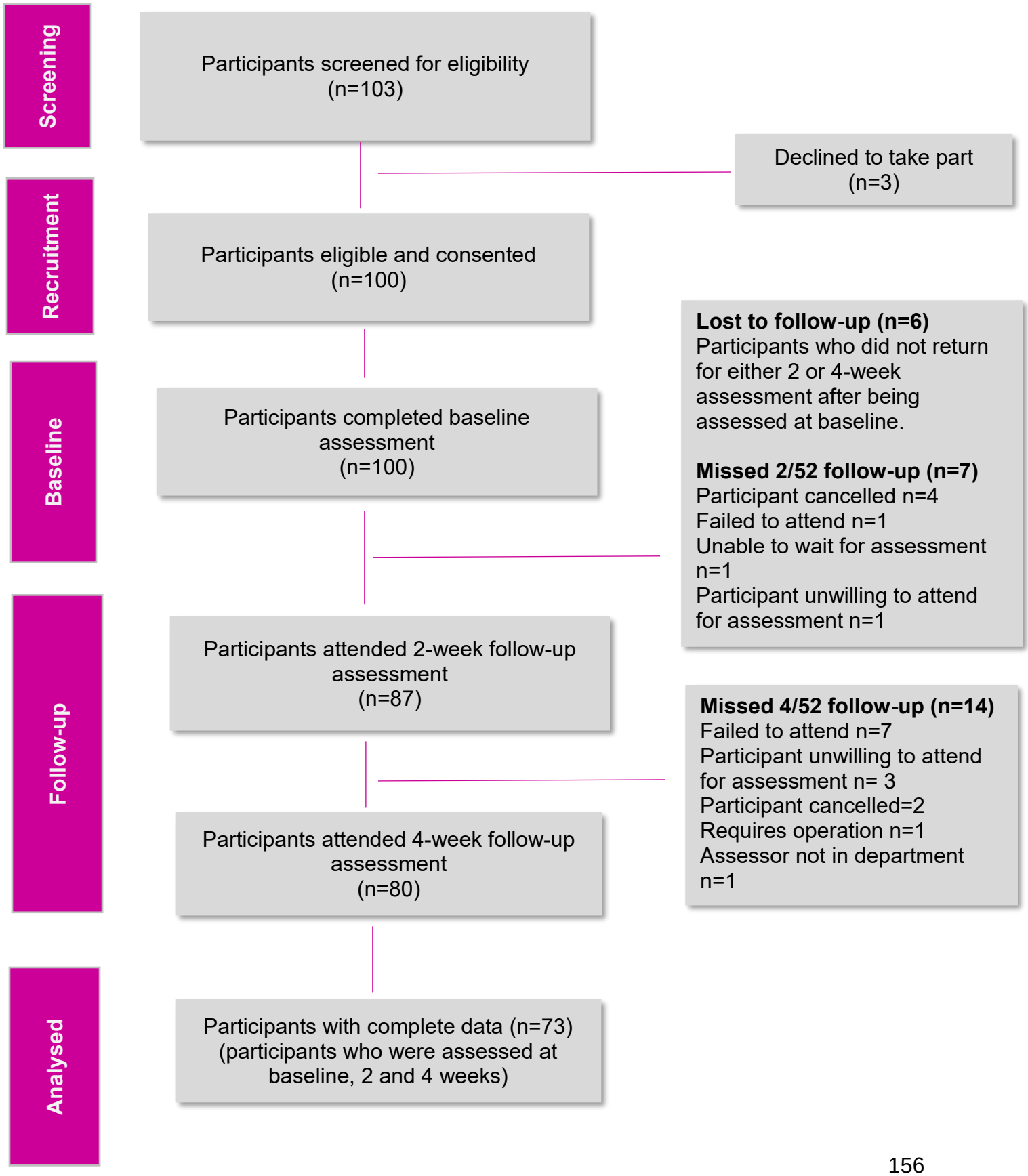
All analyses were completed using the Statistical Package for Social Science (SPSS, version 23).

6.4 Results

6.4.1 Participant flow

One hundred participants were recruited from the hand therapy department at the Norfolk and Norwich Hospital over a 14-week period. Figure 6.2 shows the participant flow through the study. A total of 103 participants were screened for eligibility, with 100 being consented. Twenty-seven participants were lost to follow-up over the 4-week assessment period, which left 73 participants with complete data who were included in the analysis.

Figure 6.2 Participant flow diagram



4.2 Sample

Recruited participants displayed a wide variety of finger, hand and wrist pathologies. Table 6.1 summaries the demographics of the participants.

Table 6.1 Baseline characteristics of the 73 participants with complete data

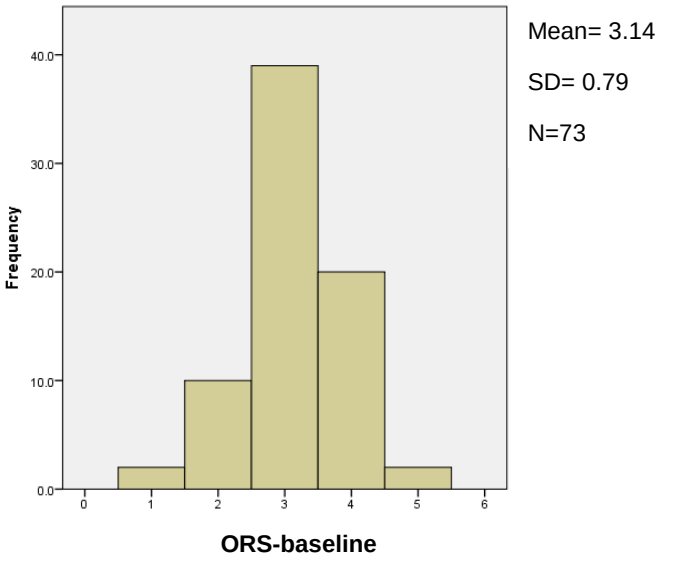
Characteristic	Result
Gender	
Male : female	37:36
Age (years)	
Mean (SD)	54.2 (14.8)
Pathology:	
Tendon transfer or repair	6 (4%)
Fracture to digit +/- dislocation (conservative management)	13 (18%)
Fracture to hand/wrist (conservative management)	10 (14%)
Soft tissue injury to digit (conservative management)	4 (5%)
Soft tissue injury to hand/wrist (conservative management)	3 (4%)
Amputation digit/s	1 (1%)
Joint fusion (hand/wrist)	2 (3%)
Joint replacement digits	1 (1%)
Trapeziectomy or joint replacement	3 (4%)
Fracture +/- dislocation fixation (digit/s)	3 (4%)
Fracture +/- dislocation fixation (hand/wrist)	5 (7%)
Nerve decompression, repair or palsy	4 (5%)
Dupuytren's contracture release	7 (10%)
Poly trauma/surgery (multiple soft tissue and/or orthopaedic injuries or procedures)	10 (14%)
Location of oedema	
Isolated digit : global oedema	32 : 41
Management	
Conservative : Surgical	30: 43

Legend: SD= standard deviation

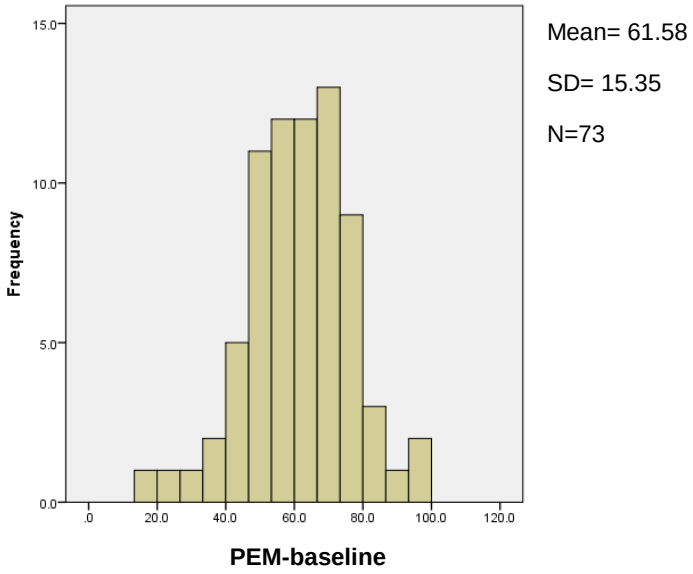
6.4.3 Correlation between clinician-derived and patient rated outcome measures

The data distributions were assessed by histograms. Data for all outcomes appeared to follow a normal distribution. Figure 6.3 display histograms for all outcomes (n=73).

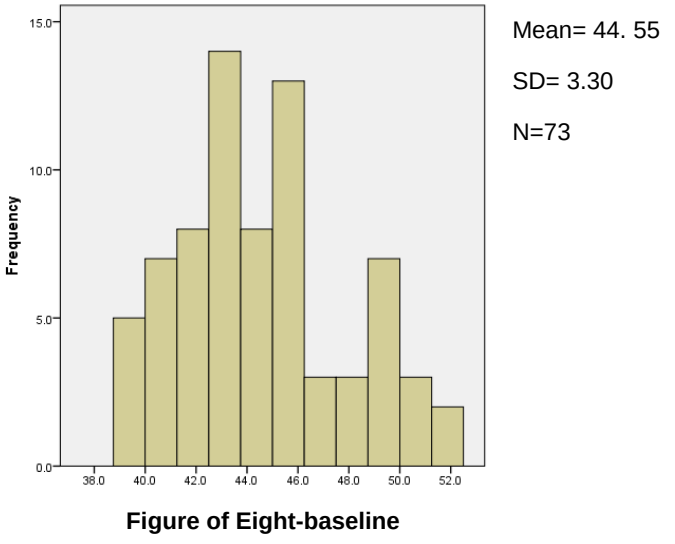
Figure 6.3 Histograms displaying distribution data for: A. Oedema rating scale (ORS); B. Patient evaluation measure (PEM); C. Figure-of-eight; and D. Volumeter



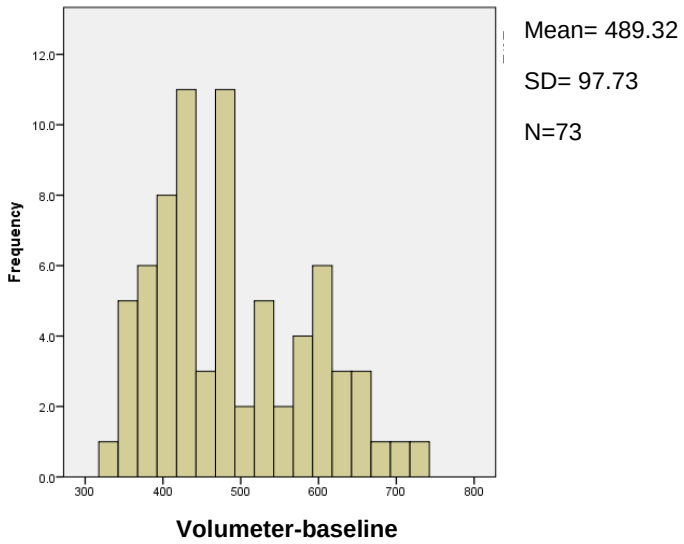
A



B



C



D

Legend: SD= Standard deviation

6.4.4 Timing of baseline assessment

Participants were recruited at any point in their treatment if their treating therapist deemed their hand oedematous, and requiring treatment. As the time since injury or surgery to baseline assessment data did not follow a normal distribution median time, range and interquartile range (IQR) in days from injury or surgery to baseline assessment were used (Table 6.2).

Table 6.2 Descriptive statistics for time since injury or surgery to baseline assessment for whole group (n=73) with complete data and subgroups

Time since injury/surgery to baseline assessment (days)	Global oedema (n=41)	Isolated digit oedema (n=32)	Group with complete data (n=73)
Median	42	42	42
Quartile 1, Quartile 3	28, 51	9, 63	28, 56
Minimum, Maximum	2,252	1,112	1,251

6.4.5 Volumeter assessment

The temperature of the water used in the volumeter was monitored and recorded prior to each assessment using a digital thermometer, bought for the purposes of this study. King, (1993[b]) suggests the water should be maintained between 18 and 24°. Warm or cold water was added to ensure the temperature remained within these limits prior to each assessment. The mean water at baseline was 21.6°, 21.3° at the 2-week assessment and 21.4° at the 4-week assessment.

6.4.6 Responsiveness

Internal responsiveness was assessed for participants with complete data (n=73) who attended all three assessments (baseline, 2 and 4 weeks) and also by subgroups of

isolated digit oedema (n=32) and global hand oedema (n=41). Results are displayed in tables 6.3 (whole group), 6.4 (global hand oedema) and 6.5 (isolated digit oedema). Results demonstrated that responsiveness statistics were larger over four weeks than two.

Table 6.3 Mean and standard deviations for assessments at baseline, 2 and 4 weeks, and 2 and 4-week change. Effect size and standardised response mean for change at 2 and 4 weeks for participants with full data only (n=73)

	Patient-rated measures		Objective assessments	
	ORS (0-6)	**PEM (%)**	**Volumeter (ml)**	**Fo8 (cm/mm)**
Baseline mean	3.14	61.57	489.32	44.54
(SD)	(0.78)	(15.35)	(97.73)	(3.29)
2 week mean	2.64	53.63	485.55	44.10
(SD)	(0.73)	(15.28)	(100.70)	(3.25)
4 week mean	2.27	44.34	473.25	44.14
(SD)	(0.94)	(20.11)	(92.90)	(3.30)
Mean change at 2 weeks	-0.49	-7.94	-3.76	-0.14
(SD)	(0.92)	(13.55)	(36.39)	(1.26)
ES 2 weeks	0.62	0.51	0.03	0.04
SRM 2 weeks	0.53	0.58	0.10	0.11
Mean change at 4 weeks	-0.86	-17.23	-16.06	-0.40
(SD)	(0.94)	(21.08)	(27.14)	(1.08)
ES 4 weeks	1.10	1.12	0.16	0.12
SRM 4 weeks	0.91	0.82	0.59	0.37

Legend: ORS= oedema rating scale, PEM= patient evaluation measure, Fo8= figure-of-eight tape measure, ES= effect size, SRM= standardised response mean, SD= standard deviation.

Table 6.4 Mean and standard deviations for assessments at baseline, 2 and 4 weeks, and 2 and 4-week change. Effect size and standardised response mean for subgroup with global hand oedema n=41

	Patient-rated Measures		Objective assessments	
	ORS (0-6)	**PEM (%)**	**Volumeter (ml)**	**Fo8 (cm/mm)**
Baseline mean	3.10	65.30	491.83	44.47
(SD)	(0.80)	(15.53)	(102.27)	(3.51)
2 week mean	2.76	56.84	494.39	44.38
(SD)	(0.80)	(15.51)	(111.86)	(3.71)
4 week mean	2.34	46.27	474.20	44.00
(SD)	(0.82)	(21.45)	(102.38)	(3.76)
Mean change at 2 weeks	-0.34	-8.45	2.56	-0.83
(SD)	(0.96)	(15.15)	(43.05)	(1.36)
ES 2 weeks	0.42	0.54	0.02	0.23
SRM 2 weeks	0.35	0.55	0.05	0.61
Mean change at 4 weeks	-0.75	-19.03	-17.63	-0.46
(SD)	(0.85)	(25.28)	(24.34)	(1.02)
ES 4 weeks	0.93	1.22	0.17	0.13
SRM 4 weeks	0.88	0.75	0.72	0.45

Legend: ORS= oedema rating scale, PEM= patient evaluation measure, Fo8= figure-of-eight tape measure, ES= effect size, SRM= standardised response mean, SD= standard deviation.

Table 6.5 Mean and standard deviations for assessments at baseline, 2 and 4 weeks, and 2 and 4-week change. Effect size and standardised response mean for subgroup with isolated digital oedema n=32

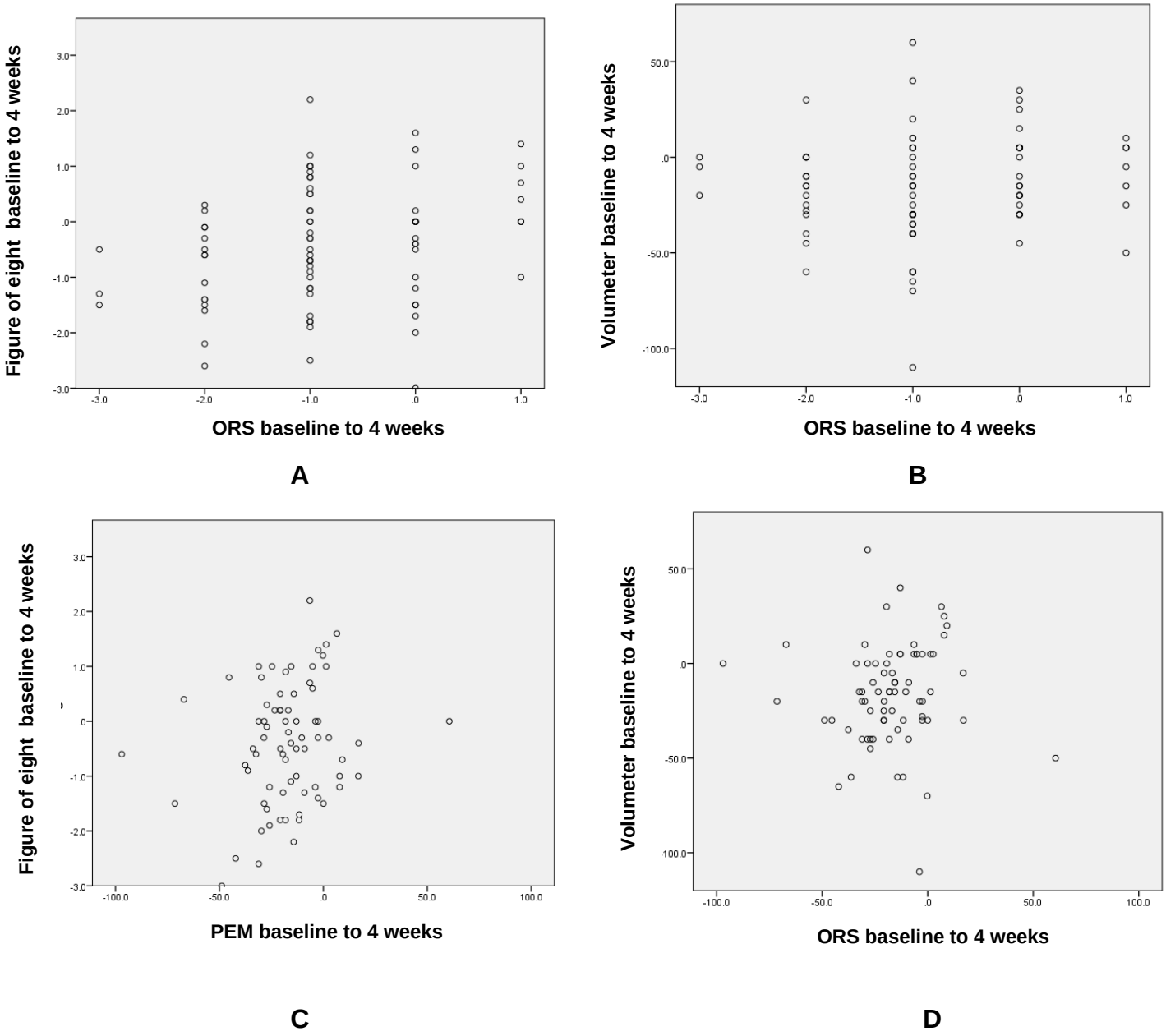
	Patient-rated measures		Clinician-derived measures	
	ORS (0-6)	**PEM (%)**	**Volumeter (ml)**	**Fo8 (cm/mm)**
Baseline mean	3.19	56.80	486.09	44.65
(SD)	(0.78)	(13.92)	(93.10)	(3.05)
2 week mean	2.50	49.51	474.22	44.43
(SD)	(0.91)	(14.16)	(84.67)	(2.06)
4 week mean	2.19	41.86	472.03	44.33
(SD)	(1.09)	(18.29)	(80.72)	(2.65)
Mean change at 2 weeks	-0.68	-7.28	-11.87	-0.21
(SD)	(0.85)	(11.37)	(23.75)	(1.13)
ES 2 weeks	0.87	0.52	0.12	0.06
SRM 2 weeks	0.80	0.64	0.49	0.18
Mean change at 4 weeks	-1.00	-14.93	-14.06	-0.31
(SD)	(1.04)	(14.06)	(30.64)	(1.16)
ES 4 weeks	1.28	1.07	0.15	0.10
SRM 4 weeks	0.96	1.06	0.45	0.26

Legend: ORS= oedema rating scale, PEM= patient evaluation measure, Fo8= figure-of-eight tape measure, ES= effect size, SRM= standardised response mean, SD= standard deviation.

The relationship between subjective and objective variables based on a 4-week change was examined in scattergraphs. Scattergraph A (Figure 6.4) suggests a linear relationship between the oedema rating scale and figure-of-eight tape measure and therefore a Pearson's product-moment correlation was performed. Scattergraph B, C

and D of Figure 6.4 shows no obvious relationship between objective and subjective outcome, indicating that any correlation test would result in a coefficient of around zero.

Figure 6.4 Scattergraphs showing relationship between: A. Oedema rating scale (ORS) and figure-of-eight tape measure; B. ORS and volumeter; C. Patient evaluation measure (PEM) and figure-of-eight; and D. PEM and volumeter, all over 4 weeks for n=80



A Pearson correlation coefficient was calculated to assess the strength and direction of the association between change scores in patient-rated outcomes and objective results for the whole group (n=80) and subgroups with global hand oedema (n=41) and isolated digit oedema (n=32) over 4 weeks.

Table 6.6 displays the results of the correlation analysis. These results indicate a weak positive (r=0.26), statistically significant (p=0.02) relationship between the ORS and figure-of-eight tape assessment over four weeks for the group completing baseline and 4-week assessments (n=80). A weak positive (r=0.33), statistically significant (p=0.04) relationship was also found between the ORS and figure-of-eight tape assessment for the subgroup with global hand oedema (n=41) over four weeks. There was also a weak (r=0.39) statistically significant (p= 0.03) correlation between the PEM and the figure-of-eight tape measure in the subgroup with isolated digit oedema (n=32). This indicates that as the results for the ORS increased (worsened), the figure-of-eight tape measure results also increased (worsened). All other correlations indicated a weak positive relationship between ORS and objective measures, which were not statistically significant.

Table 6.6 Results of the Pearson product-moment correlation analysis for participants attending baseline and 4-week assessment and subgroups with isolated or global oedema

	4-week completers n=80		Isolated digit oedema n=32		Global hand oedema n=41	
	Volumeter	**Fo8**	**Volumeter**	**Fo8**	**Volumeter**	**Fo8**
ORS						
Pearson *r*	0.19	0.26	0.21	0.27	0.13	0.33
P value	0.30	0.02*	0.51	0.01	0.42	0.04*
PEM						
Pearson *r*	-0.03	0.18	0.11	0.39	-0.04	0.11
P value	0.77	0.12	0.55	0.03*	0.80	0.49

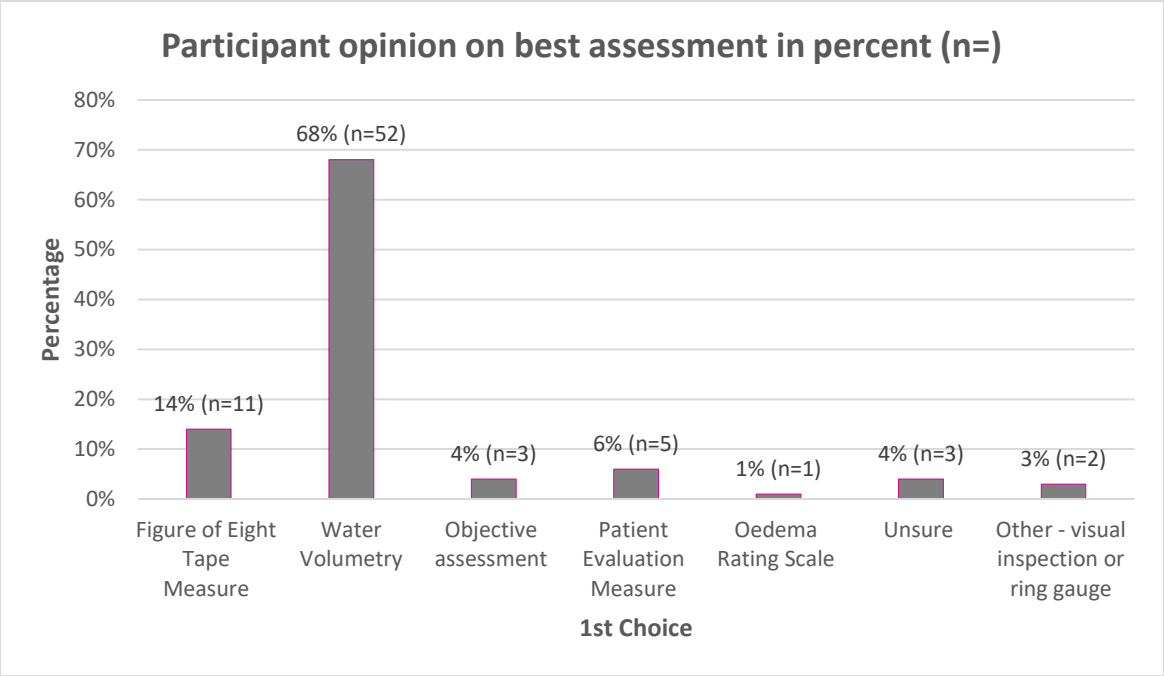
*statistically significant results at the 0.05 level.

Legend: Fo8= Figure of eight, PEM= patient evaluation measure.

6.4.7 Patient opinion

Seventy-seven participants were asked which of the four methods of assessing oedema they thought was the best. The assessor asked participants: “Of the four assessments you have just completed, which one do you think is the best way to measure hand swelling?” (see Figure 6.5). Results indicate that participants believed objective measures overall, in particular, the volumeter, were the best way of measuring hand oedema.

Figure 6.5 Bar chart depicting participant first choice of assessment methods



6.4.8 Summary

Table 6.7 depicts the numeric and colour-coded relative rank order of subjective and objective assessments based on responsiveness statistics (0-2 weeks), location of oedema and participant preference (4 weeks only). Table 6.8 depicts results for 0-4 weeks. Number 1 (green) indicates the assessment had greater responsiveness when compared to the other objective or subjective assessment, number 2 (orange) indicates the assessment had lower responsiveness relative to the other objective/subjective assessment.

Table 6.7 Summary results table over 2 weeks

	Whole group		Isolated digit oedema		Global hand oedema	
N	n=73		n=32		n=41	
	ES	SRM	ES	SRM	ES	SRM
Patient-rated measures						
PEM	2	1	2	2	1	1
ORS	1	2	1	1	2	2
Objective assessments						
Fig 8	1	1	2	2	1	1
Vol	2	2	1	1	2	2

Legend: ES= effect size, SRM= standardised response mean, PEM= patient evaluation measure, ORS= oedema rating scale, Fig 8= figure of eight, Vol= volumeter.

When comparing the relative rank order across all responsiveness statistics over two weeks, there was no clear distinction between pairs of measures. Equivocal results were seen for both the patient-rated measures and both the objective assessments. The PEM was more responsive than the ORS for those with global hand oedema, whereas the ORS was more responsive for patients with isolated digit oedema. The figure-of-eight was more responsive than the volumeter for the whole group and those with global hand oedema. In contrast, the volumeter was more responsive for those with isolated digit oedema.

Table 6.8 Summary results table over 4 weeks

	Whole group		Isolated digit oedema		Global hand oedema		Participant choice
N	n=73		n=32		n=41		n=77
	ES	SRM	ES	SRM	ES	SRM	
Patient-rated measures							
PEM	1	2	2	1	1	2	1
ORS	2	1	1	2	2	1	2
Objective assessments							
Fig 8	2	2	2	2	2	2	2
Vol	1	1	1	1	1	1	1

Legend: ES= effect size, SRM= standardised response mean, PEM= patient evaluation measure, ORS= oedema rating scale, Fig 8= figure of eight, Vol= volumeter.

At four weeks, however, there is a clearer picture emerging with the objective assessments, with the Volumeter consistently ranking higher than the figure-of-eight across all groups and responsiveness statistics. When comparing the relative rank order across all responsiveness statistics for patient-rated measures, the ORS and PEM have equal ranking, as was the case at two weeks. The additional outcome of participants' first choice of assessment method in this table shows the PEM and the volumeter were preferred by participants.

6.5 Discussion

The aims of this study were to compare the relative responsiveness of two assessments of hand volume, the figure-of-eight tape measure (Fo8) and volumeter, as well as two patient-rated measures of hand swelling and to assess the strength of association between these measures.

The responsiveness statistics obtained from measuring swelling at 2 weeks were smaller than those obtained over 4 weeks for the whole group. This is not surprising and may indicate that the oedema management interventions require a longer period of time to take effect and to show a change in hand volume. However, in the group with global hand oedema (n=41), the figure-of-eight measure had larger responsiveness statistics at 2 weeks (ES=0.23, SMR=0.61) than those obtained at 4 weeks (ES=0.13, SRM=0.45). Similarly, the SRM for the volumeter was marginally higher at 2 weeks (SRM=0.49) than 4 weeks (SRM=0.45) in the group with isolated digit oedema. With the above exceptions, over 2 weeks, responsiveness statistics were generally small to moderate. Over 4 weeks, some were moderate to large and therefore the discussion will primarily focus on change over that time interval.

In the whole group (n=73) and the two subgroups, the volumeter was consistently more responsive than the figure of eight, as demonstrated in marginally larger ES and SRMs over 4 weeks. Results for the patient-rated measures were less consistent. The ES for the whole group was similar across the two assessments (ORS ES=1.10, PEM ES=1.12), although the SRM was slightly larger for the ORS (SRM= 0.91) than the PEM (SRM=0.82). For the subgroup with isolated digit oedema (n=32) the ORS had a larger ES (2.8) than the PEM (1.07). In contrast, the PEM had a slightly larger SRM (1.06) than the ORS (0.96). In the subgroup with global hand oedema (n=41) the PEM had a slightly higher ES (1.22) than the ORS (0.93), whereas the ORS had a slightly larger SRM (0.88) than the PEM (0.75).

The weak correlations seen between patient-rated outcomes and objective measures indicates that whilst objective measures and patient-reported measures are related, one could not replace the other during a clinical assessment of hand oedema.

6.5.1 Validity of clinician-derived measures to assess hand volume in the presence of scar tissue

Fifty-nine percent (n=43) of patients were managed surgically, potentially giving rise to increased scar tissue formation compared to the 30 participants who were treated

conservatively. Scar tissue is known to be thick and dense, with excessive collagen production laid down in a haphazard form (Hardy, 1989). Clinically this can present as hard, bulky and raised scarring. It is plausible that scar tissue could have increased the measurement obtained by the figure-of-eight tape measurement and volumeter reading. Certain injuries and conditions, such as tendon repairs and Dupuytren's disease, can present with nodules and firm, thick and raised scarring. The volumeter measures the total volume of the immersed hand; therefore, irrespective of the location of scar tissue, it will give an inflated volume reading, even when this is not due to oedema. Due to the figure-of-eight placement of the tape measure, however, this will only show an inflated measurement if the raised scar is in the location of the tape. Over a 4-week period hand oedema after trauma or surgery is expected to change, whereas scar tissue requires much longer to remodel.

6.5.2 Patient-rated change and correlation with objective measures

This study showed there was only a weak correlation between the patient-rated outcome measures and the objective assessments. This is a good rationale for the inclusion of a specific patient-rated oedema scale, as it is capturing different data than the objective assessments, and therefore could be a useful addition to the assessment process in order to ensure the patient's 'voice' is taken into consideration when determining the effectiveness of interventions. Whilst it is essential to ensure there is objective evidence to assess treatment effectiveness, the patient's perception of his or her own recovery remains an important criterion of progress which needs capturing. Participants were often surprised if their objective assessments showed an increase in oedema when they had recorded an improvement on the ORS or vice versa, but were less surprised if their objective assessments were not consistent with their PEM results, as participants felt this was a more global measure which incorporated multiple dimensions associated with their progress. Often objective measurements had reduced, but the patient perceived their hand to be no different on the ORS. Over 4 weeks, only 28 participants (38%) recorded subjective assessment results that were consistent with the results from the objective assessments (improved, worsened or no change). This

corroborates the weak correlations observed between objective and subjective measures.

The COSMIN guidelines (Mokkink et al., 2010) advise that score changes over time should be compared and correlated to those of a “gold standard” or an “external criterion”. This study compared changes and correlated score changes between the oedema rating scale and the volumeter, which is considered to be the ‘gold standard’ method of assessing hand volume (Farrell et al., 2003). There is no gold standard or external criterion patient-rated oedema scale, and COSMIN admits that a gold standard is “generally impossible to find” (Angst, 2011). The COSMIN manual suggests using a global rating of change to obtain an external criterion (Mokkink et al., 2010). The limitation of this is the reliability of retrospective recall. Participants were not asked to rate or quantify their change in oedema. The oedema rating scale gave a snapshot in time of their oedema severity at the time of assessment. Participants were not reminded of their previous ORS scores, and therefore were rating their hand oedema based on their perception on the day, rather than in comparison with their previous score. The use of a gold standard and external criterion have been criticised in responsiveness studies as being unnecessary (Norman et al., 1997) where the aim is to determine whether measure A is more or less responsive than measure B. Comparing change scores from measure A and B to that of a gold standard or external criterion, however, is irrelevant to answering which measure is more responsive.

The results of the correlation analyses indicated no relationship between the volumeter and either patient-rated outcome measure. However, there was a weak to moderately strong association between the ORS and figure-of-eight tape measure (whole group and global hand oedema group) and between the PEM and figure-of-eight tape measure (for the group with isolated digit oedema) over 4 weeks. These results may be due to chance; however, the figure-of-eight correlation coefficients were consistently higher (although still small) than those of the volumeter across all groups, indicating that the way the participants rated their hand oedema was more strongly related to the figure-of-eight than the volumeter. This may be due to the location of oedema, and

suggests that participants may focus more on their hand when rating their oedema and pay less attention to the digits, as only the hand is captured in the figure-of-eight measurement.

6.5.3 Participant opinion on best assessment

The majority of participants (68% n=52) felt the water displacement method was the best way to measure hand oedema. This method appeared to have clear face validity to participants. Many were able to recall Archimedes' principle and stated that the volumeter appeared more "scientific" with "less room for error" than the tape measure method. Participants with isolated digital oedema were often unsure of the relevance of the figure-of-eight method, which did not capture the location of their swelling. The figure-of-eight tape measure method only measures the volume of the areas covered by the tape and therefore excludes the digits.

Many participants felt the patient-rated outcome measures, in particular the PEM, were not specific enough to swelling, as factors such as mood, time of day and functional ability (which could be affected by aspects such as pain, other conditions or disabilities) may have influenced their score. Nor does the PEM ask any questions directly relating to oedema, and addresses multiple items within the one questionnaire, unlike the ORS. Despite this, the PEM received more counts than the ORS, when patients were asked which assessment they felt was best at measuring oedema. This may be because the PEM focuses on the functional impact of the hand injury (which may include the impact of an oedematous hand), which patients may consider more relevant than just rating the severity of a single factor like oedema.

Some participants struggled to self-rate their hand swelling using a 7-point numerical scale for the ORS, despite the descriptors, and often asked the assessor their opinion on which box they should tick. This raises an interesting debate and one that does not appear to have received much attention in the literature. Asking patients to rate their own impairment or performance may be alien to some patients, who prefer to rely on the clinician's judgement. MacDermid, (2017) points out in her editorial in the *Journal of*

*Hand Therapy t*hat whilst in some cultures patients are happy to have their perspective incorporated in the clinical process, others may view this as a sign of clinician incompetence. On the other hand, clinicians may not appreciate the patient's symptoms, therefore there is a need to incorporate the patient's voice. Furthermore, there is evidence that patients report better outcomes (Nelson et al., 2015). A report in the *BMJ* (Nelson et al, 2015) states: "The patient-reported outcome measures (PROMs) movement has largely been driven by the agenda of researchers or service payers and has failed to focus effectively on improving the quality of care from the patient's perspective." If a patient records their oedema as worsening or remaining the same, this could prompt intervention from the clinician. In this way, the PROM is bridging the gap between the clinician's and patient's perspectives and includes the patient in treatment planning and delivery. However, it could be argued the same would occur without the PROM, based solely on results from the volumeter or figure-of-eight. A greater sense of patient satisfaction with the service received could be gained with either approach and this would depend on the patient. We have seen from the results of this study that the PROMs could not replace the clinical assessment; they are merely designed to complement an objective assessment.

The participants who struggled to rate their hand swelling may believe it is the role of the clinician to rate the severity of their symptoms and treat them accordingly; however it could also mean that rating the severity of their oedema was of little value to the patient.

6.5.4 Location of oedema

The figure-of-eight tape measures the cumulative size of the regions covered by the tape (Leard et al., 2004). As the tape measure is placed proximal to the base of the digits, it may not be the most appropriate method to use if the oedema is isolated to the digits. This may explain the slightly lower responsiveness in the subgroup with isolated digit oedema, as seen in the SRM over 4 weeks (0.26), compared to the group with global hand oedema (0.45). However, the differences were similar in the ES over 2 and 4 weeks between the subgroups for the objective assessments. Location of oedema

had a greater effect on the results of the SRM over 2 and 4 weeks. Over 2 weeks the volumeter was more responsive in patients with isolated digit oedema, whereas the figure-of-eight was more responsive in participants with global hand oedema. Over 4 weeks, the volumeter continued to be more responsive in the group with isolated digit oedema. However, in contrast to the results over 2 weeks for the global hand oedema subgroup, the volumeter went on to demonstrate greater relative responsiveness compared to the figure of eight.

The location of oedema appeared to affect the responsiveness results obtained for the patient-rated measures over 2 weeks. Across both sets of responsiveness statistics, the ORS was more responsive than the PEM for the group with isolated digit oedema, whereas the ES and SRM were larger for the PEM than the ORS in the group with global hand oedema. However, the location of oedema did not appear to affect the responsiveness results obtained for the patient-rated measures over 4 weeks. Large and very large responsiveness statistics were seen across ES and SRMs for the PEM and ORS over 4 weeks, which were largely comparable. Comparisons between the subgroups showed that the ORS had a large ES (ES=1.28) in those with isolated digital oedema, whereas the PEM had an equally large ES (ES=1.22) for the subgroup with global hand oedema, over 4 weeks. The SRM results, however, indicated that the ORS was slightly more responsive than the PEM across both subgroups.

Global hand oedema may have a broader impact on patients, compared to isolated digit oedema. For this reason the 11-item hand health profile of the PEM, which incorporates multiple factors including pain, function and appearance, may be more relevant. In contrast, the ORS may be more appropriate for those with isolated digit oedema. Of the 7% of participants (n=6) who chose a subjective assessment as the best way to measure hand oedema, 6% (n=5) thought the PEM was better than the ORS. It is acknowledged, however, that these are very small numbers.

6.5.5 Type of oedema and impact on treatment effectiveness and responsiveness

The effectiveness of oedema interventions may reduce when oedema is in a chronic phase (>12 weeks after injury or surgery), as acute fluid is replaced with more viscous, fibrotic oedema with thickening of fascial tissue. Because of this, clinically, we would expect to see less change over the 4-week period of this study in the assessments with chronic oedema. Participants may not be able to detect changes in the appearance of their hand or digit after the initial acute or sub-acute phase, with thickening of fascial tissue and scar tissue potentially maintaining the appearance of a larger digit or hand. This may make it more challenging for participants to distinguish it from tissue thickening, which is likely to be a permanent feature. Participants with isolated digit oedema had their baseline assessment a mean of 17.9 days earlier than the group with global hand oedema. The time since injury or surgery was also much shorter for those with isolated digit oedema, at 5.8 weeks compared to 8.4 weeks for those with global hand oedema. In this study, the subgroup with global hand oedema presented with oedema that was more chronic than those participants with isolated digit oedema.
In light of this, it is essential to use a measure that is sensitive enough to detect even small changes, as may be the case in participants with chronic oedema. The effect sizes for the figure-of-eight and volumeter were identical for both subgroups over 4 weeks, showing very little responsiveness regardless of the type (acute, sub-acute or chronic) or location of oedema. Standardised response means for the participants with global hand oedema showed that the volumeter had a moderate ability (SRM 0.7) to detect changes over time in this group, who had more chronic oedema, compared to the figure-of-eight which had a slightly smaller responsiveness statistic (SRM 0.5). For those participants with more acute, isolated digit oedema, the volumeter also had a greater ability to detect change over time than the figure of eight. (SRM figure of eight=0.3, Vol=0.5). This may highlight that, for those participants where we expect to see a moderate amount of change, based on their type of oedema (more acute), either measure is acceptable to use as they have similarly small to medium responsiveness. In contrast, when smaller changes are anticipated, as is the case with chronic oedema, the volumeter may have a superior ability to detect potentially smaller changes over time.

6.5.6 Reporting responsiveness

When assessing responsiveness there is an assumption that the interventions given during the observational period are known to be effective or that the change has occurred due to natural healing. The interventions prescribed by the therapists during this study were not documented, but they were all part of standard care in that department. They included compression, elevation, massage, modified manual lymph drainage, contrast bathing, kinesiology tape, exercise, positioning (splinting). There is limited low quality evidence to support the use of some, but not all, of these techniques (Miller et al., 2017[a]). Responsiveness statistics, as proposed by Cohen (1988), which were used in this study to interpret the magnitude of change in measures, have been criticised (Mokkink et al., 2010) as being too simplistic in their interpretation, by potentially disregarding the impact of the treatment effect on the result. According to the COSMIN panel (Mokkink et al., 2010), we should only interpret the ES (in terms of the responsiveness of a measure) if the treatment effect of the intervention has been hypothesised *a priori* or is already known. In this study, for example, where we have seen responsiveness statistics of or close to zero (ES for figure-of-eight and volumeter over 2 weeks), either the treatment had no effect or the measure was not responsive. Where we have seen moderate to large results (SRM for figure-of-eight and volumeter over 4 weeks), we could deduce that either the treatment effect was moderate and the measure was responsive, or the treatment effect was large or small and the outcome measure had poor responsiveness due to an over- or underestimation of the measure.

Despite statistics such as the effect size and standardised response means being widely used, recognised and recommended (Husted et al., 2000) forms of analysing responsiveness in scientific literature, measuring responsiveness has become a contentious issue which has led to this approach being viewed as inappropriate (Mokkink et al., 2012). These are considered measures of magnitude of change due to an intervention or other event, rather than measures of quality of the measurement instrument (Mokkink et al., 2010). An SRM provides an estimate of change in the measure, standardised relative to the between-patient variability in change scores. The

same guidelines, proposed by Cohen (1988) for interpretation, are used for both effect size and SRM, which further compounds the uncertainty around responsiveness. Guyatt et al., (1989) state that the between-subject variability of the individual changes in score over time is the appropriate standardisation and thus they favour the standardised response mean over the effect size. Guyatt et al., (1989) do not give any justification for this statement. ES depends on the heterogeneity of patients at baseline, whereas SRM depends upon heterogeneity of change, and both capture important factors of responsiveness. The two responsiveness statistics should not be compared to each other, but to the respective statistics across measures or subgroups.

COSMIN (Mokkink et al., 2010) argues that it is not the responsiveness statistic per se that is inappropriate, it is how it has been interpreted and reported that has often been inappropriate. As mentioned before, a measurement should not be classed as responsive, purely based on Cohen's (1988) arbitrary criteria. As Beaton et al., (1997) state, there is no 'gold standard' for summarising responsiveness, although some consensus is needed. In fact, the confusion surrounding responsiveness is much deeper than purely the interpretation of the result. Beaton et al., (1997) highlights 16 different definitions of 'responsiveness' in the literature. What Katz et al., (1990) refers to as responsiveness, Beaton et al., (1997) calls the estimated or expected change, and Husted et al., (2000) classifies as external responsiveness. Internal responsiveness, as defined by Husted et al., (2000), is what Beaton et al., (1997) calls the observed change and Katz et al., (1990) calls sensitivity. This study examined the relative responsiveness of two clinician-derived and two patient-rated measures, and therefore conclusions can only be drawn from the relative responsiveness of these measures, not their absolute responsiveness. In this group of participants, the volumeter displayed greater relative responsiveness when compared to the figure-of-eight in participants over 4 weeks. Results were comparable between the ORS and PEM across the groups.

6.5.7 Strengths and limitations

The inclusion criteria for the study were broad and included participants with various types of oedema (acute, sub-acute and chronic), which increases the generalisability of

results, given that clinicians assess hand oedema at various stages of a patient's recovery in clinical practice. However, this could also be seen as a limitation of the study, as no subgroup analyses were performed according to different stages of oedema to see if this influenced the responsiveness of the measures, or treatment effect. There are many factors which may be associated with changes in limb volume, such as environmental temperature (Glaser, 1949), limb position, time of day (Moholkar and Fenelon, 2001) and activity levels. In particular, exercises immediately prior to measurement, as is common during hand therapy appointments, were said to increase volumetric measurements, with a reduction in volume 10 minutes after exercise (McGough and Surwasky, 1991). This was tested on asymptomatic hands; therefore, the results may be underestimated as the hands used were not oedematous and therefore may respond differently to exercise. These factors were not recorded or controlled for, given the observational nature of this study. As it was not possible to standardise these variations between assessments for each participant, they could have influenced the responsiveness of the measures.

Comparing the results of Leard et al., (2008) to those obtained in this study, small effect sizes were also seen for both measures (volumeter ES=0.2, figure-of-eight ES=0.3) over 2 weeks. Conversely, the SRMs in Leard et al's (2008) study were considerably larger than those obtained in our study (volumeter SRM=1, figure-of-eight SRM=0.9) at the same time period. However, as Beaton (2000), and Beaton et al., (2001) argue, it is essential to understand the context of responsiveness studies without solely relying on, or comparing in this case, the responsiveness statistic. The different patient mix, within-person change, follow-up period and interventions between Leard et al's study (2008) and this one are all important factors to consider, and ones which could make responsiveness "a contextualised attribute rather than a static property of an instrument." (Beaton et al., 2001).

This study used a pragmatic approach to recruitment and did not exclude participants based on their type of oedema. Whilst there were considerable between-patient variations in terms of time since injury, this is reflective of clinical practice. However, these patient variations will have increased the standard deviation of the change, and

this could have resulted in smaller standardised response means. Some treatments used by hand therapists, such as kinesiology taping, do not have established effectiveness. Interventions were chosen based on the clinical reasoning and preference of the treating clinician. COSMIN (Mokkink et al., 2010) advises that events between baseline and follow-up assessments should be described; however, this data was not collected in this study.

The use of the effect size and standardised response means to calculate responsiveness could be as viewed a limitation, based on COSMIN standards (Mokkink et al., 2010). COSMIN believes that appropriate measures of assessing responsiveness should fall in line with those for criterion and construct validity, i.e. hypothesis testing.

A limitation with the wording of the ORS was commented on by some participants. The ORS was designed in conjunction with the PAG, who were all current or previous patients in hand therapy. The question asks the participant to “rate the swelling in your hand today”. In hindsight, this should have been more explicit and asked participants to rate the swelling in their hand or affected area.

6.6 Future research

The current study has only considered the volumeter in comparison to the figure-of-eight tape measure. Further investigation is needed on a ring gauge system in patients with oedema and digital pathology, or following surgery of the digit, to establish its reliability and responsiveness. Assessing responsiveness of the weighted circumferential tape measure may also shed more light on its comparability to the volumeter for isolated digit oedema. Creating standardised clinical guidelines on the assessment of hand and digit oedema would be useful for the collection of outcome data for clinical and research purposes. Additional work is warranted on whether the responsiveness statistics obtained in this study equate to a meaningful change to the patient, and/or a clinically important change in hand volume.

6.7 Conclusion

The location of oedema is an important factor to consider when deciding which outcome measure to use to detect change. The figure-of-eight tape measure was more responsive than the volumeter in participants with general hand oedema over 2 weeks, whereas the volumeter was better at detecting change in participants with isolated digit oedema. Over 4 weeks the location of oedema had less of an effect on responsiveness with the volumeter, demonstrating greater responsiveness than the figure-of-eight across all groups. Using a subjective rating of oedema should be considered to complement an objective assessment when assessing hand oedema. In light of the largely comparable results between the patient-rated measures used in this study, either the hand health profile of the PEM or the ORS could be used. However, given the symptom-specific nature of the ORS, the ease and minimal time required to complete and the slightly higher SRM over 4 weeks in the whole group (n=73), the ORS may be the preferred PROM.

This chapter has investigated the relative responsiveness of subjective and objective measures in the assessment of hand oedema in a group of symptomatic patients. The relationship between objective and subjective measures and impact of type and location of oedema on responsiveness has been discussed. The next chapter will focus on a pilot randomized controlled trial comparing two treatments for oedema and will use the most responsive measure from this study as the primary outcome.

Chapter 7 A pilot randomised controlled trial comparing kinesiology tape to treatment as usual in the management of sub-acute hand oedema after trauma or surgery

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7.1 Introduction

Despite the lack of good quality studies, kinesiology tape is used by hand therapists. Clinical anecdotal evidence that it “seems to work” and patients report a high level of satisfaction with this intervention, compared to other methods such as the Lycra glove, which suggests that this method may show potential. There is an urgent need to obtain empirical evidence on the effect of kinesiology tape and compare this with other more traditional interventions for oedema after hand injury.

This chapter is the culmination of work from the previous four chapters. The oedema management manual, developed during the Delphi consensus method, informed the content and dose parameters for the control and experimental arms of this trial. Furthermore, the most responsive subjective and objective outcome measures, established in the observational study, were used to assess hand volume and patient rated severity of their hand oedema. This chapter will focus on whether each element worked together with the others in a pilot randomised controlled trial to test trial methods, patient adherence, and to inform a definitive trial.

7.2 Methods

7.2.1 Study design

No previous studies have compared kinesiology (elevation and massage) with compression (elevation and massage) in patients with sub-acute hand oedema. A definitive (phase III) randomised clinical trial was premature and there is a need to collect preliminary information to inform a definitive trial, and to test the feasibility of the methods. A pilot randomised controlled trial was therefore carried out.

The National Institute for Health Research (NIHR) makes a distinction between pilot and feasibility trials (NIHR, 2015). It defines feasibility studies as a preliminary stage, used to estimate important parameters needed to design the main study. Feasibility

studies for randomised controlled trials do not necessarily need to be randomised themselves. Nor do they evaluate the outcome of interest - this is left for the main study. In contrast, the NIHR defines pilot studies as smaller versions of the main study used to test whether the components of the main study can all work together. The focus is on the processes of the main study, to ensure that recruitment, randomisation, treatment and follow-up assessments all run smoothly. It resembles the main study in many respects, including an assessment of the primary outcome.

Results from the previous observational study identified the most responsive outcome measure to be used as the primary outcome in this randomised controlled trial. Whilst this study tested the feasibility of its methods, primarily it was a small-scale version of a definitive trial.

The overarching aim of this pilot randomised controlled assessor-blind trial was to compare compression, elevation and massage (treatment-as-usual group) with kinesiology tape, elevation and massage (trial treatment group).

Specific objectives of this trial were to:

i) assess the feasibility of the data collection methods, assessor blinding and recruitment strategy

ii) assess adherence to and acceptance of interventions in the two treatment arms and feasibility of using a patient-completed adherence diary

iii) obtain information to inform a sample size calculation for a definitive trial

iv) obtain an initial estimate of the effect of the intervention relative to control treatments.

7.2.2 Ethical approval

Ethics and local research governance approvals were given by the East of Scotland Research Ethics Service, the Health Research Authority and Research Governance Department at the Norfolk and Norwich University Hospital. (Rec ref: 17/ES/0098 IRAS: 228812). See Appendix R for copies of approval letters. All participants gave written informed consent to participate in the study.

7.2.3 Setting

This single-centre pilot study was conducted in a regional hand therapy department at the Norfolk and Norwich University Hospital between 30 October 2017 and 31 July 2018.

7.2.4 Eligibility and recruitment

Eligible participants were aged 18 years and over, referred to the outpatient hand therapy department at the Norfolk and Norwich University Hospital, able to give informed consent, and for whom treatment of sub-acute hand oedema was indicated, as confirmed by their treating therapist.

Initially, sub-acute was defined as oedema which presented from 3 days up to 6 weeks after trauma or surgery. Due to low recruitment numbers, this timeframe was later amended to include oedema which was present up to 12 weeks following trauma or surgery. This amendment received HRA approval, see Appendix S, and was implemented from 2 April 2018, with 4 weeks of recruitment remaining.

Patients were excluded if their oedema was more than 12 weeks in duration or if they were within the specified sub-acute timeframe but had already commenced oedema management treatments (other than elevation). Patients diagnosed with lymphoedema, acute infections, deep vein thrombosis, blood clot or haematoma, active cancer, chronic heart failure, cardiac problems or renal dysfunction/failure/kidney disease, pulmonary problems or any other factor (physical or mental health) that may have affected the patient's ability to adequately and safely monitor the use of tapes or gloves were also excluded from this trial. Patients in the first 4 weeks of tendon repairs, where removal of their splints in order to apply a glove would be contraindicated, were unable to take part. Patients who did not have someone available to assist in the reapplication of kinesiology tape every 3-5 days, and who did not feel confident to reapply the tape themselves, were also excluded. Patients with fragile skin (elderly and long-term steroid use) and open wounds or with excessive amounts of forearm/hand hair (and were unwilling to shave if placed in the trial treatment group) were excluded from taking part in this trial.

Participants were identified and screened for eligibility by members of the hand therapy team. Printed checklists were available in the department to assist staff when checking eligibility. Patients who met eligibility criteria, and provided verbal consent to take part in the study, were formally recruited by the principal investigator (PI), who confirmed eligibility and took written consent. See Appendix T for copy of participant information sheet (PIS).

7.2.5 Procedures

One experienced hand therapist (LM), who was blinded to treatment allocation, assessed all participants. Participants were assessed at the time of recruitment (baseline) and at 4 and 12 weeks later. Previous studies comparing kinesiology tape to a control treatment have primarily focused on the acute inflammatory stage and therefore have a very short-term follow-up: 4 days (Tozzi et al., 2016); 6 days (Bell and Muller, 2013); 7 days (Windisch et al., 2017); 10 days (Bialowski et al., 2013); and 2 weeks (Nunes et al., 2015). Aguilar-Ferrandiz et al., (2014) and Tsai et al., (2009) focused on participants with long-term conditions (lymphoedema and CVI) and therefore chose longer follow-up periods of 1 month and 3 months respectively. Due to the fluctuating nature of sub-acute hand oedema, a 3-month follow-up period was chosen to reduce the likelihood of only capturing a temporary, reversible change in oedema which has been seen in other studies (Flowers, 1988).

Where possible, follow-up assessments were scheduled at the same time as a booked hand therapy review. In cases where this was not possible, participants were offered a reimbursement of their travel costs for the additional visit.

7.2.6 Allocation

7.2.6.1 Sequence generation

Participants were randomly allocated to either the intervention (kinesiology tape, elevation and massage) or control arm (compression, elevation and massage) group. Allocation was on a 1:1 basis (i.e. equal numbers in each arm). The allocation sequence was block randomised (with random block lengths of 2, 4 or 6) generated by the trial statistician (LS). Stratification was not used.

7.2.6.2 Allocation concealment mechanism

Sequentially numbered opaque sealed envelopes were used, which were kept inside a lockable storeroom in the hand therapy department. The trial statistician (LS) at the University of East Anglia generated the allocation sequence, and a therapy assistant who was not involved in the trial prepared the numbered envelopes. Details of this process were not made available to the hand therapists who assigned the interventions to participants, nor to the PI (LM) who enrolled participants.

7.2.6.3 Implementation

Baseline measurements were then taken by the PI. The treating hand therapist randomised the participant by opening the next numbered envelope and informing the participant which arm of the trial they had been allocated to. This allocation was kept hidden from the PI (LM). Envelopes were kept in a storage cupboard in the hand therapy department, which was only accessible to staff members and locked when not in use.

7.2.7 Interventions

Table 7.1 provides a description of the interventions following the TIDieR (template for the intervention description and reporting) structure recommended by the Equator network (Hoffmann et al., 2014) in conjunction with the CONSORT statement (Schulz et al., 2010). The template asks “how well” the treatments were delivered in accordance with the protocol. This refers to treatment fidelity which is defined as “strategies that monitor and enhance the accuracy and consistency of an intervention to ensure it is implemented as planned and that each component is delivered in a comparable manner to all study participants over time.” (Smith et al., 2007). This study utilised standardised methods of training treatment providers. Further discussion on treatment fidelity is in section 7.4.7. See appendix U for copies of the oedema management manual issued to patients.

Table 7.1 TIDieR structured intervention description

Name	Treatment as usual (TAU)	Trial treatment (TT)
Why	***Compression*** for hand oedema is usually achieved through Lycra gloves which exert around 35 +/- 5 mmHg pressure on the tissues of the hand (Newman, 1988). The garment acts as an external counter pressure (Newman, 1988) which compensates for the inelasticity of oedematous tissues, and therefore improves circulatory efficiency by facilitating venous and lymphatic flow (Villeco, 2012). ***Massage*** techniques are used to stimulate the lymphatic system (Villeco, 2012). Different methods are documented in the literature, which employ various degrees of force or pressure on the skin, directing the oedema towards regional lymph nodes. Traditional 'retrograde massage' uses a moderate force 'milking' action but this is considered too aggressive for the delicate lymphatic system to cope with and has been questioned (Pedretti and Zoltan, 1996). Instead, a lighter traction of the skin has been proposed in a longitudinal direction to produce a stretch reflex to the skin (Zuther, 2009). Both methods are used in clinical practice. ***Elevation*** permits gravity to assist with the drainage of oedema from the distal limb (Pedretti and Zoltan, 1996). Elevation alone (Watson-Jones, 1955) is not effective in reducing oedema, but is recommended in combination with other modalities.	***Kinesiology tape*** is designed to mimic the elastic properties of the skin by lifting the skin to allow greater interstitial space and encourage lymphatic drainage. In contrast to the traditional compression method, it is designed to push the fluid proximally into the venous and lymphatic system (Kase et al., 2003). The tape is said to be unique in that it mimics the elastic properties of the skin and its wave-like grain provides a pulling force to the skin, creating more space by lifting the fascia and soft tissues under the areas where it is applied (Williams et al., 2012). This multi-functional tape can be applied anywhere on the face or body. The benefit of using it in the hand, unlike an oedema glove or other form of compression, is that it leaves the majority of the skin surface free for sensory feedback, which is essential for functional use. It can also be worn in water. As the tape is elastic and stretches up to 55-60% of its length, it also allows for unrestricted movement (Williams et al., 2012, Thelan et al., 2008). **Massage -** as per TAU **Elevation -** as per TAU

	Treatment as usual (TAU)	Trial treatment (TT)
What- Materials	 **Oedema glove**  **Lycra sleeve**  **Coban wrap**   **Elevation**	 **Kinesiology tape**  **Massage**
What - Procedures	Standardised oedema management programmes designed through an internet-mediated Delphi consensus method with 8 volunteer hand therapy experts. The standardised programme was converted into a patient instruction leaflet, which was refined though a process of meetings and reviews with a patient advisory committee.	
Who	Each treatment was demonstrated to patients by the treating hand therapist. These are occupational or physical therapists who specialise in hand therapy. Hand therapists regularly advise patients about managing their oedema following injury or surgery, and prescribe a combination of compression, elevation and massage as required. All therapists involved in the trial were trained by the PI on the treatment protocol and method of implementing each treatment	
How	All therapy sessions were delivered face-to-face on an individual basis. The therapist issued participants with the materials required to complete the programme unsupervised at home.	

	Treatment as usual (TAU)	Trial treatment (TT)
Where	The initial delivery of interventions was completed in the hand therapy department at the Norfolk and Norwich Hospital. Patients received the materials (relevant to their treatment arm in the study) along with a standardised oedema management programme (leaflet), which they were instructed to carry out at home. Progress was reviewed at follow-up appointments in hand therapy.	
When and how much	Wear for 20-24 hours a day, removing for hygiene, for up to 12 weeks.	Applied to the skin full time for 3-5 days. No tension at the proximal anchor, 0-25% tension of the central tape.
	Massage: 5-10 minutes, 3-6 times a day for at least 2 weeks or until the swelling has resolved. **Elevation:** As much as possible during the day and night when the hand is not being used. Continued until the patient and therapist mutually agree the oedema has subsided.	
Tailoring	Latex-free versions available.	A 24-hour rest period can be used between applications but is not essential if there have been no issues.
	Massage: Reduce frequency and duration if unable to tolerate massage or if a smaller area is affected. **Elevation:** Active elevation or using a Bradford sling in the day and Bradford sling or pillow day or night.	
Modifications	Remove if vascularity compromised.	Remove in cases of skin irritation.
	Massage: Discontinue if pain or swelling increases. **Elevation:** Discontinue if pain (in neck, shoulder or elbow), sensation or symptoms worsen or if vascularity compromised (colour changes to digits).	
How well	All treatment providers were trained by the PI. Training involved educating treatment providers of TAU and TT, demonstration of treatment implementation by PI, use of visual images as reminders of how to apply kinesiology tape, group and individual practice of applying treatments, open access to electronic and hard copy of protocol to refer to. There were no planned or actual assessments of treatment fidelity. A patient adherence diary was used to record the extent to which treatments were adhered to on a weekly basis, either not at all, in part or as advised.	

7.2.8 Protocol deviations

Treatment was discontinued or modified at the discretion of the treating hand therapist in the following cases:

- Worsening oedema or other relevant symptoms (pain, stiffness) as assessed by the treating hand therapist via visual assessment, goniometry for range of joint motion or subjective symptom-severity reporting.
- If a patient, after starting a treatment, reported they no longer found it acceptable and wished to discontinue. Reasons (such as appearance, cleanliness etc) to discontinuing treatments were captured in the adherence diary and patient acceptability questionnaire.

Protocol deviations were recorded by the hand therapists on a study form, detailing what modification had been made to the treatment protocol, why and when.

7.2.9 Adverse events

All participants received written instruction booklets relevant to their allocated intervention. This made participants aware of any precautions and reasons for discontinuing the allocated treatment, as well as instructions to contact their treating hand therapist if adverse events occurred. Any participants contacting treating therapists with a problem relating to their allocated intervention were instructed to take a 24-hour rest period or discontinue the treatment, and were offered the next available outpatient appointment. Treating therapists documented and dealt with known issues with kinesiology tape and compression, such as skin rash, poorly fitting glove, overly tight compression, according to departmental policy. Participants were also able to record any issues with their treatment in their adherence diary. Participants who were unable to continue with their allocated intervention were offered the alternative treatment and, upon agreement, were transferred into the opposite arm of the trial. The date and reason for this change were documented on the case report form.

In the event of an unexpected adverse reaction, these would be formally reported in accordance with standard operating procedure (SOP 205 v2.3) at the Norfolk and Norwich University Hospital, using its serious adverse events (SAE) report form v1.3,

available on the hospital research and innovation website. http://www.nnuh.nhs.uk/research-and-innovation/information-for-researchers/standard-operating-procedures/

7.2.10 Acceptability of treatment

Acceptability of an intervention is an important factor in treatment adherence. A brief patient acceptability questionnaire was designed for this study and completed by the PI with all participants after their final follow-up assessment (week 12) (see Appendix V for copy of acceptability questionnaire).

This questionnaire consisted of 10 factors, such as cleanliness, durability and aesthetics, which the patient was asked to grade on a scale of zero (negative) to 10 (positive). The final open question requested feedback from the patient on any aspect not covered in the questionnaire. Responses were documented verbatim by the PI.

7.2.11 Adherence

The world health organisation (WHO) defines adherence as: “the extent to which a person's behaviour corresponds with agreed recommendations from a healthcare provider” (Sebate, 2003).

Strategies to improve adherence to intervention protocols included monitoring by a hand therapist during arranged outpatient hand therapy appointments on an individual clinical need basis. Adherence to prescribed treatments was monitored with the use of an adherence diary. For this study, a simple paper diary was designed, based on best practice recommendations (Frost et al, 2016). Whilst the use of diaries pose its own issues in terms of completion, and whether the use of a diary itself increases a patient’s awareness of adhering to a treatment, it is crucial to establish if these interventions are acceptable and being used as intended (Frost et al., 2016). Apart from stating the allocated treatment group, the diary was anonymous. See Appendix W for copy of participant adherence diary. Patients were asked to leave them in a box at the hand therapy department reception or hand them to their treating therapist or the researcher after their final assessment, in order not to unblind the assessor.

Participants' involvement in this study ended after their 12-week follow-up assessment. Participants were asked if they would like to receive a report of the results of the study once it had been completed and results analysed. Participants still undergoing hand therapy treatment continued as per the treating therapist's recommendations and departmental guidelines.

7.2.12 Blinding

It was not possible to blind the patients to treatment received in this trial. However, the assessor (LM) was blinded as a means of minimising assessor bias. Patients were reminded by their treating therapist not to reveal their treatment allocation during any follow-up assessments and were instructed to remove all oedema management garments prior to being seen by the assessor. Unintentional unblinding could have occurred due to marks left on the skin by the glove or kinesiology tape. The PI recorded when she believed she had been unblinded and how. Where blinding was maintained until after the final assessment (week 12), the PI guessed the group allocation and this was compared against chance.

7.2.13 Sample size

As a pilot study, principally conducted to assess the suitability of the chosen research methods, the sample size was not based upon the principles of statistical precision or statistical power for hypothesis testing. Instead, we aimed to recruit 100 patients in a 6-month period which we believed to be practical. Based upon the attrition rate of the previous observational study, we anticipated a loss to follow-up of between 20% and 30%, thus providing 70 to 80 completing participants.

7.2.14 Data collection time points

Patients were assessed at baseline prior to randomisation, and at 4 and 12 weeks post-randomisation.

The number of visits to hand therapy, grade of treating hand therapist and total time treating oedema were also recorded to obtain preliminary data on healthcare use and cost.

7.2.15 Outcome measures

i) Objective measures of hand volume

The primary outcome was a single measure of the affected hand using a water displacement method. This was assessed objectively using the volumeter. This method was shown to be the most responsive outcome measures from an observational study of 73 patients with hand oedema, based on data from baseline to 4-week assessment (see Chapter 6). Volumetry, which uses Archimedes' principle of water displacement, has been referred to as the gold standard method of measuring hand volume, as it has excellent inter and intra-rater reliability (Farrell et al., 2003) and responsiveness (Leard et al., 2008).The volumeter records water displacement in ml. Water temperature was maintained between 18 and 24 degrees, as has been recommended (King[b], 1993).

ii) Patient-rated oedema severity

The oedema rating scale (ORS) is a self-reported severity-of-swelling scale where the participant is asked: "Please rate the swelling in your hand today", using a 7-point ordinal scale (0=none, 6=extreme). This scale was devised in collaboration with a patient advisory group (PAG) made up of current and previous hand therapy patients, who agreed on the format and descriptors for each score. The previous observational study found it to be similarly responsive to the patient evaluation measure (PEM). In this study, the ORS was used to record perceived change in oedema due to its unidimensional nature, whereas the PEM was used to record changes in functional ability.

iii) Patient-rated functional scale

The hand health profile of the patient evaluation measure (PEM) (Dias et al., 2001) (see appendix Q), is a validated 11-item region-specific, patient-rated outcome measure (Dias et al., 2001), which was used to measure function in this study. It is scored on a 1-7 Likert scale, with the total combined score being expressed as a percentage: the higher the score, the greater the perceived disability. The PEM asks the patient to rate aspects such as grip, pain, work and activities of daily living. Unlike other commonly used patient-rated measures in hand therapy, the PEM also includes items on the 'feel' and 'appearance' of the hand, which may relate to hand

swelling, but could also relate to scarring and sensation. This, combined with the evidence on its speed and ease of completion (Dias et al., 2008), made the PEM the most appropriate patient-rated outcome measure to use in this study.

iv) Patient-rated quality of life

The EQ-5D-5L (Herdman et al., 2011) is a development of the original EQ-5D and EQ-5D-3L (EuroQol Group, 1990). See appendix X for copy of EQ-5D-5L It is a standardised measure of health status which aims “to provide a simple generic measure of health for clinical and economic appraisal” (Devlin et al., 2010). It was designed to improve the instrument’s sensitivity and reduce ceiling effects. However, it does not yet have population normative data. It is recommended by the Chartered Society of Physiotherapists to be used to measure change in musculoskeletal outpatient settings (Sephton et al., 2010). It takes around 2 minutes to complete.

7.2.16 Statistical analysis

A general linear model was used to estimate the effect of kinesiology tape relative to control, with respect to the effectiveness outcomes. This included the baseline value as a covariate and treatment arm as a fixed effect. Results for the ORS at 4 and 12-weeks were dichotomised into those participants scoring 0-2 (none, minimal, mild) and those scoring 3-6 (moderate, severe, very severe, extreme) before a logistic regression model was constructed. The between-group difference was estimated with 95% confidence intervals (though as a pilot study, it is unlikely that any conclusion regarding effectiveness would, or indeed, should, be reached). This was based upon the intention-to-treat principle (analysed by group allocated to); however, there were no plans for imputation of missing data. No subgroup analyses were performed.

Mean and standard deviations were calculated for each outcome and time point, along with the mean change from baseline to 4 and baseline to 12 weeks. Adjusted mean difference, together with a 95% confidence interval, were calculated for each outcome, assuming a normal distribution. The level of missing data was assessed and compared with baseline characteristics (i.e. to identify which groups of subjects, if any, were less likely to return full data).

Descriptive analyses were used to describe ‘patient flow’, particularly estimating the proportion of eligible patients consenting to take part, the frequency of precluding eligibility criteria, and the frequency of losses to follow-up, including active withdrawals (with the reason, where available). Each proportion was calculated with a 95% confidence interval.

Patient-reported adherence was calculated for each participant as a proportion of the total compliance (treatment ‘as advised’ according to the standardised protocol and patient instruction booklet). This was summarised as a mean with 95% confidence interval.

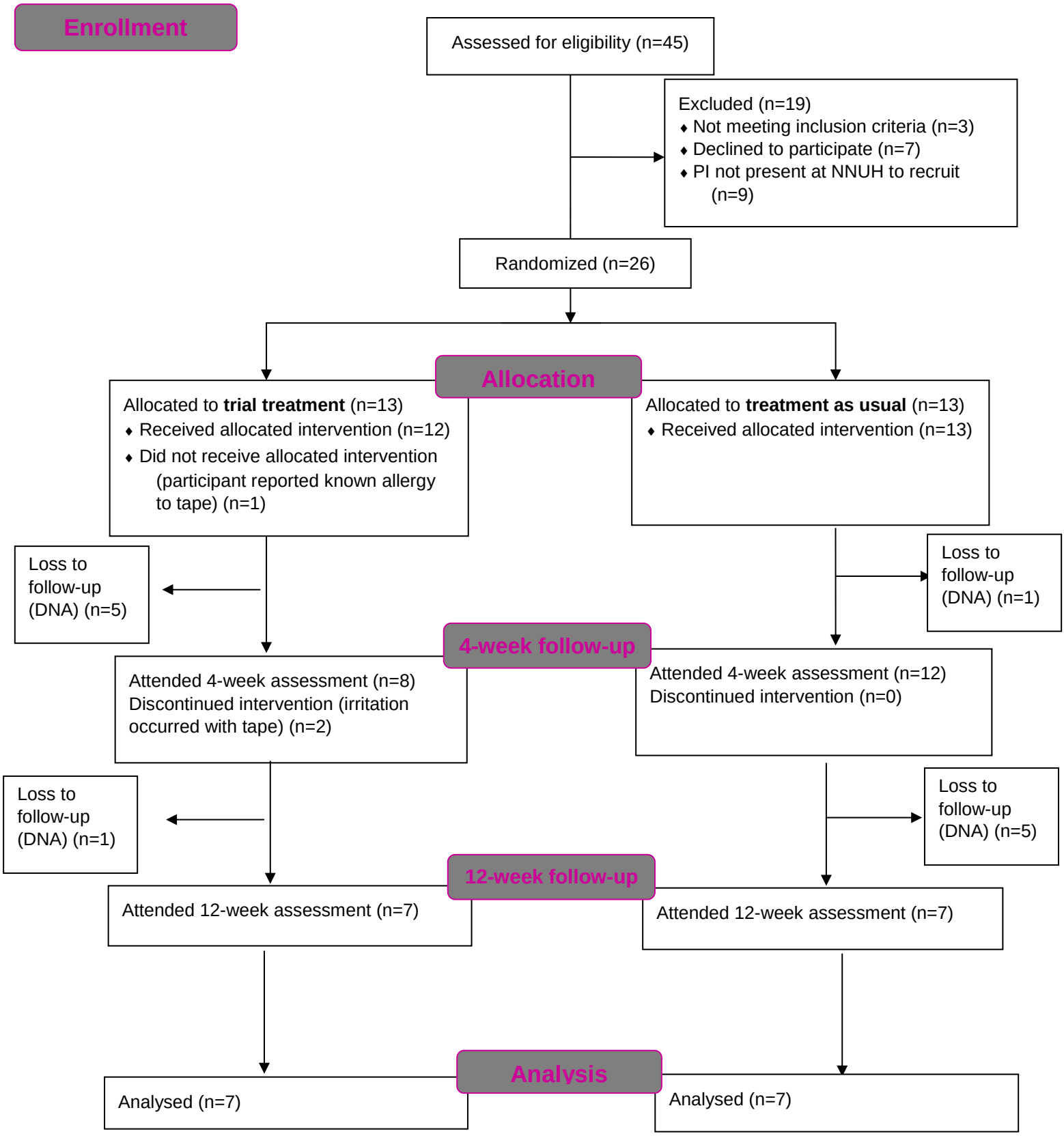
7.2.17 Data management

All patients were given a unique identifier. Pseudo-anonymised data were entered onto an Excel spreadsheet. Cells were programmed to check ranges of data value entered. This spreadsheet was stored on a password-protected UEA laptop. All data were entered by the PI (LM), who had exclusive access to the password-protected laptop purchased for the sole purpose of this programme of research.

7.3 Results

Forty-five patients were assessed for eligibility, 26 consented and were randomised. See Figure 7.1, CONSORT diagram (Moher et al., 2001). Table 7.2 shows baseline characteristics of both groups and Table 7.3 gives health resource use results across groups.

Figure 7.1 CONSORT flow diagram



DNA= Did Not Attend

Table 7.2 Baseline characteristics table

	Treatment as usual	Trial treatment
N	7	7
Gender		
Male : female	4:3	2:5
Age mean (SD)	63.6 (19.3)	60.0 (17.6)
Affected hand		
Left: right	3:4	4:3
Location of oedema		
Isolated digit: global	2:5	3:4
Reason for oedema		
Trauma: surgery	4:3	4:3
Past medical history	Osteoarthritis (n=2)	Osteoarthritis (n=3)
	Neuralgia	Type I diabetes
	Type II diabetes	Type II diabetes
	Hypertension (n=2)	Hypertension
	Chronic obstructive pulmonary disease	Shortness of breath
		Under-active thyroid
	Deaf	Anxiety
Condition/operation n= (%)		
Distal radius fracture (conservative)	n=1 (14%)	n=2 (28%)
Dupuytren's release		
Fracture/dislocation (digit)	n=1 (14%)	n=1 (14%)
Tendon repair and DR fracture	n=2 (28%)	n=1 (14%)
Distal radius fracture fixation	n=1 (14%)	n=0
Fracture/dislocation metacarpal	n=1 (14%)	n=1 (14%)
Joint replacement	n=1 (14%)	n=0
	n=0	n=1 (14%)
Time since injury mean (range)	39.3 days (21-59)	27.3 days (3-45)
SD	15.7	16.6

Legend: SD= standard deviation, DR= distal radius

Table 7.3 Health resource use data

	Treatment as usual	Trial treatment
Recruiting clinician banding		
5	n=5 (71%)	n=0
6	n=2 (29%)	n=5 (71%)
7	n=0	n=1 (14%)
8	n=0	n=1 (14%)
Total therapy staff costs treating oedema during trial period		
Midpoint band 5 £16.69 p/h	155 minutes= £43	30 minutes= £8
Midpoint band 6 £20.70 p/h	81 minutes= £28	221 minutes = £76
Midpoint band 7 £24.61 p/h	26 minutes =£11	20 minutes= £8
Midpoint band 8 £29.78 p/h	N/A	20 minutes = £10
	£82	**£102**
Total		
Total number of visits to hand therapy during trial period (mean)	31 (4.4)	28 (3.8)
Total time treating oedema during trial period (mean)	262 minutes (37.4 minutes)	291 minutes (41.6 minute)
Estimated total cost of consumables during trial period	£82.85 16 oedema gloves, 6 digit-sleeves and 3 strips of Coban™	£46.65 6 oedema gloves, 59 strips of kinesiology tape (based on 40cm strip)
Total estimated cost of staff treating oedema and oedema consumables during trial	**£164.85**	**£148.65**
Per person total cost	**£23.55**	**£21.24**

7.3.1 Adverse effects

Two participants (14%), allocated to the trial treatment group, experienced issues with the kinesiology tape which resulted in them switching to treatment as usual. One reported a rash after 1 day with the tape in situ, with small bumps under the skin

which were sore to touch, like blisters. She persevered with the tape for 4 days until she was reviewed by the hand therapist in clinic and switched to using compression. One participant reported the tape pulled her skin. Another participant, in the trial treatment group, reported an itchy rash at the anchor point (medial epicondyle of elbow crease) 6 days after commencing the trial treatment. She was advised to take a 24-hour rest period from the tape, as recommended in the trial treatment protocol and patient instruction manual. There were no further issues with the tape following this. One participant, in the treatment-as-usual group, reported issues with bruising to his hand which he stated to be as a result of using the glove for 24 hours. He was advised to remove the glove immediately, whilst continuing with elevation and massage, and returned to the clinic to be re-assessed by the hand therapist. The glove was not used as advised for the first six days of the trial but there were no reported issues after this.

7.3.2 Acceptability

Following the final assessment and after the participant had revealed their treatment allocation to the blinded assessor, a brief acceptability questionnaire was completed to gather information on the experiences and opinions of the participants. A checklist was created with 10 factors to be scored out of 10: the higher the mark, the more acceptable to treatment. Comments from the participants were documented to supplement scores.

Mean acceptability scores for each criterion in both groups are given in Table 7.4 below. Total mean acceptability score was 76.1 out of 100 for trial treatment and 87.9 for treatment as usual. Table 7.5 highlights some comments obtained during the acceptability interview.

Table 7.4 Patient-reported acceptability of treatment mean and median score and standard deviation (SD) for both groups

	0	1	2	3	4	5	6	7	8	9	10	Mean score	Median score	SD
Acceptability of treatment								*				7.0	7	1.4
										*		9.4	10	0.8
Aesthetics/appearance								*				7.4	10	3.4
											*	9.6	10	0.8
Ability to move the hand											*	9.7	10	0.5
										*		8.9	10	1.7
Ability to use the hand										*		9.3	10	1.3
										*		9.3	10	1.1
Cleanliness							*					5.6	6	2.8
								*				7.1	9	3.3
Temperature/sweating/dry skin										*		9.4	10	2.6
										*		9.3	10	1.1
Ease of donning/doffing							*					6.0	7	3.3
									*			7.9	8	2.1
Ease of replacing									*			8.0	9	3.2
										*		9.1	10	2.3
Durability								*				7.1	8	3.0
									*			7.7	10	2.9
Comfort								*				7.3	9	4.0
											*	9.6	10	0.8

BLACK= Treatment as usual, RED= Trial treatment

Table 7.5 Comments from participant acceptability interviews

Treatment as usual	Trial treatment
"It was inconvenient to notice it was dirty as I had to hide my hand"	*"Looks tatty after a few days"*
"It was tight at first- I wondered if my fingers were going blue"	*"I needed to keep trimming the edges so I carried scissors round with me"*
"[the glove] gives strength to my hand"	*"Didn't stick on digits" "needed to put fresh {tape} on every day as went loose and stringy at ends"*
"Difficulty getting it on but once on was fine"	*"Tricky to change if dominant hand is injured"*
"I preferred it on than off"	*"Discomfort when changing the tape as it pulled off my hairs"*
"Movement was easy when the glove was off" [as a result of wearing the glove]	*"I work in the food industry and was unable to wear it at work so I had to replace it daily"*
"If I did my arm again- I would want the glove"	*"I felt it pulling and squeezing, a feeling of warmth"*
"Getting glove on was a bit of a job at first"	*"It looked untidy at the [finger] tips"*
"It helped and assisted hand to do things- when it was off I was a bit more hesitant"	*"It worked!"*
"It rubbed slightly in the webspace"	
"I couldn't wear it at work as I am a builder"	
"I washed it regularly but it got dirty very quickly"	
"I wondered if it was doing anything, felt it needed to be tighter"	
"[the glove] frayed at the edges"	

7.3.3 Adherence

Thirteen adherence diaries (93%) were returned. Patient-reported adherence was calculated for each participant as a proportion of the 'total adherence' over 12 weeks, which was the frequency and duration advised by the hand therapist and documented in the patient instruction manual. Weekly adherence was also

calculated as a proportion and compared across the two groups. These are summarised as means with 95% confidence interval, assuming a normal distribution.

7.3.4 Comments from adherence diaries

"Applying the tape can be difficult on your own, also it can come loose at the finger tips and look unsightly"

"The elasticated tape appears to help with the swelling. Sometimes on the arm it felt warm and tightened. The fingers was [sic] ok but one started to use fingers all the time one week it only stayed on a short time and I was not able to re-stick it down again. It also becomes untidy after two days"

"Elastic tape pulled my skin. Glove used for two weeks but my hand started to go very numb"

"I found the massage really helpful, both in swelling management and ease of movement although at a rheumatology appointment I was told it would not be useful to continue it!!"

"All treatments possible and acceptable sometimes very painful" [Exercises not oedema management]

Seven participants (50%) stopped or were advised to discontinue treatment for oedema, as both the participant and hand therapist were in agreement that the treatment had worked. These seven cases are highlighted in Table 7.6.

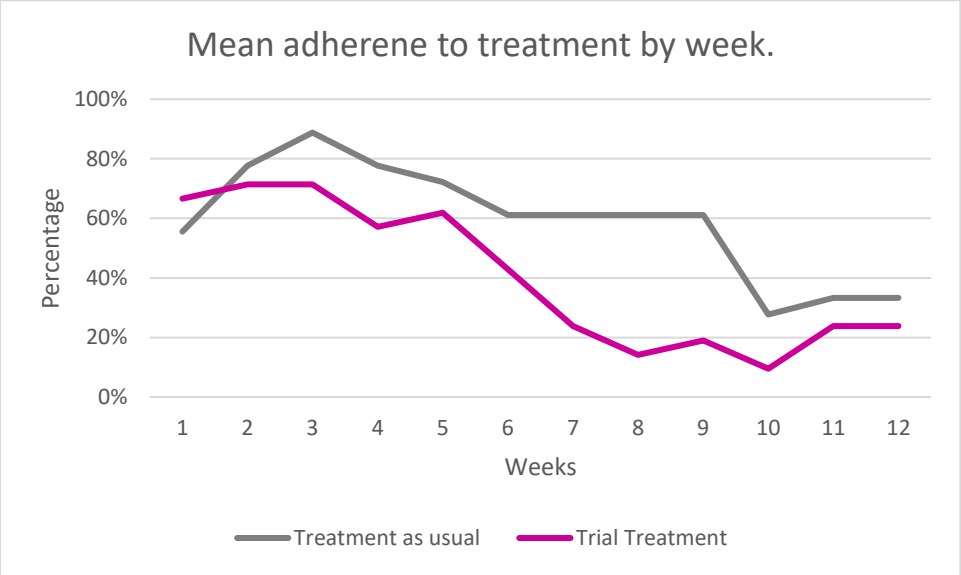
Table 7.6 Cumulative adherence as a proportion (weeks) and percentages based on the frequency and duration as advised, summarised as a mean adherence for each treatment modality and associated 95% confidence interval (CI) for actual treatment time, where known (n=7) **indicates participants who switched treatment from the tape to the glove*

Participant	Treatment as usual						Overall	Participant	Trial treatment						Overall
	Massage		Elevation		Compression				Massage		Elevation		Elasticated tape		
1	77.8%	7/9	88.9%	8/9	100%	9/9	**88.8%** **24/27**	1*	50%	6/12	50%	6/12	100%	12/12	**66.6%** **24/36**
2	100%	4/4	100%	4/4	100%	4/4	**100%** **12/12**	2*	25%	3/12	100%	12/12	16.6%	2/12	**47.2%** **17/36**
3	66.6%	8/12	41.6%	5/12	100%	12/12	**69.4%** **25/36**	3	100%	5/5	0%	0/5	60%	3/5	**53.3%** **8/15**
4	91.6%	11/12	0%	0/12	58.3%	7/12	**50%** **18/36**	4	16.7%	1/6	33.3%	2/6	66.7%	4/6	**38.8%** **7/18**
5	100%	12/12	16.6%	2/12	66.6%	8/12	**61.1%** **22/36**	5	41.6%	5/12	83.3%	10/12	91.6%	11/12	**72.2%** **26/36**
6	100%	9/9	100%	9/9	77.8%	7/9	**92.6%** **25/27**	6	55.6%	5/9	55.6%	5/9	44.4%	4/9	**51.9%** **14/27**
7	Did not return diary							7	Not completed		Not completed		66.7%	6/9	**66.7%** **6/9**
Mean	**89.3%**		**57.9%**		**83.8%**			**Mean**	**48.2%**		**53.7%**		**63.7%**		
95% CI	**74.2-100**		**10.4-100**		**63.7-100**			**95% CI**	**16.7-79.7**		**15.6-91.8**		**37.5-89.9**		

Table 7.7 Adherence as a proportion and percentage based on the frequency and duration as advised, summarised as a mean adherence for each week across the 3 prescribed modalities with associated 95% confidence interval (CI)

Week	Treatment-as-usual (6 diaries) Proportion	percentage	Week	Trial treatment (7 diaries) Proportion	percentage
1	11/18	61.1%	**1**	14/21	66.6%
2	14/18	77.7%	**2**	15/21	71.4%
3	16/18	88.8%	**3**	15/21	71.4%
4	14/18	77.7%	**4**	12/21	57.1%
5	13/18	72.2%	**5**	13/21	61.9%
6	11/18	61.1%	**6**	9/21	42.8%
7	11/18	61.1%	**7**	5/21	23.8%
8	11/18	61.1%	**8**	3/21	14.2%
9	11/18	61.1%	**9**	4/21	19.0%
10	5/18	27.7%	**10**	2/21	9.5%
11	6/18	33.3%	**11**	5/21	23.8%
12	6/18	33.3%	**12**	5/21	23.8%
Mean	**59.2%**		**Mean**	**40.4%**	
95% CI	**39.0-80.4**		**95% CI**	**17.9-62.9**	

Figure 7.2 Line graph of mean adherence to treatment by week for both groups



The treatment-as-usual group had greater overall adherence. Adherence peaked in week 3 and dipped to its lowest level in week 10 in both groups. The largest difference between groups was week 8, where those in the treatment-as-usual group were 47% more adherent than the trial treatment group.

7.3.5 Assessor blinding

At the 12 weeks assessment, the blinded assessor guessed which group the participant had been allocated to (if blinding had been maintained). Assessor blinding was maintained in 9 of the 14 participants (64%). Of these 9, the assessor guessed the correct allocation on six occasions (66.6%). Blinding was not maintained in five cases for the following reasons: assessor seeing the adherence diary, the participant asking the assessor for a new oedema glove, the assessor seeing the participant with their glove on, the participant contacting the assessor due to issues with the allocated treatment; and a therapist discussing the allocated treatment with the assessor.

7.3.6 Treatment effectiveness

Table 7.8 displays the mean and standard deviation for TAU and TT at baseline, 4- and 12-week follow-up, as well as mean change for each outcome measure. The corresponding line graph for each outcome measure is presented in Figure 7.3a-e below.

Table 7.8 Mean and standard deviations for all outcome measures at baseline, 4 and 12 weeks

	Volumeter (ml)	PEM (0-100)	ORS (0-6)	EQ-5D-5L Utility* (-0.594-1)	EQ-5D-5L VAS** (0-100)
Treatment as usual (TAU)					
Baseline mean (SD)	507.86 (70.23)	54.17 (16.98)	3.14 (0.69)	0.55 (0.22)	68.57 (11.80)
4-week mean (SD)	490.71 (59.47)	46.20 (19.39)	2.43 (0.79)	0.65 (0.14)	70.71 (14.84)
12-week mean (SD)	473.57 (60.60)	38.60 (18.15)	1.57 (0.79)	0.69 (0.21)	76.43 (15.74)
Mean change baseline-12 weeks (SD)	34.29 (27.75)	15.57 (18.18)	1.57 (0.98)	0.15 (0.26)	7.86 (20.18)
Trial treatment (TT)					
Baseline means (SD)	505.00 (102.27)	62.70 (15.61)	3.57 (0.79)	0.64 (0.13)	68.57 (11.07)
4-week mean (SD)	476.43 (103.27)	44.90 (14.57)	2.57 (1.13)	0.76 (0.13)	85.00 (12.91)
12-week mean (SD)	460.00 (97.47)	36.31 (16.98)	2.14 (1.07)	0.79 (0.13)	85.86 (16.30)
Mean change baseline-12 weeks (SD)	45.00 (48.22)	26.39 (16.40)	1.43 (1.13)	0.16 (0.16)	17.29 (21.00)

*a higher score (closer to 1) indicates higher quality of life derived health utility

**a higher score indicates better health status

Legend: SD= standard deviation, PEM=patient evaluation measure, ORS=oedema rating scale, VAS= visual analogue scale.

A greater mean change was seen in the trial treatment group for hand volume, PEM and EQ-5D-5L VAS scores. Mean change for ORS favoured the treatment-as-usual group, whereas EQ-5D-5L utility scores were similar but slightly in favour of the trial treatment group.

Table 7.9a Intention to treat analysis for primary and secondary outcomes (mean and standard deviation) at 4 weeks

	Treatment as usual n=7 Mean (SD)	Trial treatment n=7 Mean (SD)	Adjusted mean difference at 4-weeks unless stated (95% CI)	Linear regression P value
Volumeter (ml)	490.71 (59.47)	476.43 (103.27)	11.99 (-44.74 to 68.72)	0.65
PEM (0-100)	46.20 (19.39)	44.90 (14.57)	8.86 (-2.92 to 20.64)	0.13
ORS (0-6)				
0-2	n=3	n=2	1.60* (0.16 to 16.23)	0.69**
3-6	n=4	n=5		
EQ-5D-5L Utility (-0.594- 1)	0.65 (0.14)	0.76 (0.13)	-0.87 (-0.25 to 0.07)	0.25
EQ-5D- 5L VAS (0-100)	70.71 (14.84)	85.00 (12.91)	-14.29 (-31.36 to 2.79)	0.09

*adjusted (ORS score dichotomised) odds ratio

**logistic regression

Legend: SD= standard deviation, PEM= patient evaluation measure, ORS= oedema rating scale, VAS= visual analogue scale, CI= confidence interval.

Table 7.9a displays results from the intention to treat (ITT) effectiveness analysis at 4 weeks. There was no statistically significant difference between treatment-as-usual and trial treatment in any of the objective or patient-rated outcome measures. The

ORS was analysed with the generalised linear model. Results indicate that participants in the treatment-as-usual group had 1.6 times the odds of having the better ORS score than the trial treatment group.

Table 7.9b Intention to treat analysis for primary and secondary outcomes (mean and standard deviation) at 12 weeks.

	Treatment as usual n=7 Mean (SD)	Trial treatment n=7 Mean (SD)	Adjusted mean difference at 12-weeks unless stated (95% CI)	Linear regression P value
Volumeter (ml)	473.57 (60.60)	460.00 (97.47)	11.21 (-33.42 to 55.83)	0.59
PEM (0-100)	38.60 (18.15)	36.31 (16.98)	6.70 (-12.99 to 26.38)	0.47
ORS (0-6)				
0-2	n=6	n=4	4.29*	0.29**
3-6	n=1	n=3	(0.79 to 63.2)	
EQ-5D-5L Utility (-0.594-1)	0.69 (0.21)	0.79 (0.13)	-0.08 (-0.30 to 0.13)	0.42
EQ-5D- 5L VAS (0-100)	76.43 (15.74)	85.86 (16.30)	-9.43 (-29.02 to 10.16)	0.31

*adjusted (ORS score dichotomised) odds ratio

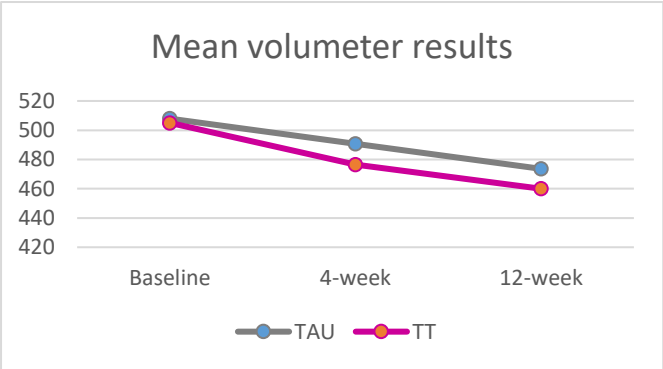
**logistic regression

Legend: SD= standard deviation, PEM= patient evaluation measure, ORS= oedema rating scale, VAS= visual analogue scale, CI= confidence interval.

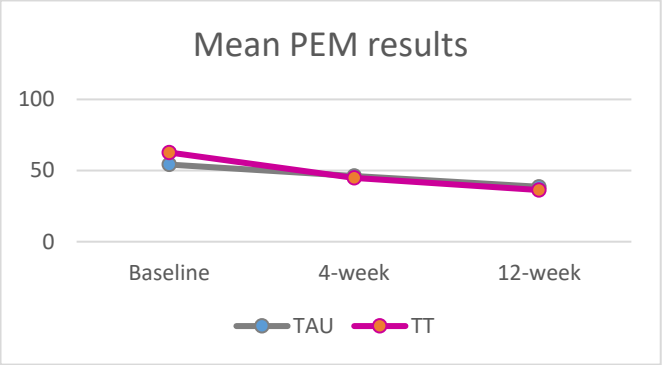
Table 7.9b displays results from a general linear model logistic regression analysis at 12 weeks. There is no statistically significant difference between treatment as usual and trial treatment in any of the objective or patient-rated outcome measures. Results for the ORS analysis indicate that participants in the treatment-as-usual group were 4 times more likely to have a better ORS score than the trial treatment group.

EQ-5D-5L derived utility scores showed no change since the 4-week assessment. Quality of life scores improved slightly in the treatment-as-usual group, but remained similar in the trial treatment group. Population norms for the EQ-5D-5L do not currently exist.

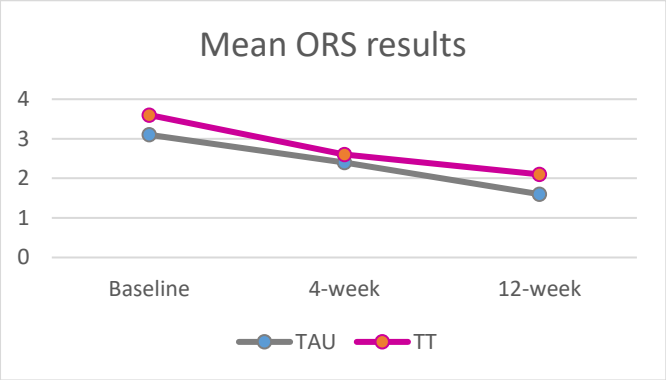
Figures 7a-7e show mean change results for each of the outcome measures over 12 weeks



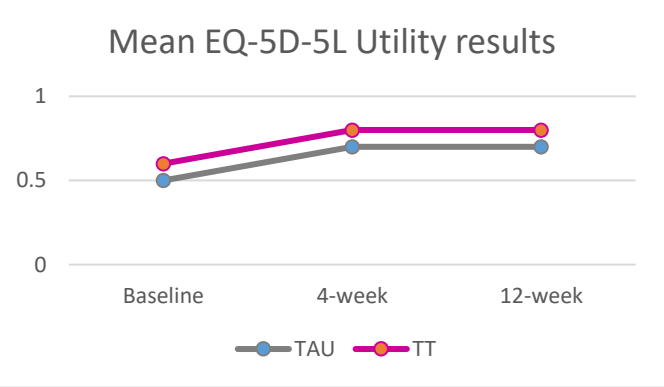
7.3a Mean volumeter results



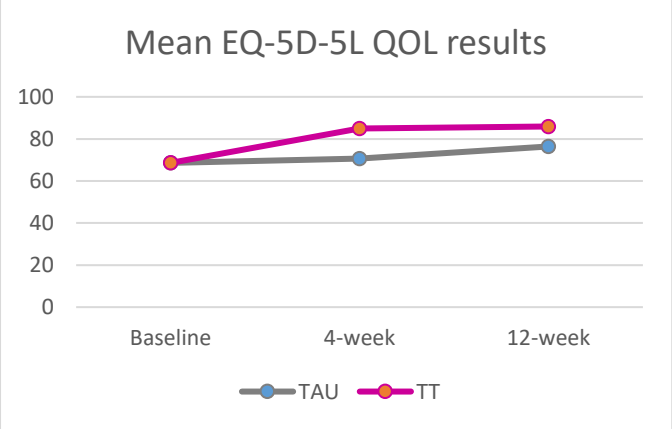
7.3b Mean PEM results



7.3c Mean ORS results



7.3d Mean EQ-5D-5L results



7.3e Mean EQ-5D-5L VAS QOL results

Legend: ORS= oedema rating scale, PEM= patient evaluation measure, VAS= visual analogue scale, QOL= quality of life, TAU= Treatment as Usual, TT= Trial Treatment

7.3.7 Lost to follow-up

A total of 12 participants (46%) were lost to follow-up. The baseline characteristics of those lost to follow-up are presented in table 7.10. There were equal numbers lost to follow-up in both treatment arms.

Table 7.10 Characteristics of lost to follow-up (n=12) in comparison to those who completed the trial (n=14)

Characteristic	Lost to follow-up n=12	Completers n=14
Gender		
Male: female	7:5	6:8
Age mean (SD)	38.6 (14.0)	61.8 (17.9)
Affected hand		
Left: right	3:9	7:7
Location of oedema		
Isolated digit: global	5:7	5:9
Reason for oedema		
Trauma: elective	11:1	8:6
Allocated treatment		
TAU: TT	7:7	7:7
Mean time since injury/surgery in days (SD)	21.3 (16.1)	33.3 (16.7)
Past medical history	Fibromyalgia (n=1) Allergy (latex) (n=1) Anaemia (n=1) Asthma (n=2) Depression (n=1) Epilepsy (n=1) Diabetes Mellitus (n=1)	Osteoarthritis (n=5) Hypertension (n=3) Type II diabetes (n=2) Type I diabetes (n=1) Hypertension (n=1) COPD (n=1) Shortness of breath (n=1) Deaf (n=1) Anxiety (n=1) Neuralgia (n=1) Under-active thyroid (n=1)

Legend: SD= standard deviation, COPD= chronic obstructive pulmonary disease, TAU= treatment as usual, TT= trial treatment.

A comparison of completers versus loss to follow-up highlighted differences in certain characteristics. It showed that non-completers were younger, more likely to have sustained trauma, or had a more acute injury with fewer comorbidities.

7.4 Discussion

The purpose of this study was to test whether each component of the trial worked together with the others, on a small scale. The results are largely in support of conducting a full trial. However, issues with recruitment and retention would need to be addressed prior to a definitive trial. Crucial experience and information was obtained whilst conducting this pilot study, which will assist in planning and improving aspects, such as recruitment and retention for a definitive trial. Pilot trials are a small-scale version of a full-scale trial, and therefore are not intended to evidence between-group differences, should they exist. It is unsurprising, therefore, that results from the effectiveness analysis are not statistically significant. The small sample size and high loss to follow-up meant very small numbers in each group and resulted in wide confidence intervals, and therefore low precision in parameter estimates. The data showed mean change from baseline to 12 weeks in four of the five outcome measures, including primary outcome of hand volume, and favoured the kinesiology tape, elevation and massage (trial treatment). However, the wide confidence intervals were indicative of the small sample size, and showed great uncertainty, therefore giving us little knowledge about the treatment effect. In pilot trials, greater focus should be placed on other important and practical outcomes, such as adherence, treatment fidelity, recruitment and retention. Greater adherence rates were seen in the treatment-as-usual group for weekly, and total treatment period adherence. Treatment-as-usual was also rated as being the more acceptable treatment. Adverse events occurred in four patients, three of whom were allocated to receive the trial treatment, resulting in two cases of protocol deviation. The total estimated per-person health resource costs (staff time and consumables) of the trial treatment were £2.31 less than the treatment as usual.

7.4.1 Randomisation process and baseline differences

Baseline characteristics were similar across the two groups with the exception of ‘since injury’, which was 12 days longer in the treatment-as-usual group, indicating

more chronic oedema than those in the trial treatment group. This could mean that their oedema was potentially more difficult to reduce, resulting in them responding less well to the intervention. Participants in the treatment-as-usual group had a mean hand volume reduction of 10.71ml less than those in the trial treatment group. A member of therapy staff who does not work in the hand therapy department and was not involved in the trial received instructions from the study statistician in order to prepare the randomisation envelopes. Although it is recognised that centralised randomisation is the gold standard for treatment allocation in clinical trials (Peto, 1999), the use of sequentially numbered opaque envelopes was a simple and cheap method which worked well in this pilot trial. A centralised randomisation system can reduce the risk of subverting the randomisation process. Hand therapists reported occasionally overstating the exclusion criteria in some cases in order to avoid randomising a potential participant who may have received the trial treatment (kinesiology tape). However, therapists confirmed that they did not open the randomisation envelopes before recruiting a participant. Some recruiting therapists commented that they had tried to predict the allocation sequence but had been unsuccessful, indicating that allocation sequence and the randomisation envelope system had been effective. A definitive trial, with a larger sample size, may benefit from a centralised randomisation system to avoid the time commitment and potential administrative errors which may occur with the preparation of hundreds of randomisation envelopes.

7.4.2 Health resource use

More participants in the treatment-as-usual group were recruited by therapists of a lower banding, indicating less experienced therapists than those recruiting participants in the trial treatment group. This may be an important factor to consider when examining treatment fidelity and will be discussed in more detail later. Participants in the treatment-as-usual group had, on average, one more treatment session than those in the trial treatment group. However, therapists spent less time in each therapy session treating oedema in the treatment-as-usual group, who required 4 minutes more treatment time. This may not be a clinically significant time increase and is possibly due to the trial treatment being a more novel treatment, which required greater explanation and demonstration.

7.4.3 Recruitment and retention

This study failed to recruit to its target of 100 participants over 6 months. The participants who were approached to participate, and were subsequently randomised, were receptive about being invited to take part in a research study. They were interested in the rationale for the study and the different treatments used in clinical practice. The failure to recruit to target was based primarily on a lack of suitable patients within the recruitment period, and not because of the research topic or participant commitment during the trial.

Participants were happy to see the assessor for their follow-up assessment either before or after their hand therapy appointment, and were keen to receive feedback about their hand volume measurements compared to before treatment (baseline). Treating therapists and the blinded assessor worked well together when co-ordinating the order of hand therapy appointments and follow-up assessments. The assessor would have the flexibility of assessing the participant prior to their hand therapy assessment, which was convenient for the therapists, particularly if they were running behind schedule. The open plan layout of the hand therapy department caused issues with recruitment. The PI was unable to recruit multiple suitable participants, who were being treated in the department by different therapists, at the same time. Some patients were unwilling to wait for the PI to become free. These participants were included in the consort flow diagram (n=7 declined to participate). Some participants were happy to attend their 12-week follow-up assessment despite already having been discharged from hand therapy. This indicated that they understood the research process and importance of collecting complete data.

However, recruiting hand therapists acknowledged that, on occasions, they were too busy to discuss the trial with a participant they believed was potentially eligible and therefore did not alert the PI to begin the consent process. Whilst some therapists reported these cases to the PI so they could be recorded, there were occasions when this did not happen. The numbers reported in the CONSORT diagram (Fig 5.1) as assessed for eligibility are therefore likely to be underestimated. Adams et al., (2015) in their paper examining the barriers and opportunities for enhancing patient recruitment and retention in clinical studies report: “Tension between clinical and research workloads was seen to interrupt patient recruitment into studies, despite

national funding arrangements to manage excess treatment costs." The findings from their study identify a "perceived gap in national provision for dealing with the additional burden that research could place on clinical teams." The hand therapists in this study were not given additional or protected time to recruit participants and because of high caseload demands and low staff numbers, the trial was sometimes forgotten about, despite the presence of the PI in the clinical department serving as a reminder. This potentially highlights a systemic issue with conducting research in busy acute NHS departments.

There were problems coordinating participant flow through the trial, as some participants cancelled or changed their follow-up appointments, without the PI (who conducted all follow-up assessments) being informed. This process was done by written or verbal messages being relayed from admin staff to the treating clinician. Clinicians may not have felt it was their responsibility to inform the PI and in some cases assumed that she would know. Given the large volume of patients on a clinician's caseload, it could be difficult for them to recall which patients were in the trial. The PI, as the blinded assessor, was unable to check therapy notes to see if changes or cancellations had been recorded (in case this led to unblinding), and therefore had to check the computerised patient booking system regularly to keep track of follow-up appointments. On occasions, appointments were rescheduled for a day when the PI was not based in the department, resulting in a missed follow-up assessment.

Despite efforts by the PI to keep staff engaged in the trial by using recruitment tally charts and prizes for top recruiters, there was a sense of apathy in the department towards research activity. Barriers were observed from an individual, departmental and organisational level, with limited top-down support or encouragement from managers.

Clinicians may have felt there was little incentive to recruit participants to someone else's doctoral research project.

7.4.4 Acceptability of treatments

The acceptability of treatments to patients is an important factor and one which should always be considered when designing a trial. There are many different ways to assess treatment acceptability (Sehkon et al., 2017), and treatment acceptability scales and inventories exist (Hunsley, 1992, Elliot and Treuting, 1991, Healey et al., 2011). However, they are validated for use with specific psychological conditions, settings (i.e. education) or population (i.e. children). Acceptability is defined as the "quality of being tolerated, allowed or accepted" (Simpson and Weiner, 1989). Given the complexity of each element which made up the control and trial treatment in this study, it was important to pick out the most relevant factors for patients to rate their acceptability. The patient acceptability questionnaire was devised by the PI based on clinical experience and patients' feedback about using these modalities. A scoping review of the existing acceptability scales suggest most of them use a Likert scale. Participants were asked to rate their acceptability on aspects such as cosmesis, cleanliness and ease of wear on an 11-point Likert scale, and their overall level of acceptability. Other factors that could be included in an assessment of acceptability are: drop-out rates, discontinuation, reason for discontinuation and withdrawal rates. Without interviewing participants who were lost to follow-up, it is difficult to attribute this to the acceptability of the treatment alone, as other factors may have led to patients discontinuing or not returning for follow-up. Two participants who experienced adverse effects from their allocated treatment switched to receive treatment-as-usual. When interviewed about their acceptability, they rated the treatment they were using (and had used for the majority of the trial) as opposed to the one that they had been allocated to. Some participants questioned the purpose of needing kinesiology tape along the entire forearm for isolated digit oedema. Hand therapists educated patients on the process of lymphatic drainage and the purpose of the tape's position. Reduced face validity may have influenced the lower acceptability scores for the trial treatment. Poor face validity could also have affected adherence. However, kinesiology tape was adhered to more so than elevation or massage in the trial treatment group.

7.4.5 Adherence

Paper adherence diaries, whilst simple and cheap, have many limitations. The reliability and accuracy of paper adherence diaries could be questioned as there is

no way of confirming when the diary was completed. Retrospective completion relies on patient recall, whereas prospective completion may result in hopeful inflation of levels of adherence. Either way, adherence diaries risk overestimating adherence levels. Whilst participants were instructed to be as truthful as possible when completing their adherence diaries, the diary may in itself have raised participants' awareness and therefore increased adherence. A study by Moseley, (2006) compared the use of a diary with no diary and overt and covert adherence monitoring of a home therapy programme. He found that adherence was greater in the group who knew they were being monitored, and used a diary. Moseley's study (2006) used electronic software to record adherence. An electronic diary or mobile app with compliance-enhancing features could be considered in a definitive trial; this could include a personalised reminder feature. Results from adherence diaries show consistently higher levels of adherence across the three elements of treatment-as-usual (massage, elevation and compression) than the trial treatment over the 12-week trial period. The treatment most adhered to in the treatment-as-usual group was massage, followed by compression, then elevation. In the trial treatment group kinesiology tape had the highest adherence rate, followed by elevation, then massage. Wide confidence intervals are seen in both groups across all the treatments, which is likely due to the small sample size. In seven cases treatment was stopped earlier than 12 weeks, as it had been deemed to be successful by the treating therapist and participant. Adherence rates were re-calculated based on the actual treatment period for the seven cases where this information was known. The results mirror that of the adherence data over 12 weeks, in that the treatment-as-usual group had greater adherence than the trial treatment group. Adherence in both groups was greater than the rates seen over 12 weeks, as these seven cases had diluted the rates for the 12-week adherence analysis. Individual adherence based on actual treatment period (where known) ranged from 39% to 100%. When looking at adherence on a week-by-week basis, overall rates were higher for the treatment-as-usual group. Adherence appeared to reduce from week 10 in the treatment-as-usual group, whereas in the trial treatment group this was earlier, at week 7. The lowest rate of weekly adherence (9.5%) was seen in week 3 in the trial treatment group, with the highest rate of adherence (88.8%) being seen in week 10 in the treatment-as-usual group. The largest difference in adherence between the two groups was seen in week 8, with participants in the treatment as usual group adhering to their

treatment 47% more than those in the trial treatment group. Lower adherence rates could have reduced the effectiveness of the intervention. However, this study observed a greater reduction in mean hand volume (from baseline to 12 weeks) in the trial treatment group, despite lower adherence rates than the treatment-as-usual group. This could indicate that the trial treatment has the potential to be a more effective treatment. Interestingly, kinesiology tape was the treatment most adhered to in the trial treatment group, with a mean adherence rate of 63.7%, 95%CI 37.5-89.9 (n=7 diaries). This could indicate that kinesiology tape is the 'active' element of this treatment that resulted in a larger reduction in hand oedema. Compression was the second most adhered to treatment in the treatment-as-usual group; however, mean adherence levels were still 20% greater than kinesiology tape (83.8%, 95% CI 63.7-100, n=6 diaries).

On occasions, treating therapists did not address oedema management with participants and assumed that the participant would continue as they had been previously advised. This lack of instruction, which may have affected adherence levels, became apparent during follow-up assessments by the blinded PI. Ensuring that treating hand therapists revisit oedema management with all participants in every therapy session, and routinely direct them to the 'as advised' dose for the appropriate duration until oedema is resolved, may increase adherence rates. Follow-up phone calls from treating therapists to study participants between therapy sessions to check progress may also be a strategy worth considering in a definitive trial, to increase adherence rates. A definitive trial may also include a per-protocol analysis to only take into account participants who were adherent to the treatment they received (rather than allocated). The limitation with this, and the previous methods of increasing adherence, is that they represent a best-case 'ideal-world' scenario, which is often not feasible in the 'real world' of NHS care. Furthermore a per-protocol analysis is at risk of bias by focusing only on participants who have completed the treatment 'as advised', neglecting other factors that may have affected adherence, and can overestimate treatment effects. An as-treated analysis, categorising patients not only by treatment but also by compliance status, could be compared to an ITT analysis to estimate the effect of adherence in a full trial. A limitation with all the above-mentioned analyses is that there is no accepted level of adherence against which to compare the results of this clinical trial. Therefore, any

adherence analysis is likely to inflate levels. Relating this to a clinical setting, a therapist will not know how much a prescribed treatment is adhered to by their patients.

7.4.6 Assessor blinding

Practical issues were noted with regards to the ratio of recruiting therapists to consenting PI, and the layout of the hand therapy department. With only one PI and up to 10 recruiting hand therapists in an open-plan department at any one time, it was impossible for the PI to consent more than one therapist's patients without being unblinded to the treatment allocation of the previously consented participant. Although there was a door separating the two areas of the department, the PI was able to hear conversations in the adjacent room and would often see the recruiting therapist visit the stock cupboard to collect items such as oedema gloves, which also caused unblinding. This issue with space continued to affect the follow-up assessments, as the PI could not see a study participant to conduct their follow-up assessment at the same time as a newly recruited patient without risk of unblinding.

According to a systematic review by Boutron et al., (2004) that examined 110 RCTs involving patients with hip and knee osteoarthritis, blinding appears to be more difficult to achieve, and unblinding may occur more often, in non-pharmacologic trials than pharmacologic trials. This may be the case for this study, due to the physical application of the treatments used, potential marks left on the participant's skin from the intervention, and the fact there was no obvious sham or placebo treatment which could have been used.

Blinding was maintained in nine participants (64%) in this study. In cases where blinding was not maintained, participants unintentionally mentioned their allocated treatment to the PI, despite being reminded before each session not to discuss the treatment with the assessor (PI). In other cases the participant was seen by the PI entering or leaving the department with their oedema treatment in situ (glove or kinesiology tape). There is only one entrance and corridor to access the department, therefore inadvertent unblinding occurred as the PI entered or left the department and saw participants who were attending or leaving their hand therapy appointment. Advising the participant not to wear their oedema garment on the way to or from their

therapy appointments could have reduced some cases of unblinding. A high level of unblinding could invalidate the results of this study if the assessor, who should retain objectivity, unintentionally introduces bias when completing the follow-up assessments.

7.4.7 Treatment fidelity

Treatment fidelity is an important aspect of therapy trials. It allows greater confidence that the results obtained were due to the effects of the given treatment, and not due to other unknown factors associated with its delivery or implementation. Treatment fidelity relates to the adherence of the treatment providers in delivering the intervention as stated in the study protocol, whereas adherence relates to the patient's ability to complete the intervention as instructed by the treatment provider.

The National Institutes of Health Behavioural Change Consortium (NIHBCC) devised a treatment fidelity checklist (Borrelli et al., 2005, Borrelli, 2011), which consists of 40 components over five domains, covering: study design, training of providers, treatment delivery, treatment receipt and treatment enactment. Each component is rated as being present (scored with 1 point), absent but should be present (scored zero), or not applicable. The breadth of this checklist highlights that treatment fidelity is a complex, multi-faceted concept.

The TIDieR checklist (Hoffman et al., 2014) used in this study focused on the assessment of treatment fidelity and neglects other important aspects covered by the NIHBCC checklist such as treatment receipt and treatment enactment. (Borrelli et al., 2005, Borelli, 2011). The fidelity strategies employed in this study concentrated on the training of treatment providers and acknowledges that further strategies, such as competency self-assessments before and after training could be implemented. A challenge of assessing treatment receipt and enactment in this study is the difficulty associated with accurately establishing if the tape, massage and compression has been applied to the participants skin to the required pressure/tension (as descried in the protocol), as this would require the use of cutaneous pressure sensors.

When planning this trial the "active ingredients" (Toomey and Hardeman, 2017) of the intervention and control arms were agreed during a Delphi Consensus Method

with eight hand therapy experts. This process established the dose, method, duration and frequency of the interventions. Before the trial commenced, therapists received training, either as a group or individually, on the process of recruitment, eligibility criteria and delivery of interventions. This involved going through the participant instruction manual, which detailed how the patient should use the treatment, when they should and shouldn't do it, and for how long. The providers instructing participants on each aspect of the treatment were qualified occupational or physiotherapists, all of whom were specialising in hand therapy, and therefore were familiar with the techniques and instructions. Despite there being no formally documented standardisation of provider training (as the NIHBCC treatment fidelity checklist requires), the PI delivered all the training sessions to the providers. This may have improved standardisation of treatment delivery by reducing the amount of variation between training sessions. Suitable wording was also suggested to providers during these training sessions. The PI was mindful of different learning styles and level of experience, and encouraged providers to practise the techniques on the PI if they felt this was needed. More participants in the treatment-as-usual group were recruited by therapists of a lower banding. A lower banding implies less experience. Bellg et al., (2005) suggest more intensive training and follow-up for less experienced providers. However, as Karas and Plankis., (2016) state: "It cannot be assumed that providers have equal understanding of a treatment based solely on their credentials or years of experience."

The physical presence of the PI in the department during the 6-month recruitment phase also served as a 'check-in' point if interventions needed to be revised. Assessment of treatment-provider skill acquisition was not formally or consistently tested. In those providers who wished to practise techniques, such as kinesiology tape application, their skill acquisition could be surreptitiously tested. However, not all techniques of the three prescribed elements in each treatment arm were practised or tested. In those providers who felt confident with the techniques, no assessment process took place. The continued monitoring of provider skill maintenance over the duration of the study or assessment of providers' adherence to delivering the treatments was impossible for the PI to complete in a clinical research scenario (i.e. with a recruited/consented participant) without being unblinded to the participant's treatment allocation. The use of a treatment manual issued to each participant

served to reiterate the verbal instructions and physical administration of modalities by the provider. Adherence diaries were used to assess if treatments were implemented as instructed, and although diaries have their own limitations (Stone et al., 2003, Farmer, 1999), these could also serve as a validation tool to establish if the participants were able to perform the treatments. This was also assessed during the 12-week acceptability questionnaire. No comments were made by participants about being unsure about how to apply the treatments (tape/glove/massage etc.) This may imply that the provider training and delivery of interventions were adequate, but do not imply that they were delivered as per the protocol.

Treatment fidelity may have been compromised in this study due to issues surrounding the continuation or discontinuation of the oedema management treatments. On occasions there was uncertainty amongst therapists as to whose responsibility it was to continue or discontinue oedema treatment, with some relying on the blinded assessor to inform the patient based on the results of their follow-up assessment. Therapists had been instructed to assess the hand oedema as normal (visual estimation) and provide appropriate advice to the patient based on their clinical judgement. During follow-up assessments (which usually followed on from the participant's hand therapy appointment), the PI would check if the participant had been advised to continue/discontinue their oedema treatments. In some cases the patient reported that they did not receive further information. The PI then had to return to the treating clinician/treatment provider and advise them that the participant required further instruction. Although this area was covered in the initial provider training, it highlighted a lack of understanding by the providers, indicating inadequate training from the PI. Using case vignettes during provider training could be one way to minimise this issue in future.

7.4.8 Loss to follow-up

Two participants in the trial treatment group reported skin rashes that prevented them from continuing with their allocated treatment. However, their adherence data was based on their use of treatment-as-usual. The use of an intention to treat (ITT) analysis ignores protocol deviations, non-compliance and withdrawal, and analyses participants according to the group they were originally allocated to. This is a 'real life' approach, as it accepts that non-compliance and changes to treatment plans

occur in clinical practice. However, the fact that only participants with full datasets were included in this analysis indicates that a true intention to treat principle was not followed.

While an ITT analysis avoids serious problems associated with attrition bias (Feinstein, 1979), it does not facilitate understanding of other key factors that may affect participant outcomes, i.e. drop-outs or withdrawals due to adverse events. There was a high (54%) loss to follow-up in this study, and whilst all loss-to-follow up patients were contacted to try and re-arrange their assessment, we have no data on their rationale for discontinuing in the study, their adherence during the study or if their behaviours changed on dropping out of the study. Some have suggested that <5% loss leads to little bias, while >20% poses serious threats to validity (Sacket et al., 1979). Whilst greater loss to follow-up introduces the potential for bias, it also depends on the pattern of missing data. Loss to follow-up in RCTs reduces statistical power and increases the potential for bias (McCarthy et al., 2016). Although this is not relevant in pilot studies, valuable information on the reasons for these losses to follow-up could help plan and improve retention in a future definitive trial. In this study, there was an even loss to follow-up in both groups, which may indicate their withdrawal was not related to the treatment but to other factors. Due to the acute nature of their hand conditions, participants may have perceived their injury to be short-term or transient and assumed their data was of little value to the researcher, particularly if the variable of interest, i.e. oedema, had resolved. Fifty-eight percent (n=7) of participants who were lost to follow-up in this study were male. The mean age of those lost to follow-up was 23 years younger than those who completed the study. Almost all (91%) of the 12 participants lost to follow-up had a traumatic injury, but only 2 (17%) had a poly trauma. Whilst there was also a greater proportion of participants with hand trauma amongst those who completed the study, the number of participants following surgery was only marginally lower (8:6). More male participants were lost to follow-up, whereas more female participants completed the study. Forty-two percent (n=5) of those lost to follow-up were aged under 30 and three (25%) of these were male. The mean time since injury or surgery was 21.3 days in the group who were lost to follow-up. This is 6 days fewer than those in the trial treatment group and 18 days fewer than those in the treatment-as-usual group. This time difference meant the 12 participants who were lost to follow-up had more

acute oedema, which may have responded quickly to intervention (compression or kinesiology tape). If treatment had been successful, they may have felt there was little point in returning to hand therapy.

A study by Madden et al., (2017), which predicted and looked at preventative strategies for loss to follow-up in adult acute trauma, determined which participant characteristics were associated with a higher risk factor of loss to follow-up. The study found that gender (male), lifestyle choices (current smokers and high alcohol consumption) and age (<30) were associated with statistically significant higher loss to follow-up. Participants with poly trauma or more severe injuries had statistically significant lower odds of being lost to follow-up (Madden et al., 2017).

7.4.9 Effectiveness results

The results of the effectiveness analysis should be interpreted with caution, as drawing conclusions from these results is not the intention of a pilot trial. The very wide confidence intervals highlight the potential magnitude of differences between the two groups, and therefore there is no evidence of treatment superiority in either direction. Recommendations for a future definitive trial are based on the results of the feasibility testing, and not the effectiveness results.

7.4.10 Considerations for a definitive trial

This study highlighted numerous issues which, although discussed under the heading of limitations, are important findings to have emerged from the pilot trial. Careful consideration of these factors would be required when planning a future definitive trial.

A formal assessment of skill acquisition and treatment fidelity was not employed during this study. Incorporating a more structured approach to provider training and assessment may improve treatment fidelity. Using an impartial research associate, with relevant knowledge of the treatment process, to observe a selection of therapy sessions at random is one way in which provider skill and treatment fidelity could be assessed in the field. A dictaphone could also be used to record the provider-participant interaction.

Greater consideration needs to be given to the number of recruiting therapists, and the size and layout of the department. A risk of unblinding was apparent with the PI consenting participants and conducting follow-up assessments at the same time as existing study participants were being treated in the department. Having a second blinded assessor could assist with this. In addition, developing a system of using clinic rooms and separating therapy rooms into a 'consenting'/randomisation room and another where only follow-up participants could be seen/treated may reduce the risk of unblinding associated with the space.

There does not appear to be any validated self-report acceptability questionnaires for physical therapy interventions. For this reason, one was designed specifically for use in this study. The questions were based on the clinical experiences of the PI from patient feedback received during clinical practice of using the treatments compared in this study. A 0-10 Likert scale was used, with zero indicating poor acceptability and 10 indicating good acceptability. Looking at the loss-to follow-up rate could be another method of assessing patient acceptability of treatments. The high drop-out rate could imply poor acceptability. The ability to follow those who were lost to follow-up could elicit useful information about the patient's perception of the treatments. The patient-rated outcomes were sent to patients who were lost to follow-up (with pre-paid envelopes), but none were returned. Follow-up phone calls to all lost to follow-up participants could be a useful way to elicit information about their acceptability of the treatment, and whether this impacted on their decision not to return for assessment.

Due to the high loss-to-follow-up rate, strategies to improve retention also need to be investigated. Completing follow-up assessment in the participant's home, particularly for those who have been discharged from hand therapy, or phone call reminders for all follow-up assessments, may be worth considering for a definitive trial.

It is likely that the health resource cost was underestimated due to treatment providers forgetting to add consumables to the case report form. The information was obtained from participants' hand therapy notes, if recorded. The balance between gathering important data and overburdening therapists is difficult. There is already considerable demand on therapists with regards to documentation. Trying to

establish an easy, quick and novel way of accurate recording health resource use needs to be looked into. Ridyard and Hughes, (2010) propose a checklist for good practice relating to economic data collection within clinical trials. This study used a basic form to record hand therapy resource use, where the treating therapist had to input their banding, number of minutes spent on oedema management and, using a tally system, record the amount of oedema-related consumables issued to participants. Switching this to a checklist style form should be considered to reduce burden and time to complete.

Three months into the recruitment period of this study, it was acknowledged that recruitment numbers were low and were unlikely to reach the estimated target of 100. The inclusion criteria were therefore amended to increase the time since injury from 6 weeks to 12 weeks. As this required a substantial amendment to the HRA, and due to the time it took to get approval, there was only one more month of recruitment left. Using the updated inclusion criteria in a definitive trial may maximise recruitment. However, a broader problem with conducting research in a busy acute department may also account for lower than expected recruitment numbers, which would require a more systematic approach. Involving a clinical manager to assist in improving the research culture within the recruiting department/trust may help therapists view research with greater significance, so that it can be seen as equally important as patient care. If supported by managers and incorporated into a therapist's job description, there may be more incentive and less resistance to recruit patients, even during busy clinics. Using support services from the local research network, including research nurses who are based in the hand therapy department and could assist in the identification and randomisation of eligible participants, may reduce pressure on clinical hand therapy staff and increase recruitment rates.

7.4.11 Sample size for a future trial

One of the objectives of this pilot study was to obtain data to inform a sample size calculation for a definitive trial. Two approaches could be used to obtain this sample size; the first is to use an effect size obtained from a pilot trial. Leon et al., (2011) states that contrary to tradition, a pilot study does not provide a meaningful effect size estimate for planning subsequent studies, due to the imprecision inherent in data from small samples. Therefore, in order to get an estimated sample size, an

alternative approach is proposed which uses a minimum difference, sufficient to make a clinically relevant change.

Using the results of the patient-rated oedema rating scale may provide us with the most appropriate clinically relevant change. Using the mean difference in hand volume for patients who had a reduction on their ORS scores could offer a minimal clinically important difference for a definitive trial.

Six participants recorded a change (reduction) of greater than or equal to 2 points on the ORS between baseline and their 12-week assessment. The volume differences of these six participants ranged from 15ml to 140ml; this equated to a 3%-25% reduction of baseline hand volume. Mean volume difference for these six participants between baseline and 12 weeks was 50ml (mean percentage loss of 9%). Dividing this by the SD of the change (45.71) gives a large standardised difference of 1.09. Using Altman's nomogram (Altman, 1991) with p=0.05 and 90% power, an estimated 35 participants would be required for a definitive study. However, given the high loss to follow-up seen in this study (47%), recruiting approximately 52 participants would account for attrition. The mean volume change of 50ml for these participants is substantial, partly due to one participant who lost 140ml of hand oedema over 12 weeks. Such a large reduction is rare. A smaller volume change, for example half of that seen in this group, could also be viewed as clinically relevant. Based on a 25ml minimum difference, and accounting for the high attrition rates seen in this study, an estimated sample size of 236 in total would be required for a definitive trial. A 25ml difference was captured within the confidence intervals of the effectiveness data at both 4 and 12 weeks.

7.5 Conclusion and recommendations

The results of this pilot trial have identified that some modifications are required in order to a make a full-scale trial feasible. Recommendations for a future definitive trial should include:

1. A multi-centred approach in order to reach target sample size (n=236)
2. The use of multiple blinded assessors in each study site

3. Use of clinical research nurses (CRN) to assist in screening patients to check eligibility and recruitment to reduce time pressures by allowing hand therapists to focus on treatment delivery
4. Using the amended inclusion criteria for time since injury (3 days to 12 weeks) from the commencement of a definitive trial
5. A local PI in each site who is not involved with the recruitment, randomisation or treatment delivery, who can assess treatment fidelity and treatment delivery. Having a local PI who is not clinically active in the recruiting department may improve methodological rigour
6. A more in-depth and detailed provider training plan including use of case vignettes and competency self-assessment before and after teaching.
7. A formal assessment of treatment fidelity in the trial protocol which takes into consideration multiple aspects of fidelity including training of providers, treatment delivery, treatment receipt and treatment enactment.
8. Follow-up assessment reminder texts or phone calls to participants to reduce non-attendance rates
9. Greater emphasis on educating patients regarding the need to return for follow-up, even if their symptoms have resolved
10. Involve managers and staff from recruiting sites more in the planning phase of a definitive trial to increase ‘buy-in’ and wider departmental support for the trial.

This chapter has presented the methods and results of a pilot randomised controlled trial to compare standard care with kinesiology tape in the treatment of hand oedema. Recruitment of participants with acute trauma identified challenges for trial retention and a high loss to follow up was seen. The practicalities of conducting a trial in a busy acute clinical department were acknowledged and discussed, with numerous recommendations being made to assist in the planning of a definitive trial. The next and final chapter will present an overview of the main conclusions and implications for clinical practice and research that have arisen from this programme of research.

Chapter 8: Conclusions and recommendations

This chapter will provide a summary of the key findings and discussion topics which have arisen from this programme of research. It will identify the unique contributions to knowledge and understanding of how hand oedema is assessed and treated, and summarises the key challenges associated with pragmatic research on this topic.

Clinicians, when faced with a patient who has an oedematous hand, are required to assess the amount of oedema prior to any intervention, and at appropriate intervals during the course of treatment to establish the effectiveness of treatment. Alongside this, clinicians have to decide how best to treat the oedema based on a number of factors, including the injury and the patient. Over the past 20 years traditional approaches to treating hand oedema, such as effleurage massage, have been questioned. The introduction of new treatments, such as kinesiology tape and lighter massaging styles, which clear proximal channels first before addressing the local oedema in the hand, have offered alternative theories of how oedema should be treated However, the quality of evidence for most oedema interventions remains poor, variations in practice continue and there are still many gaps in knowledge.

The programme of research presented in this thesis has contributed to the body of knowledge as follows:

- Provided syntheses of evidence on the psychometric properties of methods to assess hand oedema (Chapter 3) and of the effectiveness of treatments for sub-acute hand oedema post-trauma or surgery (Chapter 2)
- Confirmed that the use of visual estimation of oedema severity by hand therapists, which was the most commonly reported method of assessing oedema by clinicians (Chapter 4), should be discouraged (Chapter 2)
- Identified the diversity between and variations within practice in the UK for the assessment and treatment of sub-acute hand oedema (Chapter 4)

- Highlighted discrepancies in terminology and description of oedema treatments commonly referred to manual oedema management and manual lymphatic drainage (Chapter 2)
- Developed an oedema management manual with hand therapy experts which details method, dose, frequency, instruction for use and precautions for four oedema treatments (Chapter 5)
- Developed standardised patient information leaflets to support a home oedema programme through co-production with a patient advisory group
- Devised a new patient-rated outcome measure for oedema, which can complement objective assessments by subjectively grading severity of hand oedema (Chapter 6)
- Established volumetry as the most responsive method of measuring hand oedema in a group of 73 patients with hand oedema (Chapter 6)
- Collected preliminary data on recruitment and retention rates, adherence and acceptability of treatments in a pilot randomised controlled trial comparing kinesiology tape with compression (Chapter 7)
- Calculated a minimal clinically important difference in hand volume to be used as a sample size for a definitive trial (Chapter 7).

There are, however, a number of limitations with this programme of research. The inclusion criteria for the assessment of a hand oedema systematic review specified oedema of the ‘hand’. This excluded papers which focused on isolated digit oedema only. It became apparent during the observational study that responsiveness, when assessed at 2 weeks, was affected by the location of oedema. In light of this, the inclusion criteria should have taken into consideration both hand and digit oedema.

The low response rate to the survey of practice means that the results may not be representative of current hand therapy practice in the UK for oedema management. It may also indicate that oedema management is not a research priority, or did not interest clinicians. The results of the survey informed the first round of the Delphi, which may have meant the topics which were discussed were also not representative. Fewer than

the expected number of experts volunteered to take part in the Delphi study. Ensuring that experts did not work in the same department was not stipulated in the inclusion criteria, and details on where the experts worked were not obtained. This may have also influenced the generalisability of the results, which may not have been representative of hand therapy practice.

The inclusion of the two objective methods of assessing hand oedema (volumeter and figure-of-eight) came from the results of the survey and Delphi consensus method. These methods were also evaluated in detail during the systematic review. It excluded methods which have been published but which did not meet the inclusion criteria of the systematic review, such as the weighted tape measure, or were not readily available due to cost, such as a 3-D scanner or perometer. In hindsight the inclusion of the weighted tape measure for circumferential digit measurements may have been a useful comparator to compare the relative responsiveness for those with isolated digit oedema.

Poor recruitment and retention rates in the pilot RCT highlight issues with the inclusion and follow-up of patients, particularly those with traumatic injuries; subsequently numbers in both groups were small. Whilst a larger sample size would not have altered the conclusions that can be drawn from the efficacy analysis in this pilot study, it may have provided more comprehensive information on adherence and acceptability of treatments, which is important when planning a definitive trial.

This programme of research has assisted in synthesising current concepts on the assessment and treatment of hand oedema, but also identified gaps in knowledge, particularly surrounding an agreed dosage for implementing oedema treatments. Following the suggested recommendations would help to ensure a high quality definitive trial that could build on the current sparse evidence relating to the effectiveness of oedema treatments, in particular kinesiology tape. Only one study compared kinesiology tape to a control treatment for hand oedema, highlighting its infancy in clinical research studies for sub-acute lymphatic drainage in the hand, and therefore the need for further research.

There is a lack of high quality evidence to suggest that a single oedema modality is superior in treating hand oedema; a combination of treatments appears to demonstrate

greater effectiveness in reducing problematic oedema. The treatment of oedema is a complex combination of different interventions used in conjunction with each other. The interaction between each intervention is not understood. Aspects such as dose response and the effects of treatments on each other warrant further exploration on how combinations of treatments interact.

8.1 Personal development as a researcher

This programme of research was funded by a National Institute for Health Research (NIHR) clinical doctoral fellowship. The NIHR mission is to provide a health research system in which the NHS supports outstanding individuals working in world-class facilities, conducting leading-edge research focused on the needs of patients and public (NIHR website, 2018). It aims to develop clinical research leaders of the future through training, development and mentorship. The fellowship has been instrumental in advancing the author's (LM) skills as a clinical researcher. In particular it has:

- Developed the author's project management skills to be able to plan and coordinate multiple projects and elements of the fellowship concurrently
- Enhanced understanding and interpretation of results of statistical tests, and their interpretation for clinical practice
- Improved the author's ability to disseminate the results to different audiences
- Emphasised the importance and utility of including patients and public when planning projects, patient-facing documents and lay reports
- Increased the author's confidence and independence as an early career clinical researcher
- Improved the author's resilience to some of the challenges faced by clinical researchers, i.e. lack of dedicated time for research in clinical posts, time taken for research results to change practice
- Inspired the author, through networking events, to appreciate the need for, and value of, clinical research, to help build the research capacity of other clinicians
- Developed the author's ability to communicate research plans and outcomes with study participants, ethics committees and clinicians.

8.2 Implications for clinical practice and research

The implications of this work are various. Firstly, clinicians should be aware that the conclusions drawn from published literature on the assessment and treatment of hand oedema is limited by its methodological quality. Despite this, the best available evidence suggest that clinicians should consider the figure-of-eight tape measure as the best alternative method of assessing hand oedema in cases where the volumeter is not practical. The results of the observational study support this to some extent. The figure-of-eight tape measure may be the preferred option, particularly when assessing oedema short-term (2 weeks) and if the oedema is generalised to the whole hand. However, for longer-term follow-up (4 weeks), the volumeter retains its 'gold-standard' title regardless of where the oedema is in the hand and should be used to assess hand oedema, where practical. Clinicians should refrain from visually estimating and grading the severity of hand oedema, as this method is likely to underestimate oedema in some patients and therefore treatment is not initiated. Conversely, this method may also overestimate the presence or severity of oedema in other patients, which could lead to unnecessary treatment. When assessing hand oedema, therapists should consider a patient-rated outcome measure in addition to an objective assessment. The oedema rating scale is currently the only measure which specifically grades oedema. Incorporating a subjective measure also ensures the patient's perspective is considered in the assessment process.

Hand therapists treating oedema are faced with a myriad of different options. The choices available to clinicians may be based on cost, departmental knowledge and skill, or convenience. In situations where therapists are treating problematic sub-acute hand oedema that is not responding to 'standard treatment' alone, they should consider using manual oedema mobilisation or manual lymph drainage in addition to standard treatment. However, therapists need to educate themselves on the components of these treatments, as the terminology is often inconsistent and they are not adequately described in order to replicate. Postgraduate training is required in order to use these techniques.

Current practice amongst hand therapists in the UK contradicts that of the systematic reviews performed. Clinicians may wish to consider reviewing the literature or published systematic reviews, in order to compare their practice against it. This may highlight gaps in their own knowledge and understanding. From the author's own clinical experience numerous barriers to clinicians using or complying with evidence-based practice (EBP) have been observed and identified. On an individual level these barriers include; clinicians' own readiness and willingness to engage with evidence based ("this is how we've always done it" attitude), a lack of time and motivation and a lack of knowledge on where to find appropriate literature, how to interpret results and apply them in practice. The latter potentially being related to the amount of time since graduating. Organisational level barriers include a lack of managerial support and an organisational culture which prioritises patient contact over staff training and development. These barriers are also reported in the literature (Newman et al., 1998, Haynes and Haines 1998 and Wallis 2012). Implementation science is an approach used to promote the systematic uptake of EBP into routine practice to improve the quality and effectiveness of health care services (Eccles 2006, Nilsen 2015). Implementation theories, such as COM-B (Michie et al., 2011) may provide greater understanding and explanation of factors which influence implementation outcome. The COM-B system is a framework for understanding behaviour and the factors required in order for behaviour to change. This system acknowledges internal factors to the individual (capability and motivation), and factors which are external to the individual (opportunity) which all interact to generate a desired behaviour. A behaviour change wheel is presented whereby the three essential conditions (capability, opportunity and motivation) form the centre of the wheel, with nine intervention functions surrounding these conditions (i.e education, training, modelling), which are further surrounded by seven categories of policy (i.e guidelines and service provision). A clinician could utilise this theory by recognising deficits in their capability, motivation or opportunities, identifying which intervention functions could address these deficits and how these will be delivered in practice (policy categories) (Michie et al., 2011).

For research purposes, an agreed oedema management manual and patient information leaflet exist which could be implemented in clinical practice and future

clinical trials. This manual details frequency, duration, methods and precautions of implanting an oedema management progamme. As the oedema treatments were poorly described in the literature and there was no consensus in current practice, the process by which this manual was developed is a useful model for therapists to use in future. The oedema management manual reduces variability between patients in terms of treatments offered, whilst allowing therapists the flexibility within the programme to tailor it to the patient's needs. This could have positive implications for patient satisfaction and for them taking responsibility for their own care, which in turn may reduce time spent on treating oedema in sessions.

For clinicians who are planning research, in particular trials comparing interventions, they need to consider training on how to implement the treatments, as well as regular reviews and refreshers, should not be underestimated. It is important not to assume knowledge, even for therapists who treat oedema in their daily clinical role, as the approach they take to the same task under trial conditions is likely to be much more standardised.

8.3 Recommendations for future research

- An observational study which compares isolated digit measures, i.e. weighted tape measure or ring gauge system, with the figure-of-eight tape measure and volumeter
- A full-scale multi-centre assessor-blind randomised controlled trial, comparing treatment as usual (compression, elevation and massage) with trial treatment (kinesiology tape, elevation and massage) to gather efficacy data.

8.4 Conclusion

This programme of research aimed to establish the best method of assessing and treating sub-acute hand oedema. At present, the best methods of assessing hand oedema are the volumeter or figure-of-eight tape measure. Choice will depend on the presence of wounds or dressings, the availability of the equipment, time and space. The utility of other methods, such as 3-D lasers or scanners, may warrant further investigation but may also be limited by cost, space and time; therefore the

recommendations are based on methods which are readily available to hand therapists and have undergone greater psychometric testing on symptomatic populations. This programme of research has highlighted inconsistencies between best available evidence and current practice, and has attempted to systematically reduce the variability in how we treat hand oedema through consensus development on four oedema treatments. However, more work is needed on this with other treatments, such as manual oedema mobilisation and manual lymph drainage. Work done during the pilot RCT forms the preliminary stages for further investigations to be carried out, which may bring us closer to establishing how sub-acute hand oedema should be treated.

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Appendix A

Data extraction form treatment of oedema systematic review

Author Year Journal

Population:	Intervention Group	Control Group
Gender M/F		
Age (Range/SD)		
N= Start		
N=Finish		
Time since injury/ Surgery		
Inc/Exc		
Surgery/trauma		
Co-mo factors		
Oedema measuring method		
Outcome measures		

Intervention	Intervention Group	Control Group
Start		
Frequency		
Duration		
Follow Up?		
Description:		
Based upon:		

Author Year Journal

Quality:												
Study design	RCT	CC	Multi centre:	Y	N							
Randomisation												
Pragmatic	Y	N										
ITT Analysis	Y	N										
Blinding												
MacDermid scale	1).	2).	3).	4).	5).	6).	7).	8).	9).	10).	11).	12).
	13).	14).	15).	16).	17).	18).	19).	20).				
	20).	21).	22).	23).	24).					**Total:**	**/48**	

Intervention Group			Control Group		
Variable	Baseline	F/up	Variable	Baseline	F/up

Notes:

Appendix B

Structured effectiveness quality evaluation form (SEQES)

Evaluation Criteria	*Score*		
Study question	2	1	0
1. Was the relevant background work cited to establish a foundation for the research question?			
Study design			
2. Was a comparison group used?			
3. Was patient status at more than one time point considered?			
4. Was data collection performed prospectively?			
5. Were patients randomized to groups?			
6. Were patients blinded to the extent possible?			
7. Were treatment providers blinded to the extent possible?			
8. Was an independent evaluator used to administer outcome measures?			
Subjects			
9. Did sampling procedures minimize sample/selection biases?			
10. Were inclusion/exclusion criteria defined?			
11. Was an appropriate enrollment obtained?			
12. Was appropriate retention/follow-up obtained?			
Intervention			
13. Was the intervention applied according to established principles?			
14. Were biases due to the treatment provider minimized (i.e., attention, training)?			
15. Was the intervention compared with the appropriate comparator?			
Outcomes			
16. Was an appropriate primary outcome defined?			
17. Were appropriate secondary outcomes considered?			
18. Was an appropriate follow-up period incorporated?			
Analysis			
19. Was an appropriate statistical test(s) performed to indicate differences related to the intervention?			
20. Was it established that the study had significant power to identify treatment effects?			
21. Was the size and significance of the effects reported?			
22. Were missing data accounted for and considered in analyses?			
23. Were clinical and practical significance considered in interpreting results?			
Recommendations			
24. Were the conclusions/clinical recommendations supported by the study objectives, analysis, and results?			
Total Quality Score (Sum of above / 48) =			
Level of Evidence (Sackett) 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐			

Appendix 2
Evaluation Guidelines for Rating the Quality of an Intervention Study

To decide which score to provide for each item on your quality checklist, read the following descriptors. Pick the descriptor that sounds *most* like the study you were evaluating with respect to a given item.

Question		*Descriptors*
No.	Score	
1	2	The authors -performed a thorough literature review indicating what is currently known about the problem and the intervention at present -presented a critical, but unbiased, view of the current state of knowledge -indicated how the current research question evolves from the current knowledge base -established a clear research question(s) based on the above
	1	All of these above were not fulfilled, but a clear rationale was provided for the research question
	0	A foundation for the current research question was not developed
		Study design
2	2	Two or more contemporary (same point in time) groups of similar patients were compared (crossover trials, which include randomization/blinding of intervention order and complete washout of effects, can be considered equivalent)
	1	A comparitor group was present, but did not fulfill the above criteria
	0	No comparitor group was included
3	2	Patients were evaluated before the intervention, and at one or more clinically relevant time points, after the intervention using the same evaluation criteria
	1	Patients were evaluated at more than one point in time (including case control studies), but the above criteria were not fulfilled
	0	Patients were evaluated at only one point in time

(*continued*)

APPENDIX 2. (continued)

Question		Descriptors
No.	Score	
4	2	A standardized set of data was collected at standardized intervals according to a preplanned protocol
	1	Data were collected from patients during specified observations (i.e. not retrospectively), but it did not comply with all of the above standardization procedures
	0	Data were collected based on retrospective interpretation/recall of past events
5	2	An appropriate randomization strategy was used to allocate patients to interventions, and the specifics of randomization were described
	1	Randomization was used, but information describing the randomization process was not included or did not confirm a truly random process.
	0	Randomization was not used
6	2	Patients were blinded as to the intervention that was provided and either a post-hoc analyses indicated that blinding procedures were effective or it was evident that patients would be unable to distinguish which intervention they received
	1	Blinding patients was not possible or it was unclear whether an effective blinding strategy was used
	0	Blinding was possible but not used (includes all studies without comparison groups)
7	2	Treatment providers were blinded to the intervention they were administering, and this blinding was substantiated either through audits or other post-hoc analyses indicated that the blinding procedure was effective
	1	Blinding was not possible or it was unclear whether an effective blinding strategy was used
	0	Blinding was possible but was not used
8	2	Outcome measures were administered by an evaluator who was blind to the treatment provided and/or the purpose of the study, self-report can be considered as equivalent if provided by an independent person
	1	Evaluators were not blinded, but were not involved in treatment of patients (were independent) or self-report administered by treatment provider
	0	Outcome measures were obtained by unblinded treatment providers
		Subjects
9	2	The authors documented a specific recruitment strategy that was intended to maximize the representation of subjects in relation to specific target population, and sampling procedures were applied equally across comparison groups
	1	The study sample appears representative of the population of clinical interest, but adequate information on sampling procedures or description of the reference population is not provided
	0	Sampling biases are evident; systematic differences occurred between the comparison groups; and/or selection procedures used make it impossible to determine what types of patients were included
10	2	Specific inclusion and exclusion criteria for the study were defined and designed to yield a study group generalizable to the clinical situation
	1	Some information on the type of patients included in the study and excluded are defined, but the information is insufficient to allow the reader to generalize the study results to a specific clinical population
	0	No information on inclusion and exclusion criteria and limited patients descriptors are provided
11	2	Authors performed a sample size calculation on which their recruitment targets were defined, described the target population from which subjects were drawn, and the response from the target population in terms of participation in the study
	1	The authors performed a sample size calculation and/or provided a satisfactory rationale for the number of subjects included in the study
	0	The size of the sample or its relationship to target population were not rationalized
12	2	90% or more of the patients enrolled or eligible for study were evaluated for outcomes
	1	More than 70% of the patients eligible for study or enrolled were evaluated for outcomes
	0	Less than 70% of patients eligible for study or enrolled were evaluated
		Intervention
13	2	The parameters of the treatment (frequency, duration, application area, and other technical components) were sufficiently described that they could be replicated, and that the specific parameters used were based on published basic science or clinical evidence documenting that the specific treatment effects intended are achievable given the treatment parameters used
	1	A sound rationale OR adequate description was provided for the treatment intervention, but the above level of documentation was not cited
	0	A rationale for the treatment intervention was not provided AND an adequate description of the intervention was not included OR the application of the intervention did not conform to present knowledge on potentially effective parameters
14	2	The study was designed to minimize biases due to the treatment provider; treatment provider biases can be minimized if the treatment provider is blinded to which treatment they provide; In cases which this is impossible, methods such as equalize attention to groups, selecting treatment providers without vested interests in a specific intervention, training treatment providers according to a standardized process, or assuring a specific level of training when recruiting providers can be used to assure sufficient equipoise
	1	Minimal attention was directed either in methods or discussion to the potential for treatment provider biases, but no inherent opportunity for bias was apparent

(continued on next page)

APPENDIX 2. (continued)

Question		*Descriptors*
No.	Score	
	0	No attention was directed at the potential for treatment provider biases and the opportunity for bias is evident, given the nature in which interventions were applied
15	2	A rationale was provided for the comparison group selected; when no specific intervention has previously been demonstrated to be effective, placebo is an appropriate comparitor; a comparitor group that has previously been shown to be effective or is commonly considered as acceptable standard of care is also appropriate
	1	A rationale for the comparison group was not established
	0	No comparison group was included
		Outcome
16	2	A primary outcome measure, which represented important clinical outcomes, was selected and supported by evidence of appropriate psychometric properties (reliability, validity, responsiveness)
	1	A relevant primary outcome measure was evident, but was insufficient in either its clinical relevance or its psychometric properties
	0	A primary outcome was not evident or was inappropriate, because it was irrelevant or methodologically unsupported
17	2	Appropriate secondary outcome measures were identified that augmented the perspective provided by the primary outcome measure, ensuring a comprehensive view of outcomes was obtained; and these secondary outcome measures had sound psychometric properties
	1	Secondary outcomes were considered, but were not identified as being secondary or were deficient either in terms of their relevance or methodologic properties
	0	Appropriate secondary outcomes were not considered
18	2	Patients were followed at important time points that provided an indication as to the early response and longer-term outcomes achieved; these time points were sufficient to support a clear definition of the relative value of the intervention over a clinically meaningful time period; a rationale and/or discussion of the appropriateness of these follow-up periods was included
	1	At least one relevant follow-up evaluation was incorporated, but the study did include other important clinical time points or a rationale for the specific follow-up time
	0	The follow-up period was insufficient to establish the true outcome of the intervention
		Analysis
19	2	The statistical tests used to determine whether differences existed due to the intervention were appropriate and specifically related to their stated research objectives; the authors documented important elements on the statistical tests (software used, that statistical assumptions underlying tests were met, alpha levels)
	1	Test(s) of statistical difference was used, but were insufficient to describe whether statistical differences occurred because of treatment; or there was insufficient documentation of the specifics of the analyses performed
	0	Statistical tests were not performed or those selected were not appropriate to the research question or data collected
20	2	Power was established; a justified sample with significant statistical difference is one indication of this; if statistical differences were not obtained, a post-hoc power analysis was conducted and identified that the study was appropriately powered
	1	The sample size was substantial, but post-hoc power analyses were not conducted in response to nonsignificant results
	0	The sample size was small and post-hoc power analyses were not conducted in response to nonsignificant results
21	2	The authors appropriately conveyed both the statistical significance and size of the treatment effect when reporting the results. This could be indicated by the inclusion of p-values and the associated confidence intervals, presenting effect sizes, or other similar statistical methods
	1	Statistical significance of the outcomes achieved by the intervention group were described (means and p-values), but no quantitative description of the confidence intervals/effect sizes of these differences was presented
	0	Descriptive, statistical information on the size of the treatment effects was not reported
22	2	1) complete data collection was achieved on all subjects or 2) a specific described strategy for handling missing data was documented and when missing data occurred in more than 10% of cases, a specific analysis was conducted to determine the impact of missing data management
	1	Missing data was not an apparent issue, but the exact protocol for handling missing data was not adequately described
	0	Missing data may have been an issue and the protocol for handling missing data was not adequately described
23	2	The authors fully addressed clinical significance by relating the observed differences to that required for clinically important change (or minimally important significant differences) and described practical issues such as specific training or equipment required to achieve the effects described in the study

(continued)

APPENDIX 2. (continued)

Question		*Descriptors*
No.	Score	
	1	The relevant issues on the clinical and practical significance were addressed in the discussion of the study results but documented in relation to specifically established criteria (certifications of treatment provider's or established minimally/clinically important differences)
	0	Clinical and practical significance were not considered when interpreting the results
		Recommendations
24	2	Specific conclusions and clinical recommendations made by the authors directly related to the objectives of the study, the specific analyses conducted, and results of those analyses. Recommendations do not 1) ignore observed results, 2) overstate their generalizability/clinical application, or 3) state that the treatment is ineffective when there was insufficient power to establish this was the case
	1	Conclusions and clinical recommendations are either incomplete or generalize beyond the domain of the study or the results actually obtained
	0	Conclusions and/or clinical recommendations were not founded on the results of the study or contradict findings of the study

Appendix C

Treatment of oedema published systematic review

Journal of Hand Therapy 30 (2017) 432–446

Contents lists available at ScienceDirect

Journal of Hand Therapy

journal homepage: www.jhandtherapy.org

JHT Read for Credit Article #504.
Scientific/Clinical Article

Effectiveness of edema management techniques for subacute hand edema: A systematic review

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ARTICLE INFO

Article history:
Received 2 December 2016
Received in revised form
27 April 2017
Accepted 24 May 2017
Available online 12 August 2017

Keywords:
Edema
Compression
Hand therapy
hand
Treatment
Kinesiology tape

ABSTRACT

Study Design: Systematic review.
Introduction: Prolonged hand edema can have detrimental effects on range of motion and function. There is no consensus on how best to manage traumatic subacute edema. This is the first systematic review which examines the clinical effectiveness of edema treatments on hand volume.
Purpose of the Study: The purpose of this systematic review was to examine the evidence of effectiveness of treatments for sub-acute hand edema.
Methods: A literature search of AMED, CINAHL, Embase, and OVID MEDLINE (from inception to August 2015) was undertaken. Studies were selected if they met the following inclusion criteria: randomized controlled or controlled trials in adults who have subacute swelling after a recent upper limb musculoskeletal trauma or cerebral vascular attack or after surgery. Two independent assessors rated study quality and risk of bias using the 24-point MacDermid Structured Effectiveness Quality Evaluation Scale (SEQES).
Results: Ten studies met the inclusion criteria. Study quality ranged from 23 to 41 out of 48 points on the SEQES. A total of 16 edema interventions were evaluated across the studies. Due to heterogeneity of the patient characteristics, interventions, and outcomes assessed, it was not possible to pool the results from all studies. Therefore, a narrative best evidence synthesis was undertaken. There is low to moderate quality evidence with limited confidence in the effect estimate to support the use of manual edema mobilization methods in conjunction with standard therapy to reduce problematic hand edema.
Conclusion: Manual edema mobilization techniques should be considered in conjunction with conventional therapies, in cases of excessive edema or when the edema has not responded to conventional treatment alone; however, manual edema mobilization is not advocated as a routine intervention.
Level of Evidence: 2h.

Introduction

The management of edema is a constant challenge for hand therapists where the objective is to reduce swelling as effectively and quickly as possible to focus therapy on more functionally related goals, such as return to usual activity. "Edema is glue"[1] highlights the challenges of balancing the physiological healing process after injury with the need to maintain and restore soft tissue length, function and joint motion.

Prolonged swelling has an impact on joint range of motion, soft tissue mobility, quality of scar tissue formation, function, strength, and esthetics of the hand. These factors may delay a patient's recovery, return to work and resumption of activities of daily living and require frequent or increased outpatient appointments. Hunter and Mackin[2] advocate a comprehensive therapy program to manage edema tailored to the individual needs of the patient and comprising a combination of evidenced-based interventions. "The

Conflict of interest: All named authors hereby declare that they have no conflicts of interest to disclose.

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0894-1130/
http://dx.doi.org/10.1016/j.jht.2017.05.011

prevention and treatment of edema are of paramount importance during all phases of management of the injured hand."[2]

The most commonly used conventional treatment techniques in this phase include massage, elevation, exercise, and compression. Compression for hand edema is usually achieved through lycra gloves which exert around 35 ± 5 mmHg pressure on the tissues of the hand.[3] The garment acts as an external counter pressure[4] which compensates for the inelasticity of edematous tissues, and, therefore improves circulatory efficiency by facilitating venous and lymphatic flow.[3]

Elevation permits gravity to assist with the drainage of edema from the distal limb.[5] Elevation alone[6] is not effective in reducing edema, but is recommended in combination with other modalities. Massage involves a "retrograde" action traditionally done in a distal to proximal direction. This technique uses a moderate force "milking" action but is considered too aggressive for the delicate lymphatic system to cope with and has recently been questioned.[5]

Recent evidence suggests that massage needs to be much lighter with only minimal pressure to traction the skin.[7] It should start and end proximally to clear lymph channels proximally and make way for fluid distributed distally. This technique referred to as manual edema mobilization (MEM)[7] is complimented with other methods aimed to assist with the facilitated direction of lymphatic flow which include low-stretch bandaging and a home exercise program. MEM massage does not involve pressure and in effect is more of a stroking action where the hand is brushed across the skin with only enough force to gently drag on the skin to the point at which it creases. Evidence suggests that a pressure of less than 30 mm Hg is sufficient, greater than 60 mmHg can cause damage to the lymphatics,[8,9] and at 75 mmHg, single cell lymphatic capillaries are completely collapsed.[9]

Active exercises which enable tendon gliding and muscular contractions can act as a pump which will assist with the flow of edema away from the periphery. Exercises can be completed in conjunction with other techniques to maximize the benefit; however, in certain circumstances, depending on the nature of the injury and/or surgery, the patients' hand movements are restricted based on healing timeframes and, if unable to use other techniques, this immobilization or restricted movement phase can have a detrimental effect of edema control.

Many of the advances in the management of edema after trauma are based on the research completed on lymphedema. Manual edema mobilization (MEM), which was introduced in 1995 as a method to reduce subacute and chronic hand and arm edema, has been adapted from the principles of manual lymph drainage (MLD) which is used to treat postcancer lymphedema.[10,11]

MEM, according to Artzberger,[10] consists of massage in a proximal to distal then distal to proximal direction, exercises, pump point stimulation, a home exercise program, and low-stretch bandaging. Kinesiology tape and myofascial release can also be used where necessary as a tissue softening method. In current practice, potential issues arise with interchanging terminology and a lack of awareness of the differences between the components of each technique.

Kinesiology tape, which can be used as part of the MEM program but also as an adjunct to the more traditional techniques, is designed to mimic the elastic properties of the skin by lifting the skin to allow greater interstitial space and encourage lymphatic drainage. In contrast to the traditional compression method which, using a glove and/or retrograde massage, is designed to push the fluid proximally into the venous and lymphatic system.[12] The tape is said to be unique in that it mimics the elastic properties of the skin and its wave-like grain provides a pulling force to the skin creating more space by lifting the fascia and soft tissues under the areas where it is applied.[13]

The benefit of using it in the hand, unlike an edema glove, is that it leaves most of the skin surface free for sensory feedback which is essential for functional use. It can also be worn in water. As the tape is elastic and stretches up to 55%–60% of its length it also allows for unrestricted movement.[13,14] Kinesiology tape is becoming more popular for hand edema management and is already widely used in National Health Service clinical practice; however, there is no research evidence to suggest that it is effective in treating edema[14–16] in the hand and there is limited understanding of its mechanism of action.[17] As with some of the previous techniques mentioned, most of the research on kinesiology tape is also focused on its use in lymphedema[18] where it has been shown to be effective. Given that lymphedema is a permanent and irreversible overloading of the lymphatic system, it is plausible that its mechanism of action may be similar to subacute edema where there is only a temporary overloading of the lymphatic system.

Purpose of the study

The purpose of this systematic review was to examine the evidence of effectiveness of a range of hand edema treatments on hand volume.

Methods

We conducted a systematic review using PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-analysis) recommendations (http://www.prisma-statement.org/index.htm).[19] The review protocol was registered prospectively on PROSPERO (CRD42015026836) http://www.crd.york.ac.uk/PROSPERO.

The following electronic databases were searched: the Cochrane Library (Wiley InterScience), MEDLINE (via Ovid), Embase (via Ovid), AMED (via Ovid), CINAHL (via EBSCO), SPORTDiscus (via EBSCO), PEDro (Physiotherapy Evidence Database), Allied Health Evidence, trial registers: Cochrane (Central Register of Controlled Trials) [CENTRAL] and the WHO (International Clinical Trials Registry Platform) from inception to August 2015. Search terms included: *EDEMA THERAPY/, exp EDEMA/TH [TH—Therapy], (hand ADJ edema).ti,ab, (edematous ADJ hand).ti,ab, *CRYOTHERAPY/, *RADIUS FRACTURES/, *FINGERS/, *HAND/, *WRIST/ OR *WRIST JOINT/, [Limit to: (Language English) and (Age group Adult) and Humans].

Additional references were searched for by examining the reference list of retrieved studies.

Eligibility criteria

Criteria for inclusion were English language, randomized controlled trails (RCTs) or controlled trials of adult participants with subacute swelling, after a recent upper limb musculoskeletal, hemiplegic stroke, or after surgery (ie, orthopedic and plastic). Active treatment must have occurred during the subacute phase. Subacute refers to swelling which is present after the initial acute inflammatory phase of ~3-5 days and which persists into the fibroblastic phase between 2 and 6 weeks after trauma. Outcomes had to be assessed using a clinician derived measure of volume.

Studies were excluded if they used animals or humans where edema was investigated at an organ or cellular level. Studies using participants where edema was due exclusively to pregnancy or which only measure acute edema (day 0-14 after surgery or trauma) or chronic edema (around 3 months after surgery or trauma) were also excluded. Studies which only used a medicinal product or invasive methods to treat the edema (such as cortisone injection and anti-inflammatory drugs) were also excluded.

Data extraction

Extracting data from the included studies was done by the lead author (L.M.) using a purpose-designed standardized data extraction form. This form summarized details on study design, sample, interventions, outcomes, and results. On occasions when there was doubt over the interpretation of the data being extracted, a second reviewer (C.J.H.) also completed the data extraction independently using the same form to verify understanding and clarity of extracted data.

Assessment of methodological quality

Each included study was assessed for quality using the guidelines developed by MacDermid in the Structured Effectiveness Quality Evaluation Scale (SEQES).[20] The scale consists of 24 items

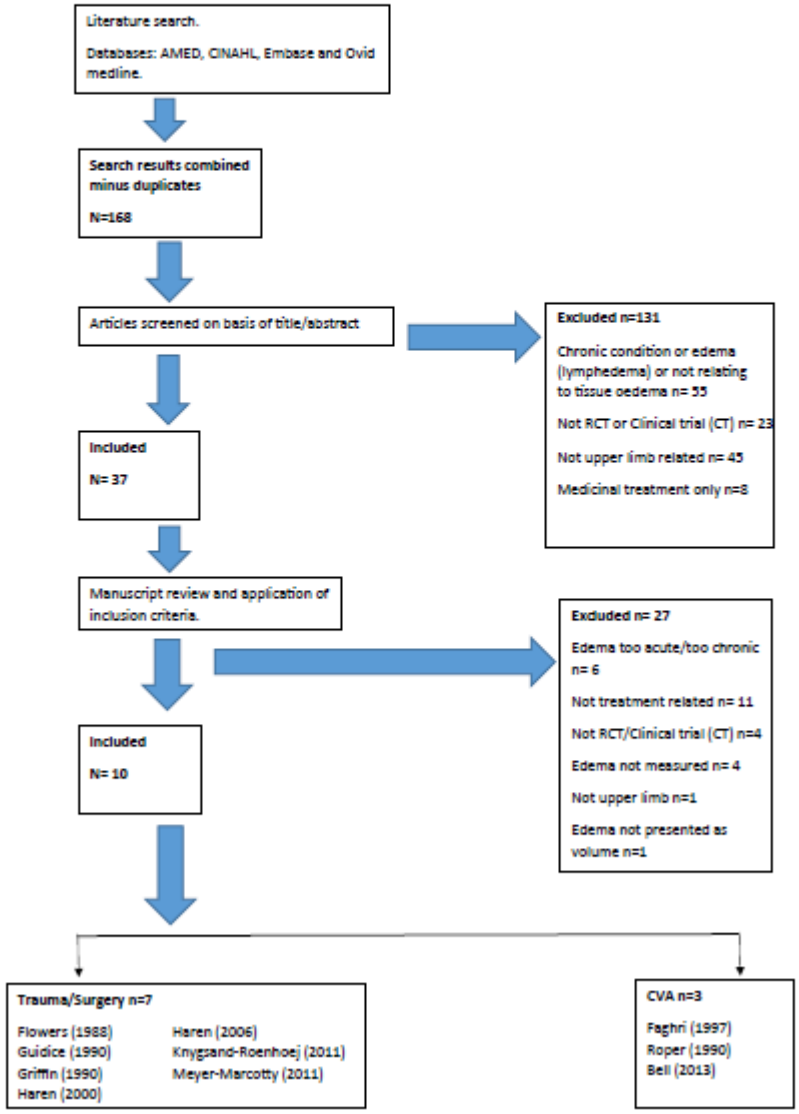

Figure 1. PRISMA flow diagram. PRISMA = Preferred Reporting Items for Systematic Reviews and Meta-analysis; RCT = randomized controlled trial; CT = clinical trial.

Table 1
Quality assessment scores (SEQES and GRADE)

Patient pathology/author	Study question	Study design						Subjects				Intervention			Outcomes			Analysis					Recommendations	Total (48)	GRADE score
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24		(4)
Trauma/surgery																										
Knygsand-Roenhoej (2011)	2	2	2	2	1	1	1	2	1	2	2	2	2	1	2	2	2	2	2	1	2	2	1	2	41	3
Haren (2006)	2	1	2	2	1	1	1	1	2	2	2	2	1	1	2	2	0	2	1	0	1	2	1	2	34	2
Griffin (1990)	2	2	2	2	1	1	1	0	1	1	0	2	2	1	1	2	0	1	2	0	1	1	1	2	29	1
Haren (2000)	2	2	1	2	1	1	1	1	2	1	0	0	2	1	1	2	0	2	0	0	2	1	0	2	28	1
Meyer-Marcotty (2011)	1	1	2	2	1	1	1	0	0	1	2	2	1	1	1	1	1	2	2	2	1	0	0	1	27	1
Guidice (1990)	2	2	2	2	1	1	1	0	0	1	0	2	1	1	1	2	1	0	1	0	1	1	1	2	26	1
Flowers (1988)	2	2	2	1	1	1	1	0	0	0	0	1	1	1	2	2	0	1	2	0	0	1	1	1	23	0
CVA																										
Faghri (1997)	2	2	2	2	0	1	1	0	1	2	0	2	2	2	2	1	0	1	2	0	1	2	1	2	30	1
Roper (1999)	2	2	2	2	1	1	1	2	2	2	0	1	1	1	1	1	2	1	1	0	1	0	1	1	29	1
Bell (2013)	2	2	2	2	2	0	1	2	2	2	0	0	1	0	1	1	1	1	1	0	1	0	1	2	26	0

Study question
1. Was the relevant background work cited to establish a foundation for the research question?
Study design
2. Was a comparison group used?
3. Was patient status at more than 1 time point considered?
4. Was data collection performed prospectively?
5. Were patients randomized to groups?
6. Were patients blinded to the extent possible?
7. Were treatment providers blinded to extent possible?
8. Was an independent evaluator used to administer outcome measures?
Subjects
9. Did sampling procedures minimize sample/selection biases?
10. Were inclusion/exclusion criteria defined?
11. Was an appropriate enrollment obtained?
12. Was appropriate retention/follow-up obtained?
Intervention
13. Was the intervention applied according to established principles?
14. Were biases due to the treatment provider minimized (ie, attention and training)?
15. Was the intervention compared with the appropriate comparator?
Outcomes
16. Was an appropriate primary outcome defined?
17. Were appropriate secondary outcomes considered?
18. Was an appropriate follow-up period incorporated?
Analysis
19. Was an appropriate statistical test(s) performed to indicate differences related to the intervention?
20. Was it established that the study had significant power to identify treatment effects?
21. Was the size and significance of the effects reported?
22. Were missing data accounted for and considered in analyses?
23. Were clinical and practical significance considered in interpreting results?
Recommendation
24. Were the conclusion/clinical recommendations supported by the study objectives, analysis, and results?
Total quality score (sum of above/48)

CVA = cerebral vascular attack; GRADE = Grading of Recommendations Assessment, Development and Evaluation.
GRADE score: high = 4/4, moderate 3/4, low 0-2/4.
Arranged in pathology subheadings and score from highest to lowest.

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Table 2
Summary of studies

Author/ date	Study design	Patients	Outcomes measured	Experimental intervention	Control	Timing of follow-up	Results		Conclusion
Trauma/surgery									
Knygsand-Roenhoej (2011)	RCT	Patients with unilateral postdistal radius fracture, treated with POP/internal or external fixation with subacute edema 4-10 wk after trauma/ surgery and with a 60 mL+ in volume difference between the upper extremities (n = 30)	1). Volumeter. standardized volumeter protocol recommended by the ASHT with 2 modifications: water temperature 23°-24° and patients were standing 2). AROM-PV distance (average of D2-D5) and thumb opposition 3). Pain using VAS 4). ADLs using custom designed questionnaire of bilateral activities and structured interviews 5). Perceived performance and satisfaction using the COPM (2+ change = clinically important)	Isotoner glove (25-35 mmHg pressure) full time (except for hygiene and massage), regular therapy: ROM/ strengthening HEP MEM: deep diaphragmatic breathing, exercises (proximal to distal), terminus stimulation, axillary stimulation (unimvolved side first), MPP stimulation to involved upper extremity, light skin traction in "U" shape massage, low stretch bandage system (if needed), exercising, and exercising during massage	Elevation Compression: Coban (digits to proximal wrist) Functional retraining solitaire in elevation for 10 min + regular therapy (ROM/ strengthening) + Flowtron intermittent compression system for 20 min. Isotoner glove (open fingers) night only (25-35 mmHg pressure)	1,3,6,9, and 26 wk after inclusion in study.	Pretreatment modified MEM group (n = 14) mean (95% CI) 86.8 (73.0-100.6) Control group (n = 15) 96.3 (83.0-109.7)	Posttreatment (9 wk) modified MEM group: 12.1 (0.2-24.1) Control group 28.3 (16.8-39.8)	Tendency for MEM group to receive 20% fewer OT session (edema and other treatments) than the control group, however not SS (P = .13) Either approach is satisfactory (statistically significant difference in edema reduction between inclusion and the last follow-up in both groups), however, as the MEM group had fewer sessions, this is recommended for subacute edema
Haren (2006)	RCT	Patients with distal radius fracture treated with plaster or external fixation with edema of hand and wrist of more than 40 mL difference between volume of uninjured and injured hand (using volumeter) (n = 51)	Volumeter with water heated to room temperature. Uninjured hand measured first. Hand dominance estimated to be 3.43% larger than nondom hand according to standard techniques. All other edema measurements were made on injured hand and compared to pretreatment volume of injured hand.	First 6 treatments included 40 min of MLD in additional to conventional treatment of elevation, active and resistive exercises (hand and wrist), and compression (edema glove-night and day until first measurement) Verbal and written instructions (HEP) Encouraged to use hand as much as possible.	Conventional treatment of: elevation, active and resistive exercises (hand and wrist), and compression (edema glove-night and day until first measurement) Verbal and written instructions (HEP) Encouraged to use hand as much as possible.	Second measurement 60 d after inclusion (49-71) for experimental group and 56 d (32-63) after inclusion for control group	Pretreatment experimental median normal size before trauma 545 mL (95% CI: 372-595) Control median normal size before trauma 453 mL (95% CI: 343-637)	Posttreatment experimental first measurement median decrease in injured hand 30 mL (95% CI: 10-55) Control median decrease in injured hand: 20 mL (95% CI: − 10 to 45) Second measurement experimental median decrease in injured hand: 40 mL (95% CI: 10-90) Control median decrease in injured hand 35 mL (95% CI: 15-80) Statistically significant difference in edema reduction with a large overall reduction in the experimental group at the first measurement (P = .005) At second measurement, a greater reduction was seen in the experimental group, but this was not statistically significant.	Study supports the use of MLD as complimentary to conventional therapy when there is excessive edema

Griffin (1990)	RCT	Patients with trauma to 1 upper extremity at least 2/52 before study participation and with clinically significant (visually detectable swelling of sufficient magnitude to be considered a problem) hand edema judged by 1 PT. ($n = 30$)	Volumeter (mL) measured in affected and unaffected sides before rest. Ten-min rest with the arm at heart level and patient seated. In second measurement, 30-min treatment, then third volumetric measurement of affected hand.	High-voltage pulsed current (HVPC); $n = 10$. One electrode over MN, other over UN, and dispersive electrode over dorsolumbar region of back. Intensity adjusted to produce observable and maintainable muscle contracture of FPL/FPB and dorsal lumbricals, 8 (twin) pulses per second alternating between 5 s of UN and 5 s of MN.	In placebo HVPC, dispersive electrode was disconnected without the subject's knowledge	Posttest (10 min) and posttreatment (30 min) measurements	Before rest: Placebo HVPC: In unaffected hand: 512.2 (SD = 104.1) And in affected hand: 573.1 (SD = 111.2) HVPC: In unaffected hand: 507.3 (SD = 54.2) and in affected hand: 553.7 (SD = 75.0) IPC: In unaffected hand: 503.8 (SD = 82.9) And in affected hand 557.4 (SD = 92.4)	After rest: Placebo HVPC: 572.1 (SD = 109.9) HVPC: 553.3 (SD = 73.8) IPC: 558.4 (SD = 92.1)	After Rx: Placebo HVPC: 570.8 (SD = 109.5) HVPC: 547.0 (SD = 73.0) IPC: 550.7 (SD = 92.1)	No change occurred after rest period therefore concluded that patient activity before session did not affect measurement. Wide variability in HVPC and IPC in amount of posttreatment change 0-15 mL hypothesis rejected. Pretest and postrest hand volumes in 30 subjects are not significantly different (Wilcoxon test $P = .761$) Mean change between before and after rest = 0.13 mL (−3 to 8) Posttreatment volume: KW test significant difference between IPC, placebo and HVPC groups ($P = .011$) Wilcoxon rank-sum significant difference between IPC and placebo ($P = .004$) No significant difference between placebo and HVPC ($P = .446$) Difference between HVPC and placebo HVPC did not reach statistical significance ($P = .036$)
Haren (2000)	RCT	Patients with distal radius fractures requiring an external fixator ($n = 26$)	Volumeter (4 measurements) difference in volume calculated in mL between uninjured and injured. Water of room temperature	Ten MLD treatments: light surface massage proximal to distal + elevation, active, passive exercises, and compression with elastic bandages (Elastomull) during	Elevation, active, passive exercises, and compression with elastic bandages (Elastomull) during ex-fix period then tubigrip or isotoner glove after removal of ex-fix. The use of	3, 17, 33, and 68 d after removal of external fixator	Experimental group mean (SD) differences between volume measures (mL) of injured and uninjured hand in d 3: 39 (SD = 12); d 17: 27 (SD = 9); d 33: 19 (SD = 9); d 68: 12 (SD = 11) 95% CI mean differences	Control group mean (SD) differences between volume measures (mL) of injured and uninjured hand in d 3: 64 (SD = 41); d 17: 50 (SD = 35); d 33; 35 (SD = 26); d 68: 24 (SD = 20)		Edema treatment should be initiated during early fracture healing Patients in MLD group will have less edema at an earlier posttraumatic stage compared with conventional

(continued on next page)

Table 2 (continued)

Author/ date	Study design	Patients	Outcomes measured	Experimental intervention	Control	Timing of follow-up	Results		Conclusion
				ex-fix period then tubigrip or isotoner glove after removal of ex-fix. The use of hand encouraged as much as possible, verbal instructions and written program for HEP.	hand encouraged as much as possible, verbal instructions and written programme for HEP.		between groups in d 3: 0.6-49.5; d 17: 2.2-43.4; d 33: −0.3 to 31.5; d 68: − 1.0 to 24.2 A significant difference in hand volume, with a lesser degree of edema in the group treated with MLD, was recorded at the first 2 measurements. Probability at the first measurement was $P = .04$ ($n = 26$), second measurement was $P = .1$, and at fourth measurement was $P = .2$		treatment, which reduces risks of edema-associated complications. MLD not proposed for all patients with hand edema after #DR but as complementary to conventional treatment when edema is troublesome
Meyer-Marcotty (2011)	RCT	Patients undergoing elective wrist arthroscopy for TFCC lesions, intracarpal ligament ruptures, and/or damage to the wrist cartilage ($n = 54$)	1). Pain VAS (0-10) + pain diary 2). ROM (extension, flexion, radial and ulnar deviation, and pro/supination) using goniometer. Overall global ROM = summation of 3 different directions of motion measured from dorsum of wrist. 3). Water displacement with volumeter. Displaced water collected and expressed in mL. Water temperature 28°. 4). DASH 0-100 score.	10 min of cooling-compression period before sterile of arm. Cryo-Cuff applied to operated wrist, 30 mmHg pressure. 3 × 10 min for 22 d (at least twice daily)	Apply cryotherapy of either mode (cool packs or crushed ice) wrapped in a towel to operated wrists. No interval or frequency given just PRN.	D 1, 8, and 21 after arthroscopy	Volume of wrist and forearm tended to be lower in experimental group from preop to d 1: 967 ± 24 to 932 ± 34 mL (not SS) The control group had slight but not significant increase in volume: 890 ± 36 to 912 ± 38 mL. Volume unchanged from preop to d 21 (not SS); in experimental: 967 ± 24 vs 954 ± 25 mL and in control: 890 ± 36 vs 905 ± 33 mL.		No difference between both study groups in terms of volume change over time. No significant effect on hand volume, pain, ROM or DASH scores between groups over a 3-wk period.
Guidice (1990)	Crossover trial	Patients with upper extremity injury/ surgery more than 4 wk ago or 4/52 after onset of upper extremity paresis ($n = 16$)	1). Circumferential measures (mm) of proximal phalanx of most visibly edematous finger 2). Finger stiffness determined by PROM of MCPJ flexion using goniometer and 200 g constant force gauge applied for 5 s 3). Volumeter (mL),	Elevation and 30 min of continual passive motion. Extension and flexion of D2-5 Wrists supported with universal wrist splint provided with CPM machine during treatment	Elevation alone (30 min) supine on flat surface, limb maintained on stand at 30° shoulder abduction, 30° shoulder flexion, and 70° elbow flexion. Wrists supported with universal wrist splint provided with CPM	Immediately after treatment	Elevation alone: Change score (SD)/% change (SD): 1) 0.6 mm (0.6)/0.8 mm (0.8) 2) 6.1 mL (9.5)/1.1 mL (1.8) CPM with elevation resulted in a significantly greater reduction of hand edema than elevation alone. Sequence effects were not significant for	CPM with elevation: Change score (SD)/% change (SD): 1) 1.4 mm (0.9)/1.9 mL (1.2) 2) 14.5 mL (8.4)/27 mL (1.6)	Measures of edema that were reduced following CPM and elevation generally returned to pretreatment level within 24 h. The greater the time after onset the greater treatment effect. The greater the amount of pretreatment

			average of 2 successive volumetric measures of affected hand		machine during treatment		measures of hand volume and finger circumference. Small-to-moderate (0.2 and 0.3) +ve relationship (between treatment outcome and time after onset) for reduction in hand volume following elevation alone. Almost no relationship was found for hand volume and finger circumference following CPM with elevation or finger circumference following elevation alone. Moderate-to-large +ve relationship (0.4 and 0.5) (between treatment effect and amount of pretreatment edema) for hand volume and finger circumference with CPM and elevation		edema, the greater the treatment effect. 30 min of CPM with limb elevation resulted in a significantly greater reduction in hand edema than 30 min of elevation alone. Findings for total group similar to subgroup analysis of CVA ($N = 11$) group suggest that CPM with elevation is an effective treatment to reduce hand edema for patients with hemiplegia after CVA
Flowers (1988)	Crossover trial	Patients with generalized hand edema due to hand or wrist injury, surgery, pregnancy, or venous stenosis ($n = 14$)	Circumferential measurement at the middle level of the PIPJ using a Jobst tape measure. PIPJs were marked with a fine-tip pen before each treatment. Proximal edge of tape measure placed over pen mark. PIPJs held in comfortable end of range extension	A). Traditional retrograde massage: Stroke distal to proximal over entire length of affected digit with a firm milking action using baby powder as lubricant. Continuous strokes for 5 min B). String wrapping: Coiling #36 ball twine around digit from nail bed to web space. Each successive loop placed directly next to preceding loop with no gaps for 5 min. Snug but not tight C). String wrapping with continuous superimposed retrograde massage: Apply string wrapping as in (B) with (A) performed over the string for 5 min D). String wrapping with intermittent superimposed retrograde massage: Massaging the string wrapped digit for 20 strokes. String wrapping removed rapidly and reapplied immediately and followed by another 20 strokes for 5 min		Immediately after treatment	Average circumferential reductions (%) A) Retrograde massage: 1.35% B) String wrapping: 1.74% C) Continuous massage with string-wrapped digits for 5 min: 3.46% D) Intermittent massage of string wrapped digit for 5 min: 2.95% No significant difference between string wrapping and retrograde massage. ANOVA showed a significant difference existed between treatments ($P \leq .001$) Wilcoxon test significant differences between the 4 techniques, except between A and B. C > A ($P = .01$) D > B ($P = .01$) C > D ($P = .05$) First digit treated showed greatest circumferential reduction Order of digit treated had no significant bearing on outcome		A combination of string wrapping with intermittent retrograde massage is consistently more effective in reducing circumferential edema in digits than either massage or wrapping alone
CVA									
Faghri (1997)	CT	Patients with visible hand edema after CVA (less than 6/12 ago) ($n = 8$)	1). Volumeter: Average of 3 successive measures (mL) of affected hand/forearm 2). Circumferential girth measures of	Neuromuscular stimulation + usual activities including treating edema. Frequency 35 Hz to create reciprocal activity of flexors and extensors of	Elevation + usual activities including treating edema. Thirty minutes of elevation in a standardized position previously recommended by	Immediately after treatment	Mean change scores: NMS: Hand volume (mL): −13.38 (SD = 2.03) Arm volume (mL): −32.63 (5.83) Lower arm girth (mm): −8.75 (1.26)	% change scores: NMS: 2.64% (SD = 0.53) 1.97% (0.45) 3.88 (0.58) 2.63 (0.64) Elevation: 1.89 (0.67)	In 8 subjects, 30 min of NMS is more effective than 30 min of elevation Measures of edema that were reduced following 30 mins of NMS returned to

(continued on next page)

Table 2 (*continued*)

Author/ date	Study design	Patients	Outcomes measured	Experimental intervention	Control	Timing of follow-up	Results		Conclusion
			upper and lower arms using flexible tape measure	lower arm. Ten-second action of wrist and finger flexors, 10-s action of wrist and finger extensors, and 10-s rest. Total treatment time: 30 min	other investigators as most effective and comfortable: lay supine, 30° shoulder abduction, 30° shoulder flexion, and 70° elbow flexion.		Upper arm girth (mm): −7.50 (1.65) Elevation: Hand volume (mL): 1.88 (3.90) Arm volume (mL): 26.5 (9.81) Lower arm girth (mm): 1.30 (2.29) Upper arm girth (mm): 1.25 (2.29)	1.35 (0.51) 0.63 (0.95) 0.35 (0.77)	pretreatment levels within 24 h No carry over effect (sequence/d of treatment) for NMES/elevation
Roper (1990)	RCT	Patients with a first ever hemisphere stroke (WHO criteria) and edema of hemiparetic hand (>20 mL volume in stroke hand compared with unaffected hand after 2 readings, 1 wk apart) ($n = 37$)	1). Volumeter (device made for study, not a standardized tool) average of 3 measurements taken from both hands. 2). Motricity Index	Intermittent pneumatic compression + standard physiotherapy. 50 mm Hg applied with a 30-s inflation and 20-second deflation cycle in 2 sessions of 2 h a day for 1 mo	Standard physiotherapy (pragmatic) included positioning and passive movements.	Weekly during a 4-wk treatment period	Pretreatment Mean volume (affected hand −unaffected hand): Experimental: 52.7 mL ($SD = 27.2$) Control: 68.7 mL ($SD = 23.7$) No change in experimental group in mean hand volume after treatment ($P = 1.0$) Nonstatistically significant decrease in mean hand volume of 3.2 mL ($SD = 33.2$) ($P = .69$) No statistically significant difference between the 2 groups ($P < .65$) T-test: treated group vs control group $P = .59$	Posttreatment mean volume (affected hand−unaffected hand) Experimental: 52.7 mL ($SD = 36.9$) Control: 60.5 mL ($SD = 32.7$)	Standard physio had a non-SS decrease in edema Edema can resolve spontaneously ($n = 17$, not eligible) Parameters of the compression machine were inadequate. IPC cannot be recommended at this pressure/ duration
Bell (2013)	RCT	Patients with hemiplegic stroke within the last 3/ 12 and presence of edema by visual inspection ($n = 17$)	1). Circumferential measurements of wrist and MCPJs using spring loaded Gulick anthropometric measuring tape 2). Upper limb portion of Fugl-Meyer Assessment (FMA). Total 66 points (higher score = better function)	Kinesiology tape with 20% stretch. Dorsal and volar application with buttonhole technique covering 2/3 of forearm for 6 d (replaced as/ when needed) + standard OT, PT, and SLT.	Standard physical, occupational, and speech and language therapy. Including positioning, active, and passive range of motion.	6 d after baseline.	Before treatment Experimental: Median MCPJ circumference (cm): 21.4 ($SD = 2.0$) Median wrist circumference (cm): 18.0 ($SD = 1.7$) Control: Median MCPJ circumference (cm): 20.7 ($SD = 1.7$) Median wrist circumference (cm): 17.8 ($SD = 1.5$) Experimental group showed a small reduction in MCP and wrist circumference measurements, greater results at MCPJ. Control group showed	After treatment Experimental: Median MCPJ circumference (cm): 0.5 ($SD = 0.65$); −0.1 to 2.2 Median wrist circumference (cm): 0.2 ($SD = 0.4$); 0 to 1.1 Control: Median MCPJ circumference (cm): −0.3 ($SD = 0.91$) −1.0 to 1.6 Median wrist circumference (cm): −0.1 ($SD = 0.57$); −0.5 to 0.8	8/9 patients (88%) had edema reduced in experimental group: 1 patient had increased edema. Median negative change in control group indicated edema worsened over the 6-d trial. ES of KT is smaller than those reported with NMES, CPM, and Lycra garments; however, KT is cheaper and quicker to apply

an increase in both areas. No statistical difference between the 2 groups for change at MCPJs (P = .111) or change at the wrist (P = .189)
A large effect size was seen at the MCPJ (0.8) and a medium ES at the wrist (0.7)

ANOVA = analysis of variance; AROM-PV = active range of motion-pulpa vola; ASHT = American Society of Hand Therapy; CI = confidence interval; COPM = Canadian occupational performance measure; CPM = continual passive motion; CT = controlled trial; CVA = cerebrovascular accident; DASH= Disability of the Arm, Shoulder and Hand; D/C = discharge; #DR = fractured distal radius; ES = effect size; FPB = flexor pollicis brevis; FPL = flexor pollicis longus; HEP = home exercise program; HVPC = high-voltage pulsed ultrasound; IPC = intermittent pneumatic compression; KT = Kinesiology tape; KW = Kruskal Wallis; MCPJ = metacarpal phalangeal joint; MCPs = metacarpal interphalangeal joints; MEM = manual edema mobilization; MLD = manual lymph drainage; MN = median nerve; MPP = manual pump point; NMS = neuromuscular stimulations; NMES = neuromuscular electrical stimulation; OT = occupational therapy; PIPJs = proximal interphalangeal joints; POP = plaster of Paris; PRN = per required need; PROM = passive range of motion; PT = physiotherapy; PV = pulpa vola distance; RCT = randomized controlled trial; ROM = range of motion; Rx = treatment; SD = standard deviation; SLT = speech and language therapy; SS = statistically significant; TFCC = triangular fibrocartilage complex; UN = ulnar nerve; VAS = visual analogue scale; WHO = World Health Organization.
Arranged in pathology subheadings and quality assessment score from highest to lowest.

covering study question, design, subjects, interventions, outcomes, analysis, and recommendations and uses a 0-2 ordinal rating scale with 48 points maximum. A score of 2 means that the criterion was fully met, 1 = partially met, and 0 = criterion not met. To assess for risk of bias, 2 blinded reviewers independently rated each study in accordance with the evaluation guidelines recommended by MacDermid.[20] This 24-item checklist covers 7 key components of risk of bias including adequacy of randomization and concealment of allocation, blinding of patients, health care providers and outcome assessors, extent of loss to follow-up, and analysis. Each of the 24 items has detailed descriptors, and scores can be summed into an overall score of methodological quality. Any disagreements between the reviewers were resolved by discussion.

The strength of the body of evidence was assessed using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) guidelines[21] which assesses the risk of bias, publication bias, imprecision (random error), inconsistency, and indirectness. This final score is based on scores from 4 categories of evidence: quality, consistency, directness, and effect size and indicates the level of confidence in the effect estimate: high = at least 4 points overall, moderate = 3 points, low = 2 points, and very low = one point or less. Low and very low categories can be combined and were done so in this systematic review.

The 10 studies were grouped according to patient population: patients with subacute edema as a result of a musculoskeletal trauma or surgery and patients with subacute edema as a result of a hemiplegic stroke. This formed the basis of how results were analyzed and reported in this systematic review.

Results

The initial search identified 168 articles for which titles and abstracts were screened. A total of 10 studies met the inclusion criteria (see PRISMA flow diagram in Figure 1) and were included in the review.

Quality scores ranged from 23 to 41 points out of 48 on the SEQES[20] and 0-3 on using the GRADE checklist.[21] Refer to Table 1 for quality assessment scores in rank order from the highest to lowest. The study characteristics of all eleven studies are summarized in Table 2.

Sample sizes ranged from 8 to 54 patients. There were a total of 361 participants across the 10 studies whose age ranged from 18 to 85 years.

A total of 16 interventions were described; these included kinesiology taping, massage (retrograde and intermittent), normal functional use, strengthening, MLD, MEM, elevation, high-voltage pulsed ultrasound, cryotherapy, neuromuscular stimulation (NMS), positioning/orthosis, active/passive exercises, and compression which was administered in numerous forms: string wrapping, isotoner glove, intermittent pneumatic, or Coban.

All studies used either circumferential measurements (in centimeters or millimeters) or volumetry (mL) to quantify volume.

Four studies[22-25] used the same method of analysis: mean volume of edema (mL), whereas some[26-28] used percentage change (mL and mm), other authors used a variety of mean difference, median decrease, and median circumference.

Only 3 of the 10 studies examined similar interventions.[22,29,30] They assessed the effectiveness of MLD/MEM vs standard treatment. Although the authors use different terminology, which in itself may not be an accurate representation of the techniques being used, they essentially comprised very similar techniques which include light massage (in a proximal to distal direction), some form of compression (low stretch bandages or a glove), elevation, exercises, and breathing techniques, hence why they have been grouped together during analysis.

These 3 studies also used the same outcome measure, the volumeter (mL), however used different methods of analysis (mean difference, median decrease, and mean volume) when expressing their outcomes. The combination of results for meta-analysis was not possible because of differences in the methods of reporting results or heterogeneity of interventions and outcomes assessed.

Interventions

Summary findings for individual studies are presented under 2 headings according to the patient type (trauma/surgery or cerebrovascular accident [CVA]) and listed from highest to lowest quality within these headings, as assessed by SEQES and GRADE scores. For full study details and results, refer to Table 2.

Evidence on edema techniques after trauma and surgery

MEM + conventional therapy vs conventional therapy[22]

Both groups had a statistically significant difference in edema reduction between inclusion in the study and penultimate follow-up (9 weeks); however, there was no statistically significant difference in any outcomes between the groups.[22] In light of this, therefore, authors conclude that using conventional therapy with or without the addition of MEM is satisfactory in treating edema; however, as the MEM group had 20% fewer sessions (not statistically significant $P = .13$) than the control group who had conventional therapy alone, this is recommended for subacute edema. The interventions were well described with the use of 2 independent therapists performing the treatment and 2 blinded assessors conducting the outcome measures.

MLD + conventional therapy vs conventional therapy alone[30]

Both groups had a reduction in edema after treatment. A statistically significant difference in edema reduction was seen with a large overall reduction in the experimental group at the first measurement ($P = .005$).[30] At the second measurement, a greater reduction was observed in the experimental group, but this was not statistically significant. The authors concluded that MLD should be used as complimentary to conventional therapy when there is excessive edema; however, there were limitations in this study such as post hoc subgroup analysis being performed, the lack of a secondary outcome, and failure to recruit their original target sample size of 82 patients. A sample size of 51 reduced the power from 90% to 73%; the confidence intervals were very wide indicating poor precision in their estimate, and therefore, their conclusion needed to be interpreted with caution.

High-voltage pulsed current (HVPC) vs intermittent pneumatic compression (IPC) vs placebo HVPC[23]

No significant difference was found between IPC and HVPC ($P = .446$), HVPC and placebo HVPC ($P = .036$), but a difference was seen between IPC and placebo HVPC ($P = .004$).[23] Overall, IPC gave the best result, with a 2%-3% reduction in edema from postrest values, however, without the effect estimates which were not documented these P values tell us very little about the strength of the effect and its clinical significance. One of the major flaws with this study was the lack of independent treatment provider and assessors. The same physical therapist administered all treatments and conducted all measurements.

MLD + conventional therapy vs conventional therapy alone[29]

Although the experimental intervention is called MLD, only massage is described which makes the use of this term misleading.[29] No inclusion or exclusion criteria were reported, no pretreatment measures were taken, and secondary outcomes were not considered. Inappropriate statistical testing was used which assumes a normal distribution (Kruskal-Wallis test instead of a Mann-Whitney test), and the lack of a sample size calculation reduces the reliability of the results and conclusions given. Patients in the MLD group were seen a mean of 3 additional times compared to the control group. The authors defend this as being necessary as they were adding MLD to conventional therapy and not trying to replace it, which may explain why they do not recommend MLD for all patients after fracture distal radius but as complementary to conventional treatment when edema is troublesome. The clinical significance is not adequately described.

Cooling compression vs cryotherapy[24]

There was no difference between groups in terms of volume change over time in this study.[24] A lack of reported detail prevented adequate comparison of baseline patient characteristics. The authors state that blinding assessors was not possible in this trial, however, as all patients will have had arthroscopy scars and could have removed the Cryo-Cuff or ice pack before their follow-up assessments on day 1, 8, and 21 after arthroscopy this could have minimized bias and improved the validity of this study. A sample size calculation was done based on a 20% difference in pain levels (primary outcome measure); however, inadequate analysis was performed for the secondary outcomes (volume change) as no effect size, P value, or confidence intervals were reported, and therefore, we are unable to assess if the study was adequately powered to identify treatment effects for edema reduction.

Elevation and continual passive motion vs elevation alone[27]

Continuous passive motion with elevation resulted in a significantly greater reduction of hand edema than elevation alone.[27] However, the reduction in edema in this group generally returned to pretreatment levels within 24 hours highlighting a limitation in their follow-up period. The use of an independent assessor was not reported, and a sampling or standardized enrollment was described with limited patient characteristics being made available, all of which could give rise to bias. This is the only study which had a mixed cohort of patients whose edema was from either a trauma/injury or paresis. Findings for the total group were similar to a subgroup analysis of the CVA group ($n = 11$) and although the authors suggests that continual passive motion and elevation is an effective treatment to reduce hand edema for patients with hemiplegia after CVA, the results do not support this given the very short term and reversible reduction in hand edema.

Retrograde massage vs string wrapping vs continuous massage and string wrapping vs intermittent massage and string wrapping[26]

This cross over trial failed to give adequate details on its study design and subjects and therefore scored the lowest in the quality assessments.[26] Although the treatment order and digit to be treated was randomized, the time between visits was not documented meaning we are unable to assess if an adequate "wash-out" period was given between each of the treatments. The lack of an independent assessor meant that the same therapist performed the treatment and administered the outcome measures. The authors chose to do a post hoc analysis which demonstrated a statistically significant difference ($t = 20$, $P = .05$) between continuous and intermittent massage (along with string wrapping), but size and significance of the treatment effects were not reported.

Evidence on edema techniques after CVA

NMS and usual activities vs elevation and usual activities[28]

Limited details regarding the study design meant we were unable to determine who issued the treatments and whether the

assessors were independent and blinded.[28] Although patients were not randomized to groups in this repeated measures study, the patients acted as their own control by receiving both treatments, therefore reducing the need for large sample sizes and homogeneity in patient characteristics such as age and severity of CVA. However, although the size and significance of the effects were reported, it was not established if the study has sufficient power. Both groups were instructed to carry out their usual activities which included treating edema. No details were given on these "other" edema treatments and whether they were standardized across both arms of the trial, and therefore, we are unable to ascertain whether the reduction in edema was purely due to the NMS.

Kinesiology tape and standard occupational therapy (OT) and physiotherapy (PT) vs standard OT and PT[31]

No sample size calculation was performed in this study and, as only 17 of the enrolled 25 patients had complete data, this loss to follow may have given rise to a type II error.[31] A qualified taping practitioner performed all taping on the patients, and 2 independent raters completed all outcome measures; however, there were no details on whether the treating therapists were blinded to the group allocation. To further reduce bias, a placebo or sham tape application could have been used in the control group, as despite using blinded raters they assessed the experimental group within 30 minutes of the tape being removed which, due to marks left on the skin, may have unblinded them.

Intermittent pneumatic compression and standard PT vs standard PT[25]

The main issues in this study relate to their analysis as it was not established that the study had significant power to identify treatment effects and the authors fail to give confidence intervals or effect sizes with the *P* values.[25] Although randomization was performed, limited detail was given on the precise method. Possible baseline differences were not adjusted in their analysis as the mean time since the stroke was nearly twice as long in the control arm and this group had more pretreatment edema (*t*-test $P = .59$); this could be a meaningful difference which may have confounded the results.

Discussion

This is the first systematic review of its kind to review the evidence on the effectiveness of conservative treatments for subacute hand edema in patients after trauma, surgery, or stroke.

Methodological quality

The overall quality of the 10 studies was low to moderate with most studies scoring consistently poor marks on 4 particular questions on the SEQES[20] relating to the lack of an independent evaluator to perform outcome measures, appropriate enrollment process, appropriateness of secondary outcomes, and sufficient power to identify treatment effects. Low scores were given when the study did not meet the criteria or where there was insufficient detail to make a judgment on that particular question.

Reporting quality

Poor reporting quality was a limitation of all the included studies. The level of detail recommended in the CONSORT 2010[32] statement's 25-point checklist was not adhered to by most of the included studies; however, 7 of the 10 studies were published before the Consolidated Standards of Reporting Trials (CONSORT) recommendations were introduced. This lack of transparency in the reporting affected our ability to adequately assess the validity of the results. In some cases, both the experimental and control interventions were not described in enough detail for them to be reproduced. The "black box" of rehabilitation is well documented[33–36] with the lack of reported detail on the components of treatments being one of the main methodological limitations of research studies in rehabilitation.

"Standard therapy/care"[25] and "usual activities"[28] were not described in sufficient detail to allow the reader to adequately understand the specific treatment that were being implemented or to differentiate between the experimental and control intervention.

Type I and II error

Seven of the 10 included studies did not document their sample size calculations so we were unable to establish if these studies had sufficient power to identify treatment effects. This may have increased the likelihood of type II errors occurring. The lack of randomization[28] and issues with blinding and/or independent assessors could also have given rise to type I errors.[24,26–28]

Heterogeneity of patients

Variations in patient characteristics within and between the 10 studies may have influenced the treatment effects and was one factor which limited comparisons as no stratification or subgroup analysis had been completed. Flowers[26] included pregnant women alongside patients with venous stenosis and after hand/wrist surgery. The differing etiology indicates that conditions such as water retention during pregnancy may be temporary, transient, and fluctuating, whereas patients with venous stenosis may have this condition due to a chronic thickening of the blood vessels secondary to trauma or external compression of the musculoskeletal system and that this may require surgical or pharmacological interventions.

Haren and Wilberg[30] included patients with external fixator 3–5 days after it had been removed. Patients with external fixators were left a mean of 47 days (experimental group) and 43 days (control group), whereas the external fixator was in place with no edema management in place. Patients treated with external fixators had this fixation on for an average of 13 days longer than those patients treated with plaster of Paris which meant the time from fracture to treatment start date was delayed. Although there was an equal distribution of plaster to external fixators in both groups, patients with external fixators may have had more, longer standing, and untreated edema which could have impacted on the success of the intervention.

Variations in interventions

Inconsistencies in how the same modality was delivered across studies, along with the issue of a lack of reported detail prevented appropriate comparison. Haren et al[29] and Flowers[26] both used massage as part of their experimental intervention; however, Flowers[26] used a one off 5-minute treatment, whereas Haren et al[29] used 10 sessions, but did not comment on the duration. In the study by Meyer-Marcotty,[24] the control group used cryotherapy either with cool packs or crushed ice to operated wrists. However, unlike the structured experimental group who were instructed to apply the Cryo-Cuff twice daily for 10 minutes, the control group had no stipulated frequency or duration. Although this "Per Required Need" approach may reflect real life, for the purposes of the research it would have been useful to document the control group

usage of cryotherapy to establish the effect of adding the regular compression element in the intervention group.

The details that were given for the interventions highlighted conflicting theories particularly relating to massage. Flowers[26] describes a "firm milking action" in a distal to proximal direction, whereas Haren et al[29] uses a "light surface massage" in a proximal to distal direction and Knygsand-Roenhoej and Maribo[22] complete "light traction massage" in a 'U' shape from proximal to distal. This difference may be due to advances in clinical practice since the 1980s when Flowers conducted his study and while "retrograde massage" is still used in clinical practice it has been adapted to a lighter action as opposed to a firm milking one which is thought to be too aggressive on the delicate lymphatic system.[37]

The interventions described by Haren et al[29,30] as MLD and Knygsand-Roenhoej[22] as modified MEM constituted a set of very similar techniques, however because of disparity in quality assessment scores, particularly between the 2 studies by Haren et al[29,30] they could not be analyzed together. Consistent terminology is required to avoid confusion and to ensure understanding of the interventions.

Length of follow-up

Follow-up ranged from immediately after treatment to day 68 after treatment (~9 weeks). Four of the 10 studies assessed edema immediately after the intervention,[23,26,28,29] and although some showed a statistically significant reduction in edema, this returned to pretreatment levels within 24 hours indicating that a longer term follow-up was required to see if the effects of the intervention have been maintained over time.

Strengths and limitations of the review

The strengths of the review include the specific inclusion criteria, the adherence to the PRISMA recommendations,[38] and a priori protocol publication on the PROSPERO Web site; however, this review also had a number of limitations. First, due to the lack of RCTs and controlled trials of edema management techniques in this specified population, older studies were incorporated with more recent ones using more current interventions, and therefore, comparison between techniques which have changed over time may indicate a limitation of including studies of any age in this systematic review. Despite the lack of comparability of included studies, this review serves as a baseline on this topic and a start point for future studies to improve on.

Conclusions

The review found limited low-to-moderate quality evidence to support the use of a combination of interventions known as MEM when treating problematic subacute hand edema compared with standard treatment alone. The results need to be interpreted with caution due to numerous limitations associated with the quality assessment of the included studies. Due to the number of different modalities used across the studies, there was little consensus in the literature of the most appropriate methods, dose response, and duration of even the "standard" interventions. Although every patient will require a tailored approach to edema management, clinical guidelines based on evidence from high-quality RCTs may aid the choice and delivery of techniques to improve effectiveness.

The clinical implications arising from the current evidence synthesis are based on the 2 studies with the highest (moderate) quality.[22,30] Therapists should continue to use a combination of conventional interventions which include elevation, exercise, and compression to manage subacute hand edema after trauma. MEM techniques should be considered, (if not medically contraindicated) in conjunction with conventional therapies, in cases of excessive edema or when edema has not responded to conventional treatment alone. Using the MEM method, in addition to conventional treatment, may reduce the number of sessions required.[22] The MEM technique used by Haren and Wilberg[30] is not described, and therefore, readers are required to refer to their earlier article[29] which gives more detail. However, it does not fully describe the correct MEM technique and is referred by the authors as MLD which is an inaccurate terminology.

Further high-quality RCTs are needed to assess the effectiveness of therapy interventions on hand volume for subacute hand edema, particularly focusing on the methods of delivery and application, instructions to patients, dosage, and duration for a range of edema treatments.

Acknowledgments

Leanne Miller is funded by a National Institute for Health Research and Health Education England Clinical Doctoral Research Fellowship. Christina Jerosch-Herold is funded by a National Institute for Health Research Senior Research Fellowship.This article presents independent research funded by the National Institute for Health Research (NIHR) and Health Education England. The views expressed are those of the authors and not necessarily those of the National Health Service, the NIHR or the Department of Health.

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Appendix D

Data extraction from assessment of oedema systematic review

Title	
1st Author	
Year	
Journal	
Study design	
Measurement tool used for swelling	
Condition/s of cohort	
N=	
Area of body being assessed for swelling	
Psychometric properties being assessed	
Duration of oedema/time since injury/surgery	

Generalizability (COSMIN checklist)

Median or mean age (with SD/range)	
Distribution of sex (M:F)	
Important disease characteristics (severity, status, duration) **rational for occurrence of swelling*	
Exclusions?	
Setting in which study was conducted (general population, primary care or hospital/rehab care/community)	
Method used to select patients (convenience, consecutive, random)	
Percentage of missing responses/data (response rate)	

Other

Indicator of acceptability to user (where documented)	
Description of tool used to measure oedema	
Professional/clinical background of person taking measurements	
Description/method used to measure swelling and conditions this was used for (i.e standardized water temperature for volumeter, specific style of tape measure etc)	

Method of analysis

Results

Conclusions drawn from study

COSMIN quality assessment

Step 1.

Tick the properties that have been assessed in the article	Tick
A. Internal consistency	
B. Reliability	
C. Measurement error	
D. Content validity (including face validity) Construct validity	
E. Structural validity	
F. Hypothesis-testing	
G. Cross-cultural analysis	
H. Criterion validity	
I. Responsiveness	
J. Interpretability	

Step 2. *(Only 1 paper so far uses a questionnaire for assessing oedema, so potentially not relevant for other papers, however this can be skipped and continue with the A-J Evaluation boxes)*

Are IRT methods used in the article?	Yes If ticked 'Yes' - complete IRT box.	No Continue to Evaluation of measurement properties boxes.

Complete for each property marked in Step 1 the corresponding box A to J

General requirements for studies that applied Item Response Theory (IRT) models	Yes	No	?
1. Was the IRT model used adequately described? e.g. One Parameter Logistic Model (OPLM), Partial Credit Model (PCM), Graded Response Model (GRM)			
2. Was the computer software package used adequately described? e.g.RUMM2020, WINSTEPS, OPLM, MULTILOG, PARSCALE, BILOG, NLMIXED			
3. Was the method of estimation used adequately described? e.g. conditional maximum likelihood (CML), marginal maximum likelihood (MML)			
4. Were the assumptions for estimating parameters of the IRT model checked? e.g. unidimensionality, local independence, and item fit (e.g. differential item functioning (DIF))			

Complete relevant boxes A-J for each study. Refer to COSMIN checklist documentation.

COSMIN checklist with 4-point scale

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Instructions

This version of the COSMIN checklist is recommended for use in systematic reviews of measurement properties. With this version it is possible to calculate overall methodological quality scores per study on a measurement property. A methodological quality score per box is obtained by taking the lowest rating of any item in a box ('worse score counts'). For example, if for a reliability study one item in the box 'Reliability' is scored poor, the methodological quality of that reliability study is rated as poor. The Interpretability box and the Generalizability box are mainly used as data extraction forms. We recommend to use the Interpretability box to extract all information on the interpretability issues described in this box (e.g. norm scores, floor-ceiling effects, minimal important change) of the instruments under study from the included articles. Similar, we recommend to use the Generalizability box to extract data on the characteristics of the study population and sampling procedure. Therefore no scoring system was developed for these boxes.

This scoring system is described in this paper:

Terwee CB, Mokkink LB, Knol DL, Ostelo RWJG, Bouter LM, de Vet HCW. Rating the methodological quality in systematic reviews of studies on measurement properties: a scoring system for the COSMIN checklist. Quality of Life Research 2011, July 6 [epub ahead of print].

Box A – internal consistency

Box A. Internal consistency				
		yes	**no**	**?**
1	Does the scale consist of effect indicators, i.e. is it based on a reflective model?	☐	☐	☐
Design requirements		**yes**	**no**	**?**
2	Was the percentage of missing items given?	☐	☐	
3	Was there a description of how missing items were handled?	☐	☐	
4	Was the sample size included in the internal consistency analysis adequate?	☐	☐	☐
5	Was the unidimensionality of the scale checked? i.e. was factor analysis or IRT model applied?	☐	☐	
6	Was the sample size included in the unidimensionality analysis adequate?	☐	☐	☐
7	Was an internal consistency statistic calculated for each (unidimensional) (sub)scale separately?	☐	☐	☐
8	Were there any important flaws in the design or methods of the study?	☐	☐	
Statistical methods		**yes**	**no**	**NA**
9	for Classical Test Theory (CTT): Was Cronbach's alpha calculated?	☐	☐	☐
10	for dichotomous scores: Was Cronbach's alpha or KR-20 calculated?	☐	☐	☐
11	for IRT: Was a goodness of fit statistic at a global level calculated? e.g. χ^2, reliability coefficient of estimated latent trait value (index of (subject or item) separation)	☐	☐	☐

Box B – reliability

Box B. Reliability: relative measures (including test-retest reliability, inter-rater reliability and intra-rater reliability)					
Design requirements		**yes**	**no**		**?**
1	Was the percentage of missing items given?	☐	☐		
2	Was there a description of how missing items were handled?	☐	☐		
3	Was the sample size included in the analysis adequate?	☐	☐		☐
4	Were at least two measurements available?	☐	☐		
5	Were the administrations independent?	☐	☐		☐
6	Was the time interval stated?	☐	☐		
7	Were patients stable in the interim period on the construct to be measured?	☐	☐		☐
8	Was the time interval appropriate?	☐	☐		☐
9	Were the test conditions similar for both measurements? e.g. type of administration, environment, instructions	☐	☐		☐
10	Were there any important flaws in the design or methods of the study?	☐	☐		
Statistical methods		**yes**	**no**	**NA**	**?**
11	for continuous scores: Was an intraclass correlation coefficient (ICC) calculated?	☐	☐	☐	
12	for dichotomous/nominal/ordinal scores: Was kappa calculated?	☐	☐	☐	
13	for ordinal scores: Was a weighted kappa calculated?	☐	☐	☐	☐
14	for ordinal scores: Was the weighting scheme described? e.g. linear, quadratic	☐	☐	☐	

Box C – measurement error

Box C. Measurement error: absolute measures				
Design requirements		**yes**	**no**	**?**
1	Was the percentage of missing items given?	☐	☐	
2	Was there a description of how missing items were handled?	☐	☐	
3	Was the sample size included in the analysis adequate?	☐	☐	☐
4	Were at least two measurements available?	☐	☐	
5	Were the administrations independent?	☐	☐	☐
6	Was the time interval stated?	☐	☐	
7	Were patients stable in the interim period on the construct to be measured?	☐	☐	☐
8	Was the time interval appropriate?	☐	☐	☐
9	Were the test conditions similar for both measurements? e.g. type of administration, environment, instructions	☐	☐	☐
10	Were there any important flaws in the design or methods of the study?	☐	☐	
Statistical methods		**yes**	**no**	**?**
11	for CTT: Was the Standard Error of Measurement (SEM), Smallest Detectable Change (SDC) or Limits of Agreement (LoA) calculated?	☐	☐	

Box D – content validity

Box D. Content validity (including face validity)				
General requirements		**yes**	**no**	**?**
1	Was there an assessment of whether all items refer to relevant aspects of the construct to be measured?	☐	☐	☐
2	Was there an assessment of whether all items are relevant for the study population? (e.g. age, gender, disease characteristics, country, setting)	☐	☐	☐
3	Was there an assessment of whether all items are relevant for the purpose of the measurement instrument? (discriminative, evaluative, and/or predictive)	☐	☐	☐
4	Was there an assessment of whether all items together comprehensively reflect the construct to be measured?	☐	☐	☐
5	Were there any important flaws in the design or methods of the study?	☐	☐	

Box E – structural validity

Box E. Structural validity				
		yes	**no**	**?**
1	Does the scale consist of effect indicators, i.e. is it based on a reflective model?	☐	☐	☐
Design requirements		**yes**	**no**	**?**
2	Was the percentage of missing items given?	☐	☐	
3	Was there a description of how missing items were handled?	☐	☐	
4	Was the sample size included in the analysis adequate?	☐	☐	☐
5	Were there any important flaws in the design or methods of the study?	☐	☐	
Statistical methods		**yes**	**no**	**NA**
6	for CTT: Was exploratory or confirmatory factor analysis performed?	☐	☐	☐
7	for IRT: Were IRT tests for determining the (uni-) dimensionality of the items performed?	☐	☐	☐

Box F – hypotheses testing

Box F. Hypotheses testing				
Design requirements		**yes**	**no**	**?**
1	Was the percentage of missing items given?	☐	☐	
2	Was there a description of how missing items were handled?	☐	☐	
3	Was the sample size included in the analysis adequate?	☐	☐	☐
4	Were hypotheses regarding correlations or mean differences formulated a priori (i.e. before data collection)?	☐	☐	☐*
		yes	**no**	**NA**
5	Was the expected *direction* of correlations or mean differences included in the hypotheses?	☐	☐	☐
6	Was the expected absolute or relative *magnitude* of correlations or mean differences included in the hypotheses?	☐	☐	☐
7	for convergent validity: Was an adequate description provided of the comparator instrument(s)?	☐	☐	
8	for convergent validity: Were the measurement properties of the comparator instrument(s) adequately described?	☐	☐	
9	Were there any important flaws in the design or methods of the study?	☐	☐	
Statistical methods		**yes**	**no**	**NA**
10	Were design and statistical methods adequate for the hypotheses to be tested?	☐	☐	☐

Box G – cross-cultural validity

Box G. Cross-cultural validity				
Design requirements		**yes**	**no**	**?**
1	Was the percentage of missing items given?	☐	☐	
2	Was there a description of how missing items were handled?	☐	☐	
3	Was the sample size included in the analysis adequate?	☐	☐	☐
4	Were both the original language in which the HR-PRO instrument was developed, and the language in which the HR-PRO instrument was translated described?	☐	☐	
5	Was the expertise of the people involved in the translation process adequately described? e.g. expertise in the disease(s) involved, expertise in the construct to be measured, expertise in both languages	☐	☐	
6	Did the translators work independently from each other?	☐	☐	☐
7	Were items translated forward and backward?	☐	☐	☐
8	Was there an adequate description of how differences between the original and translated versions were resolved?	☐	☐	
9	Was the translation reviewed by a committee (e.g. original developers)?	☐	☐	
10	Was the HR-PRO instrument pre-tested (e.g. cognitive interviews) to check interpretation, cultural relevance of the translation, and ease of comprehension?	☐	☐	
11	Was the sample used in the pre-test adequately described?	☐	☐	
12	Were the samples similar for all characteristics except language and/or cultural background?	☐	☐	☐
13	Were there any important flaws in the design or methods of the study?	☐	☐	
Statistical methods		**yes**	**no**	**NA**
14	for CTT: Was confirmatory factor analysis performed?	☐	☐	☐
15	for IRT: Was differential item function (DIF) between language groups assessed?	☐	☐	☐

Box H – criterion validity

Box H. Criterion validity				
Design requirements		**yes**	**no**	**?**
1	Was the percentage of missing items given?	☐	☐	
2	Was there a description of how missing items were handled?	☐	☐	
3	Was the sample size included in the analysis adequate?	☐	☐	☐
4	Can the criterion used or employed be considered as a reasonable 'gold standard'?	☐	☐	☐
5	Were there any important flaws in the design or methods of the study?	☐	☐	
Statistical methods		**yes**	**no**	**NA**
6	for continuous scores: Were correlations, or the area under the receiver operating curve calculated?	☐	☐	☐
7	for dichotomous scores: Were sensitivity and specificity determined?	☐	☐	☐

Box I – responsiveness

Box I. Responsiveness				
Design requirements		**yes**	**no**	**?**
1	Was the percentage of missing items given?	☐	☐	
2	Was there a description of how missing items were handled?	☐	☐	
3	Was the sample size included in the analysis adequate?	☐	☐	☐
4	Was a longitudinal design with at least two measurement used?	☐	☐	
5	Was the time interval stated?	☐	☐	
6	If anything occurred in the interim period (e.g. intervention, other relevant events), was it adequately described?	☐	☐	
7	Was a proportion of the patients changed (i.e. improvement or deterioration)?	☐	☐	
Design requirements for hypotheses testing		**yes**	**no**	**?**
For constructs for which a gold standard was not available:				
8	Were hypotheses about changes in scores formulated a priori (i.e. before data collection)?	☐	☐	☐*
		yes	**no**	**NA**
9	Was the expected *direction* of correlations or mean differences of the change scores of HR-PRO instruments included in these hypotheses?	☐	☐	☐
10	Were the expected absolute or relative *magnitude* of correlations or mean differences of the change scores of HR-PRO instruments included in these hypotheses?	☐	☐	☐
11	Was an adequate description provided of the comparator instrument(s)?	☐	☐	
12	Were the measurement properties of the comparator instrument(s) adequately described?	☐	☐	
13	Were there any important flaws in the design or methods of the study?	☐	☐	
Statistical methods		**yes**	**no**	**NA**
14	Were design and statistical methods adequate for the hypotheses to be tested?	☐	☐	☐
Design requirement for comparison to a gold standard		**yes**	**no**	**?**
For constructs for which a gold standard was available:				
15	Can the criterion for change be considered as a reasonable gold standard?	☐	☐	☐
16	Were there any important flaws in the design or methods of the study?	☐	☐	

Statistical methods		**yes**	**no**	**NA**
17	for continuous scores: Were correlations between change scores, or the area under the Receiver Operator Curve (ROC) curve calculated?	☐	☐	☐
18	for dichotomous scales: Were sensitivity and specificity (changed versus not changed) determined?	☐	☐	☐

Box J – interpretability

Box J. Interpretability				
		yes	no	?
1	Was the percentage of missing items given?	☐	☐	
2	Was there a description of how missing items were handled?	☐	☐	
3	Was the sample size included in the analysis adequate?	☐	☐	☐
4	Was the distribution of the (total) scores in the study sample described?	☐	☐	
5	Was the percentage of the respondents who had the lowest possible (total) score described?	☐	☐	
6	Was the percentage of the respondents who had the highest possible (total) score described?	☐	☐	
7	Were scores and change scores (i.e. means and SD) presented for relevant (sub) groups? e.g. for normative groups, subgroups of patients, or the general population	☐	☐	
8	Was the minimal important change (MIC) or the minimal important difference (MID) determined?	☐	☐	
9	Were there any important flaws in the design or methods of the study?	☐	☐	

Appendix E

Comparison of figure of eight method across studies

Table comparing method of administering figure of eight assessment.

	Leard 2004	Dewey 2007	Leard 2008	Borthwick 2011
Type of tape measure	Standard retractable fibreglass tape measure. Side of tape marked in English standard units was left visible for data recorder to read.	Laminated tape measure with metric units visible and blank on other side. Blank side facing up during measurements. Disinfected between patients.	Standard 0.635cm wide retractable fibreglass tape measure. Side of the tape marked with metric units left visible for examiner to read.	Blank tape measure.
Pre-measure instructions:	Patients to wash their hands		Patients to wash their hands	
Jewellery	Removed	Removed	Removed	Not documented
Dressings	Not documented	Removed	Removed	Not documented
Wounds	Not documented	Excessive wound drainage wiped clean.	Not documented	Not documented
Seated/standing	Seated. Allowed to move between each measure.	Not documented	Seated	Not documented
Position of arm	Forearm pronated rested on table with hand extending over the edge. Patients to maintain wrist in neutral flexion, extension, radial and ulnar deviation with fingers adducted.	Arm pronated with wrist neutral flexion, extension, radial and ulnar deviation. Fingers extension and in adduction.	As per Leard 2004	Arm supported on a table with the forearm pronated, wrist in neutral and fingers rested in adduction.
Measuring process	1). Starting at outermost and most distal aspect of the ulnar styloid process. 2). Crossing the ventral surface of the wrist to the most distal aspect of the radial styloid process. 3). Diagonally crossing the dorsal aspect of the hand	As per method described by Leard 2004 measuring process points 1,2 and 3. 4). The tape measure positioned over the palmar surface of the hand with the distal edge of the tape touching the MCP joint flexion crease of the index and small finger.	As per method described by Leard 2004	As per method described by Dewey 2007.

Table comparing method of administering figure of eight assessment.

	with the proximal surface of the tape measure placed over the fifth MCPJ line. 4). Crossing the ventral surface of the MCPJ and the proximal surface of the tape measure positioned over the 2nd MCPJ line. 5). Diagonally crossing the dorsum of the hand to the starting point. No skin markings used, tester had to relocate the anatomical landmarks for each trial.	5). Tape measure continued around the second metacarpal head and placed diagonally across dorsum of the hand to the starting point.		
Method of recording	Tester placed 11.9mm wide Post-it flag on the tape measure to mark the endpoint. Tester removed tape measure from patients hand and handed it to the data recorder who read the length indicated by the side of the Post-it flag closest to the beginning of the tape.	The endpoint was marked with a grease pen at the intersection of the distal edge of the starting point and the end of the tape measure. Tester removed tape measure from patients hand and handed to data recorder. Recorder documented measurement, wiped mark clean and returned tape measure to tester.	Examiner blinded to the results. The side of the tape measure marked in English standard units was blackened to blind the examiners to the measurement. The side of the tape marked in metric units was left visible for the data recorder to read but was not read by the examiner.	Tape was marked and cut beyond the mark. Tape measure passed to recorder who measured tape to the mark with the tape held taut against a wooden ruler and recorded to the nearest mm.
Unit recorded	cm	cm	cm	mm
No. of testers and measurements	2 testers took 3 assessments each.	2 testers took three consecutive measurements.	5 testers	2 testers took three measurements on each hand on every patient.
Recommendations		Disposable tape measure for clinical practice.		

Appendix F

Quality assessment tables for each psychometric property

COSMIN Quality Assessment Table- Absolute error: absolute measures.

Study/ Question No.	1	2	3	4	5	6	7	8	9	10	11	"Worst score counts"
Leard 2004	N/A	N/A	Fair	Excellent	Excellent	Excellent	Good	Excellent	Excellent	Fair	Excellent	Fair
Leard 2008	N/A	N/A	Poor	Excellent	Excellent	Excellent	Good	Excellent	Excellent	Fair	Excellent	Poor
Dewey 2007	N/A	N/A	Fair	Excellent	Excellent	Excellent	Good	Excellent	Excellent	Fair	Excellent	Fair
Lee 2011	N/A	N/A	Fair	Excellent	Excellent	Excellent	Good	Excellent	Excellent	Fair	Excellent	Fair
Borthwick 2013	N/A	N/A	Poor	Excellent	Excellent	Excellent	Good	Excellent	Excellent	Fair	Excellent	Poor

1). Was the percentage of missing items given?
2). Was there a description of how missing items were handled?
3). Was the sample size included in the analysis adequate?
4). Were there at least 2 measurements?
5).Were the administrations independent?
6). Was the time interval stated?

7). Were the patients stable in the interim period on the construct to be measured?
8). Was the time interval appropriate?
9). Were the test conditions similar for both measurements? E.g type of administration, environment , instructions
10). Were there any important flaws in the design or methods of the study?
11). For CTT: Was the Standard Error of Measurement (SEM), Smallest Detectable Change (SDC) or Limits of Agreement (LoA) Calculated?

COSMIN Quality Assessment Table- Criterion Validity

Study/ Question No.	1	2	3	4	5	6		7	"Worst score counts"
Dewey (2007)	N/A	N/A	Fair	Excellent	Fair	Excellent		N/A	Fair
Post (2003)	N/A	N/A	Good	Excellent	Excellent	Excellent		Poor	Fair
Borthwick (2013)	N/A	N/A	Poor	Excellent	Fair	Excellent		N/A	Poor
Leard (2004)	N/A	N/A	Fair	Excellent	Fair	Excellent		N/A	Fair
Lee (2011)	N/A	N/A	Fair	Excellent	Fair	Excellent		N/A	Fair

1. Was the percentage of missing items given?
2. Was there a description of how missing items were handled?
3. Was the sample size included in the analysis adequate?
4. Can the criterion used or employed be considered as a reasonable 'gold standard'?
5. Were there any important flaws in the design or methods of the study?
6. For continuous scores: Were correlations, or the area under the receiver operating curve calculated?
7. For dichotomous scores: Were sensitivity and specificity determined?

COSMIN Quality Assessment Table- Reliability

Study/ Question No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	"Worst score counts"
Leard (2008)	N/A	N.A	Poor	Excellent	Excellent	Excellent	Fair	Fair	Excellent	Fair	Excellent	N/A	N/A	N/A	Poor
Dewey (2007)	N/A	N/A	Fair	Excellent	Excellent	Fair	Fair	Fair	Excellent	Fair	Excellent	N/A	N/A	N/A	Fair
Post (2003)	N/A	N/A	Good	Excellent	Excellent	Excellent	Good	Fair	Fair	Fair	N/A	Excellent	Excellent	Good	Fair
Borthwick (2013)	N/A	N/A	Poor	Excellent	Excellent	Excellent	Good	Excellent	Excellent	Fair	Excellent	N/A	N/A	N/A	Poor
Leard (2004)	N/A	N/A	fair	Excellent	Excellent	Excellent	Good	Excellent	Excellent	Fair	Excellent	N/A	N/A	N/A	Fair
Lee (2011)	N/A	N/A	Fair	Excellent	Good	Fair	Good	Fair	Good	Fair	Excellent	N/A	N/A	N/A	Fair

1. Was the percentage of missing items given?
2. Was there a description of how missing items were handled?
3. Was the sample size included in the analysis adequate?
4. Were at least two measurements available?
5. Were the administrations independent?
6. Was the time interval stated?
7. Were patients stable in the interim period on the construct to be measured?
8. Was the time interval appropriate?
9. Were the test conditions similar for both measurements?
10. Were there any important flaws in the design or methods of the study?
11. For continuous scores: Was an intraclass correlation coefficient (ICC) calculated?
12. For dichotomous/nominal/ordinal scores: Was kappa calculated?
13. For ordinal scores: Was a weighted kappa calculated?
14. For ordinal scores: Was the weighting scheme described? e.g. linear, quadratic

COSMIN Quality Assessment Table- Responsiveness

Study/ Question No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	"Worst score counts"
Leard (2008)	N/A	N/A	Poor	Excellent	Excellent	Fair	Excellent	N/A	N/A	N/A	Excellent	Fair	Fair	Excellent	Excellent	Fair	Excellent	N/A	Poor

1. Was the percentage of missing items given?
2. Was there a description of how missing items were handled?
3. Was the sample size included in the analysis adequate?
4. Was a longitudinal design with at least two measurement used?
5. Was the time interval stated?
6. If anything occurred in the interim period (e.g. intervention, other relevant events), was it adequately described?
7. Was a proportion of the patients changed (i.e. improvement or deterioration)?
8. Were hypotheses about changes in scores formulated a priori (i.e. before data collection)?
9. Was the expected direction of correlations or mean differences of the change scores of HR-PRO instruments included in these hypotheses?
10. Were the expected absolute or relative magnitude of correlations or mean differences of the change scores of HR-PRO instruments included in these hypotheses?
11. Was an adequate description provided of the comparator instrument(s)?
12. Were the measurement properties of the comparator instrument(s) adequately described?
13. Were there any important flaws in the design or methods of the study?
14. Were design and statistical methods adequate for the hypotheses to be tested?
15. Can the criterion for change be considered as a reasonable gold standard?
16. Were there any important flaws in the design or methods of the study?
17. For continuous scores: Were correlations between change scores, or the area under the Receiver Operator Curve (ROC) curve calculated?
18. For dichotomous scales: Were sensitivity and specificity (changed versus not changed) determined?

Appendix G

Assessment of oedema published systematic review

Hand Therapy
2017, Vol. 22(4) 153–164
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DOI: 10.1177/1758998317724405
journals.sagepub.com/home/hth
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Clinical assessment of hand oedema: A systematic review

Leanne K Miller[1], Christina Jerosch-Herold[1] and Lee Shepstone[2]

Abstract

Introduction: Assessment of oedema after trauma or surgery is important to determine whether treatment is effective and to detect change over time. Volumetry is referred to as the 'gold standard' method of measuring volume. However, this has practical limitations and other methods are available. The aim of this systematic review was to evaluate the psychometric properties of alternative methods used to assess hand oedema.

Methods: A search of electronic bibliographic databases was undertaken for any studies published in English reporting the psychometric evaluation of a method for measuring hand oedema, in an adult population with hand swelling from surgery, trauma or stroke. The Consensus-based Standards for the Selection of health Measurement Instruments (COSMIN) checklist was used to evaluate the methodological quality.

Results: Six studies met the inclusion criteria. Three methods were identified assessing hand oedema: perometry, visual inspection and the figure-of-eight tape measure, all were compared to volumetry. Four different psychometric properties were assessed. Studies scored fair or poor on COSMIN criteria. There is low-quality evidence supporting the use of the figure-of-eight tape measure to assess hand volume. The perometer systematically overestimated volume and visual estimation had poor sensitivity and specificity.

Discussion: The figure-of-eight tape measure is the best alternative to volumetry for hand oedema. Benefits include reduced cost and time while having comparable reliability to the 'gold standard'. Further research is needed to compare methods in patients with greater variability of conditions and with isolated digit oedema. Visual estimation of hand oedema is not recommended.

Keywords
Hand, oedema, assessment, outcome measures, volume

Date received: 27 April 2017; accepted: 11 July 2017

Introduction

Prolonged swelling has an impact on joint range of motion, soft tissue mobility, quality of scar tissue formation, function, strength, and aesthetics of the hand. These factors may delay a patient's recovery, return to work and usual activities of daily living and require frequent or increased out-patient appointments.[1]

Assessment of hand oedema after stroke, surgery or trauma offers valuable information to the treating therapist about the effectiveness of oedema management interventions, adherence to home therapy programmes[2] and activity levels. Objective measures are particularly important in the current economic climate to ensure that interventions and therapy time can be justified. For this reason, measures need to not only be reliable but also responsive to detect clinically important change over time. While it is best practice to maintain consistency of therapists between treatment sessions, in busy clinics and regional units, patients are often seen by multiple therapists across their episode of care and therefore assessment tools are needed with a high level of inter- and intra-rater reliability.

The volumeter, which uses Archimedes' principle of water displacement,[3] has been in existence since the 1950s;[4] however, its usage in therapy departments appears to be reducing. This method has documented

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reliability and validity[2] and has a margin of error of less than 1%.[5] It is referred to as the 'gold standard' of assessing hand volume when oedema is generalised to the hand and not isolated to a digit[6]; however, it is not always a feasible method, for example where immersion of the hand in water is contraindicated due to wounds or dressings. The volumeter kit is also expensive at approximately £300 and requires a lengthy set up to ensure the water in the volumeter is completely level and a constant water temperature is maintained.[7–10] Furthermore, consistency in positioning the hand and arm is essential and the need to maintain a still limb may also exclude some patients.[11] Potential increases in pain from the dependent limb position and length of time to allow all displaced water to be collected are further limitations.[5] The volumeter is often impractical in busy clinic settings where space is limited and frequent hand oedema assessments need to be performed or in patients who have focal swelling limited to a single digit.

Alternative methods include visual inspection of the oedematous hand and documenting a grade using terminology acceptable to that department such as mild, moderate and severe for example. This subjective assessment of hand volume is based on colour and tautness of the skin and appearance of defined anatomical landmarks or lack thereof. Due to varying perceptions of severity between clinicians and difficulties with recall between sessions with the same clinician, visual inspection alone may not be sufficient to give an accurate measurement of hand volume and an objective measurement of oedema needs to be performed.

Another alternative which is quicker and cheaper is using a tape measure in a circumferential or figure-of-eight method. This technique is simple and reproducible if used with standardized landmarks and can be used in the presence of wounds. The limitation with the figure-of-eight method is its exclusion of the digits so this may not be the method of choice to use in cases of isolated digital swelling as the placement of the tape around the wrist and palm only measures the volume of the regions covered by the tape and does not include digits.

Other methods of determining volume exist such as 3D laser scanners,[12–14] 3D camera[15] and perometer[16] (an infrared optoelectric measuring device). While these methods are not routinely used by hand therapists to measure oedema, information on their application and psychometric properties could be transferable to use in clinical practice on the hand. The hand presents a unique challenge when measuring volume due to its shape and structure and this may mean some methods are not suitable to use.

In light of the information presented above, the rationale for conducting this systematic review was to establish which oedema assessment method has the strongest psychometric evidence.

The objectives of this systematic review were to:

1. establish the current quantity and quality of evidence on tools designed to assess hand oedema
2. evaluate the psychometric properties of these tools
3. identify factors affecting the standardisation of these tools.

Methods

We conducted a systematic review using PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analysis) recommendations.[17]

The following electronic bibliographic databases were searched: The Cochrane Library (Wiley InterScience), MEDLINE (via Ovid), EMBASE (via Ovid), AMED (via Ovid), CINAHL (via EBSCO), SPORTDiscus (via EBSCO), PEDro (Physiotherapy Evidence Database) – Allied Health Evidence. Trial registers (Cochrane Central Register of Controlled Trials [CENTRAL] and WHO International Clinical Trials Registry Platform) from inception to March 2017 were searched using the terms: 'Hand/', 'Edema/', 'Hand' adj 'size', 'hand' adj 'volume', 'perometer'. Additional studies were searched for by examining the reference list of retrieved studies.

Eligibility

Criteria for inclusion were: English language publications reporting psychometric evaluation of an assessment to measure hand volume in an adult population with hand oedema. Eligible forms of hand oedema were following surgery or trauma or from a disease or condition affecting the hand irrespective of any treatment given (e.g. stroke, lymphoedema), where hand oedema measurements are expressed as volume (ml), girth or circumference (cm/mm) or as a severity description.

Studies were excluded if the psychometric evaluation had been completed on healthy participants only, animal studies, studies which assessed the upper limb and forearm in addition to the hand and studies where oedema was investigated at an organ or cellular level.

Screening

One reviewer (LM) read the titles of all citations retrieved from electronic database searches and removed all citations which were not related to the assessment of hand oedema. Abstracts of the remaining articles were screened to check for eligibility by one reviewer (LM). Full text articles were obtained for all abstracts meeting the inclusion criteria.

Data extraction

Data extraction of included studies was done by the lead author (LM) using a purposely designed data extraction form. This form summarized details on study design, sample, interventions, outcomes, and results. On occasions when there was doubt over the interpretation of the data being extracted, a second reviewer (CJH) also completed the data extraction independently using the same form to verify understanding and clarity of extracted data.

Assessment of methodological quality

The Consensus-based Standards for the selection of health Measurement Instruments checklist (COSMIN)[18] was used to evaluate the methodological quality of the studies. This checklist was originally designed for use in Health Related Patient Reported Outcomes (HR-PRO) but can be used to evaluate other kinds of health measurement instruments such as performance-based tests and clinical rating scales. The COSMIN checklist is made of nine domains relating to different psychometric properties. Each study was assessed using the relevant domain for the psychometric property being evaluated, i.e. reliability, validity or responsiveness by the primary reviewer (LM). The second reviewer (CJH) completed the checklist for two of the six included studies and the agreement between the reviewers was checked to ensure consistent grading across each domain for each study. There was 86% agreement between primary and secondary reviewer on the selected two studies, the inconsistencies in scores were settled with discussion and resulted in 100% agreement. Each domain has between 7 and 14 questions which are graded on a four-point rating scale: 'excellent', 'good', 'fair' or 'poor' according to the descriptors given under each category. The lowest score counts method is recommended to give an overall quality judgement.

Included studies were grouped according to the assessment method used: figure-of-eight, perometry and visual inspection. This formed the basis of how results were reported. Meta-analysis was not possible because of heterogeneity in assessment tools, methods or reporting of results.

Results

Six studies met the inclusion criteria (see Figure 1) and were included in this review.

A total of 243 participants were included in the 6 studies, with sample sizes ranging from 24 to 88. Participants had a range of musculoskeletal injuries, burns, lymphoedema, post orthopaedic surgery or cerebrovascular accident (CVA). Only one study[19] used a healthy comparison group when assessing the reliability of the perometer in women with and without lymphoedema.

Three methods of assessing oedema were used: figure-of-eight tape measure, perometer and visual observations by clinicians. All were compared with volumetry as the 'gold standard' method, as this has excellent intra- and inter-rater reliability (ICC 0.99, respectively).[20]

Four studies[20–23] assessed the reliability of the figure-of-eight comparing it to the volumeter; however, not all statistical results were reported. Leard et al.[23] also assessed the responsiveness of these two methods of assessing oedema.

One study[24] assessed the reliability of using visual inspection compared to volumetry, and one study[19] evaluated the reliability of the perometer compared to the volumeter.

Four studies[19–22] assessed criterion-related validity and, along with Leard et al.[23] also investigated measurement error of their respective oedema assessment tools. See Table 1 for an overview of the studies and the psychometric properties they assessed.

The results are presented according to the measurement tool used. Tables 2 to 5 show the quality rating table for each psychometric property/study using the COSMIN checklist.

Perometer

Lee et al.[19] assessed 20 women with and 20 women without lymphoedema of the hand and reported reliability data both for subgroups and the whole group. Excellent inter- and intra-rater reliability was demonstrated for the perometer (ICC = 0.99; 95% CI 0.98–0.99 and ICC = 0.99; 95% CI 0.98–0.99, respectively). Similarly, excellent inter- and intra-rater reliability (ICC > 0.99) was observed for the two subgroups. There was no significant difference between measurements taken by different raters or between the two measurements taken by tester 1. While Lee et al.[19] gave confidence intervals with their ICCs they did not report the standard error of measurement (SEM) which gives an absolute index of reliability rather than a relative measure of reliability.

However, the perometer systematically overestimated hand volume by a mean of 24 ml compared with the volumeter. Mean hand volume ($n = 20$ women without lymphoedema) is 380 ml which equates to a 6% overestimation in volume. While the perometer has excellent inter- and intra-rater reliability comparable to the gold standard volumeter and a very good concordance correlation, calibration issues led to a 6% overestimation and therefore the two methods for measuring hand volume should not be used interchangeably.

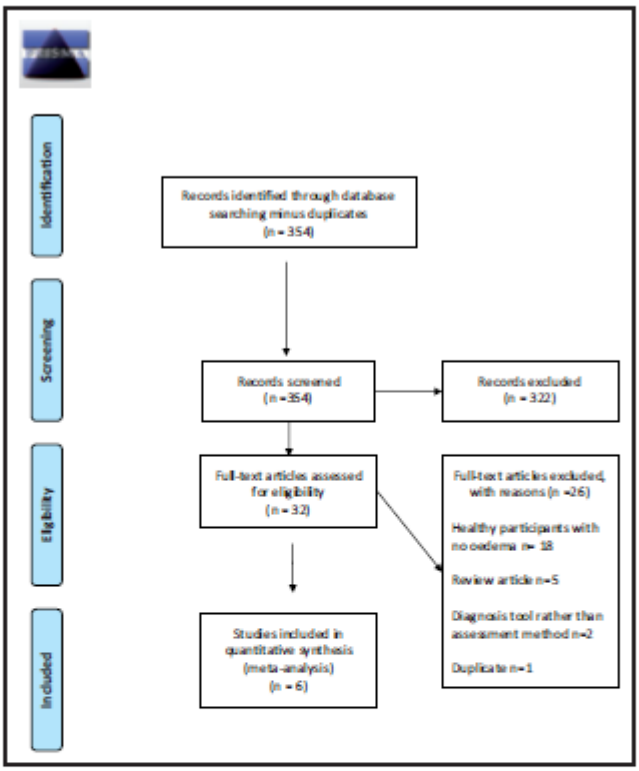

Figure 1. PRISMA 2009 flow diagram.

Table 1. Overview of included studies, cohort, assessment tool and psychometric properties assessed.

Authors	Pt type	Tools assessed	Psychometric properties assessed
Post et al.[24]	88 hands post first CVA	Visual inspection vs. volumeter	Reliability
Leard et al.[20]	33 hands post trauma/surgery	Figure-of-eight vs. volumeter	Reliability, criterion validity, measurement error.
Dewey et al.[21]	33 burnedhands	Figure-of-eight vs. volumeter	Reliability, criterion validity, measurement error.
Leard et al.[23]	25 hands post trauma/surgery	Figure-of-eight vs. volumeter	Reliability, responsiveness, measurement error.
Lee et al.[19]	20 hands with and 20 hands without lymphoedema	Perometer vs. volumeter	Reliability, criterion validity, measurement error.
Borthwick et al.[22]	24 hands with lymphoedema	Figure-of-eight vs. volumeter	Reliability, criterion validity, measurement error.

CVA: cerebrovascular accident.

Table 2. COSMIN quality assessment table – Absolute error: Absolute measures.

Study/question no.	1	2	3	4	5	6	7	8	9	10	11	'Worst score counts'
Leard et al.[20]	N/A	N/A	Fair	Excellent	Excellent	Excellent	Good	Excellent	Excellent	Fair	Excellent	Fair
Leard et al.[23]	N/A	N/A	Poor	Excellent	Excellent	Excellent	Good	Excellent	Excellent	Fair	Excellent	Poor
Dewey et al.[21]	N/A	N/A	Fair	Excellent	Excellent	Excellent	Good	Excellent	Excellent	Fair	Excellent	Fair
Lee et al.[19]	N/A	N/A	Fair	Excellent	Excellent	Excellent	Good	Excellent	Excellent	Fair	Excellent	Fair
Borthwick et al.[22]	N/A	N/A	Poor	Excellent	Excellent	Excellent	Good	Excellent	Excellent	Fair	Excellent	Poor

1. Was the percentage of missing items given?
2. Was there a description of how missing items were handled?
3. Was the sample size included in the analysis adequate?
4. Were there at least 2 measurements?
5. Were the administrations independent?
6. Was the time interval stated?
7. Were the patients stable in the interim period on the construct to be measured?
8. Was the time interval appropriate?
9. Were the test conditions similar for both measurements? E.g. type of administration, environment, instructions
10. Were there any important flaws in the design or methods of the study?
11. For CTT: Was the standard error of measurement (SEM), smallest detectable change (SDC) or limits of agreement (LoA) Calculated?

COSMIN: consensus-based standards for the selection of health measurement instrument.

Table 3. COSMIN quality assessment table – Reliability.

Study/Question No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	'Worst score counts'
Leard et al.[23]	N/A	N/A	Poor	Excellent	Excellent	Excellent	Fair	Fair	Excellent	Fair	Excellent	N/A	N/A	N/A	Poor
Dewey et al.[21]	N/A	N/A	Fair	Excellent	Excellent	Fair	Fair	Fair	Excellent	Fair	Excellent	N/A	N/A	N/A	Fair
Post et al.[24]	N/A	N/A	Good	Excellent	Excellent	Excellent	Good	Fair	Fair	Fair	N/A	Excellent	Excellent	Good	Fair
Borthwick et al.[22]	N/A	N/A	Poor	Excellent	Excellent	Excellent	Good	Excellent	Excellent	Fair	Excellent	N/A	N/A	N/A	Poor
Leard et al.[20]	N/A	N/A	fair	Excellent	Excellent	Excellent	Good	Excellent	Excellent	Fair	Excellent	N/A	N/A	N/A	Fair
Lee et al.[19]	N/A	N/A	Fair	Excellent	Good	Fair	Good	Fair	Good	Fair	Excellent	N/A	N/A	N/A	Fair

1. Was the percentage of missing items given?
2. Was there a description of how missing items were handled?
3. Was the sample size included in the analysis adequate?
4. Were at least two measurements available?
5. Were the administrations independent?
6. Was the time interval stated?
7. Were patients stable in the interim period on the construct to be measured?
8. Was the time interval appropriate?
9. Were the test conditions similar for both measurements?
10. Were there any important flaws in the design or methods of the study?
11. For continuous scores: Was an intraclass correlation coefficient (ICC) calculated?
12. For dichotomous/nominal/ordinal scores: Was kappa calculated?
13. For ordinal scores: Was a weighted kappa calculated?
14. For ordinal scores: Was the weighting scheme described? e.g. linear, quadratic

COSMIN: consensus-based standards for the selection of health measurement instrument.

Table 4. COSMIN quality assessment table – Criterion validity.

Study/ Question No.	1	2	3	4	5	6	7	'Worst score counts'
Dewey et al.[21]	N/A	N/A	Fair	Excellent	Fair	Excellent	N/A	Fair
Post et al.[24]	N/A	N/A	Good	Excellent	Excellent	Excellent	Poor	Fair
Borthwick et al.[22]	N/A	N/A	Poor	Excellent	Fair	Excellent	N/A	Poor
Leard et al.[20]	N/A	N/A	Fair	Excellent	Fair	Excellent	N/A	Fair
Lee et al.[19]	N/A	N/A	Fair	Excellent	Fair	Excellent	N/A	Fair

15. Was the percentage of missing items given?
16. Was there a description of how missing items were handled?
17. Was the sample size included in the analysis adequate?
18. Can the criterion used or employed be considered as a reasonable 'gold standard'?
19. Were there any important flaws in the design or methods of the study?
20. For continuous scores: Were correlations, or the area under the receiver operating curve calculated?
21. For dichotomous scores: Were sensitivity and specificity determined?

COSMIN: consensus-based standards for the selection of health measurement instrument

Lee et al.[19] commented on the potential issue of the perometer being its inability to discriminate interdigital spaces and therefore it interprets this space as volume and includes it in the overall volume measurement. It may also be difficult for some patients to maintain a static position over the period required to complete the assessment and therefore a slight shift of the hand may also result in an overestimation of the actual volume.

This study[19] scored 'fair' overall across absolute error, reliability and criterion validity categories of the COSMIN quality assessment.

Visual inspection

Visual observations were carried out by experienced therapists during a 1-h consultation for post-stroke arm/hand problems. The therapists classified the amount of hand swelling observed during visual inspection as being nil, minor or severe. Post et al.[24] assessed 88 hands after their first stroke. While the authors claim there was 'a clear relationship between the assessment by the physical therapists and the adjusted volume scores' (mean volumeter scores were adjusted from the population data), the results actually indicate a lack of agreement between clinical and volumetric assessment of oedema. A 67% agreement was found between classification of oedema by therapists and the volumeter. A Kappa value of 0.34 highlights a fair level of agreement. However, no confidence intervals were provided.

Although Post et al.[24] did not report sensitivity and specificity, these have been calculated from the data provided. Calculations were completed by authors LM and CJH. Sensitivity of visual inspection by therapists was 74% indicating that in 26 patients, therapists missed oedema using this technique. In 76% (22/29) of cases, the therapist reported oedema, the volumeter also agreed. Therapists' clinical judgement classified only 4.5% ($n=4$) of the group as having major oedema when the volumeter results show that actually 18.5% of the group were in this category.

Specificity of visual inspection was 63%, meaning that in 63% (37/44) of cases, the therapist reported no swelling, the volumeter also agreed. Therapists' clinical judgement classified 40% of the population ($n=44$) as having no oedema, whereas the volumeter results indicate only 2.2% of the group had no oedema.

This study scored 'fair' on the COSMIN quality assessment in both criterion validity and reliability categories.

Across the two categories scores of fair, good or excellent were given for each question. However, in light of the lack of sensitivity and specificity calculations, this brought the overall rating down to poor.

Figure-of-eight tape measure

There were slight variations in the methods used to administer the figure-of-eight assessment between the four studies[20–23] and often some details were not adequately documented.

Leard et al.'s[23] paper reports completing intra-rater reliability assessment for the figure-of-eight; however, it actually only documents inter-rater reliability results.

Intraclass correlation coefficients (ICCs) for intra-rater reliability ranged between 0.89 and 0.99 across the three studies (Leard et al.[23] did not report intra-rater reliability) demonstrating excellent levels of intra-rater reliability with the figure-of-eight method.

Table 5. COSMIN quality assessment table – Responsiveness.

Study/ Question No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	'Worst score counts'
Leard et al.[23]	N/A	N/A	Poor	Excellent	Excellent	Fair	Excellent	N/A	N/A	N/A	Excellent	Fair	Fair	Excellent	Excellent	Fair	Excellent	N/A	Poor

22. Was the percentage of missing items given?
23. Was there a description of how missing items were handled?
24. Was the sample size included in the analysis adequate?
25. Was a longitudinal design with at least two measurement used?
26. Was the time interval stated?
27. If anything occurred in the interim period (e.g. intervention, other relevant events), was it adequately described?
28. Was a proportion of the patients changed (i.e. improvement or deterioration)?
29. Were hypotheses about changes in scores formulated a priori (i.e. before data collection)?
30. Was the expected direction of correlations or mean differences of the change scores of HR-PRO instruments included in these hypotheses?
31. Were the expected absolute or relative magnitude of correlations or mean differences of the change scores of HR-PRO instruments included in these hypotheses?
32. Was an adequate description provided of the comparator instrument(s)?
33. Were the measurement properties of the comparator instrument(s) adequately described?
34. Were there any important flaws in the design or methods of the study?
35. Were design and statistical methods adequate for the hypotheses to be tested?
36. Can the criterion for change be considered as a reasonable gold standard?
37. Were there any important flaws in the design or methods of the study?
38. For continuous scores: Were correlations between change scores, or the area under the Receiver Operator Curve (ROC) curve calculated?
39. For dichotomous scales: Were sensitivity and specificity (changed versus not changed) determined?

COSMIN: consensus-based standards for the selection of health measurement instruments.

Standard Error of the Mean (SEM) ranged between 0.28 and 0.70 cm across the three studies[20,22,23] which documented this.

High inter-rater reliability was also demonstrated across the four studies with an ICC range of 0.84–0.99, and SEM range of 0.28–0.71 cm. The study which reported the highest ICC of 0.99[20] also reported the smallest SEM of 0.28 cm, and the same was true for the reverse of this, 0.86 ICC and 0.71 cm SEM.[22,23]

Leard et al.[23] also assessed the responsiveness of the figure-of-eight compared to the volumeter which demonstrated similarly small effect sizes (ESs) (ES = 0.26 for figure-of-eight and ES = 0.19 for volumeter) highlighting that the ability of the tools to detect changes in hand volume over time is comparable but slightly favours the figure-of-eight. When reporting the standardized response mean (SRM), however, the figure-of-eight had a slightly lower value (SRM = 0.87) than the volumeter (SRM = 1.04) which contrasts with the ESs. As no summary statistics were given, we are unable to replicate the analysis to verify these results.

Of the four studies which used the figure-of-eight, two scored poor[22,23] and two fair[20,21] in the COSMIN quality evaluation tool.

Discussion

The aims of this systematic review were to review the quality and quantity of current evidence on the psychometric properties of methods for assessing hand oedema and identify factors which may affect the standardisation of these methods when used on the hand. A discussion of the findings and implications for practice will be presented in this section.

The review found limited low-quality evidence to support the use of the figure-of-eight tape measure to assess hand volume in patients with acute or chronic oedema from a traumatic, lymphatic or neurological cause.

While the perometer had similar levels of reliability to that of the 'gold standard' volumeter, it showed a systematic overestimation which equated to 6% of total hand volume highlighting its incompatibility to be used interchangeably with the volumeter. Issues around hand position and accuracy of the infrared beam to discriminate hand volume and space contributed to the overestimation of hand volume.

Visual inspection had a fair level of agreement with the volumeter. However, results show that visual inspection may miss some patients with oedema and wrongly diagnose some patients as having oedema.

Assessment of methodological quality

The COSMIN[18] checklist was used to assess the methodological quality of the studies. It was developed specifically to assess health-related patient-rated outcome measures (HR-PRO). These scales or questionnaires are often made up of several items designed to measure a latent construct. Therefore, some sections and questions of the checklist are not appropriate when evaluating measures of a single domain such as hand volume.

The current scoring system works on a 4-point rating scale: excellent, good, fair and poor. This was adapted from a dichotomous response option (yes/no) and accounts for some of the issues with scoring. In the majority of questions, there are descriptors under each rating which qualifies what the paper must report in order to achieve that rating. However, in some cases, descriptors have not been included.

In these cases, the missing 'good' and 'fair' descriptions were appropriate as the question related to the completion of statistical tests which warrant only a yes (excellent) or no (poor) answer. However, in some instances, the gap or difference between descriptors seemed arbitrary and often it is difficult to find the most appropriate score based on the descriptions given to accurately reflect the quality of the paper. The working group who developed the 4-point rating scale report, that for some questions, it was not possible to define four different response options

A worst score counts method is used to give an overall quality rating for each measurement property. A poor score on any one item is thus considered to represent a fatal flaw.[25] Other methods of scoring have been considered[25,26] and while the overall score is often lower than the subjective judgement of the marker, this method has been agreed, following a Delphi consensus study[26] to be the most appropriate. The scoring method, however, is arbitrary and the validity and reliability of the current recommended scoring system have not been investigated.[25] Despite the limitations of this critical evaluation tool, it is the only standardized rating tool which can be applied to health-related clinician-derived measurement instruments.

Sample size

Four studies[19,20,21,24] scored 'fair' in all measurement properties assessed. Borthwick et al.[22] and Leard et al.[23] scored poor across all three measurement properties assessed (reliability, criterion validity and measurement error). Both studies scored 'poor' based on a single item – adequate sample size. Indicative sample sizes are given as a guide for each response option based on a 'rule of thumb',[25] however, authors report that definitions of an 'adequate' sample size may differ depending on the situation and that markers should have the flexibility to adapt the scoring system based on their own application. This explains why

certain items do not have specific criteria, such as the time between assessments in test-retest evaluation. While this flexibility is useful to ensure the scoring system is representative of a particular instrument and its setting, it may cause issues regarding the standardisation of the checklist's scoring system and comparison between markers and across papers.

Factors affecting standardisation

Perometer

Incorrect limb position has been described as the main reason for the poor accuracy of the volume measurement obtained by the perometer. This has been previously documented.[27–29] Stanton et al.[27] report that large measurement errors occurred when the limb was not perpendicular to the laser beam. Lee et al.[19] attempted to reduce measurement error arising from limb position by ensuring all patients held their digits tightly together including the thumb close against the index finger. The perometer, however, viewed the hand as an elliptical object and included interdigital air spaces as tissue and therefore this was included in the overall volume.

Inter- and intra-rater reliability was lower for the sub-group of 20 women without lymphoedema in this study. When a hand is swollen (such as in lymphoedema), it takes on more of an triaxial ellipsoid shape and thus the laser beams cannot detect the diminished or absent interdigital air spaces resulting in greater reliability measures for patients with swelling than those without.

Lee et al.[19] highlight that the perometer has advantages over the water displacement method in that it can be used on patients with skin conditions and open wounds where using the volumeter may not be feasible. It is much quicker to administer and requires less set up time; however, the measurement errors described above are not isolated to the hand. Man et al.[30] report that the angle of the knee could affect the volume measure by up to 11% using the perometer. It is possible that even with a standardized protocol and limb position, the unique position of the thumb in a frontal plane makes optoelectric imaging unsuitable for use on the hand when assessing volume. While a lightweight and portable version of the perometer exists, the standard version would require a permanent space in a clinical setting and costs between £10,000 and 15,000 depending on the model.

Figure-of-eight

The type of tape measure may also affect the accuracy of the measurements obtained. Retractable measures may have more 'give' to them and can be pulled tighter. Particularly in oedematous hands, the danger is that while concentrating on locating anatomical landmarks to achieve accurate tape placement, the tension being applied can actually displace oedematous tissue. Education, practice and standardised protocols for administration may reduce this risk, such as those provided by the American Society of Hand Therapists.[31]

Timing of assessments

Post et al.[24] highlight a limitation of their study as being the time between assessments. Median time between clinical evaluation and volumetric assessment was seven days. They report that time between assessments did not influence results. However, it was shown that visual inspection may underestimate the number of patients with oedema and overestimate the number of patients without oedema. As the clinical evaluation was performed first, the oedema could have improved spontaneously or worsened by the time the volumetric assessment took place seven days later. The authors do not report what, if any, therapy interventions took place during the seven days which may account for a change in volume. A higher level of agreement with clinical evaluation could have been observed if the volumetric assessments were completed at a more appropriate time, that is on the same day to the clinical evaluation.

Patient-rated outcome measures

To the best of the authors' knowledge, there are no patient-rated outcome measures currently being used which assess or grade swelling from the patient's perception. Although oedema is an observable condition which can be measured by the clinician using a tape measure or volumeter, it is also a subjective condition, like pain, where a patient may feel pressure or tightness which limits full movement from oedema even if this swelling is not detectable to the eye. It would be useful to assess the relationship between a clinician-derived measure such as the figure-of-eight method or volumeter and a patient-rated outcome measure which grades their perception of the swelling. This could be a valuable and time efficient method of evaluating treatment effectiveness from the patient's perspective which could compliment clinician-derived assessments and help to establish a minimally important difference for specific diagnostic subgroups.

Location of oedema

Circumferential measurements may be the only option for measuring digital swelling; however, in areas where

bony landmarks do not exist such as the mid forearm, placement of the tape measure can vary between therapists even when the location has been documented. In the hand, Maihafer et al.[5] argued that the figure-of-eight method is better able to capture hand volume than single joint or single plane measures, which do not adequately reflect volume or size; however, their study used a healthy cohort with no hand oedema. Studies which have compared circumferential measures with the volumeter in lymphoedema patients with upper limb oedema have not included circumferential measurements of the hand.[16,32,33] Previous studies investigating the psychometric properties of the figure-of-eight tape measure in comparison to the volumeter included patients with diverse hand and wrist trauma but often do not specify the exact location of oedema.[20] While previous studies have reported the figure-of-eight tape measurement method is as reliable as the volumeter,[6] these only used a healthy cohort without hand oedema and therefore the unique challenges of assessing a hand with increased fluid may not be captured.

Limitations of the review

This systematic review has a number of limitations. Firstly, the included studies focus on hand oedema only. While methods such as volumetry, perometry and visual inspection will take into account swelling of the digits as well as the hand, the figure-of-eight method neglects the digits and therefore could not be used in isolated finger swelling. Circumferential measurements of digits which are used when assessing isolated digit swelling was not a method described in the selected papers.

The volumeter also includes volume of the wrist and distal forearm along with the hand and digits, whereas the figure-of-eight starts at the ulnar and radial styloid and does not take into account the presence of any swelling at the proximal wrist and distal forearm. The inclusion criteria for this systematic review specified hand oedema only; however, as the volumeter was used as the comparator in all studies, it is feasible, particularly in patients with lymphoedema,[19,22] stroke[24] and burns[21] that the swelling extended into the arm and that this may have been included in volumetric assessment but not in the figure-of-eight measurements. It is also unclear from the literature where the exact cut-off point for the perometer's laser beam is on the hand or wrist and if the clinicians based their visual evaluation on the hand only or included the wrist or forearm.

Another limitation could be the generalisability of the results. While it appears the results are generalisable to therapists with varying levels of experience, due to the limited number of papers meeting the inclusion criteria, the results may not be generalisable to patients with different hand conditions or in different settings such as chronic, rehabilitation or very acute phase of oedema.

Conclusion

Based on a review of the current evidence, the figure-of-eight oedema assessment is the best alternative to the volumeter. It has comparable reliability to the current gold standard, the volumeter. However, replicating studies with a larger number of participants with greater variability of conditions are needed. The perometer is expensive and prone to measurement errors resulting in exaggerated oedema measurements. Many departments may not have access to a volumeter and the submersion of the hand may not be a feasible option in the presence of wounds or dressings. However, the temporary removal or reduction of dressings to assess oedema with a tape measure is a feasible option which offers therapists a quick, cheap, and simple method of objectively assessing hand volume. The use of a protocol is recommended to increase inter- and intra-rater reliability. Visual estimations should be avoided given the poor intra- and inter-rater reliability and correlation with objective measures.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: Leanne Miller is funded by a National Institute for Health Research and Health Education England Clinical Doctoral Research Fellowship (CDRF-2014-05-064). Christina Jerosch-Herold is funded by a National Institute for Health Research Senior Research Fellowship (SRF-2012-05-119). This article presents independent research funded by the National Institute for Health Research (NIHR) and Health Education England. The views expressed are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health.

Ethical approval

Not applicable.

Guarantor

LM.

Contributorship

LM researched literature and conceived the review. LM, CJH and LS were involved in protocol development, data analysis and assisting with manuscript drafting. All authors reviewed and edited the manuscript and approved the final version of the manuscript

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Appendix H

Ethical approval letters (online survey and Delphi)

Faculty of Medicine and Health Sciences Research Ethics Committee

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9.12.15

Dear Leanne,

Title: The treatment of sub-acute hand oedema post trauma- an online survey
Ref: 20152016 - 23

The submission of your research proposal was discussed at a virtual meeting of the Faculty Research Ethics Committee

The Committee were happy to approve your application in principle but have the following concerns for your main study which they would like you to address and amend accordingly:

1. Q6 of the survey - how many patients do you treat - she has include <2 patients per week which would exclude them from taking part as per inclusion criteria.
2. We would like the PIS to include
   - a statement stating then participant can withdraw at any stage and how to go about doing that.
   - Reminding participants that use of email bcc will keep their addresses confidently (a good point in the proposal).
3. We need to see a "thanks but no thanks letter" if people expressed an interest then not selected

In addition the protocol discusses a sub group of participants, self-selected as "experts" to carry out a Delphi exercise. There is not associated PIS, consent form or other paperwork.
You may wish to submit this as an extension later, or resolve this in the current submission

The PIS should include

- Estimated length of consensus study,
- how frequently they will be contacted,
- length of time they will have to response to Leanne's email,
- stating they can withdraw from consensus study,
- Reminding participants that use of email bcc will keep their addresses confidently (a good point in the proposal).

In addition to the usual details

Please write to me once you have resolved/clarified the above issues. I require documentation confirming that you have complied with the Committee's requirements. The Committee have requested that you detail the changes below the relevant point on the text in this letter and also include your amendments as a tracked change within your application/proposal. The revisions to your application can be considered by Chair's action rather than go to a committee meeting, which means that the above documentation can be resubmitted at any time. Please could you send your revisions to me as an attachment in an email as this will speed up the decision making process.

As your project does not have ethics approval until the above issues have been resolved, I want to remind you that you should not be undertaking your research project until you have ethical approval by the Faculty Research Ethics Committee. Planning on the project or literature based elements can still take place but not the research involving the above ethical issues. This is to ensure that you and your research are insured by the University and that your research is undertaken within the University's 'Guidelines on Good Practice in Research' approved by Senate in February 2012.

Yours sincerely

pp

Mark Wilkinson
Chair FMH Research Ethics Committee

10/12/15

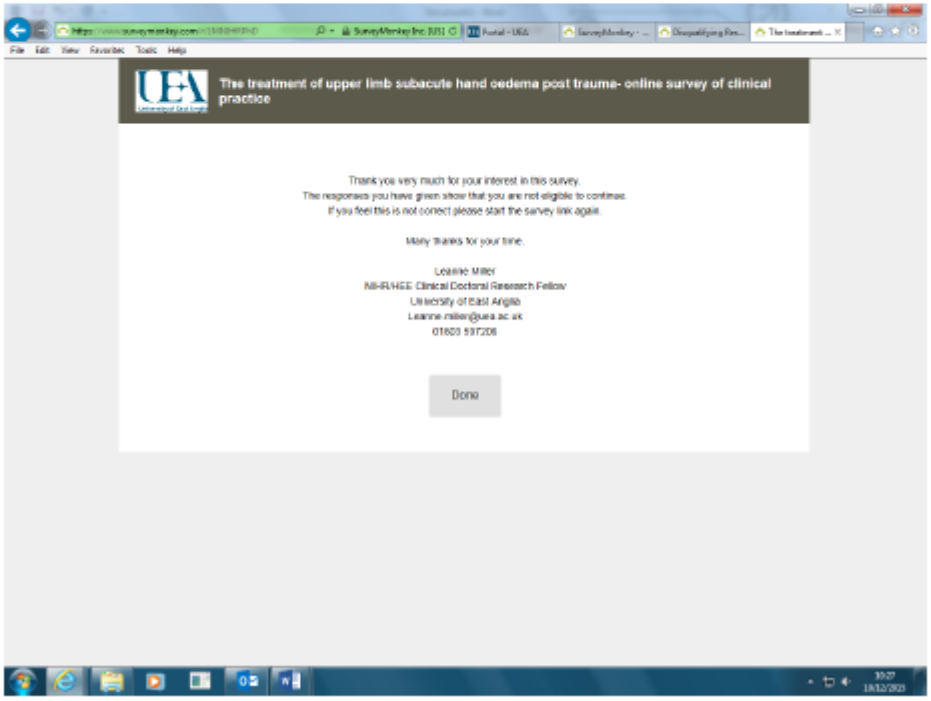
Dear Mark,

Title: The treatment of sub-acute hand oedema post trauma- an online survey
Ref: 20152016 - 23

Many thanks for your letter dated 9.12.15 regarding the ethical approval for the above study.

I have responded to each point raised below with further clarification or amendments to the original documentation and have attached this with this e-mail.

1). Q6 of the survey - how many patients do you treat - <2 patients per week is included which would exclude them from taking part as per inclusion criteria.
The addition of <2 patients was included in this question as a further filter to ensure that only therapists who regularly (at least 2 per week) treat patients with oedema are completing the questionnaire. If a therapist choses this option they are directed to a disqualification page which (see below). This disqualification page is not specific to the particular reason for disqualification from the survey as the programme (Survey Monkey) does not allow for multiple disqualification pages.



I feel this additional verification process is necessary to ensure that therapist with the specified level of knowledge and experience are completing the survey.

2). We would like the PIS to include

- **a statement stating the participant can withdraw at any stage and how to go about doing that.**
- **Reminding participants that use of email bcc will keep their addresses confidential (a good point in the proposal).**

2 sentences have been added to the PIS to fulfil the above points:

Do I have to participate?

No, it is entirely your decision if you wish to take part in this study. If you decide not to take part or wish to withdraw from the study at any point you may do so by simply exiting (closing down) the online survey without submitting your results.

Will my taking part in the study be kept confidential?

Yes, we will follow ethical and legal practice. We will not ask for any personal information and your responses will be anonymous. The link to the online survey will be attached to a BAHT E-Bulletin as well as on the BAHT website for members to click on the link in order to access the survey. The link may also be sent to your e-mail address in a special edition e-bulletin by the BAHT secretary, in this case, we will ensure that yours and other members e-mail addresses are not displayed by using the bcc (blind carbon copy) function.

3). We need to see a "thanks but no thanks letter" if people express an interest then are not selected

I am unclear if you are referring to the online survey or the Delphi study with this point. A "thanks but no thanks letter" would not be appropriate for the online survey as I will not be "selecting" therapists to complete the survey, it will be made available to the entire membership.

In relation to the Delphi study there are 2 reasons why a therapist may not be selected if they express an interest: they do not meet the eligibility criteria or I have reached the required number of volunteers already.

I have drafted a letter to this effect and attached it to this e-mail. The relevant option will be selected when sending the letter and the other option will be deleted so ensure the response letter is specific to the individual recipient.

4). In addition, the protocol discusses a sub group of participants, self-selected as "experts" to carry out a Delphi exercise. There is no associated PIS, consent form or other paperwork.

Attached draft v1 (10.12.15) of the Delphi study PIS and consent form for your consideration. These documents will be e-mailed to those participants who expressed an interest (from the survey) in participating in the Delphi study.

I look forward to hearing back from.

Yours sincerely

Leanne Miller

NIHR/HEE Clinical Doctoral Research Fellow

Faculty of Medicine and Health Sciences Research Ethics Committee

University of East Anglia

Research & Enterprise Services
West Office (Science Building)
University of East Anglia
Norwich Research Park
Norwich, NR4 7TJ

Telephone: +44 (0) 1603 591720
Email: fmh.ethics@uea.ac.uk

Web: www.uea.ac.uk/researchandenterprise

Leanne Miller
HSC

16/12/15

Dear Leanne,

Title: The treatment of sub-acute hand oedema post trauma- an online survey
Ref: 20152016 - 23

The amendments to your above proposal have been considered by the Chair of the Faculty Research Ethics Committee and we can confirm that your proposal has been approved.

Please could you ensure that any further amendments to either the protocol or documents submitted are notified to us in advance and also that any adverse events which occur during your project are reported to the Committee. Please could you also arrange to send us a report once your project is completed.

Yours sincerely,

p.p.

Mark Wilkinson
Chair FMH Research Ethics Committee

Appendix I

Online survey participant information sheet (PIS)

Invitation to participate in a research study

The treatment of sub-acute hand oedema post trauma- online survey of current practice.

Dear BAHT member,

We would like to invite you to take part in our research study. Before you decide whether you would like to take part, we need to tell you what the study is about. Please take time to read through this information. If you have any questions please do not hesitate to contact the researcher, whose contact details are provided at the end of this letter.

What is the purpose of the study?

This study is being led by Leanne Miller, who is a qualified Occupational Therapist specialising in Hand Therapy. This online survey of current practice forms part of a larger programme of research which is being completed as part of a 4 year NIHR funded PhD entitled "The treatment of sub-acute hand oedema post trauma".
The purpose of this online survey is to establish current practices in assessing and treating sub-acute oedema including: what advice is given to patients, the types of modalities used, the frequency and duration of techniques implemented and tools used for evaluating effectiveness.

Why have I been approached?

You have been approached to take part in this study as you are a member of the British Association of Hand Therapists and have agreed to receive e-mails regarding BAHT activity including research studies.

Do I have to participate?

No, it is entirely your decision if you wish to take part in this study. If you decide not to take part or wish to withdraw from the study at any point you may do so by simply exiting (closing down) the online survey without submitting your results.

What will happen if I agree to participate?

If you are willing to take part in this study it will involve completing an online survey (Survey Monkey) which will take approximately 15-30 minutes, depending on your responses. This can be done in one session or your responses can be saved for you to return and complete the survey at a later time.

What are the possible disadvantages and risks to taking part?

We cannot identify any risks involved with taking part in this study. The only possible disadvantage is that it will take 15-30 minutes of your time to complete.

What are the possible benefits of taking part?

We cannot identify any direct benefits to you by taking part in this study, however your questionnaire responses will help us in determining current practices in assessing and treating sub-acute oedema in patients with hand trauma and post-surgery. The information you provide will also help us to develop a standard oedema management guideline.

Will my taking part in the study be kept confidential?

Yes, we will follow ethical and legal practice. We will not ask for any personal information and your responses will be anonymous. The link to the online survey will be attached to a BAHT E-Bulletin as well as on the BAHT website for members to click on the link in order to access the survey. The link may also be sent to your e-mail address in a special edition e-bulletin, in this case, we will ensure that yours and other members e-mail addresses are not displayed by using the bcc (blind carbon copy) function.

What will happen to the results of this survey?

Primarily, the results of this online survey will contribute to a doctoral thesis. As well as this, responses will also assist subsequent phases of the research programme, for example, a Delphi Consensus method which will follow on from this survey. The results will also inform the "standard" care arm of a pilot randomized controlled trial to be completed in 2017-2018. We plan to publish the results in rehabilitation journals and to present at conferences. These reports will not contain any names or details that would allow individual participants to be identified.

Who is organising the research?

This study is being led by Leanne Miller who is a qualified Occupational Therapist specialising in Hand Therapy and undertaking this study as part of a 4-year NIHR Clinical Academic Training Fellowship (PhD) at the University of East Anglia. She is being supervised by Dr. Christina Jerosch-Herold, Reader in Occupational Therapy and Professor Lee Shepstone, Professor of Medical Statistics, at the UEA.

Who has reviewed the study?

Ethical approval has been sought from the University of East Anglia Research Ethics Committee. This study has been reviewed and approved by the Faculty of Medicine and Health REC. **(UEA REC ref: 20152016 – 23**)

What if there is a problem?

If you have a concern about any aspect of this study you should speak to the lead researcher Leanne Miller (Tel. 01603 597206) who will do her best to answer your questions. If you remain unhappy and wish to complain formally, you can do this by contacting the study supervisor Christina Jerosch-Herold, at the University of East Anglia (01603 593316).

Where can I obtain further information?

If you have further questions about the study and what participating would entail, please do not hesitate to contact the lead researcher, Leanne Miller on 01603 597206 or Leanne.miller@uea.ac.uk .

Thank you for reading this. If you wish to take part, please tick the "I agree" box on the next page before proceeding to the survey.

Appendix J

Consent form (online survey)

(This consent form will be made available online in survey monkey and only once all statements have been checked will the questionnaire be made available)

University of East Anglia

Consent form

Name of Researcher: Leanne Miller
Study title: The treatment of sub-acute hand oedema post trauma- online survey of current practice.

Please read the following statements carefully and click each box separately. By clicking the box you are agreeing to that point.

I confirm I have read and understood the Participant Information Sheet version 1 dated 5.10.15 ☐

I understand that my participation is voluntary and that I may withdraw from this study at any point without giving a reason. ☐

I confirm that I have been given the opportunity to ask questions about the study. ☐

I would like to participate in this research study ☐

Please continue to the next page to start the online survey.

Appendix K

Survey questionnaire (copied from SurveyMonkey questionnaire)

The treatment of upper limb subacute hand oedema post trauma- online survey of clinical practice

6. The Survey- participants demographics

The first page of questions are based on your professional background and level of experience. The survey will then progress to asking you about how you treat and assess oedema.

*** What is your profession? (Please tick only one option)**

- ◯ Occupational Therapist
- ◯ Physiotherapist
- ◯ Assistant Practitioner
- ◯ OT/PT Assistant
- ◯ Other (please specify)

*** What grade or band are you, based on NHS Agenda for Change. (Please tick only one option)**

- ◯ Band 3
- ◯ Band 4
- ◯ Band 5
- ◯ Band 6
- ◯ Band 7
- ◯ Band 8
- ◯ Other (please specify)

*** How many years of hand therapy experience have you had? (Please tick only one option)**

- ◯ Less than 2 years
- ◯ 2-5 years
- ◯ 6-10 years
- ◯ 11-15 years
- ◯ 16-20 years
- ◯ More than 20 years

*** How many patients, on average, do you treat, per week, that require some form of oedema management? This can include new referrals and returning follow-up patients seen in the same week. (Please tick only one option)**

- ◯ Less than 2
- ◯ 3-5
- ◯ 6-10
- ◯ 11-20
- ◯ More than 20

Do you use isotoner/compression/oedema gloves to treat oedema in your clinical practice?

- ◯ Yes
- ◯ No

The treatment of upper limb subacute hand oedema post trauma- online survey of clinical practice

8. Compression section

*** You have identified that you use an isotoner/ compression /oedema glove in your clinical practice to treat oedema. What are your instructions to your patient for.....**

When to wear the glove?	
When to remove the glove?	
Frequency of wear? (minutes/hours)	
Duration of wear? (days/weeks)	
Precautions?	
If you use any other form of compression i.e intermittent pneumatic compression (IPC) please tell us in the box	

Do you use Coban wrap to treat oedema in your clinical practice?

- ◯ Yes
- ◯ No

*** You have identified that you use coban wrap in your clinical practice to treat oedema. What are your instructions to your patient for.....**

Application? (method of wrapping)	
When to wear/remove?	
Frequency? (minutes/hours)	
Duration? (days/weeks)	
Precautions?	

Do you use lycra digi sleeves to treat oedema in your clinical practice?

- ◯ Yes
- ◯ No

*** You have identified that you use lycra digi sleeves in your clinical practice to treat oedema. What are your instructions to your patients for.....**

Application of sleeve?	
When to wear/remove sleeve?	
Frequency of wear (minutes/hours)	
Duration of wear (days/weeks)	
Precautions?	

Do you use kinesiology tape to treat oedema in your clinical practice?

- ◯ Yes
- ◯ No

*** You have identified that you use kinesiology tape in your clinical practice to treat oedema. Please can you give further details....**

What shape do you cut the tape in to?	

*** What colour of tape do you offer your patient? (Please tick all that apply)**

- [ ] Beige
- [ ] Black
- [ ] Pink
- [ ] Blue
- [ ] Green
- [ ] Red
- [ ] Purple
- [ ] Pattern
- [ ] Other (please specify)

*** If you only have 1 colour of tape, what colour is it?**

*** Do you believe that the colour of tape can influence its purpose?**

*** What are your instructions to your patient for.....**

Pre-application?	
Tensioning the tape?	
When to wear/remove?	
Frequency of wear? (minutes/hours)	
Duration of wear? (days/weeks)	
Precautions?	

Do you use massage to treat oedema in your clinical practice?

- ◯ Yes
- ◯ No

*** You have identified that you use massage in your clinical practice to treat oedema. Please can you give us some more details on how you do this and/or how you instruct your patient to do this themselves.....**

	Yes	No
Proximal to distal?	◯	◯
Distal to proximal	◯	◯
Light pressure	◯	◯
Firm pressure	◯	◯
Dry massage (without cream/oil)	◯	◯
With cream/oil	◯	◯

*** A few more questions about how often you advise massage?**

Length of time massaging (minutes)	
How many times per day?	
For how many days/weeks?	

Do you use elevation to treat oedema in your clinical practice?

- ◯ Yes
- ◯ No

* **You have identified that you use elevation in your clinical practice to treat oedema. Please can you give us more details on how you instruct your patient in this method?**

	Yes	No
Do you advise the use of a sling (Bedford or cloth) /collar and cuff?	○	○
Do you advise the arm should be above the level of the heart?	○	○
Do you advise exercises whilst the arm is elevated?	○	○

A few more questions about the use of elevation for oedema management...

Length of time with arm/hand elevated? (minutes/hours per day) _____

For how many days? _____

Precautions? _____

Do you use manual lymph drainage/ modified manual lymph drainage (MLD) to treat oedema in your clinical practice?

○ Yes

○ No

*** You have identified that you use manual lymph drainage (or a modified version) in your clinical practice to treat oedema. Please can you give us some more details on how you do this and what you advise your patient.**

If you follow a structured formal programme, please can you give a reference? If not, please enter N/A

If you do not use all 3 techniques (wrapping, breathing and massage), please tell us what aspects you use?

How often does the patient perform this technique? (times per day/number of days)

Do you use electrotherapy to treat oedema in your clinical practice ?

- ◯ Yes
- ◯ No

* **You have identified that you use electrotherapy in your clinical practice to treat oedema. Please can you let us know what modalities you use? (Please tick all that apply)**

- [ ] Ultrasound
- [ ] Interferential therapy
- [ ] Pulsed shortwave therapy
- [ ] Laser therapy
- [ ] High Voltage Pulsed Current (HVPC)
- [ ] Other (please specify)

* **How often would you see your patient for these modalities? (Please tick only one option)**

- ( ) Daily
- ( ) Twice a week
- ( ) Weekly
- ( ) Fortnightly
- ( ) Patients hire machines to complete at home as prescribed
- ( ) Other (please specify)

Do you use breathing exercises/techniques to treat oedema in your clinical practice?

- ( ) Yes
- ( ) No

* **You have identified that you use breathing exercises in your clinical practice to treat oedema. Please can you give us more details of what you advise your patients.**

Depth of the breath?	
Technique (i.e standing/sitting position, hand placement etc)?	
Number of breaths?	
Number of repetitions?	

Do you use exercises to treat oedema in your clinical practice?

- ○ Yes
- ○ No

* **You have identified that you use exercises in your clinical practice to treat oedema. Please can you indicate what type of exercises you advise your patients. (Please tick all that apply)**

- ☐ Active
- ☐ Passive
- ☐ Active assisted
- ☐ Resistance
- ☐ Active exercises in elevation
- ☐ Active exercises in warm water
- ☐ Active exercises with cryotherapy (ice or cold water)
- ☐ Active exercises with contrast bathing

*** Please rank the following methods in terms of how likely you are to use them. 1= most likely, 10 = least likely. Please tick N/A if you do not use this method in your clinical practice and rank the remaining options.**

Isotoner/compression/oedema glove	☐ N/A
Coban wrap	☐ N/A
Lycra digi sleeve	☐ N/A
Kinesiology tape	☐ N/A
Massage	☐ N/A
Elevation	☐ N/A
Manual lymph drainage/ modified manual lymph drainage (combination of wrapping, breathing exercises and massage)	☐ N/A
Electrotherapy	☐ N/A
Breathing techniques	☐ N/A
Exercises	☐ N/A

* **Please rank these methods in terms of which you perceive to be the most effective. Irrespective of whether you use these methods or not. 1= most effective 10=least effective**

	Isotoner/compression/oedema glove
	Coban wrap
	Lycra digi sleeve
	Kinesiology tape
	Massage
	Elevation
	Manual lymph drainage/ modified manual lymph drainage (combination of wrapping, breathing exercises and massage)
	Electrotherapy
	Breathing techniques
	Exercises

*** Please identify which of the following methods you have received training for?**

	Formal training i.e external or accredited course	In-service teaching with colleagues	No formal or informal training received, but **I do** use this method	N/A- I **do not** use this method in my clinical practice
Isotoner/compression/oedema glove	○	○	○	○
Coban wrap	○	○	○	○
Lycra digi sleeve	○	○	○	○
Kinesiology tape	○	○	○	○
Massage	○	○	○	○
Elevation	○	○	○	○
Manual lymph drainage/ Modified manual lymph drainage (a combination of wrapping, breathing exercises and massage)	○	○	○	○
Electrotherapy	○	○	○	○
Breathing techniques	○	○	○	○
Exercises	○	○	○	○

*** How do you routinely evaluate the effectiveness of your chosen oedema treatment/s? (Please tick all that apply)**

- ☐ Return to work
- ☐ Functional assessment
- ☐ Patient subjective account
- ☐ Visual inspection
- ☐ Goniometry
- ☐ Measuring tape
- ☐ Volumetry
- ☐ Patient rated outcome measure
- ☐ Strength (Grip/pinch/manual muscle testing)
- ☐ Other (please specify)

*** You have identified that you use a measuring tape to assess oedema. Please identify which method you use? (Please tick all that apply)**

- [ ] Figure of 8
- [ ] Circumferential
- [ ] Other (please specify)

*** You have identified that you use volumetry to assess oedema. How do you do this?**

What equipment do you need?

Describe your method?

*** You have identified that you use a Patient Rated Outcome Measure to assess oedema. Please identify which one/s you use? (Please tick all that apply)**

- [ ] Patient Evaluation Measure- hand health profile (PEM)
- [ ] The Disability of the Arm, Shoulder and Hand (DASH) 30 item measure
- [ ] Quick-DASH- 11 item measure
- [ ] Canadian Occupational Performance Measure (COPM)
- [ ] Upper Extremity Functional Index
- [ ] Patient Rated Wrist and Hand Evaluation (PRWHE)
- [ ] Michigan Hand Questionnaire (MHQ)
- [ ] Patient Outcome of Surgery (POS)
- [ ] Other (please specify)

Many thanks for completing this survey.
If you have any further comments which were not captured in the survey please feel free to add them to the text box below.

Appendix L

Ethical approval letters (Delphi) see also appendix H

BRITISH ASSOCIATION OF HAND THERAPISTS

15th October 2015

To Whom It May Concern,

RE **Study name:** The treatment of sub-acute hand oedema post trauma- an online survey of practice and Delphi Consensus Method
Researcher: Leanne Miller
Supervisors: Dr Christina Jerosch-Herold and Prof Lee Shepstone
Host: University of East Anglia

I confirm that the British Association of Hand Therapists gives permission for the above researcher to distribute the approved electronic survey to our members via the following means:

- Quarterly email bulletin
- Posting on the BAHT website (www.hand-therapy.co.uk)
- Posting on the BAHT facebook page
- Posting on the BAHT twitter feed
- Via the local interest group leads (contact details available on the public access section of the BAHT website)

The BAHT secretary will distribute the survey link. None of the research team will have access to individual members e-mail addresses.

We will require evidence of ethical approval before participating in this research.

Yours faithfully,

Lisa Newington
Clinical Evidence Committee (Chair)
British Association of Hand Therapists

Appendix M

Consent form (Delphi)

Invitation to participate in a research study

The treatment of sub-acute hand oedema post trauma- Delphi Consensus Method

Dear [INSERT NAME],

Many thanks for expressing an interest in this study. Before you decide whether you would like to take part, we need to tell you what the study is about. Please take time to read through this information. If you have any questions please do not hesitate to contact the researcher, whose contact details are provided at the end of this letter.

What is the purpose of the study?

The purpose of this Delphi study is to develop consensus on best practice for hand oedema interventions including the frequency, duration and instructions given to patient. It forms part of a larger programme of research which includes the online survey of current practice which you recently took part in. This part of the research will build on the responses obtained in the survey, and, using a structured method of sequential questionnaires with a group of experienced and knowledgeable "experts" we will be obtaining opinions on given questions in order to achieve agreement within the group.

Why have I been approached?

You have been approached to take part in this study as you are a member of the British Association of Hand Therapists, you have recently completed an online survey of your practice and from this have expressed an interest in taking part in this Delphi study and you meet the eligibility criteria set for an "expert" member.

Do I have to participate?

No, it is entirely your decision if you wish to take part in this study. If you decide not to take part or wish to withdraw from the study you may do so at any point and without giving a reason, even if you have already contributed to previous rounds in the Delphi.

If this is the case and you wish to withdraw from further participation, you will need to send an e-mail to the Principal Investigator, Leanne Miller to inform her, this will then ensure you do not receive further e-mails relating to this study.

What will happen if I agree to participate?

If you are willing to take part in this study it will involve completing a series of web based questionnaires circulated to you by the Principal Investigator, who will act as the group

facilitator to a panel of approximately 10 other hand therapy experts (who will remain anonymous to each other) over a period of approximately 3 months (April to June 2016).

Communication will be internet based, an e-mail will be sent to you with a link to a Survey Monkey questionnaire. You will be asked to complete this questionnaire, which will take approximately 30 minutes, within a set timeframe, of approximately 2-3 weeks. This process is classed as 1 round of the Delphi study.

There will be at least 2 rounds (and possibly up to 4 rounds depending on when the pre-agreed level of consensus has been reached) of questionnaires where you will be asked to comment on statements relating to the treatment of oedema, state how much you agree or disagree with them or rank statements in order of (perceived) importance.

After each round the facilitator will analyse and collate the responses from the group of experts, anonymise these and re-circulate this as a new version back to group for the next round of questions. This way you will be able to receive feedback on the overall group consensus.

The questionnaires for the next round, which will be also take approximately 30 minutes to complete, will again ask you to make comments, state your level of agreement and will ask specific details relating to frequency and duration of specific oedema management interventions. The link to the questionnaires for subsequent rounds will be circulated approximately 3-4 weeks after the previous round.

Full details will be given to each expert prior to each round and there will be an opportunity to ask questions and clarify your understanding of the task before proceeding.

No face to face or phone communication will be required.

What are the possible disadvantages and risks to taking part?

We cannot identify any risks involved with taking part in this study. The only possible disadvantage is that this will require approximately 30-45 minutes of your time per round. There will be at least 2 rounds between April to June 2016. The questionnaire for each round will have a time frame of at least 2 weeks in order for you to complete and submit your responses.

What are the possible benefits of taking part?

We cannot identify any direct benefits to you by taking part in this study, however your participation is an opportunity as an expert to contribute to an agreed standard guideline for treating sub-acute oedema in patients with hand trauma and post-surgery. Your participation can also be classed as research activity for your CPD portfolio.

Will my taking part in the study be kept confidential?

Yes, we will follow ethical and legal practice. We will not ask for any personal information and your responses will be anonymous. Each participant will be issued with a unique ID number to be used by the facilitator and the other participants. The bcc (blind carbon copy) function will be used to ensure anonymity of the expert volunteers therefore you will not be

able to see the e-mail addresses of the other participants and they will not be able to view yours. All questionnaire responses will be anonymous. Any names, addresses and e-mail addresses will be held securely by the principal investigator and on a password protected computer.
All data will be stored securely after the competition of the project and be kept for 5 years before being destroyed.

What will happen to the results of this survey?

Primarily, the results of this online survey will contribute to a doctoral thesis. As well as this, responses will also assist subsequent phases of the research programme, for example the results will inform the "standard" care arm of a pilot randomized controlled trial to be completed in 2018. We plan to publish the results in rehabilitation journals and to present at conferences. These reports will not contain any names or details that would allow individual participants to be identified.

Who is organising the research?

This study is being led by Leanne Miller who is a qualified Occupational Therapist specialising in Hand Therapy and undertaking this study as part of a 4-year NIHR Clinical Academic Training Fellowship (PhD) at the University of East Anglia. She is being supervised by Dr. Christina Jerosch-Herold, Reader in Occupational Therapy and Professor Lee Shepstone, Professor of Medical Statistics, at the UEA.

Who has reviewed the study?

Ethical approval has been sought from the University of East Anglia Research Ethics Committee. This study has been reviewed and approved by the Faculty of Medicine and Health REC. **(UEA REC reference number 20152016 - 23)**

What if there is a problem?

If you have a concern about any aspect of this study you should speak to the lead researcher Leanne Miller (Tel. 01603 597206) who will do her best to answer your questions. If you remain unhappy and wish to complain formally, you can do this by contacting the study supervisor Christina Jerosch-Herold, at the University of East Anglia (01603 593316).

Where can I obtain further information?

If you have further questions about the study and what participating would entail, please do not hesitate to contact the lead researcher, Leanne Miller on 01603 597206 or Leanne.miller@uea.ac.uk .

Appendix N

Consent form (Delphi)

Consent form

Name of Researcher: Leanne Miller
Study title: The treatment of sub-acute hand oedema post trauma- Delphi Consensus Method

Please read the following statements carefully and initial each box separately. By initialling the box you are agreeing to that point.

I confirm I have read and understood the Participant Information Sheet version 1 dated 10.12.15	☐
I understand that my participation is voluntary and that I may withdraw from this study at any point without giving a reason.	☐
I confirm that I meet the "expert" eligibility criteria (refer to separate pdf)	☐
I confirm that I have been given the opportunity to ask questions about the study	☐
I would like to participate in this research study.	☐

Once completed, please save this document as a pdf and e-mail it to Leanne Miller at Leanne.miller@uea.ac.uk requesting a "Read Receipt" (if able).

Appendix O

Delphi questionnaire for all rounds with responses (copied from SuveyMonkey)

Compression

Compression is used in various forms to treat oedema of the hand. In this section we are referring to the use of an oedema glove.

* 1 When issuing an oedema glove for sub-acute hand oedema, you would instruct your patient to wear it:

Please choose only one option.

- ○ During the daytime only (removing for hygiene)
- ○ During the night only
- ○ 20-24 hours a day (removing for hygiene)
- ○ Intermittently during the day (for example; 2 hours on, 2 hours off)
- ○ Other (please specify)

* 2 It is necessary to educate your patient on when the oedema glove can be worn and when it should be removed. Please identify your level of agreement with the following statement:

It is necessary to remove an oedema glove for certain activities such as: hygiene or self-care (which may include scar massage), for wet or dirty activities and to check the integrity of the skin but the glove should be worn during exercises and function (if the glove does not hinder these activities) to assist in pumping the oedema out of the hand.

If you partly agree or disagree with the statement you will be guided to a fresh page where you have the opportunity to add you amended or alterative wording or statement in a free text box.

- ○ I agree with statement and would not change it
- ○ I partly agree with this statement but would suggest the following alterations
- ○ I disagree with this statement and suggest the following alternative statement

Compression

* 3 **It is necessary to remove an oedema glove for certain activities such as: hygiene or self-care (which may include scar massage), for wet or dirty activities and to check the integrity of the skin but the glove should be worn during exercises and function (if the glove does not hinder these activities) to assist in pumping the oedema out of the hand.**

Please add your amended or alternative statement here:

Compression

* 4 When instructing your patients on the duration in which to wear their oedema glove, you advise it should be worn:

Please choose only one option.

- ○ Until told otherwise by the therapist
- ○ Until the patients feels the swelling has subsided
- ○ Up to 4 weeks post-surgery or trauma
- ○ Greater than 4 weeks post-surgery/trauma
- ○ Other (please specify)

* 5 The patient may be warned of certain situations in which they must remove the glove. Under what circumstances would you instruct your patient to remove the glove:

Choose all options that apply.

- ☐ If the glove causes discomfort
- ☐ If the fingertip colour changes to a blue/white/dark red
- ☐ If the skin becomes damaged/irritated or shows a reaction
- ☐ If sensation becomes impaired or deteriorates
- ☐ Other (please specify)

Elevation

Elevation of the hand can be done by numerous methods. Some methods may be more appropriate to use at certain times of the day or night and a combination of methods may be more beneficial.

* 6 Listed below are examples of how the hand may be elevated. Please identify if you find the method appropriate or not and when you would advise your patient to use this method.

	Appropriate to use during the daytime	Appropriate to use overnight	Appropriate to use either day or night	Not appropriate
Elevating the hand with a Bradford sling	○	○	○	○
Elevating the hand with a collar and cuff	○	○	○	○
Elevating the hand with a triangular cloth sling	○	○	○	○
Elevating the hand actively without it being held in place	○	○	○	○
Elevating the hand on pillow/s	○	○	○	○

Other (please specify)

*7 Please state your level of agreement with this statement:

In the management of sub-acute hand oedema the hand should be elevated (regardless of the method of elevating) above the level of the heart.

If you partly agree or disagree with the statement you will be guided to a fresh page where you have the opportunity to add you amended or alterative wording or statement in a free text box.

- ○ I agree with statement and would not change it
- ○ I partly agree with this statement but would suggest the following alterations
- ○ I disagree with this statement and suggest the following alternative statement

Elevation

*8 **In the management of sub-acute hand oedema the hand should be elevated (regardless of the method of elevating) above the level of the heart.**

Please add your amended or alterative statement here:

Elevation

* 9 Please identify which statement you feel is most appropriate in relation to the 'dose' of elevating the hand.

Please choose only one option.

- ○ As much as possible during the day when the hand is not being used (function, hygiene etc)
- ○ As much as possible during the day and overnight
- ○ During exercises only
- ○ For a specified period of time directed by the therapist based on clinical need i.e 30-60 minutes at a time.

Please justify your above response

*11 There may be numerous reasons when it is necessary to stop or amend your advice regarding elevation, some of these reasons are listed below.

Please state if you agree with each reason and if necessary add 'other' relevant circumstances.

	Yes- I agree this is a reason to stop or amend advice about elevation	No- I do not agree with this as a reason to stop or amend advice about elevation
If capillary refill of the hand is compromised	○	○
If hand sensation becomes impaired or deteriorates from baseline	○	○
If other musculoskeletal problems increased (neck/shoulder/elbow issues)	○	○
If swelling begins to reduce	○	○
If elevation is preventing safe functional use	○	○

Other (please specify)

Elevation

* 10 In relation to the duration of hand elevation please identify which option you feel is most appropriate.

Please choose only one option.

- ○ Until the patient feels the swelling has subsided
- ○ Until advised to stop by the therapist
- ○ For 1-2 weeks
- ○ Between 2-4 weeks
- ○ Other (please specify)

*12 For each aspect of this method please identify whether you agree or disagree with the following statements.

If you partly agree or disagree with the statement you will have the opportunity to offer an amended or alterative wording or statement. Free text boxes allow you to justify your responses to questions if needed.

When using massage for the management of sub-acute hand oedema it should be performed:

	I agree with this statement and would not change it	I partially agree with this statement but would suggest the following alterations **(use text box)**	I disagree with this statement and would suggest the following alternative statement **(use text box)**
In a distal to proximal direction with light pressure using creams or oils	○	○	○
For approximately 10 minutes	○	○	○
At least 3 times per day	○	○	○
For a minimum of 2 weeks	○	○	○

Please add your amended or alternative statement here

Kinesiology Tape

*13 Do you use or have you received formal or informal training on kinesiology tape?

- Yes
- No

Kinesiology Tape

*14 Please identify if you agree or disagree with these statements relating to the pre-application conditions for using kinesiology tape.

When using kinesiology tape for sub-acute hand oedema post trauma or surgery it should be cut into a fan shape with a proximal anchor (refer to picture below)

If you partly agree or disagree with the statement you will be guided to a fresh page where you have the opportunity to add you amended or alterative wording or statement in a free text box.

- I agree with this statement and would not change it
- I partly agree with this statement but would suggest the following amendments
- I disagree with this statement and would suggest the following alternative statement

Kinesiology tape cut into fan shape.

Kinesiology Tape

*16 Please state your level of agreement with the following statement:

The tape should be applied to clean (no oils or creams, hair shaved if needed), dry and unbroken skin.

If you partly agree or disagree with the statement you will be guided to a fresh page where you have the opportunity to add you amended or alterative wording or statement in a free text box.

- ○ I agree with statement and would not change it
- ○ I partly agree with this statement but would suggest the following alterations
- ○ I disagree with this statement and would suggest the following alternative statement

Kinesiology Tape

*17 **The tape should be applied to clean (no oils or creams, hair shaved if needed), dry and unbroken skin.**

Please add your amended or alterative statement here:

Kinesiology Tape

* 18 Please state your level of agreement with the following statement:

The colour of the tape does not influence its effects.

If you partly agree or disagree with the statement you will be guided to a fresh page where you have the opportunity to add you amended or alterative wording or statement in a free text box.

- ○ I agree with this statement and would not change it
- ○ I partly agree with this statement but would suggest the following alterations
- ○ I disagree with this statement and suggest the following alternative statement

Kinesiology Tape

* 19 **The colour of the tape does not influence its effects.**

Please add your amended or alterative statement here:

Kinesiology Tape

*20 Please specify how much tension should be applied to the central portion (not ends) of the tape when using for sub-acute hand oedema.

Choose only one option.

- ○ No tension, also referred to as "paper-off tension"
- ○ 5-25% tension
- ○ 26-40% tension
- ○ Greater than 40% tension
- ○ Other (please specify)

Kinesiology Tape

*21 Please state your level of agreement with the following statement:

The anchor section of the tape should have no tension applied.

If you partly agree or disagree with the statement you will be guided to a fresh page where you have the opportunity to add you amended or alterative wording or statement in a free text box.

- ○ I agree with this statement and would not change it
- ○ I partly agree with this statement but would suggest the following alterations
- ○ I disagree with this statement and suggest the following alternative statement

Kinesiology Tape

* 22 **The anchor section of the tape should have no tension applied.**

Please add your amended or alternative statement here:

Kinesiology Tape

* 23 Please state your level of agreement with the following statement:

The tape should be worn full time until it starts to peel off the skin naturally (approximately 3-5 days)

If you partly agree or disagree with the statement you will be guided to a fresh page where you have the opportunity to add you amended or alterative wording or statement in a free text box.

- ○ I agree with this statement and would not change it
- ○ I partly agree with this statement but would suggest the following alterations
- ○ I disagree with this statement and suggest the following alternative statement

Kinesiology Tape

* 24 **The tape should be worn full time until it starts to peel off the skin naturally (approximately 3-5 days).**

Please add your amended or alternative statement here:

Kinesiology Tape

* 25 Please state your level of agreement with the following statement:

If a patients clinical status is stable and there have been no problems wearing the tape, the skin should be given a rest day (24 hours) before re-application (by therapist or patient)

If you partly agree or disagree with the statement you will be guided to a fresh page where you have the opportunity to add you amended or alterative wording or statement in a free text box.

- I agree with this statement and would not change it
- I partly agree with this statement but would suggest the following alterations
- I disagree with this statement and suggest the following alternative statement

Kinesiology Tape

* 26 **If a patients clinical status is stable and there have been no problems wearing the tape, the skin should be given a rest day (24 hours) before re-application (by therapist or patient).**

Please add your amended or alterative statement here:

Kinesiology Tape

* 27 Please choose **one option** which best describes the duration in which you advise your patient wears the tape.

- ○ Until told to discontinue by the therapist
- ○ Until the patient feels the swelling has subsided
- ○ 1-2 weeks
- ○ 2-4 weeks
- ○ Other (please specify)

*28 The following statement refers to the contraindications and precautions which apply to the use of kinesiology tape. Please identify your level of agreement.

Kinesiology tape for the management of sub-acute hand oedema should not be used on patients with open wound, active infections, thin skin from the use of long-term steroids, allergies to medical grade adhesives or those with conditions affecting the heart, liver or who have had lymph node dissection. The tape should be removed if skin rash or irritation occurs.

If you partly agree or disagree with the statement you will be guided to a fresh page where you have the opportunity to add you amended or alterative wording or statement in a free text box.

- ○ I agree with the statement and would not change it
- ○ I partly agree with the statement but would suggest the following alterations
- ○ I disagree with the statement and suggest the following alternative statement

Kinesiology Tape

*29 **Kinesiology tape for the management of sub-acute hand oedema should not be used on patients with open wound, active infections, thin skin from the use of long-term steroids, allergies to medical grade adhesives or those with conditions affecting the heart, liver or who have had lymph node dissection. The tape should be removed if skin rash or irritation occurs.**

Please add your amended or alterative statement here:

Welcome to the 2nd Delphi round.
Please read this instruction page carefully.

Thank you for contributions in round 1 and for your continued support in round 2.

The purpose of this round is to feedback the responses from the previous round and try to obtain agreement on some questions which did not meet the required level of consensus.

The aim of a Delphi method is to gain consensus, it is not necessary to gain 100% agreement but through the Delphi process the opinions of the group move towards something that represents a majority view and can therefore also be considered as representative. At the outset I set the consensus threshold at 75% - this means that where 75% or more of the experts agree this will be classed as achieving sufficient consensus and therefore that item will not be open for voting again. Where there is a difference of opinion between experts and agreement is lower than the 75% level further clarification will be sought and you will be asked once again to give your view.

The responses from the previous round have been reviewed and will be presented to you throughout this round (highlighted in bold text). All individual comments will be labelled Expert #1, Expert #2 etc, so whilst you may recognize your own comments they will remain anonymous to myself and to the other experts.
Seeing comments from other experts may shape your own opinion and in turn this may help you confirm or rethink your responses.

You will need to complete all questions before navigating to the next page however you can go back and revise your responses as often as you like before submitting your final answers.

Please note that the results presented here are given to you as part of the ongoing Delphi process but should remain confidential and not be cited or published. At the end of the final round when consensus has been achieved the results will be submitted for publication. All data will remain anonymous.

If you have any questions before proceeding please do not hesitate to contact me on Leanne.miller@uea.ac.uk

It is important to remember that during this Delphi Method the term "sub-acute" refers to oedema which persists beyond the early acute stage (3-5 days) and is present between 2-6 weeks post trauma or surgery.

Compression

25% (n=2) of the experts would instruct their patient to wear an oedema glove 20-24 hours a day (removing for hygiene).

75% (n=6) chose the 'other' option to this question. Individual comments included:

Expert #1 " I usually tell the patient to remove these at night unless they find the swelling increased in the morning then I would ask them to wear it an night too"

Expert #3 "almost constantly (one slightly less firm firmly fitting glove for night) night and day

Expert #5 "daytime and night time, removing for hygiene/dirty tasks. If the glove impeded function then I would advise they remove. If peripheral circulation was a concern then the patient should be comfortable with the fit during the daytime before wearing overnight."

Expert #8 "generally day time only but if patients finds it useful and wishes to wear at night that is allowed"

* 1 When issuing an oedema glove (isotoner, lycra, tubifast, or other) you would instruct your patient to wear this 20-24 hours a day , removing for hygiene, scar massage, exercise and dirty tasks. Initial use may focus on day time hours but could be extended to wear overnight if there are no circulatory concerns and the amount of oedema warranted increased use.

- ○ I agree with this statement and would not change it
- ○ I partly agree with this statement but would suggest the following alterations
- ○ I disagree with this statement and would suggest the following alternative statement
- ○ I do not issue any type of oedema glove

Compression

* 2 **Please add your amended or alternative statement here:**

Compression

It is necessary to remove an oedema glove for certain activities such as: hygiene or self-care (which may include scar massage), for wet or dirty activities and to check the integrity of the skin, but the glove should be worn during exercises and function (if the glove does not hinder these activities) to assist in pumping the oedema out of the hand.

75% (n=6) consensus achieved.

100% (n=2) chose the 'other' option in relation to the duration in which to wear the oedema glove.

Expert #4 commented "Up to 12 weeks post trauma/surgery, but reviewed regularly in hand therapy and discontinued when oedema has subsided.

* 3 When instructing your patient on the duration in which the oedema glove will be needed, you advise it may be worn up to 12 weeks post trauma/surgery, that wearing the glove will be reviewed in hand therapy appointments and discontinued when the oedema has subsided.

- ○ I agree with this statement and would not change it
- ○ I partly agree with this statement but would suggest the following alterations.
- ○ I disagree with the statement and would suggest the following alterations

Compression

4 **Please add your amended or alterative statement here:**

Compression

Situations in which to remove the glove created a equal spread of responses across all 5 options.

* 5 The patient may be warned of certain situations in which they must remove the glove. These situations may include: if the glove causes discomfort, if the fingertip vascularity is compromised, if the skin becomes damaged, irritated or shows a reaction and if the sensation becomes impaired or deteriorates.

- ○ I agree with this statement and would not change it
- ○ I partly agree with this statement but would suggest the following alterations
- ○ I disagree with this statement and would suggest the following alterative

Compression

6 **Please add your amended or alterative statement here:**

Elevation

You were asked to identify which methods of elevating the hand you felt were appropriate and at what time of day/night you thought this was suitable.

Consensus was reached on 2 of the 5 methods;

Elevating the hand with a triangular cloth sling is not appropriate (75% n=6)
Elevating the hand actively without it being held in place is an appropriate method to use during the day (75% n=6)

The use of Bradford slings, collar and cuff and pillows did not meet agreement however some respondents agreed they were suitable for use in the day only, some agreed they were suitable to use at night only and others thought they were appropriate to use either day and night. These responses have been merged to highlight a method may be suitable for day and/or night.

* 7 There are numerous methods of elevating the hand. It is important to educate your patient on the different ways in which they can elevate their hands as the method should be changed regularly during the day depending on the patients' activities and location to avoid neck or upper limb issues.

Elevating the hand with a Bradford sling is appropriate for use day and/or night

- ○ I agree with this statement
- ○ I disagree with this statement

Elevation

* 8 **Please justify your response here:**

Elevation

* 9 Elevating the hand with collar and cuff may not be appropriate due to the dependent position of the hand (wrist flexion and ulnar deviation) despite the forearm being elevated.

- ○ I agree with this statement
- ○ I disagree with this statement

* 10 **Please justify your response here:**

Elevation

*11 Elevating the hand on pillow/s may be appropriate during the day and/or overnight

- ○ I agree with this statement
- ○ I disagree with this statement

Elevation

*12 **Please justify your response here:**

Elevation

Consensus was not reached on the following statement:

"In the management of sub-acute hand oedema the hand should be elevated (regardless of the method of elevation) above the level of the heart". 62.5% (n=5) agreed with this however 3 responders only partly agreed and suggest alterations which include:

Expert #1 I would add "unless there are concerns regarding perfusion of the hand"

Expert #3 " Care with elevation may be necessary after some vascular repairs"

Expert #4 "However it is important to perform range of motion exercises with the uninvolved joints, to incorporate the hand into functional activity where possible and to avoid undue strain on the shoulder and neck as well as prolonged elbow flexion"

* 13 In the management of sub-acute hand oedema the hand should be elevated (regardless of the method of elevation) above the level of the heart. The exceptions to this are when there are concerns regarding the vascular perfusion of the hand following repair or insufficiency. it is also important to perform range of motion exercises with the uninvolved joints, to incorporate the hand in functional activity (where possible) and to avoid undue strain on the shoulder and neck as well as positions of prolonged elbow flexion.

- ○ I agree with the statement
- ○ I do not agree with this statement

Elevation

* 14 **Please justify your response here:**

Elevation

Consensus was not reached on the appropriate 'dose' of elevation of the hand. 66.67% (n=2) of experts agreed it should be "as much as possible during the day when the hand is not being used (function, hygiene) and 33.33% (n=1) thought it should be "as much as possible during the day and night". In light of the responses these categories have been merged.

* 15 Elevation of the hand should be advised (with the safety instruction mentioned previously) as much as possible during the day and overnight when the hand is not be used for function, hygiene and exercise.

- ○ I agree with this statement
- ○ I disagree with this statement

Elevation

* 16 **Please justify your response here:**

Elevation

33% (n=1) of experts felt elevation could be discontinued when advised by their therapist. Other experts felt this should be a decision made between the therapist and the patient at hand therapy reviews.

* 17 Elevation of the hand may be discontinued when the patient and therapist mutually agree the oedema has subsided or if the patients symptoms increase due to elevation.

- ○ I agree with this statement
- ○ I disagree with this statement

Elevation

* 18 **Please justify your response here:**

Elevation

Consensus was reached on the reasons to stop or amend elevation.

100% (n=3) of experts agreed that compromised capillary refill is a reason to stop of amend advice about elevation

100% (n=3) of experts agreed that impaired hand sensation of a deterioration from baseline would be a reason to stop or amend advice about elevation.

100% (n=3) of experts agreed that if elevation was preventing safe functional use they would stop or amend their advice about elevation.

Massage

Questions which focused on massage technique, direction, frequency and duration did not reach consensus. Based on the responses and the individual comments this question had been reformatted to give wider ranges for the frequency and duration and divided the amount of pressure from the direction of massage.

62% (n=5) agreed that massage should be performed in a distal to proximal direction with light pressure using creams or oils, 37.5% (n=3) partly agreed with this as they felt the massage pressure should be firmer to the point of "blanching the skin" (Expert #3) "effleurage massage" (Expert #5) and that proximally areas should be massaged prior to distal areas

* 19 For each aspect of this method please identify whether you agree or disagree with the following statements. If you partly agree or disagree with the statement you will have the opportunity to offer amended or alternatively worded statement.

When using massage for the management of sub-acute hand oedema it should be performed:

	I agree with this statement and would not change it.	I partially agree with this statement but would suggest the following alterations **(use text box)**	I disagree with this statement and would suggest the following alternative statement **(use text box)**
Light pressure just enough to see the skin move under the touch	☐	☐	☐
In a proximal to distal then distal to proximal direction	☐	☐	☐

	I agree with this statement and would not change it.	I partially agree with this statement but would suggest the following alterations **(use text box)**	I disagree with this statement and would suggest the following alternative statement **(use text box)**
For approximately 5-10 minutes (less if unable to tolerate/ smaller area of oedema)	☐	☐	☐
Between 3-6 times per day	☐	☐	☐
For at least 2 weeks or until the swelling has resolved (this may be longer depending on severity and responsiveness to treatment)	☐	☐	☐

Please add your amended or alterative statement here:

Kinesiology Tape

* 20 I currently use kinesiology tape in my clinical practice, which may include the application for oedema.

- ○ Yes, I do use this technique
- ○ No, I do not use this technique

Kinesiology Tape

75% (n=6) of experts report they use or have received formal or informal training on kinesiology tape.

Consensus was nearly met (71.43%, n=5) on the shape the tape should be cut into when using it for sub-acute oedema of the hand however those who partly agreed or disagreed highlighted there may be other styles of cutting the tape which may be suitable. This question has now be reworded based on experts comments.

* 21 When using kinesiology tape for sub-acute hand oedema post trauma or surgery it may be cut in to a fan shape with a proximal anchor, however other methods exist and could include volar and dorsal strips with slots for the fingers to pass through.

- ○ I agree with this statement and would not change it
- ○ I disagree with the statement and would suggest the following alternative statement

Kinesiology Tape

* 22 **Please add your alternative statement here:**

Kinesiology Tape

100% (n= 7) of experts agreed that the tape should be applied to clean (no oils or creams, hair shaven if needed), dry and unbroken skin.

Consensus was agreed (85.1% n=6) on the colour of the tape not influencing its effects. One expert did comment that the colour may influence compliance (Expert #1)

Consensus was not achieved on the amount of tension which should be applied to the central portion of the tape when using it for sub-acute oedema.

57.14% (n=4) of experts thought no tension (paper-off tension) should be applied, while 28.57% (n=2) felt the tension should be between 5-25%. One expert (Expert # 1) stated "there is no published evidence to suggest that K tape is effective in the management of oedema and therefore no evidence of any difference with different tensions.

* 23 When applying kinesiology tape for sub-acute hand oedema, the tension of the **central portion** is recommended (as per manufacturer/inventor instructions) to be between 0-25%

- ○ I agree with this statement and would not change it
- ○ I disagree with this statement and would suggest the following alternative statement

Kinesiology Tape

* 24 **Please add your amended or alternative statement here:**

Kinesiology Tape

100% (n=6) of experts agreed that the anchor section of the tape should have no tension applied to it.

Consensus was not reached on the duration in which the tape can/should be worn. 42.86% (n=3) of experts agreed that the tape should be worn full time until it starts to peel of naturally (approximately 3-5 days). 57.14% (n=4) of experts only partly agreed with this and offered comments to suggest that the tape should be replaced sooner if it gets soiled and if any irritation occurs.

* 25 The tape should be worn full time until it starts to peel off the skin naturally (approximately 3-5 days) exceptions to this are if the tape is soiled it will need replacing sooner. The tape will need to be removed if any adverse reactions occur i.e irritation. Regular monitoring of the skin condition is recommended.

- ○ I agree with this statement and would not change it
- ○ I disagree with this statement and would suggest the following alterative statement

Kinesiology Tape

26 **Please add your amended or alternative statement here:**

Kinesiology Tape

Consensus was not reached on whether a rest day (24 hours) is required between tape applications. 50% (n=3) of experts agreed that a rest period of 24 hours was required to allow the skin a break, 33.33% (n=2) partly agreed with this time period and 16.67% (n=1) disagreed. Experts commented on the fact a rest period may be offered but may not be necessary if no problems have occurred. The statement has been amended in light of these comments.

* 27 If a patients clinical status is stable and there have been no problems wearing the tape the skin can be given a rest day (24 hours) before re-application (by therapist or patient). If there have been no adverse reactions to using the tape it can be reapplied continuously.

- ○ I agree with this statement and would not change it
- ○ I disagree with this statement and would suggest the following alternative statement

Kinesiology Tape

28 **Please add your amended or alternative statement here:**

Kinesiology Tape

Consensus was not reached on when the tape should be discontinued. 33.33% (n=2) of experts would advise their patients to wear the tape until told to discontinue by their therapist, 33.33% (n=2) stated the tape should be worn until the patient felt the swelling had subsided, the remaining 2 experts (Expert #3 and Expert #4) who completed this section gave 'other' comments which highlighted that the decision should be made "mutually" between the therapist and the patient.

* 29 The tape should be worn until both the therapist and patient agree that the swelling has subsided and the tape is no longer beneficial

- ○ I agree with this statement and would not change it
- ○ I disagree with this statement and would suggest the following alterative statement

Kinesiology Tape

30 **Please add your amended or alternative statement here:**

Kinesiology Tape

Consensus was reached on the precautions and contraindications to using kinesiology tape. 83.33% (n=5) of experts agreed that "Kinesiology tape for the management of sub-acute hand oedema should not be used on patients with open wounds, active infections, think skin from the use of long-term steroids, allergies to medical grade adhesives or those with conditions affecting the heart, liver or who have had lymph node dissection. The tape should be removed if skin rash or irritation occurs."

The End

This concludes round 2 of the Delphi study.

Many thanks for your time and contribution. The level of consensus reached in this round will determine whether a 3rd round is required.

There is still a chance to review your answers by using the Prev button before submitting your responses. Once you have submitted please do not try to complete the survey again as this will generate duplicate responses. If you have any problems please contact the researcher Leanne Miller directly via e-mail. When you are ready to submit your answers please click on SUBMIT SURVEY button.

Many thanks

Leanne

Welcome to the 3rd Delphi round.
Please read this instruction page carefully.

Thank you for contributions in the previous two rounds. This is the third and final round.

Consensus (75% agreement level) was achieved on 14 of the 15 questions in round 2. In this round I will feedback the responses from the previous round and focus on the question which did not meet the required level of consensus. This question related to the use of massage for sub-acute oedema.

You will need to navigate through each page of feedback in order to get to the question which needs your response.

Please note that the results presented here are given to you as part of the ongoing Delphi process but should remain confidential and not be cited or published. At the end of the final round when consensus has been achieved the results will be submitted for publication. All data will remain anonymous.

If you have any questions before proceeding please do not hesitate to contact me on Leanne.miller@uea.ac.uk

It is important to remember that during this Delphi Method the term "sub-acute" refers to oedema which persists beyond the early acute stage (3-5 days) and is present between 2-6 weeks post trauma or surgery.

Compression

When issuing an oedema glove (isotoner, lycra, tubifast, or other) you would instruct your patient to wear this 20-24 hours a day , removing for hygiene, scar massage, exercise and dirty tasks. Initial use may focus on daytime hours but could be extended to wear overnight if there are no circulatory concerns and the amount of oedema warranted increased use.

85.71% (n= 6) of respondents agreed with this statement and would not change it.
1 respondent (14.29%) reported not issuing any type of oedema glove and therefore skipped further questions in the "Compression" section.

Compression

When instructing your patient on the duration in which the oedema glove will be needed, you advise it may be worn up to 12 weeks post trauma/surgery, that wearing the glove will be reviewed in hand therapy appointments and discontinued when the oedema has subsided.

100% (n=6) of respondents agreed with this statement.

Compression

The patient may be warned of certain situations in which they must remove the glove. These situations may include: if the glove causes discomfort, if the fingertip vascularity is compromised, if the skin becomes damaged, irritated or shows a reaction and if the sensation becomes impaired or deteriorates.

66.67% (n=4) agreed with this statement
33.33% (n=2) partly agreed with this statement but suggested the following alterations:

Expert #5 "I would include.....and if the glove impedes functional use of the hand"
Expert #1 "....or if wearing the glove inhibits use of the hand"

The statement has been amended to incorporate these comments and now reads:

The patient may be warned of certain situations in which they must remove the glove. These situations may include; if the glove causes discomfort or impedes functional use of the hand, if the fingertip vascularity is compromised, if the skin becomes damaged, irritated or shows reaction and if the sensation becomes impaired or deteriorates.

Elevation

There are numerous methods of elevating the hand. It is important to educate your patient on the different ways in which they can elevate their hands as the method should be changed regularly during the day depending on the patients' activities and location to avoid neck or upper limb issues.

Elevating the hand with a Bradford sling is appropriate for use day and/or night.

Consensus was achieved, 85.71% (n=6) agreed with this statement.

Elevation

Elevating the hand with collar and cuff may not be appropriate due to the dependent position of the hand (wrist flexion and ulnar deviation) despite the forearm being elevated.

100% (n=7) of respondents agreed with this statement.

Elevation

Elevating the hand on pillow/s may be appropriate during the day and/or overnight

100% (n=7) agreed with this statement

Elevation

In the management of sub-acute hand oedema the hand should be elevated (regardless of the method of elevation) above the level of the heart. The exceptions to this are when there are concerns regarding the vascular perfusion of the hand following repair or insufficiency. it is also important to perform range of motion exercises with the uninvolved joints, to incorporate the hand in functional activity (where possible) and to avoid undue strain on the shoulder and neck as well as positions of prolonged elbow flexion.

100% (n=7) of respondents agreed with this statement.

Elevation

Elevation of the hand should be advised (with the safety instruction mentioned previously) as much as possible during the day and overnight when the hand is not be used for function, hygiene and exercise.

100% (n=7) of respondents agreed with this statement

Elevation

Elevation of the hand may be discontinued when the patient and therapist mutually agree the oedema has subsided or if the patients symptoms increase due to elevation.

100% (n=7) of respondents agreed with this statement.

Massage

Questions which focused on massage frequency and duration achieved consensus.

85.71% (n=6) of respondents agreed that massage should be completed "For approximately 5-10 minutes (less if unable to tolerate/ smaller area of oedema")

85.71% (n-6) of respondents agreed that massage should be performed "Between 3-6 times per day"

100% (n=7) agreed that massage should be performed "For at least 2 weeks or until the swelling has resolved (this may be longer depending on severity and responsiveness to treatment)"

Questions which focused on massage technique in terms of pressure and direction did not reach the required level of agreement. Comments highlighted the need to differentiate between retrograde massage and massage typically associated with a Manual Oedema Mobilisation / Modified Manual Oedema Mobilisation (MOM) programme.

Firstly we need to establish when you would use retrograde massage and when MOM massage would be more appropriate.

*1 Please select the most appropriate style of massage for each situation in the treatment of **sub-acute hand oedema.**

Please select one massage technique per row.

	Retrograde Massage	Manual Oedema Mobilisation Massage
Small area of localised, isolated oedema	○	○
Significant global hand/wrist oedema	○	○
Stubborn oedema which does not respond to conventional oedema management (i.e elevation, compression)	○	○
Sub-acute oedema (i.e oedema which persists beyond the early acute phase (3-5 days) and is present between 2-6 weeks after trauma or surgery.	○	○

Other (please specify)

2 Please specify what pressure you think should be exerted for each style of massage:

Light massage is defined as an effleurage stroking action with some pressure which mobilises or skims the skin, often referred to as skin traction.

Deep massage is defined as a firm milking action creating pressure on the skin and underlying tissues.

Please select only one response per row.

	Light massage	Deep massage
Retrograde massage	○	○
Manual oedema mobilisation massage	○	○

Other (please specify)

* 3 Now lets establish which direction the massage should be performed in. For each style of massage please specify which direction you think it should be performed in.

Please select only one direction per massage technique.

	Distal to proximal direction only	Clear proximal channels (i.e elbow, axilla or trunk) first then massage distal to proximal.	Massage proximal to distal then distal to proximal	Proximal to distal only.	It does not matter where you start or end the massage
Retrograde massage	○	○	○	○	○
Manual Oedema Mobilisation Massage	○	○	○	○	○

Other (please specify)

Kinesiology Tape

71.43% (n=5) of respondents use kinesiology tape in their clinical practice

100% (n=5) agreed that when using kinesiology tape for sub-acute hand oedema post trauma or surgery it may be cut into a fan shape with a proximal anchor, however other methods exists and could include volar to dorsal strips with slots for the fingers to pass through.

Kinesiology Tape

Consensus was agreed (80%, n=4) that the tension applied to the central portion of the tape (as per manufacturer/inventor instructions) should be between 0-25%.

Kinesiology Tape

The tape should be worn full time until it starts to peel off the skin naturally (approximately 3-5 days) exceptions to this are if the tape is soiled it will need replacing sooner. The tape will need to be removed if any adverse reactions occur i.e irritation. Regular monitoring of the skin condition is recommended.

100% (n=5) agreement was achieved on this statement.

Kinesiology Tape

If a patients clinical status is stable and there have been no problems wearing the tape the skin can be given a rest day (24 hours) before re-application (by therapist or patient). If there have been no adverse reactions to using the tape it can be reapplied continuously.

Consensus was achieved on this statement with 100% (n=5) of respondents agreeing.

Kinesiology Tape

The tape should be worn until both the therapist and patient agree that the swelling has subsided and the tape is no longer beneficial.

100% (n=5) of respondents agreed with this statement.

The End

This concludes round 3 of the Delphi study.

Many thanks for your time and contribution.

There is still a chance to review your answers by using the Prev button before submitting your responses. Once you have submitted please do not try to complete the survey again as this will generate duplicate responses. If you have any problems please contact the researcher Leanne Miller directly via e-mail. When you are ready to submit your answers please click on SUBMIT SURVEY button.

Many thanks

Leanne

University of East Anglia

Norfolk and Norwich University Hospitals NHS
NHS Foundation Trust

Stretch
Study to examine the treatment
of sub-acute hand oedema post trauma

Dear [INSERT NAME],

I would like take this opportunity to personally thank you for volunteering your time and expertise to take part in my Delphi Consensus Study (as part of my NIHR Clinical Academic Training Fellowship/PhD) between April and July 2016.

Your contributions, as an 'expert' in the field of hand therapy, have been invaluable to this project and have enabled me to form a standardised definition of what constitutes an oedema management programme. This will be used to inform the control arm of a pilot randomized controlled trial investing the effectiveness of kinesiology tape versus standard treatment in the management of sub-acute hand oedema post trauma or surgery in 2017.

The results of this Delphi study (along with the online survey of UK Hand Therapists which you completed prior to the Delphi) will be presented as an E-Poster at the International Federation of Societies for Hand Therapy and Hand Surgery triennial congress in Buenos Aires in October 2016. The aim is also to publish the results in a peer-reviewed journey.

Research activity is an essential aspect of clinical practice as we strive to improve and add to the body of evidence surrounding the interventions and modalities we use with our patients.

I hope this letter of thanks can be used as evidence of your continued involvement in research.

With kind regards

Leanne K Miller

NIHR/HEE Clinical Doctoral Research Fellow
University of East Anglia
BSc (Hons) OT, MSc Clinical Research, Accredited Hand

Appendix P

Ethical approval letters (observational study)

NHS
Health Research Authority

Miss Leanne Miller
NIHR Clinical Doctoral Research Fellow
University of East Anglia
Elizabeth Fry Building 1.33
Norwich Research Park
University of East Anglia, Norwich
NR4 7TJ

Email: hra.approval@nhs.net

24 October 2016

Dear Miss Miller

Letter of HRA Approval

Study title:	**The treatment of sub-acute hand oedema post trauma- a longitudinal observational study of clinician-derived methods to assess hand oedema and patient rated outcome measures.**
IRAS project ID:	**209952**
Protocol number:	**R200503**
REC reference:	**16/EE/0365**
Sponsor	**University of East Anglia**

I am pleased to confirm that HRA Approval has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read *Appendix B* carefully**, in particular the following sections:

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before

NHS
Health Research Authority
East of England - Cambridgeshire and Hertfordshire Research Ethics Committee
The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

25 August 2016

Miss Leanne Miller
NIHR Clinical Doctoral Research Fellow
University of East Anglia
Elizabeth Fry Building 1.33
Norwich Research Park
University of East Anglia, Norwich
NR4 7TJ

Dear Miss Miller,

Study title:	**The treatment of sub-acute hand oedema post trauma- a longitudinal observational study of clinician-derived methods to assess hand oedema and patient rated outcome measures.**
REC reference:	**16/EE/0365**
Protocol number:	**R200503**
IRAS project ID:	**209952**

Thank you for your letter of 24th August 2016, responding to the Proportionate Review Sub-Committee's request for changes to the documentation for the above study.

The revised documentation has been reviewed and approved by the sub-committee.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager Miss Jessica Parfrement, nrescommittee.eastofengland-cambsandherts@nhs.net. Under very limited circumstances

Norfolk and Norwich University Hospitals NHS
NHS Foundation Trust

Miss Leanne Miller
University of East Anglia
Research Associate and Senior Hand Therapist
School of Allied Health Professions
Queens Building
Norwich Norfolk
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Research & Development Office
Level 3 East
Norfolk & Norwich University Hospitals NHS Foundation Trust
Colney Lane
Norwich
NR4 7UY

direct dial: 01603 289808
Ext:: 5808
e-mail: rdoffice@nnuh.nhs.uk
website: www.nnuh.nhs.uk

20/12/2016

Dear Miss Leanne Miller

R&D Reference Number: 209952 (165-09-16)
Title: The treatment of sub-acute hand oedema post trauma- a longitudinal observational study of clinician-derived methods to assess hand oedema and patient rated outcome measures

I am pleased to inform you that the Norfolk & Norwich University Hospitals NHS Foundation Trust has confirmed to the sponsor that we have the capacity and capability to take part in the above study.

Please note you cannot begin this study until you have received confirmation to do so from the study sponsor.

The agreed total local recruitment target for your study is 112 participants.

To support requirements of the National Institute of Health Research (NIHR) we will be monitoring and publishing outcomes of recruitment into your study. This includes benchmarking against a 70 day period from the time of receipt of a valid local document set to the time of recruitment of the first patient for your study.

The date of receipt of a valid local document set for this study is 29/11/2016 and the benchmark of 70 days to recruit the first patient is 07/02/2017.

Please notify the R&D department when the first patient is enrolled/consented into the study. Wherever the duration exceeds 70 days of the Trust receiving a valid local document set, the Investigator will be expected to explain the reason for the delay in writing.

If you have any queries regarding this or any other project please contact **Laura Harper**, Research Study and Recruitment Facilitator, at the above address. Please note, the reference number for this study is **209952 (165-09-16)** and this should be quoted on all correspondence.

Appendix Q

Observational study participant information sheet (PIS) and consent form

University of East Anglia

Norfolk and Norwich University Hospitals NHS
NHS Foundation Trust

Stretch
Study to examine the treatment of sub-acute hand oedema post trauma

CONSENT FORM

REC ref: 16/EE/0365

IRAS ID: 209952

Study title: What is the best way to assess hand swelling?

Name of Researcher: Leanne Miller

Please initial each box below

1. I confirm that I have read the information sheet dated 20/10/2016 (version 1.3) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐
3. I understand that relevant direct quotations may be used when presenting the results of this study and in publications however my identity will remain anonymous. ☐
4. I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐
5. I agree to take part in the above study. ☐

Name of participant	Signature	Date

Name of Researcher	Signature	Date

(1 copy to participant, 1 copy to researcher, 1 copy for Hand Therapy notes)

Does kinesiology tape reduce hand swelling after trauma or surgery?

Invitation to participate in a research study- can you help?

We would like to invite you to take part in our research study. Before you decide whether you would like to take part or not, we need to tell you what the study is about, why it is being done and what it would involve. Please take time to read through this information. If there is anything that is not clear or if you have any questions please do not hesitate to contact the researcher, whose contact details are at the end of this letter.

What is the purpose of the study?

Following a hand injury or operation the hand may become swollen. This is a normal part of the healing process. Therapists use different methods to reduce the swelling in the hand and prevent it from causing problems for joint movement and function.

In order to see how well the treatment for swelling works therapists need to measure it. There are different ways of measuring how swollen the hand is. The purpose of this project is to establish the best way to measure swelling in the hand.

Why have I been approached?

You have been given this information sheet because you have either sustained a hand injury or undergone surgery and may experience some swelling in your hand, and will be receiving hand therapy at the Norfolk and Norwich University Hospital NHS Trust.

Do I have to participate?

No, it is entirely your decision if you wish to take part in this study. If you decide not to take part or wish to withdraw from the study at any point you may do so without giving a reason. This will not affect the standard of treatment you receive in the future.

What will happen if I agree to participate?

We will also ask you to complete some questions about the swelling and how it affects you and your hand.

Figure 2: The volumeter

What are the possible disadvantages and risks to taking part?

We cannot identify any risks involved with taking part in this study. The only possible disadvantage is that it will take an additional 15-30 minutes to complete the assessment and treatment process. If the allocated treatment given to you does not work or there are reasons for you having to stop the treatment, your hand therapist will be able to choose an alternative treatment to try and reduce your hand swelling. If this happens, you are still able to take part in the study.

What are the possible benefits of taking part?

We cannot identify any direct benefits to you by taking part in this study, however by helping with this research we will be closer to finding out if certain treatments help swelling in patients with hand injuries and post-surgery. This could help future patients with hand swelling and future studies into treatments for hand swelling.

Will my taking part in the study be kept confidential?

Yes, we will follow ethical and legal practice to ensure only the relevant members of the medical and therapy team are informed of your participation. Only members of the clinical hand therapy team and direct research team will have access to the research data. All the information relating to your participation in this research study will be confidential and kept in a secure filing cabinet or password protected database by the lead researcher. At the end of the study, anonymised electronic data will be stored on password protected hardware. Hard copies of study data will be kept in a locked filing cabinet at the UEA and will only be accessed by members of the research team.

What will happen to the results of this study?

This study is being conducted as part of doctoral degree and will be written up as a thesis. The results may show that further research is needed on this topic. We plan to publish the results in medical journals and to present at conferences, direct quotations from participants made be used but your identity will be kept anonymous. You will be given the option to request details of the research findings once the study has been completed. None of these reports will contain any names or details that would allow individual participants to be identified.

Who is organising and funding this research?

This study is being led by Leanne Miller**,** a qualified Occupational Therapist specialising in Hand Therapy, studying for a doctoral degree at the University of East Anglia. Leanne's doctoral degree has been funded by the NHS National Institute for Health Research (the research arm of the NHS). She is being supervised by Dr. Christina Jerosch-Herold, Reader in Occupational Therapy and Professor Lee Shepstone, Professor of Medical Statistics at the University of East Anglia.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. This study has been reviewed and approved by the East of England- Cambridgeshire and Hertfordshire Research Ethics Committee (REC Ref: 16/EE/0365). IRAS ID: 209952

What if there is a problem?

If you have a concern about any aspect of this study you should speak to:

Lead researcher:

Leanne Miller ☎ 01603 597206 ✉ Leanne.miller@uea.ac.uk

If you remain unhappy and wish to complain formally, you can do this by contacting:

Study supervisor:

Christina Jerosch-Herold ☎ 01603 593316 ✉ c.jerosch-herold@uea.ac.uk

If you wish to make a formal complaint to the NHS, you can do this by contacting:

Patient Advice and Liaison Service (PALS):

☎ 01603 289036 or 10603 289045 (24 hour answerphone in operation)
✉ pals@nnuh.nhs.uk

Where can I obtain further information?

If you have further questions about the study and what participating would entail, please do not hesitate to contact the lead researcher on the details above.

Thank you for reading this information sheet, which is yours to keep.

Appendix R

Patient evaluation measure (PEM)

PEM Hand Health Profile

For each statement you are asked to use a rating scale of 1 to 7. The words at each end of the scale describe the severity or frequency of a problem, where 1 means normal or the absence of the problem and 7 the worst state. Please circle one number only

1. The feeling in my hand is now:

normal	1	2	3	4	5	6	7	absent

2. When my hand is cold and/or damp, the pain is now:

non-existent	1	2	3	4	5	6	7	unbearable

3. Most of the time, the pain in my hand is now:

non-existent	1	2	3	4	5	6	7	unbearable

4. The duration my pain is present is:

never	1	2	3	4	5	6	7	all the time

5. When I try to use my hand for fiddly things, it is now:

skilful	1	2	3	4	5	6	7	clumsy

6. Generally when I move my hand it is:

flexible	1	2	3	4	5	6	7	stiff

7. The grip I my hand is now:

strong	1	2	3	4	5	6	7	weak

8. For everyday activities my hand is now:

no problem	1	2	3	4	5	6	7	useless

9. For my work my hand is now:

no problem	1	2	3	4	5	6	7	useless

10. When I look at the appearance of my hand, I feel:

unconcerned	1	2	3	4	5	6	7	embarrassed and selfconscious

11. Generally when I think about my hand I feel:

unconcerned	1	2	3	4	5	6	7	very upset

Appendix S

Ethical approval letters (pilot RCT)

NHS
Health Research Authority

Miss Leanne Miller
NIHR Clinical Doctoral Research Fellow
University of East Anglia
Elizabeth Fry Building 1.33 Norwich Research Park
University of East Anglia
Norwich
NR4 7TJ

Email: hra.approval@nhs.net

02 August 2017

Dear Miss Miller,

Letter of HRA Approval

Study title:	**The treatment of sub-acute hand oedema post trauma- a pilot randomized controlled trial.**
IRAS project ID:	**228812**
Protocol number:	**R200503**
REC reference:	**17/ES/0098**
Sponsor	**University of East Anglia**

I am pleased to confirm that HRA Approval has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read *Appendix B* carefully**, in particular the following sections:

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit

NHS SCOTLAND

East of Scotland Research Ethics Service *(EoSRES)* **Research Ethics Service**

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

TAyside medical Science Centre
Residency Block Level 3
George Pirie Way
Ninewells Hospital and Medical School
Dundee DD1 9SY

Miss Leanne Miller
NIHR Clinical Doctroral Research Fellow
University of East Anglia
Elizabeth Fry Builidng 1.33 Norwich Research Park
University of East Anglia
Norwich
NR4 7TJ

Date: 01 August 2017
Your Ref:
Our Ref: LR/17/ES/0098
Enquiries to: Mrs Lorraine Reilly
Direct Line: 01382 383878
Email: eosres.tayside@nhs.net

Dear Miss Miller

Study title:	**The treatment of sub-acute hand oedema post trauma- a pilot randomized controlled trial.**
REC reference:	**17/ES/0098**
Protocol number:	**R200503**
IRAS project ID:	**228812**

The Research Ethics Committee reviewed the above application at the meeting held on 21 July 2017. Thank you for attending via Skype video calling to discuss the application.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact hra.studyregistration@nhs.net outlining the reasons for your request.
Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Our Vision
To provide every patient with the care we want for those we love the most

Norfolk and Norwich University Hospitals NHS
NHS Foundation Trust

Tracy Moulton
Research and Innovation Services
The Registry
University of East Anglia
Norwich
Norfolk
NR4 7TJ

Please reply to: Research and Development Department
Level 3, East Block, Room 032
Norfolk & Norwich University Hospitals NHS Foundation Trust
Colney Lane
Norwich
Norfolk
NR4 7UY
Direct Dial: 01603 289808
Internal: 5808
e-mail: rdoffice@nnuh.nhs.uk
Website: www.nnuh.nhs.uk

4th October 2017

Dear Tracy,

Confirmation of Capacity and Capability

RE: 228812 (112-07-17).

Study Title: The treatment of sub-acute hand oedema post trauma- a pilot randomized controlled trial.

This letter confirms that **Norfolk and Norwich University Hospitals NHS Foundation Trust** has the capacity and capability to deliver the above referenced study. Please find attached our agreed Statement of Activities as confirmation.

We agree to start this study on a date to be agreed when the sponsor gives the green light to begin.

If you wish to discuss further, please do not hesitate to contact me.

Kind regards

Professor Alastair Forbes
Chief of Research and Innovation

Cc. Leanne Miller

Appendix T

Amended ethical approval letters (pilot RCT)

NHS SCOTLAND
Research Ethics Service

East of Scotland Research Ethics Service *(EoSRES)*

TAyside medical Science Centre
Residency Block Level 3
George Pirie Way
Ninewells Hospital and Medical School
Dundee DD1 9SY

Miss Leanne Miller
NIHR Clinical Doctroral Research Fellow
University of East Anglia
Elizabeth Fry Builidng 1.33 Norwich Research Park
University of East Anglia
Norwich
NR4 7TJ

Date: 12 October 2017
Your Ref:
Our Ref: LRMAG17/ES/0098
Enquiries to: Arlene Grubb
Direct Line: 01382 383848
Email: eosres.tayside@nhs.net

Dear Miss Miller

Study title:	**The treatment of sub-acute hand oedema post trauma- a pilot randomized controlled trial**
REC reference:	**17/ES/0098**
Protocol number:	**R200503**
Amendment number:	**AM01(REC reference only)**
Amendment date:	**11 October 2017**
IRAS project ID:	**228812**

Thank you for your letter of 11 October 2017, notifying the Committee of the above amendment.

- Removal of treatment for compression that contains latex

The Committee does not consider this to be a "substantial amendment" as defined in the Standard Operating Procedures for Research Ethics Committees. The amendment does not therefore require an ethical opinion from the Committee and may be implemented immediately, provided that it does not affect the approval for the research given by the R&D office for the relevant NHS care organisation.

Documents received

Appendix U

Pilot RCT participant information sheet (PIS) and consent form

Does elasticated tape reduce hand swelling after an injury or surgery?

Invitation to participate in a research study- can you help?

We would like to invite you to take part in our research study which is being conducted as part of a doctoral degree. Before you decide whether you would like to take part or not, we need to tell you what the study is about, why it is being done and what it would involve. Please take time to read through this information. If there is anything that is not clear or if you have any questions please do not hesitate to contact the researcher, whose contact details are at the end of this letter.

What is the purpose of the study?

Following a hand injury or operation the hand may become swollen. This is a normal part of the healing process but can limit joint movement and function. Therapists use different methods to reduce the swelling in the hand, however, we don't know which method works best. The purpose of this study is to establish the best way to treat swelling in the hand.

Why have I been approached?

You have been given this information sheet because you have either sustained a hand injury or undergone surgery and may experience some swelling in your hand, and will be receiving hand therapy at the Norfolk and Norwich University Hospital NHS Trust.

Do I have to participate?

No, it is entirely your decision if you wish to take part in this study. If you decide not to take part or wish to withdraw from the study at any point you may do so without giving a reason. This will not affect the standard of treatment you receive in the future. Identifiable data collected with consent will be retained and used in the study. No further data will be collected or any other research procedures carried out.

What will happen if I agree to participate?

Compression and Elasticated Tape (also called kinesiology tape) are two commonly used treatments routinely used to treat hand swelling, however, we do not know which is best.
In order to find out whether compression or elasticated tape (kinesiology tape) is better we are inviting patients like you to take part in a research project in which some patients will be given compression and some patients elasticated tape (kinesiology tape). The results from these two groups of patients will be compared.

The treatment you receive will be chosen by a process called randomisation, the treatment is randomly allocated by computer, which is like making a choice by tossing a coin. This means that you have an equal chance of being treated with one of the above treatments.


Treatment as Usual group will receive either a compression glove, finger sleeve or finger wrap (depending on the location of your swelling) along with advice on keeping your hand raised (elevated) and massaging the swelling from your hand.


Trial treatment group will also receive the same advice on elevating and massaging the hand but will be given an elasticated tape (kinesiology tape) to apply to the hand **instead of** a compression garment.

The majority of these treatments do not contain latex. Latex free alternatives are available.

Both groups will receive full instructions from a hand therapist on how to apply the treatment as well as an instruction booklet to take home with you. Other parts of your hand therapy treatment, such as exercises, will be tailored to you by your hand therapist depending on your condition or surgery.

A person not involved in your treatment will measure the volume of your hand using a tool called the Volumeter. This will involve placing your hand into a container of water.

We will also ask you to complete some questions about the swelling and how it affects you and your hand. You will be given a diary to record if you have been able to complete the treatments.

We will take the same measurements 4 and 12 weeks later. Whenever possible we will combine these with your usual therapy appointments. If you need to attend only for the purposes of the study then we will reimburse your travel and parking expenses.

At the end of the study we will ask you what you thought about the treatment you were given.

What are the possible disadvantages and risks to taking part?

There are very few risks associated with taking part in this study. If you are not responding to the allocated treatment your hand therapist will adjust the treatment. In the unlikely event that you experience any reaction to the treatment given (such as skin allergy) the treatment will be stopped or changed by your hand therapist.

A possible disadvantage is that your therapy session will take a little longer.

What are the possible benefits of taking part?

We cannot identify any direct benefits to you by taking part in this study, however by helping with this research we will be closer to finding out which treatments work for hand swelling after an injury or surgery. This could help future patients with hand swelling and future studies into treatments for hand swelling.

Will my taking part in the study be kept confidential?

Yes, we will follow ethical and legal practice to ensure only the relevant members of the medical and therapy team are informed of your participation. Only members of the clinical hand therapy team and direct research team will have access to the research data. All the information relating to your participation in this research study will be confidential and kept in a secure filing cabinet or password protected database by the lead researcher. At the end of the study, anonymised electronic data will be stored on password protected hardware. Hard copies of study data will be kept in a locked filing cabinet at the UEA and will only be accessed by members of the research team. The lead researcher will retain participant names and hospital numbers in a locked cupboard in the Hand Therapy department at the Norfolk and Norwich Hospital for a period of 3-6 months after the study has finished in order to send copies of the research results if you have opted to receive them.

What will happen to the results of this study?

This study is being conducted as part of doctoral degree and will be written up as a thesis. The results may show that further research is needed on this topic. We plan to publish the results in medical journals and to present at conferences, direct quotations from participants made be used but your identity will be kept anonymous. You will be given the option to request details of the research findings once the study has been completed. None of these reports will contain any names or details that would allow individual participants to be identified. You should expect to receive the results through the post within 3-6 months of the study finishing in July 2018.

Who is organising and funding this research?

This study is being led by Leanne Miller**,** a qualified Occupational Therapist specialising in Hand Therapy, studying for a doctoral degree at the University of East Anglia. Leanne's doctoral degree has been funded by the NHS National Institute for Health Research (the research arm of the NHS). She is being supervised by Dr. Christina Jerosch-Herold, Reader in Occupational Therapy and Professor Lee Shepstone, Professor of Medical Statistics at the University of East Anglia.

Who has reviewed the study?

The East of Scotland Research Ethics Service REC 1, which has responsibility for scrutinising all proposals for medical research on humans, has examined the proposal and has raised no objections from the point of view of research ethics. It is a requirement that your records in this research, together with any relevant medical records, be made available for scrutiny by monitors from the University of East Anglia and Norfolk and Norwich University Hospital NHS Foundation Trust, whose role is to check that research is properly conducted and the interests of those taking part are adequately protected. **REC reference**: 17/ES/0098. **IRAS ID:** 228812

What if there is a problem?

If you have a concern about any aspect of this study you should speak to:

Lead Researcher:

Leanne Miller ☎ 01603 597206 ✉ Leanne.miller@uea.ac.uk

If you remain unhappy and wish to complain formally, you can do this by contacting:

Study supervisor:

Christina Jerosch-Herold ☎ 01603 593316 ✉ c.jerosch-herold@uea.ac.uk

If you wish to make a formal complaint to the NHS, you can do this by contacting:

Patient Advice and Liaison Service (PALS):

☎ 01603 289036 or 10603 289045 (24 hour answerphone in operation)
✉ pals@nnuh.nhs.uk

Where can I obtain further information?

If you have further questions about the study and what participating would entail, please do not hesitate to contact the lead researcher on the details above.

Thank you for reading this information sheet, which is yours to keep.

University of East Anglia

Norfolk and Norwich University Hospitals NHS
NHS Foundation Trust

Stretch
Study to examine the treatment of sub-acute hand oedema post trauma

CONSENT FORM

REC ref: 17/ES/0098 **IRAS ID:** 228812

Study title: Does kinesiology tape reduce hand swelling after an injury or surgery?

Name of Chief Investigator: Leanne Miller

Please initial each box below

1. I confirm that I have read the information sheet dated 11/10/2017 (version 1.3) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐
3. I give permission for any identifiable data collected up to the point of withdrawal to be used for the purposes of this study. ☐
4. I understand that relevant direct quotations may be used when presenting the results of this study and in publications however my identity will remain anonymous. ☐
5. I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐
6. I agree to take part in the above study. ☐

Name of participant	Signature	Date

Name of Chief Investigator (CI)	Signature	Date

(1 copy to participant, 1 copy to CI, 1 copy for Hand Therapy notes)

Appendix V

Oedema management patient instruction sheets

Stretch
Study to examine the treatment of sub-acute hand oedema post trauma

University of East Anglia

Norfolk and Norwich University Hospitals NHS Foundation Trust

You will also be given a diary by the lead researcher.

Please try to fill this in as truthfully as possible at the end of each week.

This will help researchers see how acceptable these treatments are and if you are able to follow them at home.

If you have any questions about your treatment please contact the **Hand Therapy Department** on ☎01603 286990

IRAS ID: 228812
Control patient instruction manual v1.2 11.10.17

Stretch
Study to examine the treatment of sub-acute hand oedema post trauma

INSTRUCTIONS
Treatment As Usual

This booklet explains three treatments to help reduce the swelling in your hand. Your hand therapist will explain these treatments to you and show you how to do them yourself at home.

It is important you try to complete these treatments in the same way they were shown to you and the same number of times you have been advised to do them.

! If you experience an increase in swelling or pain please follow the instructions in this booklet , contact the department and tell your hand therapist at your next appointment. !

Instructions	Massage 	Elevation  	Compression  
HOW TO DO IT? 	Massaging the hand with firm pressure from the fingertips to wrist/forearm.	• Keep the hand raised/rest on the opposite shoulder (daytime only) • Use a Bradford sling (day or night) IF you have been given one. • On pillows (day or night)	You will be given one of the following methods of compression by your therapist; • Compression glove • Elasticated wrap • Finger compression sleeve
WHEN TO DO IT? 	Massage should be performed for approximately 5-10 minutes (less if unable to tolerate or only a small area of swelling) between 3-6 times per day.	Keep the hand above the level of your heart as much as possible during the day and overnight. It is important to keep your shoulder, neck and elbow flexible and to avoid staying in 1 position for too long.	Wear your compression garment 20-24 hours a day, this includes during exercises and everyday activities. You may wish to start this during the day initially and extend overnight if you have no problems.
WHEN NOT TO DO IT? 	When the hand is being used for everyday activities, hygiene or exercise, or overnight.	When the hand is being used for everyday activities, hygiene or exercise.	Remove for hygiene, checking the skin, scar massage (if appropriate), wet/dirty tasks (if appropriate) and during exercises (ONLY if you find it too restrictive)
HOW LONG TO DO IT FOR? 	For **at least** 2 weeks after your injury or surgery or until the swelling has reduced. Your hand therapist will give you advice on when to stop massaging during your appointments.	Continue to keep your hand elevated until your therapist advises you to stop.	Compression may be needed for up to 12 weeks after your injury or surgery but this will be reviewed regularly by your hand therapist during appointments.
	**Stop massaging the hand if your swelling or pain increases.**	**Stop elevating the hand if your swelling increases, if pain in your hand neck, shoulder or elbow increases, if the feeling in your hand worsens, if you notice your hand is colder than usual or has gone white/blue in colour.**	**Most methods of compression do not contain latex (latex free alternatives are available). Remove the item immediately if your skin becomes irritated, the feeling in your hand/fingers worsens, if your fingers look white/blue and if your pain increases.**

Stretch
Study to examine the treatment of sub-acute hand oedema post trauma

UEA University of East Anglia

Norfolk and Norwich University Hospitals NHS

You will also be given a diary by the lead researcher.

Please try to fill this in as truthfully as possible at the end of each week.

This will help researchers see how acceptable these treatment are and if you are able to follow them at home.

If you have any questions about your treatment please contact the **Hand Therapy Department** on ☎01603 286990

IRAS ID: 228812
Instructions- trial treatment v1 2.6.17

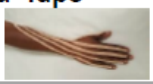
Stretch
Study to examine the treatment of sub-acute hand oedema post trauma

INSTRUCTIONS
Trial Treatment

This booklet explains three treatments to help reduce the swelling in your hand. Your hand therapist will explain these techniques to you and show you how to do them yourself at home.

It is important you try to complete these treatments in the same way they were shown to you and the same number of times you have been advised to do them.

! If you experience an increase in swelling or pain please follow the instructions in this booklet , contact the department and tell your hand therapist at your next appointment. !

Instructions	Massage 	Elevation  	Elasticated Tape  
HOW TO DO IT? 	Massaging the hand with firm pressure from the fingertips to wrist/forearm.	• Keep the hand raised/rest on the opposite shoulder (daytime only) • Use a Bradford sling (day or night) IF you have been given one. • On pillows (day or night)	Your therapist will show you how to apply the tape and will give replacement strips of tape. You may wish to take a photo of the tape on your arm/hand to remind you of how to reapply it. Do not put tension on the tape when applying.
WHEN TO DO IT? 	Massage should be performed for approximately 5-10 minutes (less if unable to tolerate or only a small area of swelling) between 3-6 times per day.	Keep the hand above the level of your heart as much as possible during the day and overnight. It is important to keep your shoulder, neck and elbow flexible and to avoid staying in 1 position for too long.	The tape can be worn full-time (24 hours a day) for approximately 3-5 days until it starts to peel off the skin naturally. It needs to be applied to clean, dry, moisturising cream free skin. The tape can get wet and should be patted dry. Use your hand and exercise with the tape on.
WHEN NOT TO DO IT? 	When the hand is being used for everyday activities, hygiene or exercise, or overnight.	When the hand is being used for everyday activities, hygiene or exercise.	Replace the tape if it becomes soiled or dirty.
HOW LONG TO DO IT FOR? 	For **at least** 2 weeks after your injury or surgery or until the swelling has reduced. Your hand therapist will give you advice on when to stop massaging during your appointments.	Continue to keep your hand elevated until your therapist advises you to stop.	You should continue to wear the tape until you and your therapist agree the swelling has reduced and it is no longer needed. Regular monitoring of your skin is recommended when using this tape. A 24 hour rest period can be used before reapplication.
	**Stop massaging the hand if your swelling or pain increases.**	**Stop elevating the hand if your swelling increases, if pain in your hand neck, shoulder or elbow increases, if the feeling in your hand worsens, if you notice your hand is colder than usual or has gone white/blue in colour.**	**The tape does not contain latex but you should remove it if you notice a rash or if skin becomes irritated. You should not wear this tape on open wounds, if you have an infection in your hand/forearm, have thin skin or are allergic to adhesives.**

Appendix W

Acceptability questionnaire

University of East Anglia

Norfolk and Norwich University Hospitals NHS
NHS Foundation Trust

Stretch
Study to examine the treatment of sub-acute hand oedema post trauma

Acceptability questionnaire

To be completed by Chief Investigator

Patient Name:		**Patient D.O.B**	
Patient Hosp. No:		**Patient Study ID:**	
Date interview completed:		**Treatment allocation:**	Treatment As Usual / Trial Treatment

Was assessor blinding maintained? Y / N

If yes, guess group allocation? Treatment as Usual Trial Treatment

	0	1	2	3	4	5	6	7	8	9	10
Acceptability of treatment											
Aesthetics/ appearance											
Ability to move the hand											
Ability to use the hand											
Cleanliness											
Temperature/sweating/dry skin											
Ease of donning/doffing											
Ease of replacing											
Durability											
Discomfort											

Can you give me any further feedback about the treatment you received?

Appendix X

Adherence diaries

Stretch
Study to examine the treatment of sub-acute hand oedema post trauma

Please make any further notes or comments on the treatments for swelling here:
For example: reasons for not using, difficulties, likes

Please either give this to your hand therapist or place it in the box at hand therapy reception when you have finished.

Many thanks for your time and help with this study.

If you have any questions about this diary please contact:
Leanne Miller (Lead Researcher)
✉ Leanne.miller@uea.ac.uk
☎01603 597206

Patient Diary- trial treatment v1.2 14.9.17 IRAS ID: 228812

Norfolk and Norwich University Hospitals NHS Foundation Trust
Stretch
Study to examine the treatment of sub-acute hand oedema post trauma
University of East Anglia

DIARY Trial Treatment

Please complete this diary **weekly** by estimating to what extent you have used the treatments to **reduce the swelling in your hand** as you have been instructed.

Please tick the number which best describes the extent to which you have completed the treatments.
For example, if you only completed the treatments on some days you would tick 'in part.'

0	5	10
Not at all	In part	As advised

✓

Please try to fill this diary in as truthfully as possible so researchers can see how acceptable these treatments are and if you are able to follow them at home.

	Massage			Hand elevation			Elasticated tape (kinesiology tape)		
Scale	0 *Not at all*	5 *In part*	10 *As advised*	0 *Not all all*	5 *In part*	10 *As advised*	0 *Not at all*	5 *In part*	10 *As advised*
Week 1									
Week 2									
Week 3									
Week 4									
Week 5									
Week 6									
Week 7									
Week 8									
Week 9									
Week 10									
Week 11									
Week 12									

Please write any comments you have about the treatment in the box over the page →

Stretch
Study to examine the treatment of sub-acute hand oedema post trauma

Please make any further notes or comments on the treatments for swelling here:
For example: reasons for not using, difficulties, likes

Please either give this to your hand therapist, or place it in the box at the hand therapy reception when you have finished.

Many thanks for your time and help with this study.

If you have any questions about this diary please contact:
Leanne Miller (Lead Researcher)
✉ Leanne.miller@uea.ac.uk
☎ 01603 597206

Norfolk and Norwich University Hospitals NHS
NHS Foundation Trust

Stretch
Study to examine the treatment of sub-acute hand oedema post trauma

UEA
University of East Anglia

DIARY
Treatment As Usual

Please complete this diary **weekly** by estimating to what extent you have used the treatments to **reduce the swelling in your hand** as you have been instructed.

Please tick the number which best describes the extent to which you have completed the treatments.
For example, if you only completed the treatments on some days you would tick 'in part'.

0	5	10
Not at all	In part	As advised

✓

Please try to fill this diary in as truthfully as possible so researchers can see how acceptable these treatments are and if you are able to follow them at home.

Patient diary- treatment as usual v1.2 14.9.17. IRAS ID: 228812

	Massage			Hand elevation			Compression		
Scale	0 *Not at all*	5 *In part*	10 *As advised*	0 *Not at all*	5 *In part*	10 *As advised*	0 *Not at all*	5 *In part*	10 *As advised*
Week 1									
Week 2									
Week 3									
Week 4									
Week 5									
Week 6									
Week 7									
Week 8									
Week 9									
Week 10									
Week 11									
Week 12									

Please write any comments you have about the treatment in the box over the page →

Appendix Y

EQ-5D-5L

Under each heading, please tick the ONE box that best describes your health TODAY

MOBILITY

I have no problems in walking about ❑
I have slight problems in walking about ❑
I have moderate problems in walking about ❑
I have severe problems in walking about ❑
I am unable to walk about ❑

SELF-CARE

I have no problems washing or dressing myself ❑
I have slight problems washing or dressing myself ❑
I have moderate problems washing or dressing myself ❑
I have severe problems washing or dressing myself ❑
I am unable to wash or dress myself ❑

USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*

I have no problems doing my usual activities ❑
I have slight problems doing my usual activities ❑
I have moderate problems doing my usual activities ❑
I have severe problems doing my usual activities ❑
I am unable to do my usual activities ❑

PAIN / DISCOMFORT

I have no pain or discomfort ❑
I have slight pain or discomfort ❑
I have moderate pain or discomfort ❑
I have severe pain or discomfort ❑
I have extreme pain or discomfort ❑

ANXIETY / DEPRESSION

I am not anxious or depressed ❑
I am slightly anxious or depressed ❑
I am moderately anxious or depressed ❑
I am severely anxious or depressed ❑
I am extremely anxious or depressed ❑

- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
  0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY = ☐