Exploring psychological peritraumatic risk factors and safety behaviours as key mechanisms in the onset and maintenance of PTSD; a Systematic Review and Meta-Analysis

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Thesis Portfolio Abstract

Background

After Post-Traumatic Stress Disorder (PTSD) was first conceptualised in 1980, decades of valuable research have contributed to the development of cognitive theories and evidence-based treatments, which are used as front-line treatments in NHS services in line with NICE guidance. However, there are some elements of the cognitive model which are under-researched, such as the role of safety behaviours in the development and maintenance of PTSD. Research is also yet to provide clarity on the role of psychological peritraumatic risk factors for PTSD in adults.

Method

This portfolio contains two systematic reviews and meta-analyses. The first review concerns the relationship between safety behaviours and PTSD in adults, and includes six studies (n = 628). The second review explores peritraumatic risk factors for PTSD in adults, and includes 63 studies (n=20,335).

Results

The first paper regarding safety behaviours yielded a large effect r=0.62, supporting the idea that engaging in safety behaviours is associated with the development and/or maintenance of PTSD in adults. Regarding the second paper, peritraumatic subjective threat and peritraumatic dissociation yielded moderate estimates of population effect size (r=.39, r=.39), and peritraumatic data-driven processing yielded a small estimated population effect size (r=.26). Both studies were affected by high levels of heterogeneity. Each paper discusses the outcome of moderator analyses, limitations, clinical implications and suggestions for future research.

Conclusion

Overall, there were a small number of studies available for inclusion in the first review, despite safety behaviours forming an important part of the cognitive model for over twenty years. While the findings are in line with the Ehlers and Clark model (2020), more research is needed to clarify the directionality of the relationship. The second meta-analysis highlighted the need for more studies to investigate the predictive risk of a wider range of peritraumatic emotions e.g. guilt, shame, anger and disgust.

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CHAPTER ONE

Introduction to the Thesis Portfolio

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Post-traumatic Stress Disorder (PTSD) is a mental health condition that can develop after experiencing a traumatic event (Hamblen, 2009). Fortunately, most people who are exposed to traumatic events do not go on to develop PTSD, but a significant minority will go on to develop symptoms which meet diagnostic criteria and may require evidence-based psychological support to aid recovery (Simmons & Granvold, 2005).

Post Traumatic Stress Disorder (PTSD) is categorised in the Diagnostic and Statistical Manual (DSM-V) as a trauma and stressor related disorder. The disorder is comprised of eight criteria including; a) Exposure to actual or threatened death, serious injury or sexual violence b) presence of intrusion symptoms associated with, and beginning after, the traumatic events. This could include recurrent, involuntary and distressing memories or dreams related to the event. It could also include dissociative reactions such as flashbacks or otherwise intense psychological distress upon exposure to associated stimuli, with marked physiological reactions. C) Persistent avoidance of external or internal stimuli related to the traumatic event e.g. avoiding distressing thoughts or feelings, or people, places and activities. D) Negative alterations in mood and cognition associated with the traumatic event which could include; inability to recall important aspects of the event, persistent negative beliefs about oneself, others or the world; persistent negative emotional states, feelings of detachment from others and an inability to experience positive emotions. E) Marked alterations in arousal associated with the traumatic event such as feeling irritable, engaging in reckless behaviour, increased hypervigilance and difficulties with sleep and concentration.

If the above criteria are present, in order to obtain a diagnosis of PTSD, the symptoms must have been present for at least one month in duration, cause clinically significant distress and not be attributable to another condition.

The prevalence rate for PTSD in adulthood in the UK is reported to be 3.7% of men and 5.1% of women (McManus et al, 2016). However, prevalence rates are known to vary due to differences in the definition of PTSD, as well as the influence of various methodological factors (Brewin, Miller & Burchell, 2022). For example, figures can vary depending on whether the DSM-5 or ICD-11 criteria are used and whether Complex PTSD is included or counted separately. It is also possible for PTSD to emerge after many months or even years after a traumatic event, which may lead to underreporting.

The risk of developing PTSD is known to vary depending on the type of traumatic event. Interpersonal traumatic events e.g. violent assault or rape carry the highest risk for developing PTSD at 20.9% (Cole, Sprang & Silman, 2019). The impact of PTSD is far-reaching with difficulties affecting relationships with family members and friendships (McFarlane & Bookless, 2001), intimate partners (Lambert, et al 2012) mother-infant attachment in the case of PTSD to childbirth, employment (Lu et al, 2022) and physical health (Pacella, Hruska & Delahanty, 2013).

One of the most recognised models of PTSD is the cognitive behavioural model devised by Ehlers and Clark in 2000. The main tenet of the model is that PTSD develops due to the individual experiencing a current and ongoing sense of threat or danger. In clinical practice, trauma-focussed cognitive therapy for PTSD (CT-PTSD) is an empirically supported treatment which has been developed from the Ehlers and Clark (2000) model. The approach is recommended in the NICE guidance (NICE, 2018) as a first-line treatment.

The model itself includes the following components; describing the characteristics of the trauma and exploring prior experiences relevant to the traumatic event; understanding the individuals cognitive processing during the trauma; establishing the nature of the trauma memories themselves e.g. how they are re-experienced; identifying matching triggers which helps to direct memory processing tasks; identifying negative appraisals of the trauma which may affect the individuals view of themselves, others, the world and/or their future; and formulating the individuals current strategies to cope (i.e. safety behaviours) with the continued sense of current threat.

Cognitive processing for PTSD has been shown to be effective across a number of different trauma-populations. For example, King, McKenzie-McHarg and Horsch (2017) tested the cognitive model to predict PTSD following childbirth. They found that all variables derived from Ehlers and Clark's cognitive model significantly explained variance in PTSD symptoms following childbirth, even when additional variables were controlled for in the analysis. The results demonstrated that the cognitive behavioural model is both relevant and useful in understanding PTSD to childbirth. Chard (2005) evaluated cognitive processing therapy for PTSD related to childhood sexual abuse and found the treatment to be more effective for reducing trauma-specific symptoms compared to a control group, with the results being maintained for at least one year. In terms of secondary evidence, Cusack et al 2016 conducted a systematic review and meta-analysis of psychological treatments for adults with PTSD and found evidence to support the efficacy of the cognitive and behavioural model of PTSD.

In addition to the wide support for the usefulness of the Ehlers and Clark model, there is continuous work by the original authors and others to refine and test various aspects of the model and its mechanisms to improve and elaborate on the original theory. For example, Beierl et al (2020) tested the cognitive model prospectively using path analyses with

survivors of assaults or road traffic collisions. Their theoretically derived predictions were found to be consistent with the model. Lancaster, Rodriguez and Weston (2011) also used a path analysis approach to test the cognitive model, and while overall their results supported the model, the analysis questioned the impact of trauma memories based on their level of integration. By using structural equation modelling methods, this allows researchers to assess key variables and assumptions of the model through multiple causal pathways, revealing inconsistencies or gaps in knowledge to be addressed in the process.

There is ongoing work to address gaps in the field of PTSD research, such as, improving the theoretical understanding of delayed-onset PTSD (Utzon-Frank et al 2014), delivering cognitive therapy for PTSD online (Wild et al, 2020) and efforts to better understand how PTSD may be prevented (Greenberg, Brooks & Dunn, 2015). In light of the covid-19 pandemic, significant focus has been drawn towards bettering our understanding of medical trauma (Murray et al 2020) and moral injury (Murray, 2021).

One particular component of Ehlers and Clark's (2000) model relates to an individual's use of 'safety behaviours'. Safety behaviours are defined as behaviours which are carried out in specific situations in order to prevent feared outcomes (Salkovskis, 1991) and are common in anxiety-related mental health disorders, including PTSD. Safety behaviours can be overt or covert typically manifest as taking excessive precautions, as well as excessively avoiding any reminders related to the trauma. The literature describes two main subtypes of safety behaviours: avoidance-based and impression-management based behaviours (Grey, Beierl & Clark, 2019)

Some safety-seeking behaviours are appropriate and adaptive, as long as the particular threat is real and the behaviour has a good chance of alleviating the danger. However, sometimes safety-behaviours can be used against perceived threats, where there is no genuine

danger, which can maintain the cycle of anxiety. This is because the individual's conclusion as to why the feared situation did not arise is attributed to the use of the safety behaviour, strengthening the conditional relationship between employing safety behaviours and preventing the feared outcome. This maintains the individual's belief that the feared situation would likely occur unless the safety behaviour was utilised (Ehlers & Steil, 1995).

Another key component of the Ehlers and Clark model is to understand the individuals experience and cognitive processing while the trauma was happening, also referred to as 'peritraumatic experiences'. The model considers a number of factors which are known to affect cognitive processing during a traumatic event, such as; the characteristics of the trauma e.g. the duration of the event and predictability of the event occurring; whether the individual has experienced previous traumas and the coping strategies used; prior beliefs about the world and others; and whether the individual was under the influence of substances. The way in which an individual appraises the way they may have felt or behaved during a traumatic event can have a long-term negative consequence on their recovery, which can include re-experiencing emotions or sensory impressions during subsequent flashbacks.

A range of peritraumatic reactions have been linked with the subsequent development of PTSD (Vaiva et al, 2003; Thomas, Saumier & Brunet, 2012). While there is considerable research on the role of peritraumatic dissociation (PD) and subsequent PTSD, the results are mixed with some studies finding PD to be a strong predictor of PTSD, while other studies have found contradictory outcomes (van der Velden & Wittman, 2008; Candel & Merckelbach, 2004). This mixed pictures raises the question as to whether there may be other variables may be confounding or mediating the findings (Thompson-Hollands, Jun & Sloan, 2017). Other peritraumatic experiences which have caught the interest of researchers include data-driven processing (Rattel et al, 2022), peritraumatic fear (Dewey, Schuldberg & Madathil, 2014)) and peritraumatic threat (Kaysen et al, 2005)

The papers presented in this portfolio explore factors which contribute to the onset and maintenance of PTSD in adults. The papers are connected by their focus on cognitive mechanisms, which are defined as "the way people think about, interpret, evaluate and therefore act upon information received" (Heinstrom, 2010).

The first paper examines the relationship between safety behaviours and PTSD, in the context of the cognitive model (Ehlers & Clark, 2000), with the aim of quantifying the strength of the relationship for the first time. The second paper to be presented examines psychological peritraumatic factors (subjective threat, dissociation and data-driven processing) which are relevant to the potential development of PTSD in adults. This work will be the first meta-analysis to summarise quantitative data from adult populations.

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CHAPTER TWO

Exploring the relationship between safety behaviours and PTSD in adults: a systematic review and meta-analysis

To be prepared for submission to the Journal of Affective Disorders

(Author Guidelines found in Appendix A)

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Abstract

Background

Safety behaviours are a key element of the cognitive model of the Ehlers and Clark PTSD Model (2000). However, to date there has not to our knowledge been a comprehensive review of its role.

Aim

The aim of this work was to conduct the first known quantitative systematic review and meta-analysis of studies exploring the relationship between safety behaviours and PTSD in adults, in the context of the cognitive model.

Method

Six studies were included (n=628). Random effects meta-analyses were run, the first including all studies, then two additional analyses with the removal of one study, and the adjustment of one follow up time point.

Results

The result yielded a large effect r=0.62, supporting the idea that engaging in safety behaviours is associated with the development and/or maintenance of PTSD in adults.

Limitations

All studies included focussed on single event traumas and predominantly motor vehicle accidents or assaults. Most studies used self-rated measures and total scores, preventing a more detailed analysis. Estimates of heterogeneity were moderate to large, or large, across all meta-analyses (I^2 = 78.64, I^2 = 66.30 and I^2 = 79.69, respectively).

Conclusion

Holding in mind the large amounts of heterogeneity, this study supports the literature which states that safety behaviours are important in the development and/or maintenance of PTSD in adults (Ehlers & Clark, 2000). This finding supports the case for targeting safety behaviours in the clinical management of PTSD. The paper discusses the outcome of moderator analyses, limitations, clinical implications and suggestions for future research.

Key Words

Post-Traumatic Stress Disorder; PTSD; Safety Behaviour; Meta-Analysis

Exploring the relationship between safety behaviours and PTSD in adults: a systematic review and meta-analysis

Introduction

The concept of 'safety-seeking behaviours' was first introduced in the scientific literature in 1984, in relation to avoidance behaviours observed in agoraphobic patients. Rachman (1984) described a 'safety-signal perspective', which he argued helped to explain the "puzzling persistence of agoraphobia avoidance behaviours". Rachman hypothesised that agoraphobic patients behave in ways to establish and maintain a sense of safety, even if this was not always an explicit aim identified by the patient.

Since then, safety-seeking behaviours (or 'safety behaviours') have been highlighted as important features in a range of mental health disorders including Generalised Anxiety (Gustavsson, Salkovskis & Sigurosson, 2021), Panic Disorder (Salkovskis et al, 1999), obsessive-compulsive disorder (Levy & Radomsky, 2016), Social Anxiety (McManus, 2006; Plasencia, Alden & Taylor, 2011) and Post-Traumatic Stress Disorder (Ehlers & Clark, 2000). The discovery of the role of safety behaviours led to the assertion that treatment should focus on the elimination of such behaviours, which could otherwise undermine the chance of recovery (Salkovskis, 1991).

Across anxiety disorders, safety behaviours are described as those carried out in specific situations in order to prevent feared outcomes (Salkovskis, 1991). Behaviours can be overt or covert, and can be enacted prior to, or during, a feared situation. The aim of the behaviour is to reduce negative feelings which arise, as well as to extinguish the sense of threat. However, while this strategy may be effective in the short-term, the use of safety-seeking behaviours can paradoxically lead to the perpetuation of anxiety in the long-term. This is because using safety-behaviours prevents the individual from learning that a situation

is in fact safe, and therefore does not require the use of the behaviour to ensure or maintain safety.

While safety behaviours are described as 'behaviours', they can also manifest as internal processes not observable to others. For example, individuals may use cognitive strategies such as neutralising, rehearsal or thought suppression. Safety behaviours can also be used to varying degrees, despite usually being measured dichotomously i.e. to execute or not (Wong, 2022). If an individual is unable to use a safety behaviour to manage internal distress, they may avoid situations altogether, if they feel their safety cannot be guaranteed.

The role of safety behaviours are explicitly incorporated in the cognitive model of PTSD (Ehlers & Clark, 2000). The authors explain that safety behaviours are typically selected because they have a meaningful link to the person's appraisal of their trauma, in addition to their general beliefs about the best approach to cope with the aftermath of the event. They argue that strategies used to control a perceived threat can maintain PTSD through three key mechanisms: a) by directly producing PTSD symptoms; b) preventing change in negative appraisals of the trauma/its sequelae; and c) preventing change in the nature of the traumatic memory. The treatment element of the model advocates for maladaptive safety behaviours to be dropped in order to achieve symptom amelioration.

As part of a psychological formulation, the therapist works with the patient to identify which safety behaviours they are engaging in, and explores how those behaviours are contributing to the maintenance of the patients' symptoms. The cognitive model offered by Ehlers and Clark (2000) provides a clear framework for supporting patients to gain insight into the potential role of safety behaviours in maintaining their PTSD. Arriving at this shared understanding is essential as it provides a rationale for utilising therapeutic techniques such as behavioural experiments, and to begin challenging the function of the safety behaviours.

Behavioural experiments would need to be designed in a way that would involve exposure to a feared situation without the use of the safety-behaviour to target beliefs which the patient believes protect them from future harm.

The safety behaviours selected are meaningfully linked to the individual's appraisal of their traumatic experience, as well as other factors, such as their general beliefs, and friends or family's responses to the event. For example, someone who was mugged at night at knifepoint may refrain from leaving the house when it is dark, they may carry a weapon to protect themselves from future threatening encounters or they may resort to taking taxi's or talking to a friend on a mobile phone to ensure they are not alone in public.

While the individual usually engages with safety behaviours with the aim of reducing distress, the behaviours can sometimes lead to an increase in one or more unpleasant PTSD symptoms. For example, refraining from sleep until the early hours of the morning to avoid experiencing nightmares may inadvertently lead to difficulties with poor concentration and irritability. Similarly, selectively attending to threat cues through hypervigilance may lead to an increase in the frequency of intrusions and associated emotions. This could be due to a tendency to exaggerate the probability of further traumatic events, or due to an overgeneralisation of risk associated with otherwise normal activities (Ehlers and Clark, 2000).

Although behavioural experiments are proposed to be a key component of cognitive therapy, research has shown that they can be overlooked by therapists for several reasons. One barrier to their routine inclusion is due to practical constraints such as lack of time during sessions to plan and carry out experiments (Murray, 2017). Another barrier is therapist apprehension about their own abilities, with concerns that there may be unpredictable outcomes from the experiment which may be unhelpful to the therapeutic process. This can lead therapists to either omit the experiments altogether, or leave such tasks to patients to complete in their

own time. Unfortunately, this could lead to potentially poorer outcomes for clients with PTSD who are not receiving the full complement of evidence based techniques as part of their therapy (Harned et al, 2011).

Aim of this review

The NICE guidance for PTSD (NG116) outlines the best available evidence for the treatment of PTSD, which includes the use of trauma-focussed Cognitive Behaviour Therapy, Cognitive Processing Therapy and Prolonged Exposure Therapy. The guidance was previously issued in 2005, and more recently updated in December 2018. While several treatment manuals that describe the cognitive techniques have been developed over the years, for example Resick and Schnicke (1993), Foa and Rothbaum (1998) and Blanchard and Hickling (2004), it is Ehlers and Clark's (2000) model which is commonly used to inform today's practice. The CBT competence framework for PTSD (UCL, PTSD Competency Framework), which sets out how to carry out CBT effectively and in line with best practice, is based on the Ehlers and Clark model and stresses the importance of safety behaviours. It is therefore imperative that researchers and therapists are clear about the potential link between safety behaviours and the maintenance of PTSD symptoms.

However, to date there has not to our knowledge been a comprehensive quantitative review of the role of safety behaviours in the maintenance of PTSD, as described in Ehlers and Clark's (2000) model. It is important that this integral mechanism of the cognitive model of PTSD is adequately reviewed due to the potentially significant implications for psychological treatment recommendations. This meta-analysis represents the first known attempt to pool existing quantitative findings on this topic.

Methods

Search Strategy

This review was registered on the PROSPERO register of systematic reviews on 4th May 2022 (CRD42022321531). The initial search was completed in June 2022 using the University of East Anglia's Online Library facility. All database providers, 52 in total, were searched including APA PsychInfo, MEDLINE Ultimate, Academic Search Ultimate, Complementary Index, CINAHL Ultimate, ScienceDirect, Directory of Open Access Journals, Supplemental Index, Social Sciences Citation Index, Journals@OVID, Science Citation Index Expanded, Scopus, APA PsychArticles, OpenDissertations, Child Development & Adolescent Studies, SPORTDiscus with Full Text, ERIC Research Starters, Business Source Ultimate, British Library EThOS, JSTOR Journals, UEA Library Catalogue, AMED – The Allied and Complementary Medicine Database, ProjectMUSE, APA PsychArticles, IEEE Xplore Digital Library, Europeana, Alexander Street, Communication & Mass Media Complete, Open Research Library, eBook Collection (EBSCOhost), eBook Academic Collection (EBSCOhost), Teacher Reference Centre, Emerald Insight, UEA Digital Repository, eArticle, GreenFILE, British Education Index, ACM Full-Text Collection, EconLit with Full Text, Wiley Online Reference Works, Arts and Humanities Citation Index, Credo Reference: Academic Core, MLA International Bibliography, Philosphers Index with Full Text, Routledge Handbooks Online, OAPEN Library, Gale OneFile: LegalTrac, Marketline Advantage, Westlaw UK, Bloomsbury Collections, MathSciNet via EBSCOhost.

. The reference sections of included papers, as well as relevant meta-analyses, were reviewed to look for additional papers which met the inclusion criteria for the study. The search terms were "ptsd" or "post traumatic stress disorder" or "posttraumatic stress disorder" or "post-

traumatic stress disorder" AND "safety-behavio*" or "safety behavio*" or "safety-seeking behavio*" or "safety seeking behavio*". The search terms were run using the 'advanced search' menu and the following parameters; full-text only; English language only; and all geographical locations. The date of the search was restricted from 1980 to 2022, as Post-Traumatic Stress Disorder was first recognised in the Diagnostic and Statistical Manual of Mental Disorders (DSM-III) in 1980 (American Psychiatric Association, 2013). An additional search of the literature was conducted through a general internet search thought Google Scholar, using the search terms above.

Inclusion and exclusion criteria

A number of criteria were applied to ensure only the most appropriate studies were included. The assessment of PTSD must have been completed using a valid and reliable measure (although the norms could be from within any population, not solely the population of this study). The PTSD measure must have considered the DSM diagnostic criteria for PTSD, which includes: exposure to death/threatened death, actual or threatened serious injury or sexual violence (Criterion A); intrusion symptoms (Criterion B); avoidance (Criterion C); negative alterations in cognition or mood (Criterion D) and alterations in arousal and reactivity (Criterion E). Self-reported or clinician-reported measures must have been included. Studies were excluded if they only assessed Acute Stress Disorder, or if the PTSD assessment took place less than 4 weeks following the traumatic event. According to DSM-5 (American Psychiatric Association, 2013), PTSD can only be diagnosed after a minimum of 1 month from the traumatic event.

The studies must also have each provided a clearly defined assessment of at least one Safety Behaviour. No time limit was set between the assessment of PTSD and safety behaviours. Studies were included if all participants were aged 18 and over. Both clinical and

community samples were included, as long as the clinical samples did not include participants who were selected primarily due to a specific comorbid disorder. Clinical samples were excluded if participant data included only those with an existing PTSD diagnosis: to be included, a non-PTSD comparison group was required to allow a between groups effect size to be calculated. Studies were excluded if they focused solely on participants with a brain injury.

Studies were only retained if they provided adequate statistics to calculate relevant effect sizes. All academic sources including doctoral and master's theses, longitudinal, follow-up and cross-sectional studies were included. Treatment or intervention studies, single-case designs, qualitative studies and meta-analyses were excluded.

Data Extraction

A number of rules were set prior to data extraction to clarify any uncertainties in the process. If PTSD data were presented for both continuous measures (symptom severity) and dichotomous measures (diagnosis), the effect sizes for continuous measures were prioritised to avoid an underestimation of the effect size from dichotomous data. For prospective longitudinal studies with multiple assessment time points of PTSD, effect sizes were selected from the first available time point (as long as this was at least one month after the traumatic event, as well as being after the measurement of safety behaviours) with data from subsequent time points disregarded. If studies included effect sizes for both self-rated and interviewer-rated PTSD measures, interviewer-rated measures were prioritised due to the more robust validity of the approach to assessment.

Calculating Effect Sizes

Pearson's correlation coefficient, *r*, was used as the effect size for this study. All included studies provided this data, precluding the need for effect size conversion. Pearson's correlation

coefficient is straight-forward to interpret, with 0.1 considered to be a small effect size, 0.3 a medium effect size and $r = 0.5$ or high representing a large effect size (Cohen, 1988).

Quality Assessment and Risk of Bias

The quality of studies and risk of bias was assessed using a quality assessment tool devised by Memarzia et al (2021). The tool was based on the NICE Quality Assessment Checklist for Studies reporting Correlations and Associations (2012) and the NIH Quality Assessment Tool for Observational Cohort and Cross-section Studies (National Heart Lung and Blood Institute, 2014). The following areas were included: 1) how well the study population was defined e.g. clear description of demographics and trauma characteristics; 2) whether an appropriate sampling method was used; 3) whether the non-response rate was reported, as well as whether it was minimal and/or accounted for (e.g. if less than 40%, did the authors discover significant differences between responders and non-responders, based on key indicators such as age, gender etc.); 4) whether loss to follow up was minimal and/or accounted for (prospective longitudinal studies only); 5) the reliability of the PTSD measure and 6) the reliability of the safety behaviour measure. Each item was given a score of 0, 1 or 2, with 0 indicating low quality and 2 indicating high quality. Higher quality represents lower risk of bias. The scores for each study were then added and converted to a percentage score. Studies which scored >70% were rated as High quality, 50-69% as Medium quality, and <50% as Low quality. The lead author (JB), and a second rater (JP), both completed quality ratings for all of the studies included. An intra-class correlation coefficient (ICC) (Koo and Li, 2016) was calculated to assess the level of agreement between raters, ICC = 0.834, which corresponds to good reliability.

Further steps were planned to complete during the analysis to explore the risk of bias. Specifically, publication bias was going to be examined using a funnel plot to visually represent

the data with the aim of identifying signs of asymmetry. However, due to the small sample of studies, it was not possible to present or interpret this data accurately.

Meta-analytic Method

The meta-analysis was conducted using R (version 4.1.3) with the 'metafor' (version 3.8-1) package. For R code, see appendix C. A random effects model was utilised for all meta-analyses conducted in this review. The raw correlation data (r) were extracted from the comma separated value file into the R software and transformed into Fisher's Z scores. The scores were then transformed back into r correlation coefficients before presenting the results. The analysis examined the heterogeneity of the effect sizes by calculating a Q statistic. If the Q statistic is significant ($p<0.05$), this signals that effect size variation is present. The amount of variation present was considered by estimating the I^2 statistic (Higgins et al 2003), which ranges from 0-100%. If the I^2 estimation is 25% this is considered to be a small degree of heterogeneity, 50% is moderate and 75% is considered to be a large degree of heterogeneity.

In addition to calculating the overall effect sizes, the 'prediction interval' was also presented for each analysis. The prediction interval presents the expected range of true effects in similar studies if conducted in the future (IntHout et al, 2015).

Moderator Analyses

A meta-analysis was planned to explore how study quality may be related to variation in effect sizes across studies. Prior to commencing the study, a number of possible moderators were suggested in the PROSPERO proposal, such as exploring differences between studies which reported on overt compared to covert safety behaviours, and between avoidance and escape related safety behaviours. However, this level of detail was not available in the studies selected, therefore this analysis could not be completed.

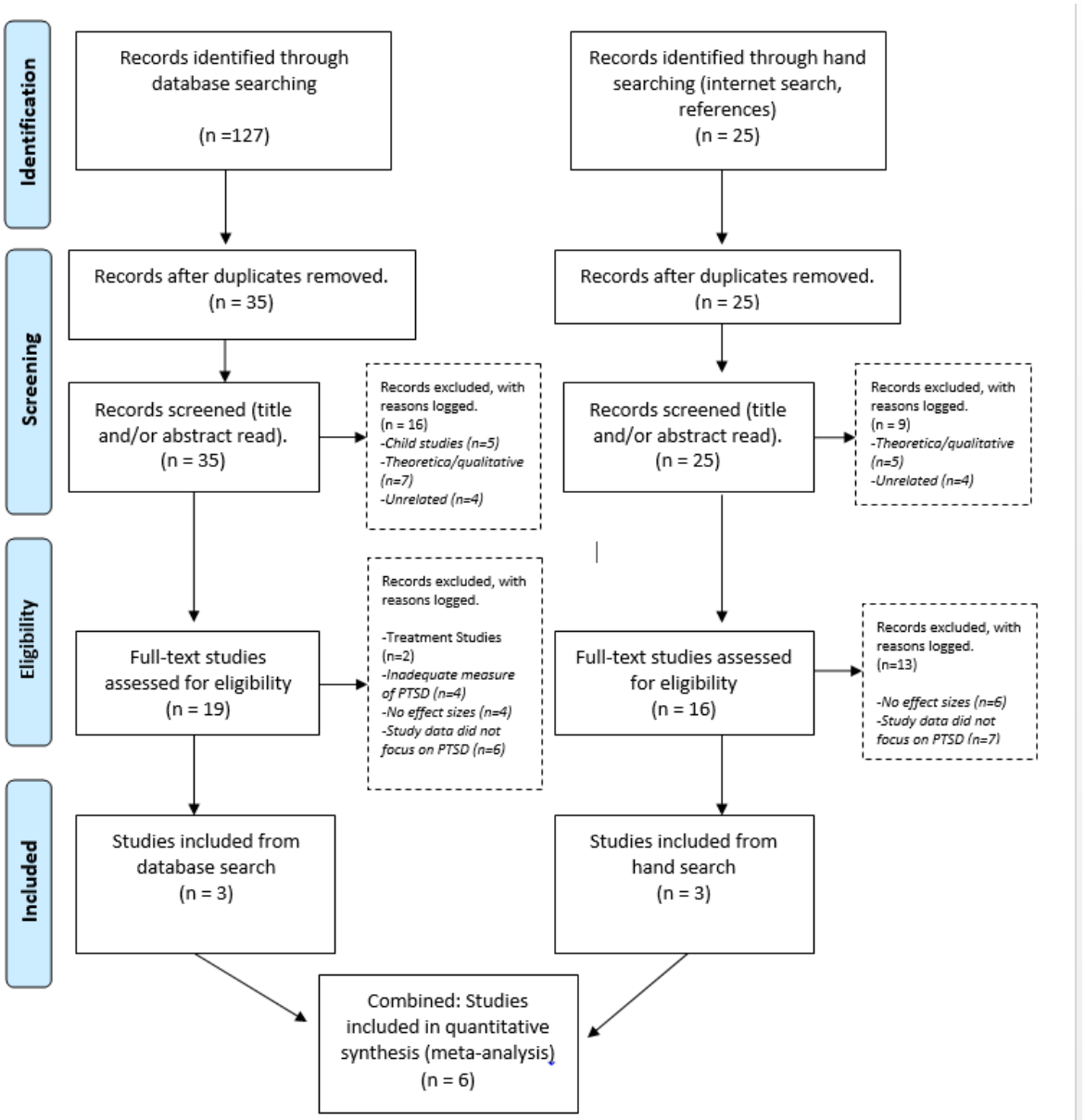

Fig 1. The PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses; Moher et al, 2009) flow diagram outlines the inclusion and exclusion process.

Results

Study Characteristics

Six studies were included, each providing one effect size towards the meta-analysis to estimate the strength of the relationship between safety behaviours and PTSD. Table 1 provides a summary of each study's characteristics.

Table 1

Characteristics of studies included in meta-analysis

Article	Trauma Type	N	Age Range	Mean age (SD)	% female	Country	Ethnicity	Study Type	PTSD Measure	Interview or self-report questionnaire	Safety Behaviour Measure	Interview or self-report questionnaire	Study Quality
Blakey 2020a	Endorsed exposure to at least one potentially traumatic event	89	18+	20.32 (4.17)	82%	USA	78% White	Cross Sectional	Clinician Administered PTSD Scale (CAPS-5)	Interview	Post Traumatic Safety Behaviour Questionnaire	Self-report	Medium
Dunmore 2001	Physical or sexual assault	57	Adult sample, not specified	35.4 (12.8)	54%	UK	98% Caucasian, 2% Non-Caucasian	Prospective Longitudinal	PTSD Symptom Scale (PSS-SR)	Self-report	Maladaptive control strategies; 2 subscales 'Avoidance/safety seeking' and 'Undoing'	Self-report measure designed for this study, using a Likert Scale	Medium
Ehlers 2010	Motor vehicle accidents and physical assaults	162	18 – 61	31.9 (10.9)	43.9%	UK	40.9% Black, 33.3% White, 25.8% Other	Cross Sectional	PTSD Diagnostic Scale (PDS)	Self-report	Safety Behaviours Questionnaire	Self-report	High
Ehring 2006	Motor vehicle accidents	101	18 – 65	34.95 (10.6)	43.6%	UK	76.3% White, 17.8% Black, 5.9% Other	Cross Sectional	PTSD Diagnostic Scale (PDS)	Self-report	Safety Behaviours Questionnaire	Self-report	High
Ehring 2008	Motor vehicle accidents	125	18 – 65	35.17 (9.4)	33.3%	UK	68.7% White, 22.4% Black, 8.8% Other	Prospective Longitudinal	PTSD Diagnostic Scale (PDS)	Self-report	Safety Behaviours Questionnaire	Self-report	High
Freeman 2013	Assault Victims	94	16 – 85	34.4 (11.6)	25%	UK	52% White, 14% Black Caribbean, 13% Black African, 21% Other	Prospective Longitudinal	PTSD Diagnostic Scale (PDS)	Self-report	Safety Behaviours Questionnaire	Self-report	High

Blakey (2020a) consisted of two samples, described as 'Western' and 'Southeastern', however, only the Western sample met inclusion criteria for this review. All of the included studies assessed single event traumas, except for Blakey (2020a) which included a small number of participants who had experienced trauma related to combat (n=3). Blakey (2020a) was the only study to include a range of traumas (ten categories in total), whereas all other studies focussed on either motor vehicle accidents, assaults or a combination of both. Three of the studies were cross-sectional (safety behaviours and PTSD symptoms were assessed at the same time) and three were prospective longitudinal studies. Follow-up time points for each of the prospective longitudinal studies differed as follows; Dunmore (2001) collected data at 6 and 9 month time points, Ehring (2008) collected data at 1, 3 and 6 month time points, and Freeman (2013) collected data at 6 months only.

Four of the studies (Ehlers, 2010; Ehring, 2006; Ehring, 2008 and Freeman 2013) used the Safety Behaviours Questionnaire (SBQ). This measure was developed over a series of studies conducted by the authors and their colleagues (Dunmore et al., 1999, 2001; Ehring et al., 2006) and has shown good internal consistencies and correlations with PTSD severity (Chronbach's alpha = .94). Blakey (2020a) used the Post Traumatic Safety Behaviour Questionnaire (PSBQ), a 23-item novel measure designed specifically for the study. The authors comment that the items were derived from existing literature on PTSD and safety behaviours by Clapp et al., 2011; Dunmore et al., 2001; Ehlers and Clark, 2000; Foa et al., 2007; Kamphuis and Telch, 1998; Telch and Lancaster, 2012. The PSBQ showed acceptable-to-good internal consistency for the sample included in this study (alpha = .77).

Dunmore (2001) investigated safety behaviours from the perspective of 'maladaptive coping strategies'. The authors created a questionnaire consisting of two subscales. The first subscale included various forms of avoidance and safety seeking e.g. avoidance of situations, cognitive avoidance and active attempts to feel safe. The second

subscale ‘undoing’, included examples of attempts to mentally erase or alter memories of the traumatic event. The authors decided that data relating to the latter subscale would be discarded from the analysis, as this construct could be argued to be too similar to rumination. Therefore, only data relating to the former subscale ‘avoidance/safety-seeking’ was included.

All studies utilised a validated questionnaire to measure PTSD. However, only Blakey (2020a) used an interviewer-rated measure. All other studies used self-report questionnaires to measure PTSD.

Assessment of study quality and risk of bias

All six included studies were scored against the quality assessment framework (see appendix B*).* Four of the studies were rated as high quality, and two as medium quality. A meta-analysis was planned to remove low quality studies from the analysis to determine if the results would be significantly different. However, as only two studies were rated as medium quality with the remaining rated as high quality, it was not deemed necessary to remove these studies as any impact would likely be minimal.

The analysis was repeated with the removal of Dunmore (2001), due to the different approach taken to measure safety behaviours, compared to the other studies included. Despite disregarding data for the ‘undoing’ subscale, the authors had concerns about the appropriateness of the ‘avoidance/safety-seeking’ subscale. While several examples described in the paper accurately define safety-seeking behaviours, the addition of avoidance behaviours to the same subscale could be argued to dilute the targeted safety-seeking behaviours sought in this meta-analysis.

An analysis was also completed to examine the impact of follow up time points for the three prospective longitudinal studies. The initial analysis adhered to the a priori rule of selecting data from the first available follow up time point. However, as all three studies

provided data at a 6 month time point, the 6 month data from the Ehring (2008) paper was added in place of the 1 month time point data, so that all studies shared the same follow up time frame.

Meta-analyses: safety behaviours, all studies

A meta-analysis of all studies, with a total sample size of 628 participants, revealed an overall effect size of r = 0.62 (95% CI=0.50-0.72), as is evidenced in Figure 2. The estimated heterogeneity was significant, highlighting large variance across studies (Q = 21.7845, df=5, p<0.0006; I^2=78.64%). The prediction interval ranged from 0.30 to 0.82. A funnel plot was produced to scrutinise the presence of asymmetry which may indicate publication bias, however, due to the small number of studies, it was not possible to interpret accurately and has therefore not been included.

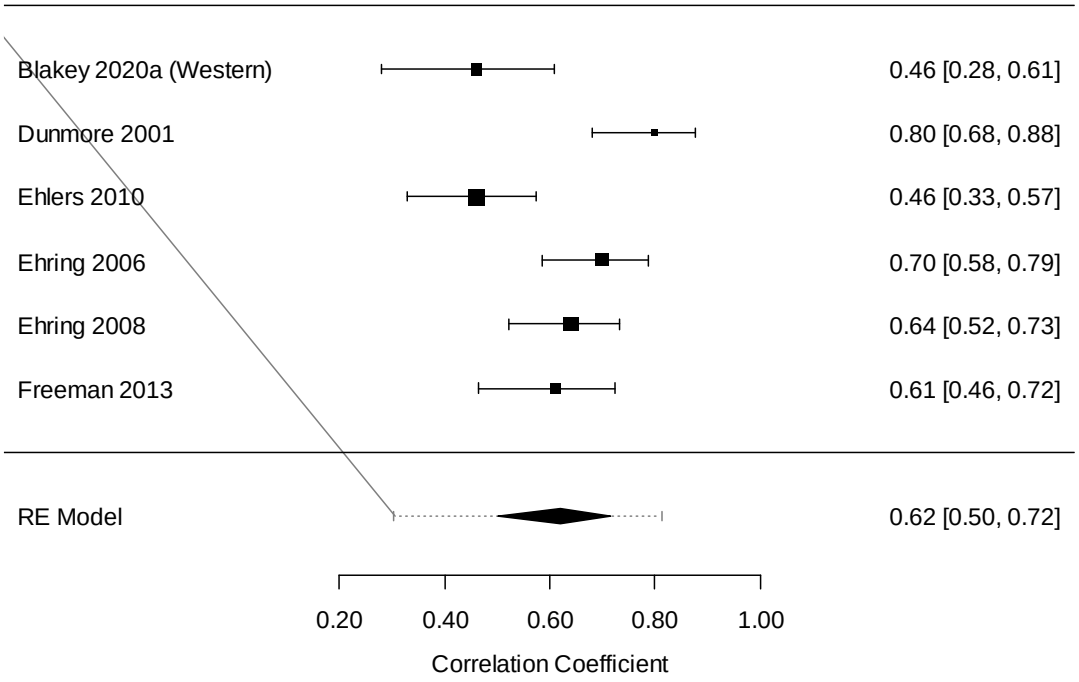

Fig 2. Forest plot for meta-analysis of safety behaviours and PTSD, all studies included. Includes effect sizes (r) for each study with confidence intervals, prediction interval (dotted line), and estimated overall effect size of the relationship between safety behaviours and PTSD in adults.

The meta-analysis was repeated with the exclusion of Dunmore (2001). The revised total sample size of 571 participants revealed an overall effect size of r = 0.58 (95% CI=0.47-0.66), as is evident in the Forest plot in Figure 3. The estimated heterogeneity was significant, highlighting moderate to large variance across studies (Q = 12.0722, df=4, p<0.0168; I^2=66.30%). The prediction interval ranged from 0.34 to 0.75. The Fail-safe N calculation was significant (95%, p<0.001, N=438).

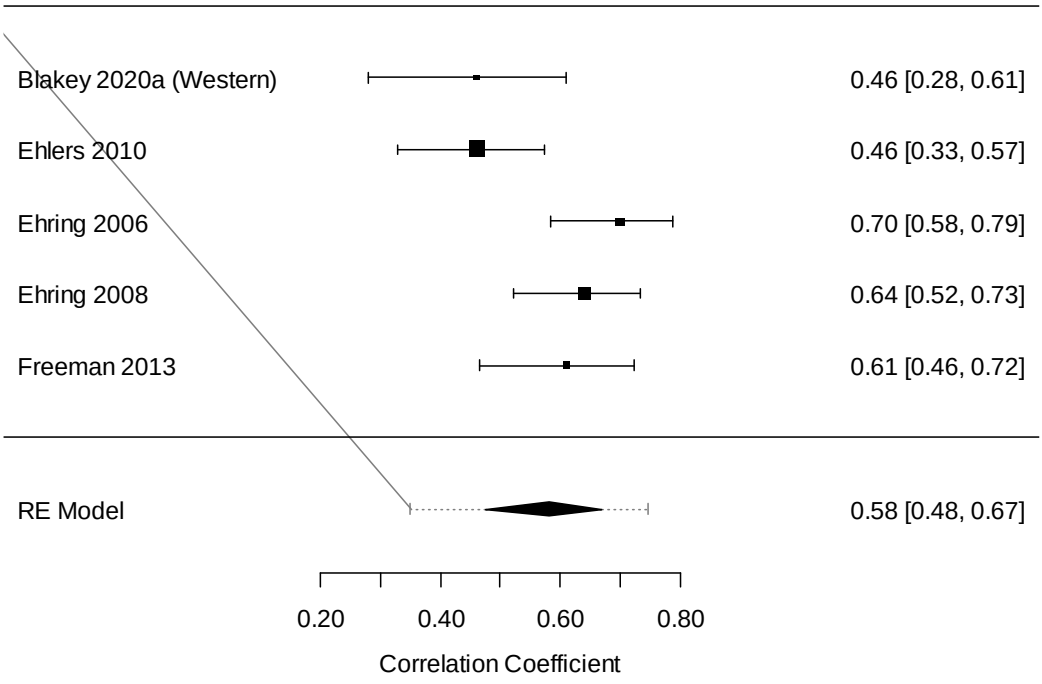

Fig 3. Forest plot for meta-analysis of safety behaviours and PTSD, excluding Dunmore (2001). Includes effect sizes (r) for each study with confidence intervals, prediction interval (dotted line), and estimated overall effect size of the relationship between safety behaviours and PTSD in adults.

A final meta-analysis was completed to incorporate the six month follow up data for Ehring (2008), in place of one month follow up data, so that all three prospective longitudinal studies were analysed using the same time six month point.

The overall sample size increased to 643 and revealed an overall effect size of r = 0.60 (95% CI=0.48-0.70), as displayed in Figure 4. The estimated heterogeneity was significant,

highlighting large variance across studies (Q = 21.7281, df=5, p<0.0006; I^2=79.69%). The prediction interval ranged from 0.27 to 0.81.

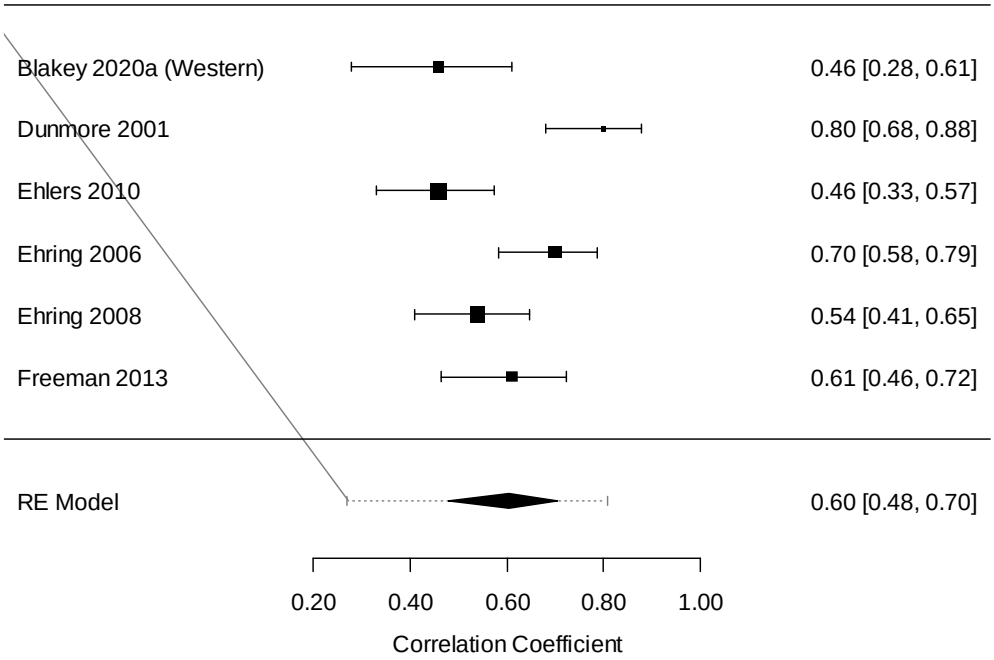

Fig 4. Forest plot for meta-analysis of safety behaviours and PTSD, all prospective longitudinal studies 6 month follow up data. Includes effect sizes (*r*) for each study with confidence intervals, prediction interval (dotted line), and estimated overall effect size of the relationship between safety behaviours and PTSD in adults.

A summary of the three meta-analyses is provided in Table 2.

Table 2

A summary of meta-analyses of the relationship between safety behaviours and PTSD.

Meta-analysis	N	Effect size	=95% Confidence Interval	Q	I^2	Prediction Interval
All 6 studies	628	.62	.50, .72	p=<.0006	78.64%	.30, .82
5 Studies (excluding Dunmore (2001)	571	.58	.47, .66	P=<.0186	66.30%	.34,– .75
All 6 studies, 6 month follow up	643	.60	.48, .70	P=<.0006	79.69%	.27, .81

Discussion

Overall findings

The current review provides the first known quantitative analysis of the relationship between safety behaviours and PTSD in adults. Six studies were found to provide the required correlational data to meet inclusion criteria for this study. A meta-analysis of all effect sizes found a large effect, r=0.62. This result supports the idea that engaging in safety behaviours is associated with the development and/or maintenance of PTSD in adults. Additional meta-analyses involving the removal of one study that used a measure of safety behaviours that also included some avoidance items, and the adjustment of one follow-up time point, found similarly large overall effect sizes (r=0.58, r=0.60 respectively). All three meta-analyses were characterised by a large degree of heterogeneity.

Theoretical and Clinical Implications

The findings from this review support the view that safety behaviours are a key mechanism in the Ehlers and Clark (2000) model. While it was expected that a link would be apparent, this study represents the first attempt to pull together the published literature to confirm the size of this relationship. The number of studies included was small, with half of the studies cross-sectional and the other half prospective longitudinal. As the data were analysed together, it is therefore not possible to offer comment on the direction of the relationship i.e. whether PTSD symptoms are driving safety behaviours, or whether it is the safety behaviours which drive PTSD.

Nevertheless, as a relationship has been established, it is now important to consider the potential implications for routine clinical practice. The data summarised here support the case for targeting safety behaviours in the clinical management of PTSD; several specific implications are now outlined. The first consideration relates to the assessment of safety

behaviours. Four of the studies in this review used the SBQ, which was derived from work on social anxiety, not specifically PTSD. One study used the PSBQ, which is the only known PTSD specific measure of safety behaviours. The creators of the questionnaire acknowledge that it is not an exhaustive list of PTSD-specific safety behaviours, and not all people with PTSD would endorse all of the behaviours listed. In time, it would be helpful to review the use of the PBSQ and which specific behaviours tend to be endorsed, to better understand which safety behaviours are most common for this client group. Conducting an assessment which includes an assessment of safety behaviours would be helpful, in particular, to elucidate examples of more covert behaviours, which are often harder to recognise and often go undetected in therapy.

One of the criticisms of safety behaviour questionnaires is that safety behaviours are often so unique to individuals that attempts to create a standardised questionnaire would likely be unsatisfactory, as one measure would be unable to capture the nuance and function of each individual's behaviours, particularly if the measure is self-reported. Blakey et al (2020) advocate for self-report measures to be supplemented with an interviewer-led discussion about the motivations behind the behaviours, as part of a wider psychological formulation. The authors recommend that assessors are trained in the conceptualisation of PTSD and safety behaviours in order for this approach to be effective.

Another criticism of the measurement of safety behaviours relates to the lack of anchoring to a specific traumatic event. If the responder is not instructed to hold a specific event in mind, it is possible that the questionnaire may inadvertently pick up on pre-existing safety behaviours or habits which are not used to reduce trauma-related distress. The PSBQ does in fact provide an instruction to the responder to focus on behaviours associated to the index trauma, which is a key strength of this measure developed by Blakey et al (2020).

Future development of PTSD safety behaviour measures should consider the issues of self-report questionnaires and the importance of anchoring index events prior to data collection.

The NICE guidance for PTSD (NICE, NG116) recommends that family or carers should be involved in treatment, if appropriate. As some safety behaviours are socially normative e.g. asking family or friends for repeated reassurance, or to accompany them to feared locations, it could be that these behaviours are inadvertently reinforced by others. Completing a functional analysis, with collaborative input from family, to support the individual to work on safety behaviours outside of the therapy session may be helpful (Abramowitz, 2011).

It is also important that therapists are able to feel confident in working with clients with PTSD and to address safety behaviours as part of evidence-based treatment. Therapists need to be supported with adequate training, with top-up skills training if needed (Murray, 2017). Becker et al (2004) highlighted how some clinicians may avoid conducting exposure components of trauma-focussed therapies, due to hesitancy or anxiety about using the techniques, which needs to be addressed.

There are a number of avenues for future research in this area. Blakey et al (2020) suggest examining bidirectional effects of safety behaviours during trauma-focussed treatment. They suggest time-series analyses to look at session-by-session changes in PTSD symptoms and safety behaviours. It is important to clarify whether tackling safety behaviours is an essential part of recovery from PTSD. Safety-behaviours comprise one part of the model, but is unclear how critical it is to recovery whether safety behaviours are specifically targeted or not. Cognitive models advocate for the importance of safety behaviours and encourage reduction of such behaviours in order to maximise therapy outcomes. However, empirical evidence remains inconclusive (Meulders et al, 2016).

Future studies would need to consider safety behaviours in the context of therapist assisted versus self-help approaches, speed of recovery based on the inclusion or exclusion of safety behaviour intervention, as well as dropout rates. It would also be helpful to clarify at what stage of therapy it might be most useful to address safety behaviours.

While the research regarding PTSD and safety behaviours is relatively scant, work is underway. In 2021, American Psychologist Dr Jason Goodson created a CBT-informed treatment for PTSD named '(Safety) Behaviour Therapy for PTSD' or '(S) B-PTSD', comprising of a client manual and a therapist manual (Goodson and Haeffel, 2002; Goodson, 2021, *unpublished*). His work recognises how safety behaviour research has garnered little attention, and as far as the authors are aware, there are no PTSD treatments that have been developed that focus solely on safety behaviours. This apparent gap in the literature prompted Goodson to develop a bespoke treatment which includes components of mindfulness and attention training. Dr Goodson and Dr Haeffel are understood to be conducting an anxiety prevention study using his safety behaviour approach. It will be interesting to consider the findings of their work and how they contribute to the evolving debate of if, how and when to address safety behaviours in PTSD.

Limitations

There were a number of limitations inherent in this study which are important to note. Firstly, with the exception of a few participants in one study (Blakey, 2020a), all of the studies focussed on single event traumas. Therefore, this study cannot conclude that the results apply to sustained or multiple traumas e.g. domestic violence or imprisonment. Furthermore, the types of traumatic events were narrowed to predominantly motor vehicle accidents and assaults, which prevents the authors from advocating for the generalisability of these findings to populations with different trauma types e.g. natural disaster or life-threatening illness.

Regarding the demographics of participants across studies, the majority were young adults based in western countries. Four studies included predominantly white participants, and five studies were conducted in the UK. This further limits the generalisability of the review's findings, and strongly suggests that research across different countries and settings in to this issue is warranted.

While all studies demonstrated the use of validated questionnaires to measure PTSD, only one study used an interviewer-rated approach to assessment. All studies used self-report measured to assess safety behaviours, with two studies creating their own set of questions for the purpose of their study. Studies tended to rely on total scores to report safety behaviours, without providing further detail about the scoring by item. It was therefore not possible to apply additional moderator analyses to certain types of safety behaviours e.g. overt vs covert, or escape vs avoidance behaviours.

Finally, due to the small number of studies in this review, it was not possible to consider publication bias more fully.

Conclusion

Overall, there were a small number of studies included in this review, despite safety behaviours forming an important part of the cognitive model for over twenty years. Holding in mind the large amount of heterogeneity, this study supports the literature which states that safety behaviours are important in the development and/or maintenance of PTSD in adults (Ehlers & Clark, 2000). More research is needed however to clarify inconclusive findings in the small literature to date. For now, a considered and strategic approach to the use of safety behaviours in therapy is nevertheless warranted. Safety behaviours appear to have a nuanced role which warrants further exploration.

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CHAPTER THREE

Psychological peritraumatic risk factors for PTSD in adults: a meta-analytic review

To be prepared for submission to the Journal of Affective Disorders

(Author Guidelines found in Appendix A)

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Abstract

Background

The inclusion and subsequent removal of peritraumatic reactions (A2 criteria) from the Diagnostic and Statistical Manual of Mental Disorders (DSM-III, DSM-5) has created a lengthy and ongoing debate about the importance of peritraumatic reactions in the development of PTSD.

Aim

The aim of this work was to conduct the first known comprehensive systematic review and meta-analysis of studies exploring peritraumatic risk factors for PTSD in adults.

Method

Sixty-three studies, totalling sixty-five samples were identified (n=20,335). Random effects meta-analyses were run, with additional moderator analyses completed for the role of type of trauma (intentional vs non-intentional), assessment measure, use of statistics (beta vs r), method of assessment (self-report vs interview) and study design (cross-sectional vs prospective longitudinal).

Results

Peritraumatic subjective threat and peritraumatic dissociation yielded moderate estimates of population effect size, and peritraumatic data-driven processing yielded a small estimated population effect size.

Limitations

Estimates of heterogeneity were high in the subjective threat and dissociation group of studies (I^2 = 96.3%%, 90.1% respectively). Few studies specifically addressed peritraumatic emotions other than fear.

Conclusion

The current review supports previous assertions that peritraumatic experiences, including subjective threat, dissociation and data-driven processing, are important risk factors in the development of PTSD in adults. It is recommended that clinicians consider peritraumatic risk factors as part of a person-centred assessment and formulation of PTSD. The paper discusses the outcome of moderator analyses, limitations, clinical implications and suggestions for future research.

Key Words: PTSD, Meta-Analysis, threat, dissociation, data-driven processing

Introduction

Post-Traumatic Stress Disorder (PTSD) was first described in the third edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-III) by the American Psychiatric Association (APA) in 1980 as "a recognizable stressor that would evoke significant symptoms of distress of almost anyone" (American Psychiatric Association, 1980, p.200). As such, PTSD was conceptualised as a catastrophic stressor e.g. torture or earthquakes which specifically surpassed an individual's adaptive capacity , in contrast to other stressful life events such as divorce or serious financial difficulty, which were considered to be more common and more likely to fit other diagnostic categories such as 'adjustment disorder'.

Seven years later, a revised version of the DSM-III was released, which not only specified a Criterion A event as "an event outside the range of usual human experience", but also added a subjective requirement, known as 'A2', which referred to the individuals peritraumatic stress reaction. This represents the emotional reaction experienced as the trauma is happening. The APA defined this reaction as "usually experienced with intense fear, terror, and helplessness" (American Psychiatric Association, 1987, p.247).

The inclusion of an objective and a subjective component of a Criterion A event created considerable debate for over two decades. After careful consideration of the evidence, the subjective 'A2' component was removed with the release of DSM-5 in 2013 (Friedman et al, 2011). The reasoning behind the decision was led by the poor predictive value of A2 towards chronic PTSD (Bedard-Gilligan & Zoellner, 2008), as well as evidence that many individuals were able to meet the remaining B-F criteria (after meeting the objective component of a Criterion A1 event), without meeting the A2 component (O'Donnell et al, 2010). Kilpatrick's (1998) work also highlighted how prevalence rates of PTSD were not

affected by the inclusion or exclusion of the A2 criterion. Another change brought in by the release of DMS-5 was the re-classification of PTSD from an anxiety disorder to a "trauma and stress-related disorder", with some authors arguing that the original description of "fear, helplessness and horror" did not adequately capture the full range of peritraumatic emotions e.g. guilt, shame, disgust, which had also been shown to be predictive of PTSD (Brewin, Andrews & Rose, 2000).

However, despite the removal of A2 criteria from formal diagnosis criteria, this does not equate to peritraumatic reactions being considered irrelevant or unworthy of further investigation. In fact, because peritraumatic reactions are thought to be near-universal, much effort has been geared towards understanding the links between peritraumatic reactions and the development of PTSD (Vance, Kovachy & Dong, 2018). The subject of peritraumatic reactions has thus increasingly garnered interest from researchers over the past 30 years. During the early 90's, there were fewer than 100 studies per year published containing the word 'peritrauma'. However, this number has grown exponentially, with more than 800 papers published annually since 2015 (Massazza, 2021).

Brewin's Dual Representation Theory (Brewin et al, 1996) describes how intrusive memories, a hallmark symptom of PTSD, develop due to different ways memories are encoded during a traumatic experience i.e. peritraumatically. Sensory representations or 'S-Reps' are responsible for sensory data (affect/emotional state) which is encoded in a 'raw' format and which can be re-activated involuntarily when matching triggers are present in the environment. The 'C-Reps' are responsible for contextual memory i.e. spatial and personal details of the person experiencing the trauma. C-reps represent higher-level contextual information which can be retrieved either voluntarily or involuntarily, and can be verbalised. Intrusive memories are thought to occur when S-reps are disproportionally greater, and disconnected from C-reps, which leads to unpleasant re-experiencing in the absence of

contextual information. This disconnection is due to the affective salience of the traumatic event, possibly combined with a downregulation of the hippocampal memory system (Brewin & Burgess, 2014, Layton & Krikorian, 2002).

The importance of peritraumatic reactions is also recognised in Ehlers and Clark's (2000) widely used cognitive model of PTSD. They acknowledge that most patients with persistent PTSD experience a range of negative emotions, with predominant emotional responses depending on particular appraisals e.g. appraisals concerning perceived danger leading to fear, and appraisals concerning a violation of one's personal standards leading to shame. The model states that the way an individual felt or acted during an event can have long-term threatening implications for the way they may view themselves, other people, the world or their future.

The aim of this review was to conduct a thorough meta-analysis of the available quantitative data related to psychological peritraumatic risk factors in the development of PTSD in adults. This review looks to include a wide range of peritraumatic risk factors, with the aim of identifying if any have stronger or weaker relationships with PTSD symptoms. From a practice point of view, the ability to predict who may be more likely to go on to develop PTSD is a key clinical interest. To the authors' knowledge, this is the first known quantitative meta-analysis of peritraumatic risk factors in adults.

Method

Search Strategy

This review was registered on the PROSPERO register of systematic reviews on 25th August 2021 (CRD42021272837).

The initial search was completed in August 2021 and repeated in January 2022 to ensure search results were as recent as possible. The search was conducted using the University of East Anglia's Online Library facility. All database providers, 52 in total, were searched, including APA PsychInfo, MEDLINE Ultimate, Academic Search Ultimate, Complementary Index, CINAHL Ultimate, ScienceDirect, Directory of Open Access Journals, Supplemental Index, Social Sciences Citation Index, Journals@OVID, Science Citation Index Expanded, Scopus, APA PsychArticles, OpenDissertations, Child Development & Adolescent Studies, SPORTDiscus with Full Text, ERIC Research Starters, Business Source Ultimate, British Library EThOS, JSTOR Journals, UEA Library Catalogue, AMED – The Allied and Complementary Medicine Database, ProjectMUSE, APA PsychArticles, IEEE Xplore Digital Library, Europeana, Alexander Street, Communication & Mass Media Complete, Open Research Library, eBook Collection (EBSCOhost), eBook Academic Collection (EBSCOhost), Teacher Reference Centre, Emerald Insight, UEA Digital Repository, eArticle, GreenFILE, British Education Index, ACM Full-Text Collection, EconLit with Full Text, Wiley Online Reference Works, Arts and Humanities Citation Index, Credo Reference: Academic Core, MLA International Bibliography, Philosphers Index with Full Text, Routledge Handbooks Online, OAPEN Library, Gale OneFile: LegalTrac, Marketline Advantage, Westlaw UK, Bloomsbury Collections, MathSciNet via EBSCOhost

The search terms were 'PTSD OR posttraumatic stress disorder OR post-traumatic stress disorder OR posttraumatic stress OR post-traumatic stress AND Peri-traum* OR

peritraum* OR during AND Dissociat* OR fear OR helpless* OR horror OR confus* OR threat* OR defeat OR perceive* OR perception OR panic OR emotion* OR distress* or data-driven OR "data driven" OR cognit* OR process* OR numb*. The search terms were selected based on Memarzia (2017)'s search strategy. The search terms were run using the 'advanced search' menu and the following parameters: full-text only; English language only; and all geographical locations. The date of the search was restricted from 1980 to 2022 as Post-Traumatic Stress Disorder was first recognised in the Diagnostic and Statistical Manual of Mental Disorders (DSM-III) in 1980.

Inclusion and exclusion criteria

A number of criteria were applied. Studies were required to provide data on risk or predictive factors for PTSD for adult populations. The assessment of PTSD must have been completed using a valid and reliable measure (although the psychometric properties could have been established from within any population, not solely the population of this study). The PTSD measure must have considered the DSM diagnostic criteria for PTSD, which includes: exposure to death/threatened death, actual or threatened serious injury or sexual violence (Criterion A); as well as intrusion symptoms, avoidance and alterations in arousal and reactivity. Self-reported and clinician-reported measures were included. Studies were excluded if they only assessed Acute Stress Disorder, or if the PTSD assessment took place less than four weeks following the traumatic event.

The studies must also have each provided a clearly defined assessment of at least one psychological peritraumatic risk factor. A psychological peritraumatic risk factor was defined as 'the experience of cognitive and/or emotional distress which occurs during or in the immediate aftermath of a traumatic event'. The assessment of peritraumatic experiences had to have been completed within six months post trauma. This cut off was chosen due to the unstable

nature of individual's reports of peritraumatic experiences. Candel and Merckelback (2004) highlighted the role of attrition, forgetting and malingering when asking participants to provide retrospective accounts of their reactions and past emotional states. This is further supported by Thompson-Hollands et al (2022) who found that self-reported peritraumatic dissociation was not stable when measured at multiple time points over a four year period.

Studies were included if all participants were aged 18 and over. Both clinical and community samples were included, as long as the clinical samples did not include participants who were selected primarily or in the presence of a specific comorbid disorder. Clinical samples were excluded if participant data included only those with an existing PTSD diagnosis (in these instances, a non-PTSD comparison group was needed to allow an effect size of risk factors for PTSD to be calculated). Studies were excluded if they focused solely on participants with a brain injury.

Studies were excluded if the study did not give a clear timescale as to when the trauma occurred, or if the timescale between the trauma, recruitment and assessment was unclear. Studies were only retained if they provided adequate statistics to calculate relevant effect sizes.

All research studies including doctoral and master's theses, longitudinal, follow-up and cross-sectional studies were included. Treatment or intervention studies, single-case designs, qualitative studies and meta-analyses were excluded.

The PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses; Moher et al, 2009) flow diagram (Fig.1) outlines the inclusion and exclusion process.

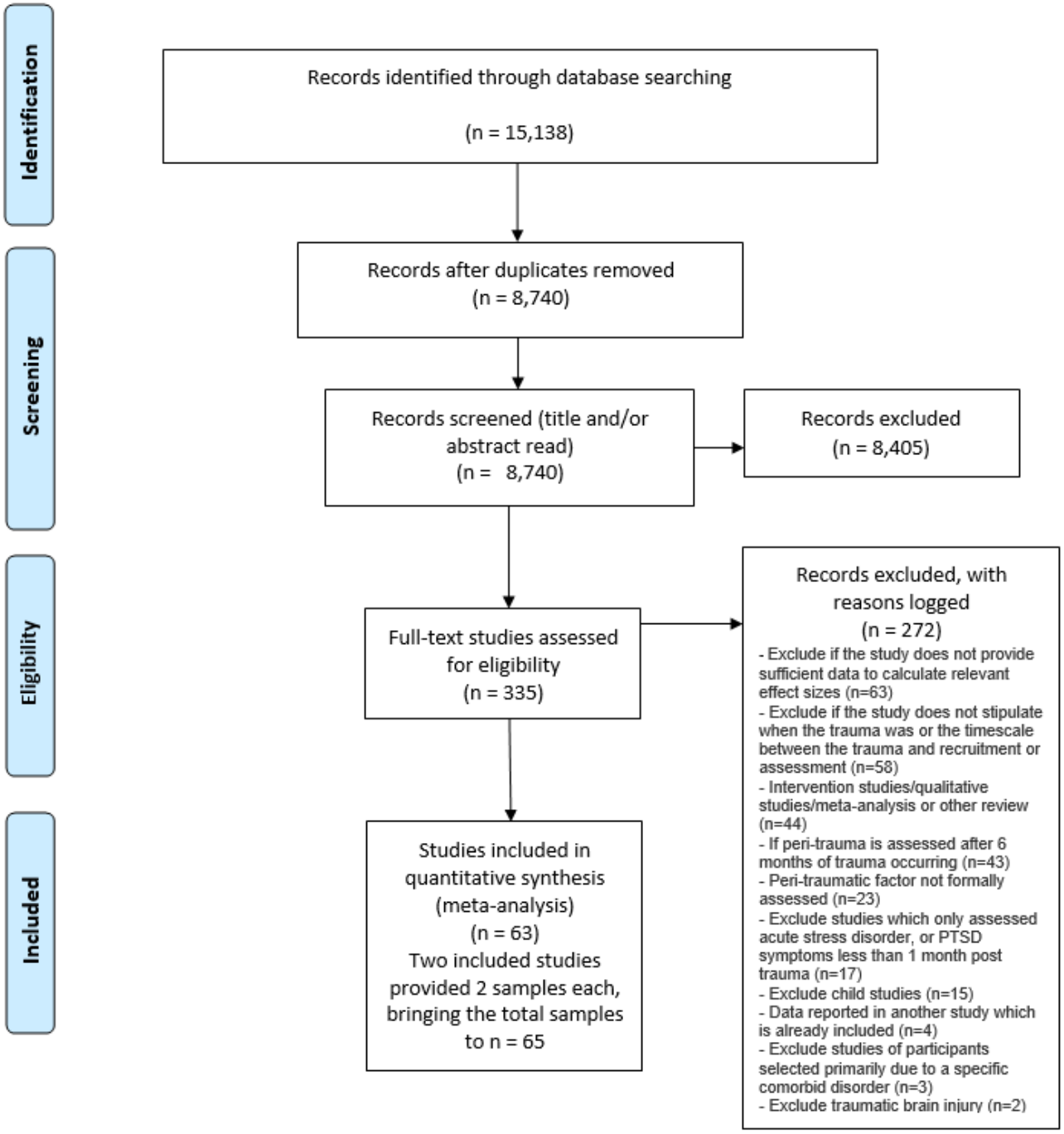

Fig. 1 PRISMA flowchart (Preferred Reporting Items for Systematic Reviews and Meta-Analyses; Moher et al, 2009) flow diagram outlines the inclusion and exclusion process.

Data extraction

A number of rules were set prior to data extraction to clarify any uncertainties in the process. If PTSD data were presented for both continuous measures (symptom severity) and dichotomous measures (diagnosis), the effect sizes for continuous measures were prioritised to avoid an underestimation of the effect size. For prospective longitudinal studies with multiple assessment time points of PTSD, effect sizes were selected from the first available time point (as long as this was at least one month after the traumatic event, and the initial assessment of peritrauma symptoms) with data from subsequent time points disregarded. If studies included effect sizes for both self-rated and interviewer-rated PTSD measures, interviewer-rated measures were prioritised due to the more robust validity of the approach to assessment.

Grouping of peritraumatic factors

The included studies measured a range of different peritraumatic risk factors. In order to conduct a meaningful analysis, it was necessary to subsume similar factors into groups. After careful consideration, three clear groupings emerged as follows. The first was ‘subjective threat’, which included descriptions such as ‘peritraumatic distress’, ‘peritraumatic emotions’, ‘subjective threat’, ‘threat to life’ or ‘A2 criteria (fear, helplessness, horror)’. A second group of effect sizes focussed on experiences of peritraumatic dissociation. This grouping was more clearly defined within studies, with more frequent use of validated questionnaires e.g. Peritraumatic Dissociative Experiences Questionnaire (PDEQ). The third group of effect sizes related to ‘data-driven processing’, as outlined in the cognitive model of PTSD (Ehlers & Clark, 2000). This was defined as feelings of confusion, with an emphasis on sensory impressions, rather than conceptual level processing.

Calculating effect sizes

Pearson's correlation coefficient, *r*, was used as the effect size for this study. Pearson's correlation coefficient is straight-forward to interpret, with 0.1 considered to be a small effect size, 0.3 a medium effect size and $r = 0.5$ or higher representing a large effect size (Cohen, 1988).

Most of the included studies provided this statistic for their analysis of risk factors for PTSD. However, a number of studies reported beta (β) or odds ratios, which were converted to '*r*' effect sizes using standardised tools (e.g. Borenstein et al, 2009)

Quality Assessment and Risk of Bias

The quality of studies and risk of bias was assessed using a quality assessment tool devised by Memarzia et al (2021) see appendix E. The tool was based on the NICE Quality Assessment Checklist for Studies reporting Correlations and Associations (2012) and the NIH Quality Assessment Tool for Observational Cohort and Cross-section Studies (National Heart Lung and Blood Institute, 2014). The following areas were included: 1) how well the study population was defined e.g. clear description of demographics and trauma characteristics; 2) whether an appropriate sampling method was used; 3) whether the non-response rate was reported, as well as whether it was minimal and/or accounted for (e.g. if less than 40%, did the authors discover significant differences between responders and non-responders, based on key indicators such as age, gender etc.); 4) whether loss to follow up was minimal and/or accounted for (prospective longitudinal studies only); 5) the reliability of the PTSD measure and 6) the reliability of the safety behaviour measure. Each item was given a score of 0, 1 or 2, with 0 indicating low quality and 2 indicating high quality i.e. representing lower risk of bias. The scores for each study were then added and converted to a percentage score. Studies which scored >70% were rated as High quality, 50-70% as Medium quality, and <50% as Low quality.

The lead author (JB), completed quality ratings for all studies included. A second rater (LP, fellow trainee clinical psychologist), completed checks against the inclusion and exclusion criteria for a random sample of 20% of the studies included. There was 'near perfect' agreement (kappa=0.9) (McHugh, 2012). Following this, quality checks were completed for a random sample of 20% of the included studies. An intra-class correlation coefficient (ICC) (Koo and Li, 2016) was calculated to assess the level of agreement between raters, ICC = 0.76, which corresponds to good reliability.

Additional steps were also planned for completion during the analysis to further explore the risk of bias. Specifically, publication bias was examined using funnel plots to visually represent the data with the aim of identifying signs of asymmetry, with asymmetry tested using Egger's test..

Meta-analytic method

The meta-analysis was conducted using R (version 4.1.3) with the 'metafor' (version 3.8-1) package. A random effects model was utilised for all meta-analyses conducted in this review. The raw correlation data (r) were extracted from the comma separated value file into the R software and transformed into Fisher's Z scores. The scores were then transformed back into r correlation coefficients before presenting the results. The analysis examined the heterogeneity of the effect sizes by calculating a Q statistic. If the Q statistic is significant ($p<0.05$), this signals that effect size variation is present. The extent of variation between studies that cannot be accounted for by error was then considered by estimating the I^2 statistic (Higgins et al, 2003), which ranges from 0-100%. If the I^2 estimation is 25% this is considered to be a small degree of heterogeneity, 50% is moderate and 75% is considered to be a large degree of heterogeneity between studies that cannot be attributed to error.

In addition to calculating the overall effect sizes, the 'prediction interval' was also presented for each analysis. The prediction interval presents the expected range of true effects in similar studies if conducted in the future (IntHout et al, 2015).

The meta-analysis was conducted by combining all studies for both cross-sectional and prospective longitudinal studies, and analysing for each of the three groups, i.e. subjective threat, dissociation and data-driven processing. For assessment time points, see appendix D.

Moderator analyses

Moderator analyses were planned to explore whether different study characteristics were related to the size of relationship between peritraumatic psychological factors and PTSD severity. These variables included study quality, whether the traumatic event was intentional or unintentional, whether the study used the Peritraumatic Distress Inventory (PDI), whether studies used the Peritraumatic Dissociative Experiences Questionnaire (PDEQ), study design (prospective vs cross-sectional), method for assessing PTSD (self-report questionnaire vs interview), and use of beta statistics (i.e. from regression models, vs zero-order correlation coefficients). A meta-regression was planned to investigate any differences between high, middle and low income countries. However, 61 studies were rated as high income, two as middle income, and zero as low income. Therefore, this analysis was not possible.

Results

Study characteristics

Sixty-three studies were included, with two studies Murray (2002) and Hoffman (2016) providing two separate samples each towards the analysis, bringing the total to sixty five separate samples. The total number of participants for all studies included was 20,335.

Fifteen samples provided cross-sectional data (where peritrauma was assessed at the same time as PTSD), and 50 studies provided prospective longitudinal data.

Table 1 summarises the characteristics of the studies included. Most of the studies included focussed on single event traumas. Two studies involved sustained trauma from war or conflict.

Table 1

Study Characteristics for included studies

Article and Year	Study Type	Peritraumatic risk factor assessed	Trauma Type	N	Mean age	% Female	Country	PTSD Measure	Interview or self-report questionnaire	Peritraumatic Measure * all self-rated
Aftyka 2021	CS	Distress	Parents of ill children in hospital	135	34.4	100	Poland	IES-R	Self-rated	PDI
Alatawi 2020	CS	Perceived threat	Covid-19	1249	5	50.36	Saudi Arabia	PCL-S	Self-rated	BIP-Q5
Allenou 2010	PL	Distress; Dissociation	Motor Vehicle Accident	94	41.7	91.7	France	PCL-S	Self-rated	PDEQ
Angerpointer 2020	PL	Distress	Road Traffic Accident	36	39.8	25	Germany	IES-R	Self-rated	PDI
Anticevic 2021	CS	Dissociation	Covid-19	1238	39.7	82.1	Croatia	PCL-5	Self-rated	PDI
Birmes 2003	PL	Dissociation	Severe physical injury	35	44.1	57	France	IES-R	Self-rated	PDEQ
Blekas 2020	CS	Distress	Covid-19	270	37.6	77.1	Greece	PTSD-8	Self-rated	PDI

Bronner 2009	PL	Dissociation	Parents of ill children in hospital	86	NA	31.40	Netherlands	SRS-PTSD	Self-rated	PDEQ
Bryant 2011	PL	Dissociation	Level 1 trauma	208	39.1	21	Australia	CAPS-IV	Interview	PRS
Bui 2010	PL	Distress; Dissociation	A+E patients	25	74.7	64	France	CAPS	Interview	PDI, PDEQ
Camille 2020	PL	Distress; Dissociation	Cancer patients	129	46.1	54	France	PCL-S	Self-rated	PDI, PDEQ
Cornelius 2019	PL	Threat	Acute Coronary Syndrome	871	60.8	43.92	USA	PCL-S	Self-rated	ED Threat Perceptions questionnaire
Delahanty 2003	PL	Dissociation	Motor Vehicle Accident	59	37.3	36	USA	SCID-PTSD	Interview	PDEQ
Duncan 2013	CS	Dissociation	Earthquake	101	42.9	77	New Zealand	TSQ	Self-rated	PDEQ
Dunmore 2001	CS/PL	Data-driven processing	Assault	57 (CS) 49 (PL)	35.4	54	UK	PSS-SR	Self-rated	Questionnaire with 4 subscales; mental defeat, mental planning, mental confusion and detachment

Ehlers 1998	PL	Perceived threat; Dissociation	Motor Vehicle Accident	888	33.4	46	UK	PSS	Self-rated	Likert Scales
Elklit 2004	PL	Dissociation	Physical assault	128	29.7	23.44	Denmark	HTQ–Part IV	Self-rated	Trauma Symptom Checklist
Engelhard 2003	CS/PL	Dissociation	Pregnancy loss	118 (CS) 104 (PL)	31	100	Netherlands	PSS-SR	Self-rated	PDEQ - modified
Engelhard 2011	CS/PL	Disgust; Fear	War	174 (CS) 107 (PL)	24	Data not available	Netherlands	PSS	Self-rated	Disgust: DS-R Fear: Likert Scale
Ennis 2021	PL	Distress	Traumatic Injury	235	46.7	Data not available	USA	PCL-5	Self-rated	PDI
Epstein 1998	PL	Data-driven processing, dissociation	Air show disaster	307	31.9	35.3	Germany	IES, SCLR90	Self-rated	Open-ended questions which were categorised by raters
Freedman 1999	PL	Dissociation	Medical emergency	236	Data not available	Data not available	USA	CAPS	Interview	PDEQ
Ehring 2008	PL	Perceived threat; data-	Accident survivors	53	34	26.4	UK	PDS	Self-rated	Likert Scale, 8 items.

		driven processing								
Gabert Quillen 2011	PL	Distress; Dissociation	Traumatic Injury	45	42.8	32	USA	IES-R	Self-rated	PDI, PDEQ
Gandubert 2016	PL	Distress; Dissociation	Experienced 'criterion A event'	89	36.5	61.8	France	Watson's PTSD Interview	Interview	PDI
Greene 2018	PL	Dissociation	Israel Gaza conflict	96	30	70.8	Israel-Gaza	PCL-5	Self-rated	DSS
Hansen 2014	PL	Dissociation; Panic	Bank robberies	371	42.3	70	Denmark	HTQ	Self-rated	PDEQ, PRS
Hoffman (a) Israel Gaza conflict 2016	CS	Nearness to death	Conflict – missile attacks	1268	36.9	53.2	Israel	PCL-5	Self-rated	Single item on a 7-point scale.
Hoffman (b) Israeli Palestine Conflict 2016	CS	Nearness to death	Terror attack	628	36.6	60	Israel	ICD-11 PTSD Symptom Survey	Self-rated	Single item on a 7-point scale
Hussain 2013	PL	Fear	Tsunami	674	43	53.3	South East Asia	IES-R	Self-rated	Five-point Likert scale

Irish 2011	CS/PL	Perceived threat; Dissociation	Motor Vehicle Accident	356 (CS) PL (251)	38.7	41	USA	IES-R	Self-rated	Threat: Single item, Likert Scale, PDEQ
Johansen 2007	CS/PL	Perceived threat; Dissociation	Non-domestic Violence	70 (CS) 70 (PL)	31	20	Norway	IES-R	Self-rated	Semi-structured interview with categorisation
Kaczmarek 2012	CS	Perceived threat; Dissociation	Motor Vehicle Accident	458	34.4	44	Poland	PTSD Inventory Factorial Version	Self-rated	Threat to life: 3 questions about being in danger. Peritraumatic dissociation: 5 questions addressing the experience.
Kessler 2021	PL	Distress; Dissociation	Motor Vehicle Collision	666	NA	73	USA	PCL-5	Self-rated	PDI, MCEPS
Kristensen 2014	PL	Perceived threat	Death of relative from cancer	54	60	78	Denmark	HTQ	Self-rated	A2 Criterion: fear, helplessness and horror
Kunst 2017	PL	Distress	Crime victims	201	NA	NA	Netherlands	TSQ	Self-rated	PDI

Lawyer 2006	CS	Dissociation; emotional reaction	Terror Attack	2001	NA	53.5	USA	Women's PTSD Study Module	Interview	Diagnostic Interview Schedule, IRS
Marchand 2015	PL	Dissociation; emotional reaction	Experienced 'criterion A event'	79	33	24	Canada	SCID-PTSD	Interview	PDEQ, ISR
Marke 2013	PL	Distress	Acute cardiac event	150	62.6	44	Wales	PDS	Self-rated	PSEI (Fear and Dissociation subscales) and Subjective Cardiac Threat Scale.
Marshall 2002	PL	Dissociation	Blunt or penetrating trauma	305	24.3	6	USA	PCL	Self-rated	PDEQ - Modified
Meli 2019	PL	Perceived threat	Cardiac event survivors	284	61	49	USA	PCL-S	Self-rated	12 items
Moss 2020	PL	Perceived threat	Life threatening medical emergency	99	59	39	USA	PCL-5	Self-rated	Perceived Threat Measurement Tool (7 items)

Murray (a) (inpatient) 2002	PL	Dissociation; data-driven processing	Road Traffic Accident	27	33.9	22	UK	PDS	Self-rated	Dissociation: SDQ, Data-Driven: 2 questions
Murray (b) (outpatient) 2002	PL	Dissociation; data-driven processing	Road Traffic Accident	176	33.8	46	UK	PDS	Self-rated	State Dissociation Questionnaire (SDQ), Data-Driven: 2 questions
Narisawa 2021	PL	Distress	Suspected heart attack	97	63.4	14.4	Japan	IES-R	Self-rated	PDI
Nishi 2010	PL	Distress	Sever motor vehicle accident	79	39.8	20.3	Japan	IES-R	Self-rated	PDI
Nishi 2012	PL	Distress	Earthquake	173	38.8	43.4	Japan	IES-R	Self-rated	PDI
Nobakht 2019	CS	Dissociation	Earthquake	230	25	51	Iran	IES-R	Self-rated	PDEQ
Olde 2005	PL	Dissociation; emotional reaction	Childbirth	140	31.5	100	Netherlands	PSS-SR	Self-rated	PDEQ, Somatoform Dissociation Questionnaire - Peritraumatic (SDQ-P)
Palgi 2020	PL	Distress	Community fires	223	40.2	73.9	Israel	PCL-5	Self-rated	PDI
Pires 2013	PL	Dissociation	Motor Vehicle Accident	124	34.5	27.4	Portugal	RTES	Self-rated	PDEQ

Psarros 2018	CS	Fear	Wildfires	102	40	0	Greece	Interview based on ICD-10 criteria	Interview	Single question, Likert scale
Rahmat 2021	PL	Fear	Blunt trauma	59	55	36.9	USA	PDS	Self-rated	Single question, Likert Scale
Ranieri 2021	CS	Dissociation	Covid-19	36	37.3	100	Italy	IES-R	Self-rated	PDEQ
Shiban 2018	PL	Distress	Spinal surgery	89	58.1	41.6	Germany	IES-R	Self-rated	PDI
Shigemura 2014	CS	Distress	Nuclear disaster	1411	Data not available	5.2	Japan	IES-R	Self-rated	PDI
Sijbrandij 2013	PL	Distress; perceived life risk	Accident and assault	236	40.4	49.6	Netherlands	Structured Interview for PTSD	Interview	PDEQ
Thiel 2020	CS	Dissociation	Childbirth	685	31.4	100	Worldwide	PCL-5	Self-rated	PDEQ
Thormar 2014	PL	Distress	Earthquake	470	Data not available	25.7	Indonesia	IES-R	Self-rated	PDI
Ursano 1999	CS/PL	Dissociation	Motor Vehicle Accident	112 (CS) 122 (PL)	35.6	47.5	USA	SCID-PTSD	Interview	PDEQ
Velden 2006	PL	Dissociation	Explosion	662	43.5	57.3	Netherlands	IES	Self-rated	PDEQ

Vossbeck-Elsebusch 2014	CS	Perceived threat; Dissociation	Childbirth	224	30.5	100	Germany	PDS	Self-rated	PEQ, PDEQ
Werner 2012	PL	Dissociation	Physical and sexual assault	92	35.2	100	USA	CAPS	Interview	PDEQ, Clinician Administered Dissociative States Scale (CADSS)
Wittman 2006	PL	Dissociation	Accident	214	42	34.6	Switzerland	CAPS	Interview	PDEQ
Youngner 2012	PL	Dissociation	Traumatic injury	48	34	62.5	USA	PDS	Self-rated	Immediate Stress Reaction Checklist (ISRC), then derived Peritraumatic Dissociation from 4 questions

Note: IES-R = Impact of Events Scale – Revised, CAPS = Clinician Administered PTSD Scale, PDS = PTSD Symptom Scale, TSQ = Trauma Screening Questionnaire, HTQ = Harvard Trauma Questionnaire, RTES = Response to Traumatic Event Scale, SCID-PTSD, SCLR-90, PSS-SR, PCL-5, BIP-Q5 = Brief Illness Perception Questionnaire, PDI = Peritraumatic Distress Inventory, PDEQ = Peritraumatic dissociative experiences questionnaire, PRS = Physical reactions scale, PEQ = Peritraumatic Emotions Questionnaire, PRS: Physical Reactions Scale, DSS = Dissociative Symptoms Scale, MCEPS = Michigan Critical Events Perception (revised), ISR = Initial Subjective Reaction Scale of the Potential Stressful Events Interview, SDQ = State Dissociation Questionnaire. CS – Cross Sectional, PL – Prospective Longitudinal

The studies covered a range of trauma types; medical trauma (n=23); motor vehicle accidents (n=12); natural disaster (n=6); childbirth (n=4); COVID-19 (n=4); other disasters e.g. air crash, nuclear accident (n=4); physical/sexual assault (n=3); war/conflict (n=3); terror attacks (n=2); 'criterion A event' (n=2) and crime victims e.g. armed robbery (n=2).

Assessment of study quality and risk of bias

All 63 studies were scored against the quality assessment framework, see Supplementary Materials for full details. Thirty-nine studies were rated as high quality, twenty-two studies were rated as medium quality, and four studies were rated as low quality. Low quality indicates high risk of bias. For full details, see appendix F.

Meta-analysis: combined data

Subjective Threat

Combined: overall subjective threat

A meta-analysis of all effect sizes related to 'subjective threat', which included 44 studies with a sample size of 16,278, was undertaken. An overall effect size of r=0.39 (95% CI=0.32-0.46) was estimated. Estimates for heterogeneity showed significant and large variation across studies (See table 2). For forest plot, see Fig. 2. The prediction interval ranged from -0.12 to 0.74. A leave-one-out meta-analysis calculation was completed to see if any individual studies could be distorting the results. The test did not reveal any studies to have excessive influence. A funnel plot (see appendix G) was generated and inspected for asymmetry which may indicate publication bias. No asymmetry was identified, and zero null studies were estimated to be missing. A regression test for funnel plot asymmetry indicated no publication bias (z=0.85, p=0.40).

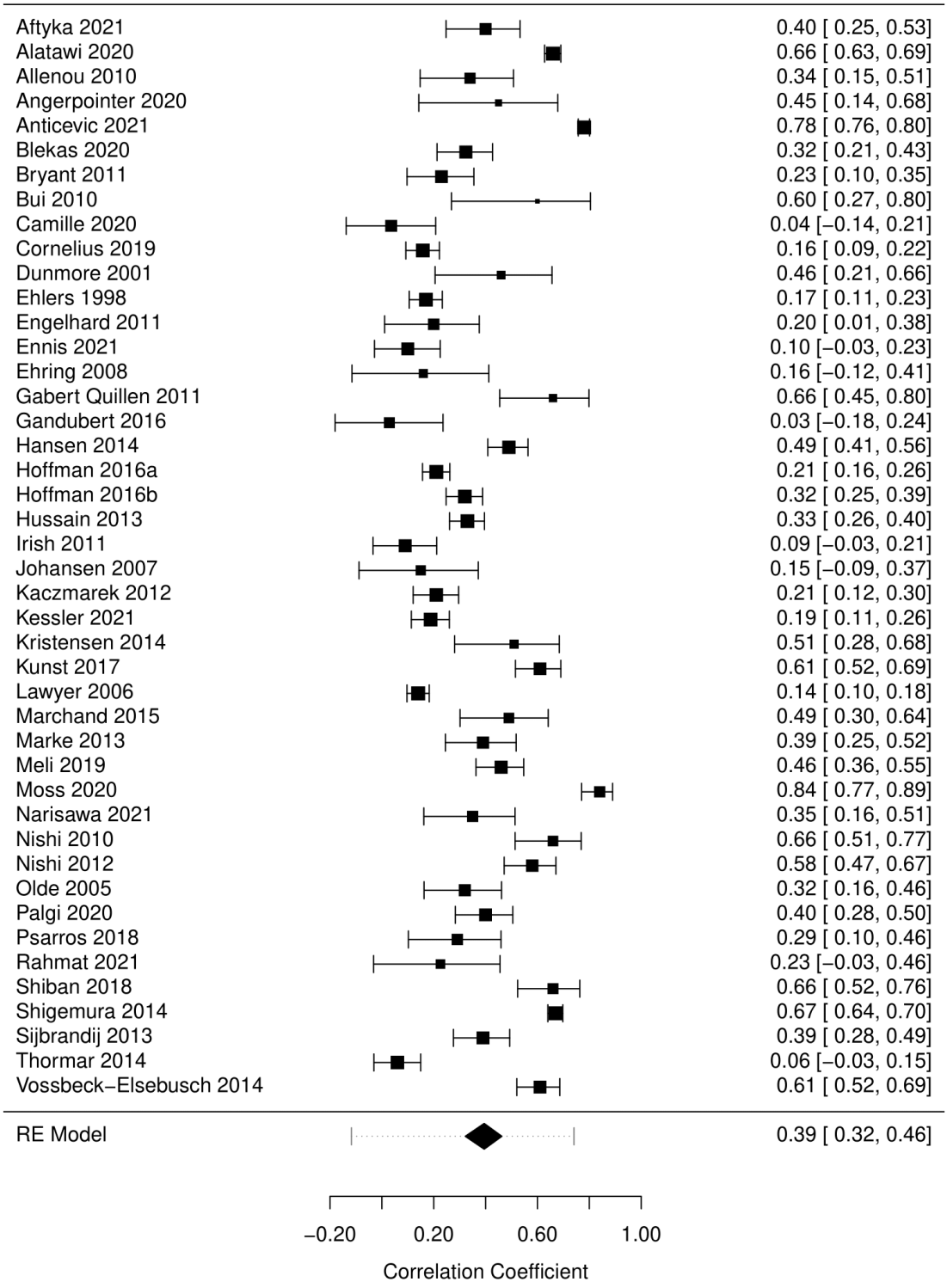

Fig 2: Forest plot for meta-analysis of peritraumatic subjective threat. Illustrating effect sizes 'r' for each study, the estimated overall effect size of the relationship between peritraumatic subjective threat and PTSD symptoms in adults, and the prediction intervals.

Moderator analyses

The relationship between subjective threat and PTSD severity was not moderated by type of trauma (intentional vs non-intentional), measure of subjective threat (PDI vs non-PDI), or the use of beta statistics (i.e. beta statistics vs r statistics); for full results see Table 2. While assessment type (i.e. self-report questionnaire vs interview measures of PTSD) was also a non-significant moderator, a trend was apparent (p=.05), with the relationship for self-report studies (r=.43) almost double the size of the effect for interview-based studies (r=.22).

Dissociation

Combined: overall dissociation

A meta-analysis of all effect sizes related to 'dissociation', which included 38 studies with a sample size of 9,692, was calculated. An overall effect size of r=0.39 (95% CI=0.33-0.45) was estimated. Estimates for heterogeneity showed significant and large variation across studies (see Table 2). For forest plot, see Fig. 3. The prediction interval ranged from 0.03 to 0.67. A leave-one-out meta-analysis calculation was completed to see if any individual studies could be distorting the results. The test did not reveal any studies to have excessive influence.

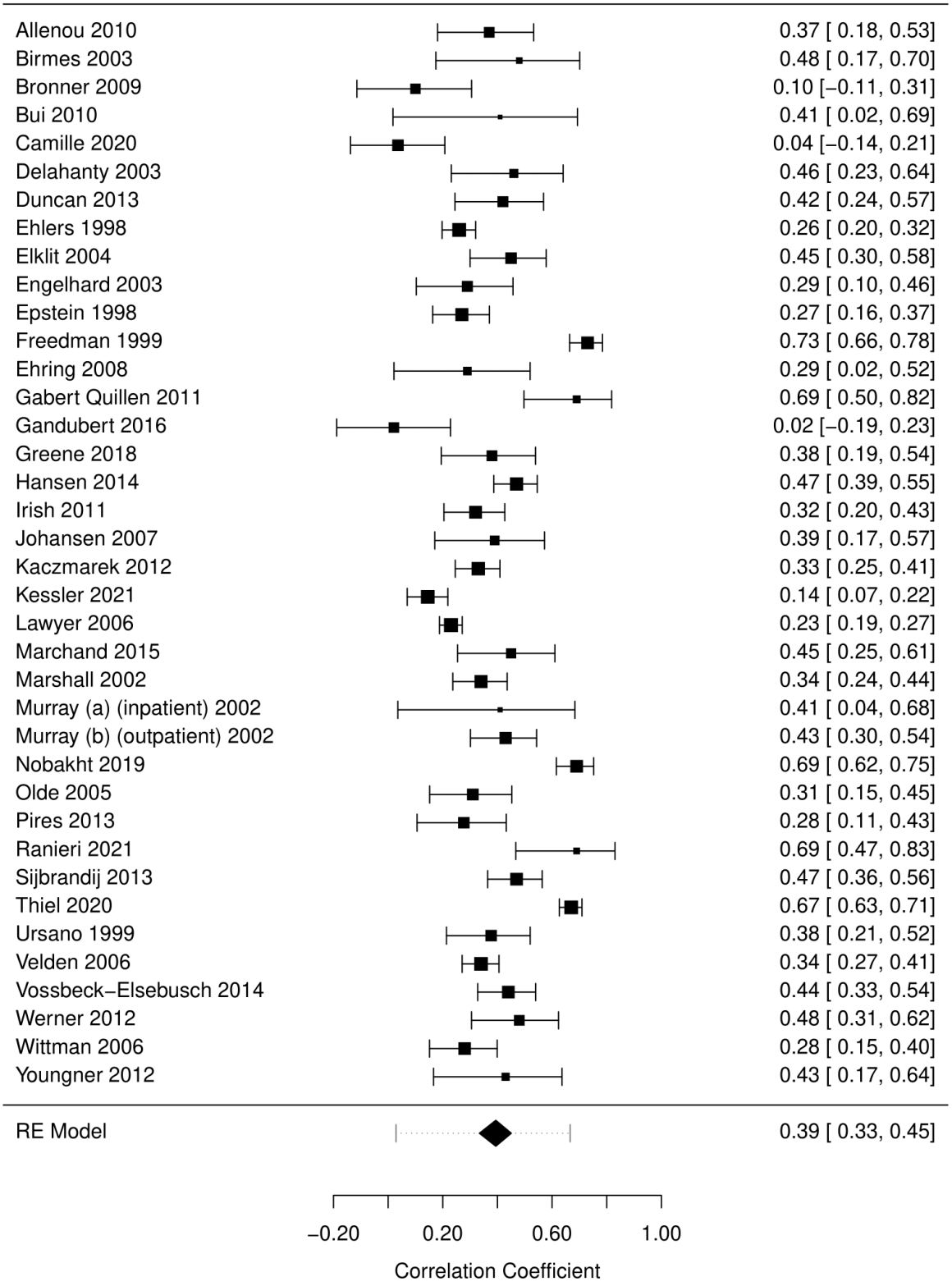

Fig 3. Forest plot for meta-analysis of peritraumatic dissociation. Illustrating effect sizes '*r*' for each study, the estimated overall effect size of the relationship between peritraumatic dissociation and PTSD symptoms in adults, and the prediction intervals.

A funnel plot was generated and inspected for asymmetry which may indicate publication bias. No asymmetry was identified, and zero null studies were estimated to be missing. A regression test for funnel plot asymmetry indicated no publication bias (z=0.86, p=0.397). (See appendix H).

Moderator analyses

The relationship between dissociation and PTSD severity was not moderated by type of trauma (intentional vs non-intentional), assessment type, measure of subjective threat (PDEQ vs non-PDEQ), or the use of beta statistics (i.e. beta statistics vs r statistics). However, study design was a significant moderator (p=.04), with cross-sectional studies showing a stronger relationship for cross-sectional studies (r=.51) compared to prospective longitudinal studies (r=.36). For full results see Table 2.

Data-driven Processing

Combined: overall data-driven processing

A meta-analysis of all effect sizes related to 'data-driven processing', which included 4 studies with a sample size of 585, was calculated. An overall effect size of r=0.26 (95% CI=0.15-0.36) was estimated. Estimates for heterogeneity showed a non-significant and relatively small degree of variance across studies. (See Table 2) For forest plot, see Fig. 4. The prediction interval ranged from 0.10 to 0.40. A leave-one-out meta-analysis calculation was completed to see if any individual studies could be distorting the results. With only four studies, evaluation of publication bias was not possible (see appendix I), and moderator analyses were not undertaken.

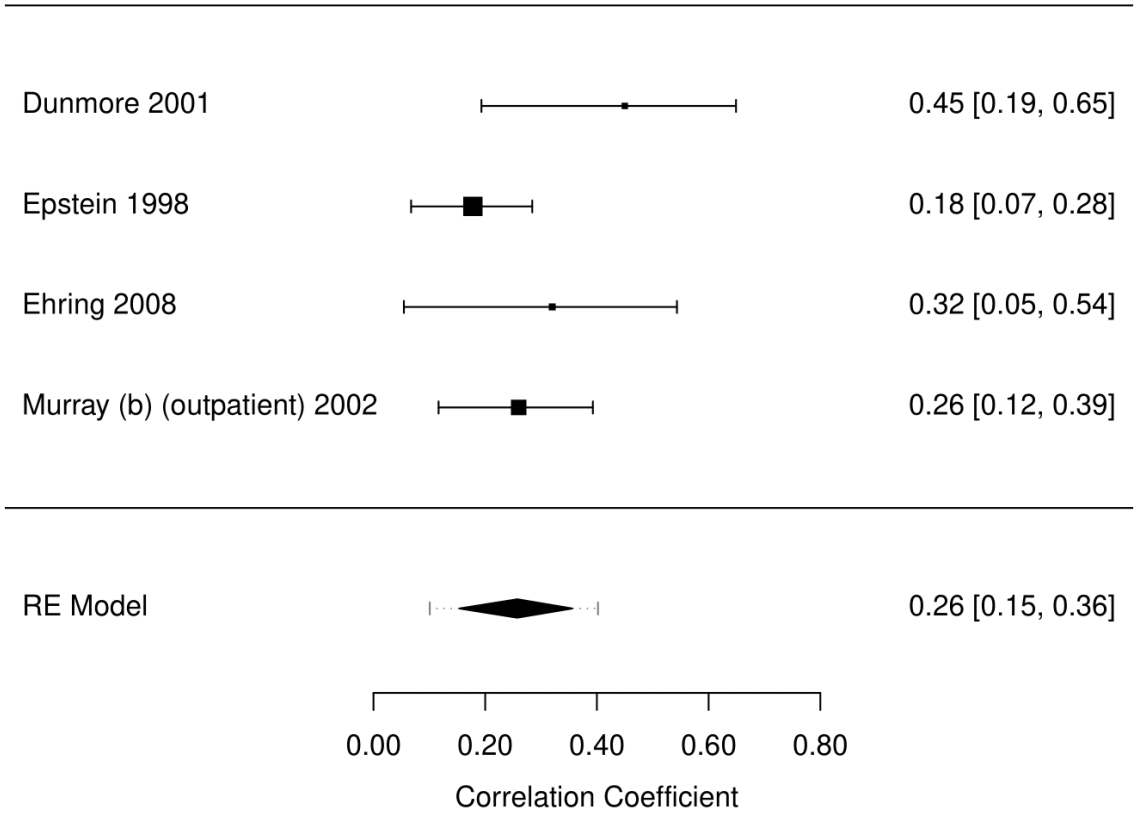

Fig 4. Forest plot for meta-analysis of peritraumatic data-driven processing. Illustrating effect sizes '*r*' for each study, the estimated overall effect size of the relationship between peritraumatic data-driven processing and PTSD symptoms in adults, and the prediction intervals.

Table 2

Results of meta-analyses: all studies

Meta-analysis/ moderator	k	N	Pooled estimate, *r*	95% CI	Q	*p*	I^2	Prediction interval
Subjective threat	44	16,278	.39	.32, .46	1573.64	<.0001	96.3	-.12, .74
Moderator, intent	*Moderation test, Q = 0.5506, p = .46*							
Intentional	8	4695	.33	.19, .46	105.10	<.0001	94.2	-.07, .64
Non-intentional	26	10285	.40	.30, .49	1137.28	<.0001	96.4	-.11, .75
Moderator, assessment	*Moderation test, Q = 3.80, p = .05*							
Self-report	36	13429	.43	.35, .50	1336.88	<.0001	96.4	-.09, .76
Interview	8	2849	.22	.11, .33	27.98	<.0002	77.3	-.06, .47
Moderator, PDI	*Moderation test, Q = 1.27, p = .26*							
PDI	19	5705	.44	.31, .55	732.36	<.0001	96.1	-.13, .79
Non-PDI	25	10573	.36	.27, .44	572.52	<.0001	95.8	-.10, .69
Moderator, beta stats	*Moderation test, Q = .54, p = .46*							
Beta statistics	9	2176	.45	.24, .61	160.70	<.0001	96.4	-.23, .84
r coefficients	35	14102	.38	.30, .45	1397.90	<.0001	96.0	-.10, .71
Moderator, study design	*Moderation test, Q = .94, p = .33*							
Prospective longitudinal	33	7294	.37	.29, .45	348.51	<.0001	93.2	-.11, .72
Cross-sectional	11	8984	.45	.29, .58	1046.55	<.0001	98.6	-.13, .80
Dissociation	38	9692	.39	.33, .45	414.483	<.0001	90.1	.03 - .67
Moderator, intent	*Moderation test, Q = .31, p = 0.58*							
Intentional	7	2793	.38	.30, .48	36.88	<.0001	72.1	.18, .58
Non-intentional	23	5836	.37	.29, .44	266.20	<.0001	89.7	.00, .65
Moderator, Assessment	*Moderation test, Q = .40, p = .53*							
Self-report	*29*	6548	.40	.34, .46	263.93	<.0001	85.9	.09, .64
Interview	9	3144	.36	.18, .51	132.01	<.0001	94.2	-.19, .75
Moderator, PDEQ	*Moderation test, Q = .14, p = .71*							
PDEQ	25	4538	.41	.33, .48	212.28	<.0001	87.3	.03, .68
Non-PDEQ	12	4266	.38	.27, .48	129.52	<.0001	91.6	.00, .67
Moderator, beta stats	*Moderation test, Q = .14, p = .71*							
Beta statistics	*7*	844	.42	.26, .55	47.60	<.0001	84.2	-.02, .72
r coefficients	31	8848	.39	.32, .45	352.35	<.0001	90.8	.02, .66
Moderator, study design	*Moderation test, Q = 4.03, p = .044*							
Prospective longitudinal	31	5957	.36	.30, .42	180.48	<.0001	83.7	.04, .62
Cross-sectional	7	3735	.51	.35, .64	224.06	<.0001	96.2	.04, .79
Data-driven	4	585	.26	.15, .36	4.38	.22	30.8	.10, .40

Notes. PDI = Peritraumatic Distress Inventory, PDEQ = Peritraumatic Dissociative Experiences Questionnaire

Discussion

This review provided a quantitative summary of the available research relating to peritraumatic reactions and the development of PTSD in adults. Sixty-three studies were included, with 65 samples overall, providing effect sizes estimates towards the strength of the relationship between peritraumatic risk factors and PTSD.

The 'subjective threat' group, largely relating to A2 criteria such as fear, helplessness and horror, yielded a medium effect size for the relationship between these variables and PTSD (r=.39). The result supports the claim that experiencing peritraumatic threat is likely to play a role in the likelihood of developing PTSD in adults. However, as it is a moderate effect, experiencing peritraumatic threat is not necessarily enough to explain why some adults go on to later develop PTSD. Some adults who experience peritraumatic threat will not go on to develop PTSD. The reasoning behind the removal of A2 criteria from the DSM-5 therefore sits in line with these findings (Friedman et al, 2011). The moderator analysis for method of assessment revealed a trend for a stronger relationship between peritraumatic threat and PTSD for studies that used self-report methods compared to interviewer based methods. Interview based assessment is known to result in lower diagnosis rates of PTSD (Stevens, Fabra & Thies (2013), so it could be that self-report methods represent inflated scores.

For the dissociation group, the effect size was also medium (r=.39). Dissociation has long been regarded as a predictor for PTSD (Candel and Merckelbach, 2004), and the result of this meta-analysis confirms the strength of this relationship. The only moderator to show significance in our analyses was study design which showed a stronger relationship between peritraumatic dissociation and the development of PTSD for cross-sectional studies compared to prospective longitudinal studies.

This finding must be considered with caution however, as there were significantly more prospective longitudinal studies (k=31) compared to cross-sectional studies (k=7). Therefore, the cross-sectional studies may be overestimating the role of peritraumatic dissociation and subsequent development of PTSD. It is also important to note the quality of studies included in this analysis. While the vast majority of studies included in this study overall were high quality, for the cross-sectional grouping in this analysis, two were rated as high quality, four were rated as medium quality and one of low quality. Therefore, there is a higher possibility of bias in the analysis of those seven studies. The confidence and prediction intervals for the cross-sectional results are also wider than those of the prospective longitudinal study grouping which indicates higher amounts of variance in comparison to the prospective longitudinal studies.

Data-driven processing yielded a small to medium effect size (r =.29), but only comprised of four studies, so conclusions are limited for this group. Unlike subjective threat and dissociation, there was a lower amount of heterogeneity amongst studies in this group.

A strength of this study is the large number of studies included in the review (n=63), as well as the large number of participants (n = 20,335). The study also included a wide range of trauma types, and 77% of the data were extracted from prospective longitudinal studies. Only four of the studies were rated as ‘low’ quality, and there was high inter-rater agreement for the study inclusion and quality ratings. Furthermore, no outliers needed to be removed. A further strength was the time frame in which peritrauma was assessed. Given the unstable nature of retrospective reports of peritraumatic experiences, the majority of studies in this review completed assessment well within the 6 month time frame stipulated, strengthening the accuracy of reported reactions. See appendix D for full details.

The current review supports previous assertions that peritraumatic experiences, including subjective threat, dissociation and data-driven processing, are important risk factors in the development of PTSD in adults (Halligan, Clark & Ehlers, 2002; Otis, Marchand & Courtois, 2012; Massazza et al, 2021) These findings are in line with cognitive models of PTSD which described how they ways individuals process the trauma leads to a sense of current threat (Brewin et al, 1996; Ehlers and Clark, 2000). The effect sizes ranged from low to medium, suggesting that the presence of peritraumatic psychological factors does not always lead to the development of PTSD, and that other factors are likely involved. There were also high levels of heterogeneity which suggests an inconsistent picture, which requires further investigation. The presence and impact of peritraumatic psychological factors should not be overstated as a result of these findings. This study supports the presence of associations between peritraumatic factors and PTSD, but cannot comment on causal links.

Clinical Considerations

Peritraumatic threat was most one of the most common peritraumatic reactions which emerged from this review, and given the original conceptualisation of PTSD, it is understandable that a large proportion of the published literature focus on this area. However, the conceptualisation of PTSD as a fear-based disorder has been challenged over time. The revised conceptualisation of PTSD as a ‘trauma and stressor-related disorder’ makes room for other emotions which may be more prominent for some people who go on to develop PTSD. Grey, Holmes and Brewin (2001), for example, conducted a case series which revealed that while peritraumatic fear was frequently present, so too were a number of other peritraumatic emotions such as guilt, shame, anger and disgust. They hazard that clinicians who focus exclusively on fear-based peritraumatic emotions may be at risk of overlooking the importance of other emotions, which may not respond to exposure techniques in the same way and may be associated with more nuanced cognitions.

Interestingly, the only study in this review to explicitly measure peritraumatic disgust was Engelhard (2011). The study found that greater peritraumatic disgust and fear independently predicted PTSD-symptom severity at 6 months. However, two or more studies are needed to complete a meta-analysis. The study by Ehring (2008) provided a 'guilt/shame' predictor variable for PTSD, which was significant at two weeks, but not at six months. Anger was not found to be predictive of PTSD at either two weeks or six months. It is recommended that clinicians consider peritraumatic risk factors as part of a person-centred assessment and formulation of PTSD.

Limitations

There were a number of limitations inherent in this study which are important to note. Firstly, the vast majority of studies related to single event traumas. Therefore, this review cannot conclude that the results apply to sustained or multiple traumas. Regarding the demographics of participants across studies, the majority were from western countries. Moreover, the study did not report data on participant ethnicity. There was also large amounts of heterogeneity within the subjective threat and dissociation analyses, which further limits generalisation.

As noted above, unfortunately this review did not pick up on many studies which specifically addressed peritraumatic emotions other than fear. Few studies were found relating to data-driven processing. There are a couple of possible reasons for this. Firstly, it appears that many studies relied on the use of general peritraumatic emotion measures e.g. Peritraumatic Distress Inventory or Peritraumatic Emotions Questionnaire, and while a range of emotions are included in the items, the total scores are often what is reported in the analysis. Another possibility is that the search terms selected for this review were not specific enough to target the inclusion of specific emotions. General search terms such as 'peritrauma' and 'emotion' were perhaps not efficient in finding all relevant studies. It may be helpful to

revise the search terms to include words such as ‘shame’, ‘guilt’ and ‘anger’ to see if this yields additional studies. Another possible solution would be to conduct a search by selecting studies based on specific measures, for example, all studies which have used the ‘Data-driven Processing Scale’ (Halligan, Clark & Ehlers, 2002) or the ‘Disgust Scale’ (Haidt et al, 1994; Engelhard, Olatunji & Jong, 2011). Vance, Kovachy and Dong (2021) conducted a 15-year review and synthesis of peritraumatic distress by anchoring their search to studies using the Peritraumatic Distress Inventory specifically, which might be a useful approach when reviewing other peritraumatic factors. It is also possible that there are simply not many published studies which focus on the predictive risk of other peritraumatic emotions.

Future Research

This study highlights the need for more studies to investigate the predictive risk of a wider range of peritraumatic emotions e.g. guilt, shame, anger and disgust.

Future research should also endeavour to measure psychological peritraumatic factors as early as possible to minimise recall bias, using interviewer rated measures where possible to assess PTSD. This information can be used clinically, as part of patient triage, to inform risk of chronic PTSD development, improving prognostic accuracy. Future studies are also needed to further explore the breadth of psychological peritraumatic emotional reactions and to determine which are most predictive of PTSD development (Massazza et al, 2021). This will allow for PTSD treatments which are better able to target shame or guilt for example (Litz, 2009, Lancaster & Larsen, 2016).

Future research is needed related to multiple and sustained traumatic events. Whilst this may be more of a complex study for researchers to design, it would be beneficial to assess multiple time points for ‘within trauma’ cognitions, as well as emotional and physiological experiences (Memarzia, 2021). More research is also needed in in non-western

populations. Further moderators could additionally be completed on variables such as: trauma type, age at time of trauma and gender to explore potential differences.

Peritraumatic experiences are known to be wide ranging, covering physiological, emotional and cognitive responses. Indeed, Bovin and Marx (2011) argue that peritraumatic experiences should be conceptualised as "a rich integration of appraisals, action tendencies and physiological changes" which allows for a better understanding of traumatic stress responses. There is an urgent need to better understand posttraumatic pathways, which includes the consideration of pre-traumatic, peritraumatic and post traumatic risk factors, as well as protective factors. This study did not unfortunately have the scope to cover literature concerning other peritraumatic reactions such as physiological reactions e.g. cortisol changes (Sherin, 2011) or reflexive reactions e.g. tonic immobility which are known to be associated with the development of PTSD (Lima et al, 2010). Future meta-analyses would help in summarising this literature. The results of this study would also benefit from updating in the coming years as more research is published.

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CHAPTER FOUR

General discussion

Word Count (excluding references): 1,665

General Discussion

Summary of Results

The first systematic review and meta-analysis in this thesis highlights a strong relationship between the use of safety behaviours and PTSD in adults. A total of 6 studies were found to have looked at this relationship since 2001. The lack of available studies was surprising given that safety behaviours have been incorporated into cognitive models of PTSD for several decades. Until this review, the strength of the relationship had not been quantified. However, caution must be exerted as the number of studies was small and revealed high levels of heterogeneity. It was not possible to perform more detailed subgroup analyses to explore and explain the amount of heterogeneity. This study supports the existing literature which states that safety behaviours are important in the onset and/or maintenance of PTSD. Unfortunately, it is not yet possible to offer comment on the directionality of the relationship.

While clarity on this relationship will require time for researchers and clinicians to resolve, the association between safety behaviours and the development of other anxiety disorders is similarly unclear. Meulders et al (2016) conducted the first known meta-analysis to bring together the existing literature on whether allowing safety-behaviours during cognitive-behavioural treatment hampers or facilitates the reduction of fear. Twenty studies were included, however, the analysis could not provide persuasive evidence to support the inclusion or elimination of safety behaviours during exposure tasks. There was however, some tentative evidence in favour of dropping safety-seeking behaviours.

Given the small number of papers published regarding safety behaviours and PTSD, there are considerable gaps in our knowledge. Therefore, there are a number of key areas for future research to focus when it comes to increasing our understanding of safety behaviours and PTSD. Firstly, it will be helpful to determine whether safety behaviours need to be

targeted specifically and directly in therapy, or whether it is possible for safety behaviours, and their impact on the maintenance of PTSD, to resolve gradually when other aspects of the model are given priority. A head-to-head study where one group of patients receives targeted in-vivo interventions to address safety behaviours as a core element of their trauma-focussed therapy and another group of patients receives a course of trauma-focussed therapy without reference or focus on safety behaviours could be conducted to investigate this possibility.

Another recommendation for future research is to contribute to clarifying *'when'* it might be useful to target safety behaviours in trauma-focussed therapy. Some researchers have argued that using safety behaviours with guidance from a therapist can actually enable patients to approach feared situations, which otherwise may be avoided completely (Levy & Radomsky, 2014). In this scenario, permitting safety behaviours in the initial stages of therapy may be beneficial to the longer term effectiveness of the treatment. Similarly, Telch & Lancaster (2012) advocate for a 'fading approach' i.e. a gradual reduction in safety behaviour use over time, rather than a sudden abandonment. This judicious use of facilitative safety behaviours in the context of exposure tasks within therapy has been endorsed by many studies, particularly during the early stages of therapy when patient engagement is critical (Rachman, Radomsky, & Shafran, 2008). One possibility for future research is to use a cross-sequential design, where a cohort of patients are offered a block of trauma-focussed therapy sessions, and safety behaviour specific work is introduced for each patient at a different session time point. This approach could simultaneously review the impact of drop-out rates and the effectiveness of the treatment at symptom reduction at a designated follow up time point.

In order to examine the impact of specific types of safety behaviours on PTSD, first researchers must focus more intensely on collecting data using a PTSD-specific measure such as the PSBQ. This will allow researchers to acquire data on safety behaviours which are

directly linked to a specified traumatic event. With an adequately powered sample, it could then be possible to begin identifying emerging subtypes of safety behaviours for PTSD patients, and may reveal safety behaviours which are more likely to occur from one trauma type to another. This approach would aim to tighten our understanding of which safety behaviours tend to be more prevalent, which will be important for clinicians to be aware of when delivering trauma-focussed interventions.

Once research has been conducted to better explain the relative necessity and timing of targeting safety behaviours in trauma-focused treatment, it would then be helpful to address '*how'* clinicians may best support patients to tackle safety behaviours. This may be through optimising and refining existing strategies and techniques e.g. in vivo exposure work, or devising other effective techniques.

The second systematic review and meta-analysis aimed to explore the relationship between psychological peritraumatic risk factors for PTSD in adults. This was a large study, involving sixty-five samples and 20,335 participants. Three groups of peritraumatic factors were created: subjective threat, dissociation and data-driven processing. The former two groups yielded medium effect sizes, and the latter group a small effect size. This study revealed high levels of heterogeneity, which were not adequately explained by subgroup analyses.

Strengths and Weaknesses

Both of the studies included in this portfolio represent the first known quantitative meta-analyses addressing the relationships of safety behaviours and psychological peritraumatic reactions to the onset and development of PTSD in adults. This work is an attempt to fill important gaps in the clinical literature, opening up conversations about next steps.

The reviews adhered to a strict systematic approach, informed by the PRISMA protocol. The study protocols were registered on PROSPERO prior to commencing the research and a number of criteria were set a-priori to minimise bias. The searches were conducted using all available databases and second-raters were recruited to provide quality ratings, ensuring there was a high level of inter-rater reliability. Making sure that each step of the methodology was detailed and followed closely was a priority to ensure robustness, allowing future studies to replicate the methodology. The coding script and data extraction sheets are also available for readers, offering full transparency and allowing open scrutiny of the research process.

One of the main limitations was the high levels of heterogeneity found in both systematic reviews. Within the peritraumatic factor review, ten moderator analyses were conducted, although only one was significant (study design for dissociative group) and one was borderline significant (method of assessment for subjective threat group). Moderator analyses also yielded high levels of heterogeneity. These analyses were sub-group meta-analyses using dichotomous rather than continuous variables. Disappointingly, high levels of heterogeneity rendered the findings less interpretable and minimised the strength of these studies, despite efforts to ensure the reviews were conducted with detailed methodologies.

It is difficult to pinpoint the exact cause of the heterogeneity, although there are a few possibilities to consider. The evidence may lie with variations between studies in any of the

following: target populations, measurement instruments, differences in follow up time points, analytical methods, and varied study quality to name a few. It could also be that the breadth of the peritraumatic factor review was too broad, attempting to converge too many variables.

Due to a lack of time, it was decided that the analysis plan for the peritraumatic factor study would be altered to minimise the length and complexity of the results section. The original plan was to complete one analysis with all studies (cross-sectional and prospective longitudinal 'combined'), and then a further two separate analyses with cross-sectional studies only, and prospective longitudinal only. The same moderator analyses were to be applied to the separated analyses too. However, only the 'combined' analysis was included in this portfolio, with the cross-sectional and prospective longitudinal aspect introduced as a moderator.

Reflections on the findings of this paper and Dr Jessica Memarzia's work

Dr Jessica Memarzia completed her work titled 'Psychological peritraumatic risk factors for post-traumatic stress disorder in children and adolescents: A meta-analytic review' in 2017. Dr Memarzia's work had originally intended to include data on adults as well as children. However, the size of the data set was preventative for the scope and timescale of the DClinPsy project, and she made a decision to use data relating to children and adolescents only.

This left an opportunity for myself and my supervisory team to explore psychological peritraumatic risk factors using adult specific data. The searches were re-run to ensure all studies published up to the present day were included. The study groupings were similar to Dr Memarzia's, but not identical, with Dr Memarzia adding one additional group 'pure perceived life threat', which did not emerge from my data. However, there were also some key methodological differences, for example, my paper reviewed 52 databases whereas Dr

Memarzia selected three leading psychological and medical literature databases. My paper restricted the reporting of peritraumatic experiences to within a six month time frame, as evidence suggests reports beyond this time frame can be unstable. However, Dr Memarzia's paper was not able to adhere to that criteria due to the number of studies which exceeded it. It is also important to note that Dr Memarzia's study yielded 32 studies overall, whereas my paper yielded 65 samples from 63 studies, with vastly different overall numbers of participants. There are further differences with regards to the approach to the meta-analysis itself, as well as the moderators selected.

Having said that, the overall conclusions of the papers are similar, being that peritraumatic experiences were found to be important correlates of the subsequent development of PTSD. The current study and Memarzia et al (2017) both found moderate effect sizes for the peritraumatic subjective threat group (r = 0.37 and r=0.39 respectively). The papers differed with respect to the dissociation group, with the current paper finding a moderate effect size (r=0.39) and Memarzia et al (2017) finding a small effect size of r=0.17. Both the current paper and Memarzia et al (2017) found small effect sizes for their data-driven processing groups (r=0.29 and r=0.29 respectively). High levels of heterogeneity were found across the two papers for the peritraumatic subjective threat groups, but low levels of heterogeneity were found in both data-driven processing groups.

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Personal Reflections

Undertaking this portfolio of research has been a significant challenge, with multiple setbacks, in addition to navigating training during the global pandemic. After my first thesis fell through I was able to pull timelines back on course and was optimistic I could regain lost ground. However, after the second thesis fell through, and after I was faced with additional obstacles beyond my control with my Service Related Project, I found it impossible to manage the domino effect of impending deadlines, in addition to expectations to perform at a consistently high level on placement.

Reluctantly, I made the decision with the support of my advisor and supervisor to request an extension for submission of my thesis. Unfortunately, despite my best organisational efforts and attempts to take care of myself, my mental health has suffered significantly as a result of the workload.

I had initially focussed my research interests around the field of brain injury, as I am looking ahead to completing the Qualification in Clinical Neuropsychology (QiCN), and I felt that this would help contribute to building my knowledge base in that area. However, the setbacks led to the serendipitous opportunity to work with Prof Richard Meiser-Steadman again in the field of PTSD. Prof Broomfield has remained steadfast in his support throughout the changes, for which I am also very grateful. PTSD is another interest area of mine, and I was delighted to have been involved in co-authoring three published papers related to the covid-19 pandemic, with two related specifically to PTSD, alongside my studies in the early part of training.

One of the early challenges of creating this work was trying to find a gap in the literature. Completing meta-analyses was agreed to be a safe approach for project selection as I didn’t have the time to navigate NHS ethics processes at that stage of training. However, the

field of PTSD is fairly well served by systematic reviews and it took some time to find an appropriate project which provided an original contribution to the field of PTSD. I am grateful to Dr Jessica Memarzia for her blessing to conduct my main study following on from her doctoral thesis in 2017, but with an adult population. Another challenge has been the unforeseen size of the main study, which has often felt unmanageable. I have missed having the time to fully immerse myself in the literature and to connect with the material on a deeper level, as I frequently found myself tied up in task-oriented data-management.

However, it hasn't all been bad. I am grateful to have had the opportunity to tackle two very interesting research topics, which have felt relevant to my clinical interests, and have motivated me to try to make a meaningful contribution to the literature. I have really valued the time spent in supervision discussing the reasoning behind different methodological decisions, as well as learning how to translate raw data into an analysable format. While the outcomes leave lots of room for further research, I am pleased to have had a small part of the effort to advance these conversations for the greater good.

APPENDICIES

Appendix A – Journal of Affective Disorders: Guide for Authors

Description

The Journal of Affective Disorders publishes papers concerned with **affective disorders** in the widest sense: **depression, mania, anxiety and panic**. It is interdisciplinary and aims to bring together different approaches for a diverse readership. High quality papers will be accepted dealing with any aspect of affective disorders, including biochemistry, pharmacology, endocrinology, genetics, statistics, epidemiology, psychodynamics, classification, clinical studies and studies of all types of treatment.

Submission checklist

You can use this list to carry out a final check of your submission before you send it to the journal for review. Please check the relevant section in this Guide for Authors for more details.

Ensure that the following items are present:

One author has been designated as the corresponding author with contact details:
• E-mail address
• Full postal address

All necessary files have been uploaded:
Manuscript:
• Include keywords
• All figures (include relevant captions)
• All tables (including titles, description, footnotes)
• Ensure all figure and table citations in the text match the files provided
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Author Statement Contributors, Role of the Funding Source and Acknowledgements are mandatory and must be retained in the Author Statement (submission file type) under their respective headings.
Graphical Abstracts / Highlights files (where applicable)
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Appendix B - Quality Assessment for Safety Behaviour Systematic Review

1.	**Was the study population clearly defined?** *(consider clear description of age, gender, location, ethnicity, demographics)*	
	Yes- descriptive statistics reported on participant demographics (including age range and mean, gender split) and trauma characteristics (type of trauma, injuries or impact, if natural disaster indicates some level of exposure)	2
	Some descriptive statistics reported but some missing information.	1
	No clear description of sample and trauma characteristics	0
2	**Was some form of random selection used to select the sample or a method of sampling appropriate to the study?** *(consider random, cluster, or systematic sampling, consecutive recruitment if appropriate, or approached all eligible participants if possible, for example approached all students involved in a specific trauma occurring at one school)*	
	Clear report given on random selection method or appropriate recruitment strategy	2
	Some sampling method used, but not totally random	1
	Unclear whether appropriate sampling method was used, or inappropriate or non-random sampling method used	0
3	**Was non-response bias minimal or accounted for?** *(consider if the response rate was >40%. If response rate was an analysis was <40%, consider if authors assessed and reported no significant difference between responders and non-responders in key indicators e.g. age, gender, trauma type)*	
	Yes; more than 40% of eligible and approached participants took part and, if reported, there were no significant differences between those who took part and those who did not.	2
	No but accounted for; less than 40% of those approached took part, but there were no significant differences between those who participated and those who did not.	1
	No; less than 40% of those approached took part, and differences between those who took part and those who did not were not reported or highlighted significant differences. Or, response rate was not reported.	0
4	**For longitudinal/prospective studies: was loss to follow-up 20% or less?**	
	Yes; participant drop-out or non-response was less than 20%.	2
	No, but accounted for; loss to follow up was more than 20% (but less than 40%) but differences between those who completed the full study and those who did not were assessed and reported as showing no significant differences in key indicators (e.g. in age, gender, trauma characteristics or symptoms)	1
	No; loss to follow up was more than 20% and difference between complete cases and incomplete cases were not assessed or reported, or showed significant differences.	0
	Not applicable; this was a cross-sectional study	N/A
5	**Was the measure of PTSD valid and reliable?** *(consider if they reference the use of the measure in other research; if they report internal consistency; Cronbach's alpha, as at least 0.7; if this was interview based or self-report; and if they reference the measure as being informed by diagnostic manual criteria for PTSD)*	
	Yes; a well-validated interview or self-report measure based on diagnostic manual criteria was used.	2

	A validated interview or self-report measure was used but was not based on diagnostic manual criteria of PTSD	1
	No; a poorly validated or unknown measure of PTSD was used.	0
6.	**Was the measure of safety behaviours reliable?** *(Consider how well the authors described this measurement; if a validated full-scale, or multiple items from another scale, or just a single item was used to assess each safety behaviour; and consider if this was assessed by interview or self-report measure)* **If multiple safety behaviours are assessed in one study, please complete this question for each behaviour.*	
	A specific and validated full-scale measure (self-report or interview), or multiple items from a semi-structured interview was used to assess safety behaviours.	2
	A total or mean score from multiple self-report items, either designed specifically for the study or taken from within an existing measure (with good internal consistency for these items, if reported) or A score from a single item from an existing and validated measure	1
	Response on a single item or another single way of assessing safety behaviours was used, or poor description was given of how this factor was assessed.	0

Total Quality Assessment score ***(*note if different total score according to different safety behaviours)***	
For longitudinal studies: **____ / 12** **= ____ %**	**For cross-sectional studies:** **____/10** **= ____ %**
>70% = high quality study	
50-70% = medium quality study	
<50% = low quality study	

Appendix C: R Analysis Code – Safety Behaviour Systematic Review and Meta-Analysis.

```
setwd("C:\\Users\\tkb14umu\\OneDrive - University of East Anglia\\UEA ClinPsyD TRAINEES\\Jennifer Birch\\SR - analysis") # sets working directory

library("metafor")

mydata = read.csv("sr.csv") #reads from a .csv file

# MAIN ANALYSIS – ALL IN

mydata <- escalc (measure="ZCOR", ri=sb, ni=ni, data=mydata)

# ZCOR signifies that ri is raw correlation data; escalc will transform to Fisher's z

res.all <- rma(yi, vi, data=mydata) # yi is effect, vi is variance

res.all # this will be transformed values!

predict(res.all, transf=transf.ztor) # transforms back to r from Fisher's z

# work out N for this

mydata.all <- subset (mydata, sb !="NA") #creates data object with just valid cases

sum(mydata.all$ni) # creates N

# forest plot

forest (res.all, transf=transf.ztor, slab = paste(mydata$study), digits=2, addpred=TRUE, refline=NA)

# funnel plot

funnel(res.all)

# MAIN ANALYSIS – EXCLUDE DUNMORE

mydata = read.csv("sr.csv") #reads from a .csv file

mydata <- escalc (measure="ZCOR", ri=sb, ni=ni, data=mydata)

# ZCOR signifies that ri is raw correlation data; escalc will transform to Fisher's z

res.sens <- rma(yi, vi, data= mydata, subset=sens=="yes")

res.sens

predict(res.sens, transf=transf.ztor) # transforms back to r from Fisher's z
```

```
# forest plot

forest (res.sens, transf=transf.ztor, slab = paste(mydata$study), digits=2, addpred=TRUE,
refline=NA)

# work out N for this

mydata.sens <- subset (mydata, sens="yes") #creates data object with just valid cases

sum(mydata.sens$ni) # creates N

# MAIN ANALYSIS – USE EHRING 2008 6m data

mydata = read.csv("sr.csv") #reads from a .csv file

mydata <- escalc (measure="ZCOR", ri=sb2, ni=ni2, data=mydata)

# ZCOR signifies that ri is raw correlation data; escalc will transform to Fisher's z

res.6m <- rma(yi, vi, data= mydata)

res.6m

predict(res.6m, transf=transf.ztor) # transforms back to r from Fisher's z

# work out N for this

mydata.6m <- subset (mydata, sb2 !="NA") #creates data object with just valid cases

sum(mydata.6m$ni2) # creates N

# forest plot

forest (res.6m, transf=transf.ztor, slab = paste(mydata$study), digits=2, addpred=TRUE,
refline=NA)
```

Appendix D - Assessment time points, all studies

Article and Year	Time between trauma and initial assessment for peritrauma	PTSD Assessment follow up time point, after assessment of peritraumatic factor. *NA = cross-sectional study
Aftyka 2021	1 month	NA
Alatawi 2020	June 2020 (Covid-19)	NA
Allenou 2010	1 week	1-3 months
Angerpointer 2020	Within 4 days	1-3 months
Anticevic 2021	1 month after pandemic started	NA
Birmes 2003	Within 24 hours of assault	1-3 months
Blekas 2020	April 2020 (Covid-19)	NA
Bronner 2009	Peritrauma assessed after transfer out of PICU	1-3 months
Bryant 2011	Mean 5.3 days post injury	1-3 months
Bui 2010	Within 1 week	1-3 months
Camille 2020	2 weeks after cancer diagnosis	1-3 months
Cornelius 2019	Mean = 14.92 hours	1-3 months
Delahanty 2003	Mean = 31.5 hours after their accident	1-3 months
Duncan 2013	Average 4 weeks	NA
Dunmore 2001	4 months	4-6 months
Ehlers 1998	20% on the same day, 50% within 3 days, and 75% within 8 days of the accident	1-3months
Elklit 2004	2 weeks	4-6 months
Engelhard 2003	1 month	4-6 months
Engelhard 2011	6 months	12+ months

Ennis 2021	During hospital admission (within hours/days)	1-3 months
Epstein 1998	6 months	6 - 18 months
Freedman 1999	1 week	4 -6 months
Ehring 2008	Less than 12 hours	4 - 6 months
Gabert Quillen 2011	After ~2 days	1-3 months
Gandubert 2016	Median = 5 (2-7 days)	1-3 months
Greene 2018	Between 8-24 days	1-3 months
Hansen 2014	Mean = 9.89 days after robbery	4-6 months
Hoffman (a) Isreal Gaza conflict 2016	December 2014 – January 2015	NA
Hoffman (b) Israeli Palestine Conflict 2016	2months after conflict started	NA
Hussain 2013	6 months	12+ months
Irish 2011	Mean = 26 hours	1-3 months
Johansen 2007	A few days to 16 weeks	1-3 months
Kaczmarek 2012	1-6 months Mean = 3.65 months	NA
Kessler 2021	Mean = 9.7 days (7-11days)	1-3 months
Kristensen 2014	1 month	4-6 months
Kunst 2017	Within 1 month Mean = 20.7 days	1-3 months
Lawyer 2006	4-5 months	NA
Marchand 2015	5-15 days	1-3 months
Marke 2013	While in hospital (within hours/days)	1-3 months
Marshall 2002	Mean = 9.55 days	1-3 months

Meli 2019	During ED stay or within 1 week, median = 3 days,	1-3 months
Moss 2020	Within 5 days, range 2-7	1-3 months
Murray (a) (inpatient) 2002	Within 24 hours	1-3 months
Murray (b) (outpatient) 2002	Questionnaires sent out within 48 hours, 82% returned in first week	1-3 months
Narisawa 2021	Within 7 days	4-6 months
Nishi 2010	2 days (range = 0-23 days)	1-3 months
Nishi 2012	1 month	4-6 months
Nobakht 2019	3-4 months	3-4 months
Olde 2005	1 week	1-3 months
Palgi 2020	Within 1 month	4-6 months
Pires 2013	Average of 5 days	4-6 months
Psarros 2018	1 month	NA
Rahmat 2021	3-5 days	1-3 months
Ranieri 2021	March 2020	NA
Shiban 2018	1 week	1-3 months
Shigemura 2014	2-3 months	NA
Sijbrandij 2013	1 week	1-3 months
Thiel 2020	Within 6 months	NA
Thormar 2014	6 months	12+ months
Ursano 1999	1 month	1-3 months
Velden 2006	2-3 weeks	12+ months
Vossbeck-Elsebusch 2014	1 – 6 months	NA
Werner 2012	M = 28.2 days, SD = 15.3, Range 5 - 87	7 + months

Wittman 2006	5 days	4-6 months
Youngner 2012	Mean = 11 hours	1-3 months

Appendix E - Quality Assessment for Peritraumatic Risk Factors Systematic Review

1.	**Was the study population clearly defined?** *(consider clear description of age, gender, location, ethnicity, demographics)*	
	Yes- descriptive statistics reported on participant demographics (including age range and mean, gender split) and trauma characteristics (type of trauma, injuries or impact, if natural disaster indicates some level of exposure)	2
	Some descriptive statistics reported but some missing information.	1
	No clear description of sample and trauma characteristics	0
2	**Was some form of random selection used to select the sample or a method of sampling appropriate to the study?** *(consider random, cluster, or systematic sampling, consecutive recruitment if appropriate, or approached all eligible participants if possible, for example approached all students involved in a specific trauma occurring at one school)*	
	Clear report given on random selection method or appropriate recruitment strategy	2
	Some sampling method used, but not totally random	1
	Unclear whether appropriate sampling method was used, or inappropriate or non-random sampling method used	0
3	**Was non-response bias minimal or accounted for?** *(consider if the response rate was >40%. If response rate was an analysis was <40%, consider if authors assessed and reported no significant difference between responders and non-responders in key indicators e.g. age, gender, trauma type)*	
	Yes; more than 40% of eligible and approached participants took part and, if reported, there were no significant differences between those who took part and those who did not.	2
	No but accounted for; less than 40% of those approached took part, but there were no significant differences between those who participated and those who did not.	1
	No; less than 40% of those approached took part, and differences between those who took part and those who did not were not reported or highlighted significant differences. Or, response rate was not reported.	0
4	**For longitudinal/prospective studies: was loss to follow-up 20% or less?**	
	Yes; participant drop-out or non-response was less than 20%.	2
	No, but accounted for; loss to follow up was more than 20% (but less than 40%) but differences between those who completed the full study and those who did not were assessed and reported as showing no significant differences in key indicators (e.g. in age, gender, trauma characteristics or symptoms)	1
	No; loss to follow up was more than 20% and difference between complete cases and incomplete cases were not assessed or reported, or showed significant differences.	0
	Not applicable; this was a cross-sectional study	N/A
5	**Was the measure of PTSD valid and reliable?** *(consider if they reference the use of the measure in other research; if they report internal consistency; Cronbach's alpha, as at least 0.7; if this was interview based or self-report; and if they reference the measure as being informed by diagnostic manual criteria for PTSD)*	
	Yes; a well-validated interview or self-report measure based on diagnostic manual criteria was used.	2

	A validated interview or self-report measure was used but was not based on diagnostic manual criteria of PTSD	1
	No; a poorly validated or unknown measure of PTSD was used.	0
6.i	**Was the measure of peri-traumatic factors reliable?** *(Consider how well the authors described this measurement; if a validated full-scale, or multiple items from another scale, or just a single item was used to assess each peri-traumatic factor; and consider if this was assessed by interview or self-report measure)* **If multiple peri-traumatic factors are assessed in one study, please complete this question for each factor, labelling each factor assessed here:* *Peri-traumatic factor (e.g. fear, perceived life threat…):*	
	A specific and validated full-scale measure (self-report or interview), or multiple items from a semi-structured interview was used to assess peri-traumatic factors.	2
	A total or mean score from multiple self-report items, either designed specifically for the study or taken from within an existing measure (with good internal consistency for these items, if reported) or A score from a single item from an existing and validated measure	1
	Response on a single item or another single way of assessing a peri-traumatic factors was used, or poor description was given of how this factor was assessed.	0
6.ii	**Was the measure of peri-traumatic factors reliable?** *(Consider how well the authors described this measurement; if a validated full-scale, or multiple items from another scale, or just a single item was used to assess each peri-traumatic factor; and consider if this was assessed by interview or self-report measure)* **If multiple peri-traumatic factors are assessed in one study, please complete this question for each factor, labelling each factor assessed here:* *Peri-traumatic factor (e.g. fear, perceived life threat…):__*	
	A specific and validated full-scale measure (self-report or interview), or multiple items from a semi-structured interview was used to assess peri-traumatic factors.	2
	A total or mean score from multiple self-report items, either designed specifically for the study or taken from within an existing measure (with good internal consistency for these items, if reported) or A score from a single item from an existing and validated measure	1
	Response on a single item or another single way of assessing a peri-traumatic factors was used, or poor description was given of how this factor was assessed.	0
6.iii	**Was the measure of peri-traumatic factors reliable?** *(Consider how well the authors described this measurement; if a validated full-scale, or multiple items from another scale, or just a single item was used to assess each peri-traumatic factor; and consider if this was assessed by interview or self-report measure)* **If multiple peri-traumatic factors are assessed in one study, please complete this question for each factor, labelling each factor assessed here:* *Peri-traumatic factor (e.g. fear, perceived life threat…):__*	
	A specific and validated full-scale measure (self-report or interview), or multiple items from a semi-structured interview was used to assess peri-traumatic factors.	2

	A total or mean score from multiple self-report items, either designed specifically for the study or taken from within an existing measure (with good internal consistency for these items, if reported) or A score from a single item from an existing and validated measure	1
	Response on a single item or another single way of assessing a peri-traumatic factors was used, or poor description was given of how this factor was assessed.	0

Total Quality Assessment score ***(*note if different total score according to different peri-traumatic factor)***	
For longitudinal studies: **____ / 12** **= ____ %**	**For cross-sectional studies:** **____/10** **= ____ %**
>70% = high quality study	
50-70% = medium quality study	
<50% = low quality study	

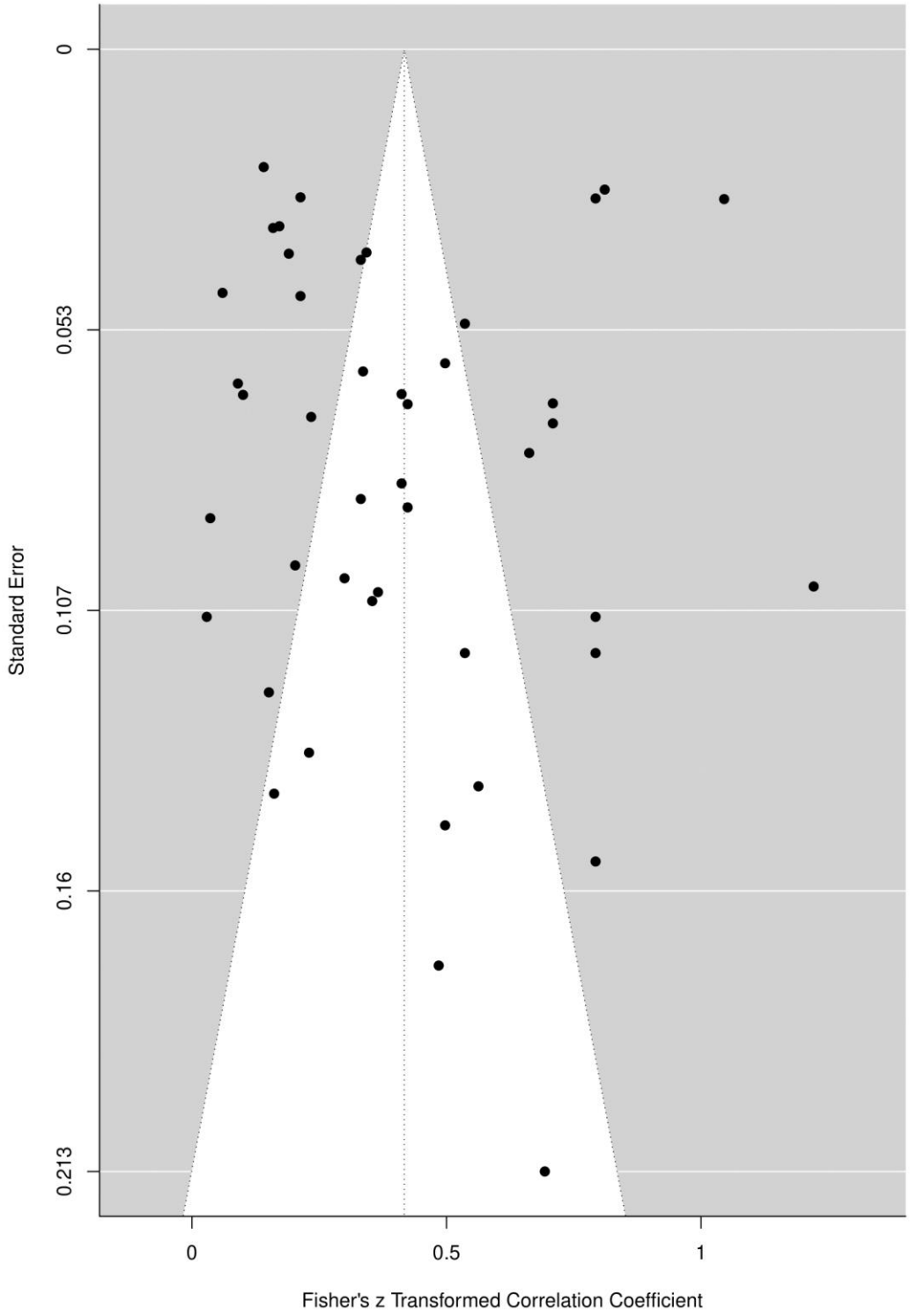
Appendix F - Study Quality Ratings

Article and Year	**Quality Rating**
Aftyka 2021	medium
Alatawi 2020	medium
Allenou 2010	high
Angerpointer 2020	high
Anticevic 2021	medium
Birmes 2003	high
Blekas 2020	medium
Bronner 2009	high
Bryant 2011	high
Bui 2010	high
Camille 2020	high
Cornelius 2019	medium
Delahanty 2003	high
Duncan 2013	medium
Dunmore 2001	medium
Ehlers 1998	high
Elklit 2004	high
Engelhard 2003	medium
Engelhard 2011	medium
Ennis 2021	high
Epstein 1998	medium
Freedman 1999	medium
Ehring 2008	high

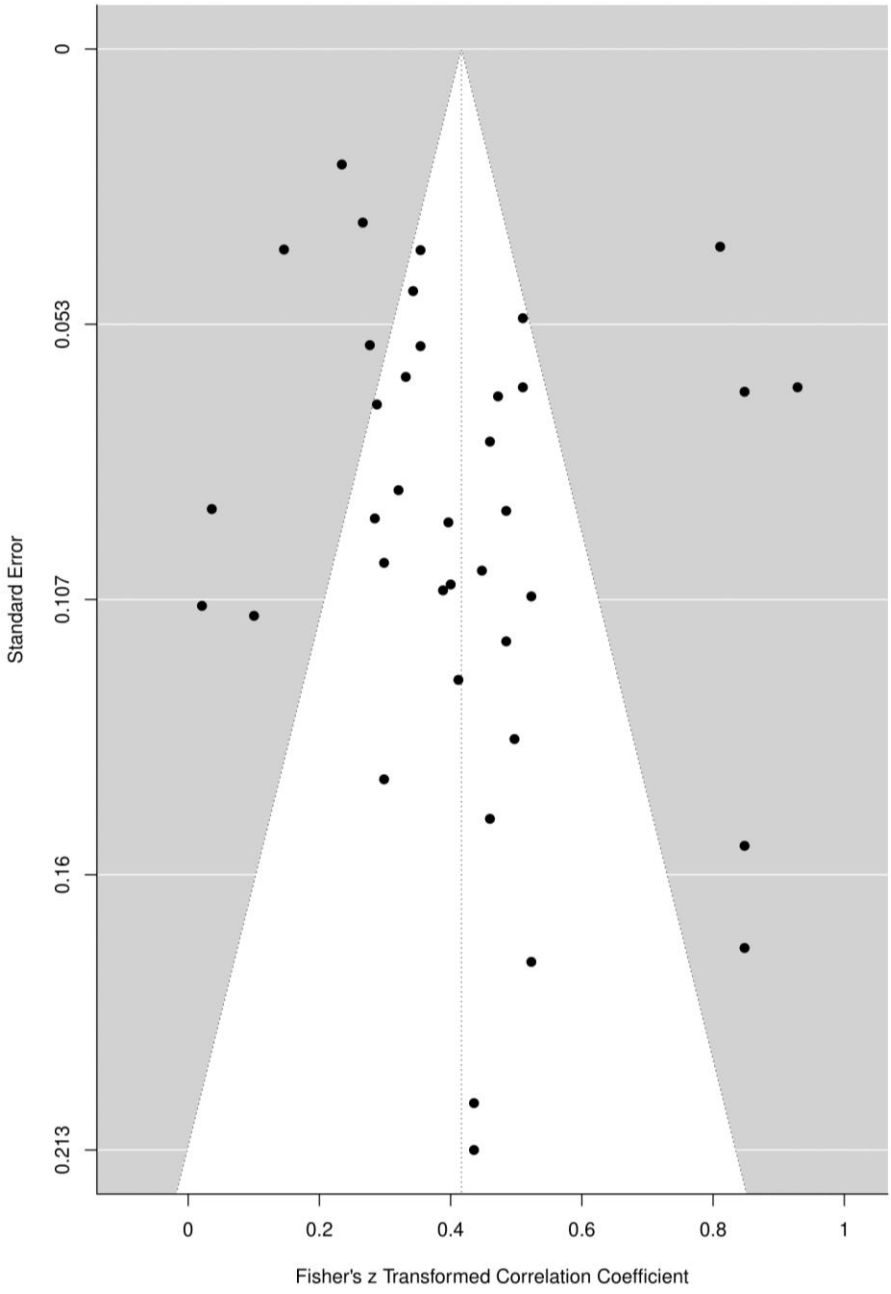
Gabert Quillen 2011	high
Gandubert 2016	medium
Greene 2018	medium
Hansen 2014	high
Hoffman (a) Israel Gaza conflict 2016	low
Hoffman (b) Israeli Palestine Conflict 2016	low
Hussain 2013	high
Irish 2011	high
Johansen 2007	high
Kaczmarek 2012	low
Kessler 2021	high
Kristensen 2014	high
Kunst 2017	high
Lawyer 2006	medium
Marchand 2015	high
Marke 2013	medium
Marshall 2002	high
Meli 2019	low
Moss 2020	high
Murray (a) (inpatient) 2002	high
Murray (b) (outpatient) 2002	high
Narisawa 2021	high
Nishi 2010	high
Nishi 2012	medium

Nobakht 2019	high
Olde 2005	medium
Palgi 2020	medium
Pires 2013	high
Psarros 2018	high
Rahmat 2021	high
Ranieri 2021	medium
Shiban 2018	medium
Shigemura 2014	high
Sijbrandij 2013	medium
Thiel 2020	high
Thormar 2014	high
Ursano 1999	high
Velden 2006	high
Vossbeck-Elsebusch 2014	medium
Werner 2012	high
Wittman 2006	high
Youngner 2012	high

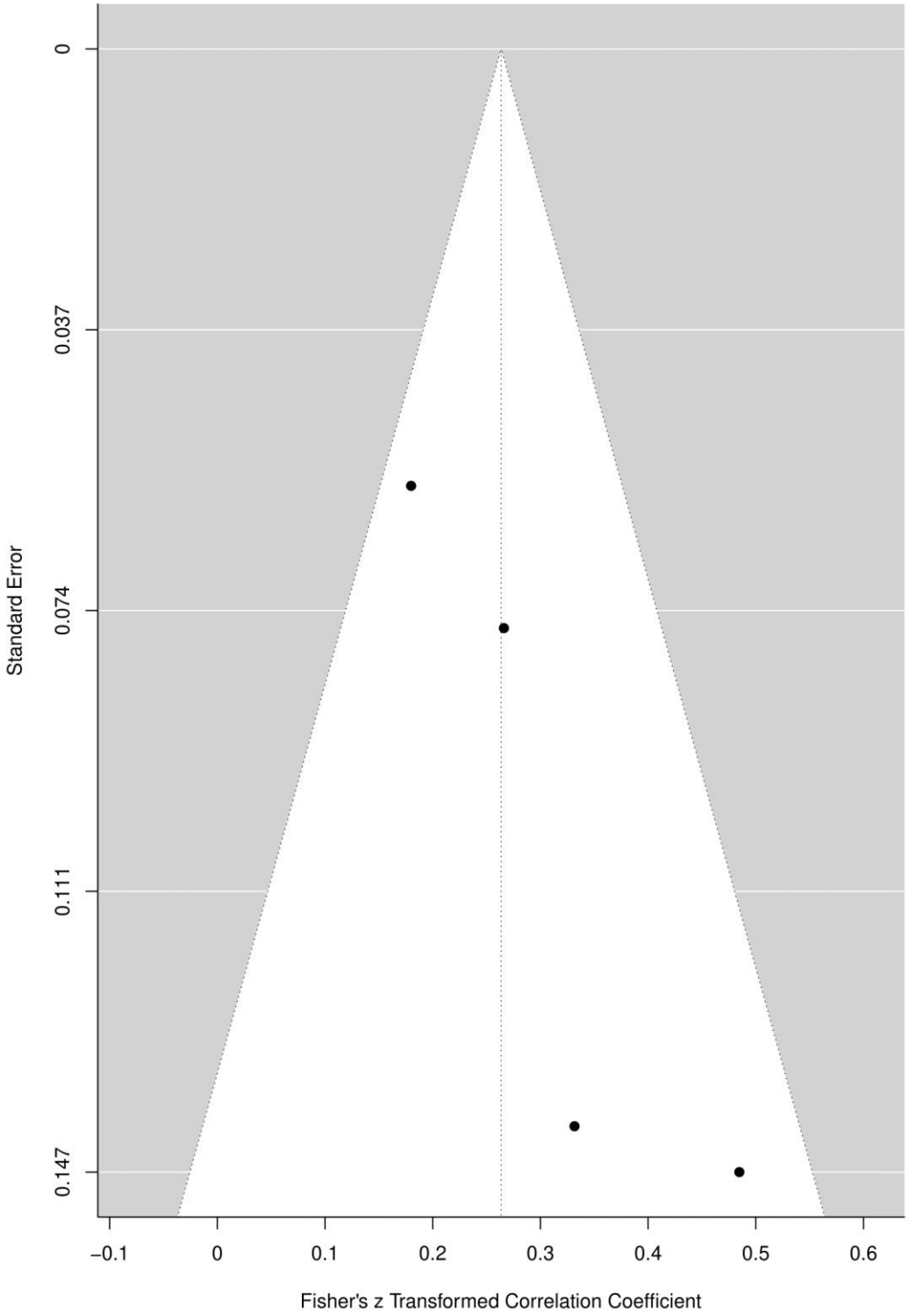
Appendix G - Funnel plot generated from random effects model for the meta-analysis of peritraumatic subjective threat effect sizes



Appendix H - Funnel plot generated from random effects model for the meta-analysis of peritraumatic dissociation effect sizes



Appendix I - Funnel plot generated from random effects model for the meta-analysis of peritraumatic data-driven processing effect sizes



Appendix J

Thesis Proposal: Systematic Review and Meta-Analysis:
Treatment of sleep disorders in adult stroke survivors

Jennifer Birch

XWC19VAU

Supervisors: Professor Niall Broomfield & Dr Alpar Lazar

University of East Anglia

Faculty of Medicine and Health Services

Doctoral Programme in Clinical Psychology

Submission Date: 25 August 2020

Word Count: 3,730

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Aims

- To explore the range and type of sleep disorder treatments available for post-stroke patients (including psychological and non-psychological treatments)
- To establish the current effectiveness of sleep disorder treatments post-stroke
- To identify the gaps in the research and outline future research needed to address these gaps

Rationale

To the authors knowledge, this meta-analysis represents the first of its kind. Whilst there are many studies describing the prevalence (Harbison et al, 2002; Baylan et al 2020) and mechanisms of sleep disorders post stroke (Ferre et al, 2003; Brown et al, 2006; Hermann & Bassetti, 2016) there are no meta-analytic reviews which have sought to synthesise the treatment outcome data.

The focus of the review will be on the treatment of sleep disorders only. Sleep disorders are commonly experienced post-stroke, causing significant burden to an individuals recovery as well as posing a potential barrier to effective rehabilitation (Iddagoda et al, 2020).

The results of this review will be beneficial for several reasons. Firstly, given the frequency of sleep disorders post-stroke, it will be beneficial for patients to be provided with the most up to date evidence-based information and treatments. This could help to improve rehabilitation outcomes with potential secondary benefits across cognitive (Kim et al 2019), functional (Ryan et al 2011), emotional outcomes (Johansson & Ronnback, 2014). Secondly, the results will be of benefit to clinicians providing rehabilitation to stroke survivors. Clinicians will be better placed to provide recommendations. Thirdly, commissioners will be

better informed to assigned funds to deliver treatments within existing settings. Pulling together research in this way allows clinicians and commissioners to stay on top of the literature. Lastly, the review will establish the current knowledge about sleep disorder treatments, and simultaneously highlight where future research needs to be focused in order to build on this knowledge. If gaps in the research are identified, this could enable funders to more confidently back new trials (Fagard, Staessen & Thijs, 1996).

Protocol Design and Registration

The author will use a systematic review and meta-analysis study design to summarise treatment studies published since inception (Field & Gillett, 2010). This study design is appropriate for synthesising data from multiple individual studies to a) determine if an effect exists b) identify if the effect is positive or negative and c) if possible, to obtain an overall summary estimate of any identified effect(s). Meta-analyses can help to overcome the limitations of small sample sizes, by increasing the statistical power, and researchers can go further by evaluating the effects in different subsets of participants (Valentine, Pigott & Rothstein, 2010). This method can be particularly beneficial if there are conflicting results between studies and can allow for more reliable and valid conclusions to be drawn (Haidich, 2010).

The present systematic review and meta-analysis will be pre-registered with PROSPERO (Booth et al 2012). The review will be produced in accordance with Preferred Reporting Items for Systematic Reviews and Meta-Analysis Protocol (PRISMA) recommendations (Moher et al, 2016). See Appendix A. By submitting to PROSPERO, all decisions are made fully explicit which helps to counteract researcher bias. Any edits to the protocol will be updated on the PROSPERO system, which will be public and date-stamped to ensure transparency.

Introduction

Every year in the UK, over 100,000 people have a stroke, and current estimates predict there are around 1.2 million stroke survivors in need of holistic support and rehabilitation (State of the Nation Stroke Statistics, 2018). Overall, stroke is the fourth leading cause of death in the UK, with an economic cost of around £1.7billion (King et al, 2020). However, stroke is the leading cause of disability, as two in three people who are discharged from hospital continue to live with the physical, cognitive and emotional effects with varying degrees of severity (Scarborough et al, 2009; Johnson et al, 2019).

Stokes are categorized in to two main types, both of which can be fatal (Neaton et al, 1993). Ischemic strokes are caused by a blood vessel in the brain becoming blocked. This can either be due to a blood clot forming in an artery leading to the brain, called a thrombotic stroke, or it can be caused by a clot forming in other parts of the body, such as the heart or neck, which breaks off and travels to the brain, called an embolic stroke (Suwanwela & Koroshetz, 2007).

A hemorrhagic stroke is caused by a bleed within the brain or on the surface of the brain, usually as a result of a weakened blood vessel. A hemorrhage can be an Aneurysm, which is when the ballooning of a blood vessel eventually weakens and bursts, with the blood causing damage to the surrounding brain tissue. Alternatively, a hemorrhage can be the result of an Arteriovenous Malformation, which is a cluster of abnormally formed blood vessels in the brain, which have the potential to rupture (Unnithan & Mehta, 2020).

The effects of a stroke can be wide ranging and depend on the location of the stroke within the brain (Lefkovits et al 1992). The aftereffects can be described by the following categories; Physical, Cognitive, Emotional and Communication. Physical effects can include;

limb weakness, seizures, difficulties with balance, changes to bladder and bowel control, visual difficulties and swallowing problems. Cognitive effects can include difficulties with memory, concentration, planning, problem-solving, recognition and proprioception (Cumming et al, 2013). Emotional changes can include anxiety, depression, emotionalism, frustration and anger (Fure, 2007). Communication effects can include difficulties with speaking, understanding, reading and writing (Borthwick, 2012).

Another major consequence of stroke is sleep disorders (Pasic et al, 2011). Sleep disorders are conditions that result in a change to the individuals typical sleep pattern, such as the quality, timing or amount of sleep, which can cause issues with functioning and distress during the daytime (Chokroverty, 2010). Following stroke, individuals can have difficulty falling asleep, difficulty staying asleep and/or may find it difficult to wake up in the way they used to.

Current estimates state that 50% of stroke survivors experience some form of sleep disorder (Khot et al 2019), although this varies by type of sleep disorder. Insomnia, for example can affect between 20-56% of stroke survivors (Ferre et al, 2013). Insomnia is the inability to fall asleep at night or sustain sleep throughout the night, leading to tiredness (Morin & Benca, 2012). Sleep apnea, which is when breathing pauses and restarts during sleep, is a sleep disorder which causes snoring and gasping sounds during sleep. This leads to restless sleep and subsequent tiredness and concentration difficulties the following day (Strollo, Patrick & Rogers, 1996) Sleep apnea can affect between 50-70% of stroke survivors (Sharma & Culebras, 2016). Importantly, untreated sleep disorders can negatively impact rehabilitation efforts and lengthen hospital stays (Wallace et al, 2012). According to the National Sleep Foundation, adults age 18 – 64 need seven to nine hours of sleep per night, and adults over 65 need seven to eight hours per night (Hirshkowitz et al 2015). Having an adequate amount of sleep is important for a healthy immune system (Besedovsky et al 2012),

emotional wellbeing (Vandekerckhove & Cluydts, 2010) and memory processing (Krause et al 2017).

A lack of sleep can cause a plethora of consequences, such as irritability and lack of concentration, and it can exacerbate existing anxiety and depression disorders (Wells & Vaughn, 2012). But in turn, anxiety and depression can cause difficulties with sleep, creating a vicious cycle (Alvaro et al, 2013). Sleep deprivation can also have effects on physical health, as research suggests it can increase the risk of diabetes, heart problems and obesity. Having good quality sleep also plays a direct crucial role in stroke recovery as it allows neuroplasticity, which can bypass the structural and functional changes to the brain following the stroke. This in turn allows new neuronal pathways to develop which can help to mitigate any resulting disability (Mensen et al, 2019).

Currently, there are no specific National Institute for Health and Care Excellence (NICE) guidance recommendations for sleep disorder screening post stroke. Screening for sleep disorders in clinical practice is inconsistent which means that many cases are left untreated. The predictive value of screening questionnaires is poor, whereas physiological measures such as capnography and nocturnal oximetry produce better predictive results (Takala et al, 2018). They are, however, expensive and impractical for use in routine practice. More research needs to be conducted to improve the validity and reliability of self-rated and clinician-rated measures. This will help to increase awareness and enable more stroke survivors to be identified, and in turn lead to appropriate sleep disorder treatments being offered to patients. By providing effective sleep treatments post-stroke, this could help to improve recovery trajectories, reduce length of hospital stay, and reduce the likelihood of further strokes i.e. secondary prevention (Khot & Morgenstern, 2019).

Treatments for sleep disorders are varied, with psychological and non-psychological treatments currently (see 'Types of sleep disorders' section). It is important to consider the full range of interventions available, as it is not yet clear which treatment or treatments are the most effective. It is also unclear whether certain treatments may be more effective for patients with particular types of stroke.

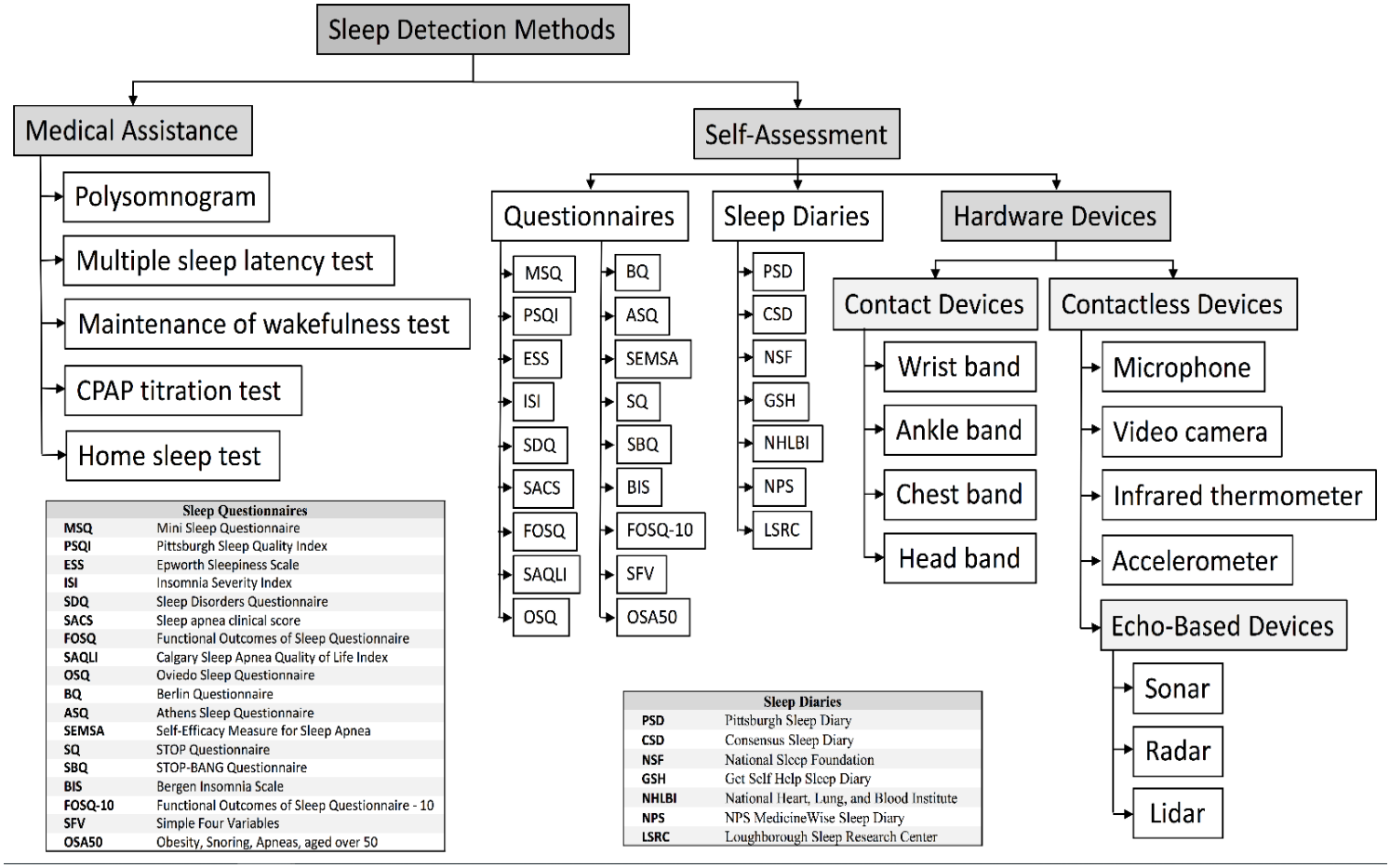
Research Questions

- What treatments are available to support adults with sleep disorders post-stroke?
- How effective are sleep disorder treatments for adult survivors of stroke?
- Are there particular sleep disorder treatments which are more effective for certain types of stroke?
- Are there differences in effect between psychological vs non-psychological sleep disorder interventions post-stroke?

Primary Outcomes

- **Improvement in sleep** This could be measured by a) latency b) efficiency c) total sleep time and d) wake after sleep onset. This could be measured objectively e.g. actigraphy or polysomnography or subjectively e.g. self-report or diary entry. All examples within Figure 1 will be considered for inclusion (Ibáñez, Silva & Cauli, 2018).

Figure 1:



Add to Fig 1: Sleep Condition Indicator (Espie et al, 2014)

Secondary Outcomes

Improvements in the following areas as a function of sleep improvement (primary outcome)

- Improvement in cognitive outcomes e.g. attention, executive function, memory, visuospatial function and language as assessed by MoCA, ACE-III, although other measures will be considered
- Improvement in functional outcomes e.g. degree of disability in carrying out daily activities as assessed by Modified Rankin Scale or Barthel Scale, although other measures will be considered

- Improvement in emotional outcomes e.g improvement in mood/respective reduction in distress as measures by HADS or PHQ-9, although other measures will be considered.

Eligibility Criteria

The titles and abstracts for all identified papers will be screened against the following criteria:

Inclusion

- English only
- No restrictions on date of published study
- Must have diagnosis of stroke (ischemic or haemorrhagic)
- No limit on time since stroke
- Must have used recognised measurement tools
- Psychological and non-psychological interventions will be included.
- Peer-reviewed studies only
- Adult participants only age 18+, no upper age limit
- No restrictions on participants gender, ethnicity, nationality or any other demographic characteristic.
- Sleep disorders described in the study must be one of those listed in International Classification of Sleep Disorders (ICSD-3)
- If the sample includes a combination of stroke survivors and people with acquired brain injuries, data will only be included if at least 75% of the sample are stroke survivors.

Exclusion

- Studies which focus on children only – *this is because the aetiology of childhood stroke is different to adult stroke, and is beyond the scope of this review.*

- This study will not include traumatic or non-traumatic brain injuries – *these are broad categories which is beyond the scope of this review.*
- Studies which focus on fatigue – *due to a lack of consensus around the operational definition of fatigue, it was felt this term would be too complex to include given the parameters of this review.*
- Not include Transient Ischemic Attack (TIA) or Subarachnoid Haemorrhage (SAH) – *Both TIA and SAH injuries are typically treated separately within clinical settings*
- This study will not include pre-print studies or student dissertations – *to ensure the highest quality evidence possible, only peer-reviewed published studies can be considered.*
- Qualitative studies and single-case studies will not be included – *the focus of this review is quantitative studies only as it is appropriate to the chosen methodology.*

Types of sleep disorders post-stroke to be included

International Classification of Sleep Disorders (ICSD-3) (Sateia, 2014):

1. Insomnia (chronic, short-term, other)
2. Sleep related breathing disorders (e.g. obstructive or central sleep apnea, Cheyne-Stokes breathing, hypoventilation)
3. Central disorders of hypersomnolence (e.g. narcolepsy, Kleine-Levin syndrome, hypersomnia,
4. Circadian rhythm sleep-wake disorders (e.g. delayed sleep-wake phase disorder, advanced sleep-wake phase disorder, irregular sleep-wake rhythm disorder, Non-24hr sleep-eake rhythm disorder)

5. Parasomnias (e.g. NREM-related parasomnias i.e. confusional arousals, sleepwalking, terrors, sleep-related eating-disorder, REM-related parasomnias (e.g. REM sleep behaviour disorder, recurrent isolated sleep paralysis, nightmare disorder, Other i.e. exploding head syndrome, sleep-related hallucinations, sleep enuresis)
6. Sleep Related movement disorders (e.g. restless leg syndrome, periodic limb movement disorder, sleep-related leg-cramps, sleep-related bruxism, sleep-related rhythmic movement disorder, propriospinal myoclonus at sleep onset)
7. Other sleep disorders (e.g. excessive daytime sleepiness, sleep fragmentation, chronic fatigue)

Types of sleep disorder treatments

There are a number of treatments for sleep disorders. Psychological and non-psychological treatments will be included in this study. The following list is not exhaustive, and any additional treatments identified in the search will be included;

- Mandibular advancement
- Supine avoidance
- Oxygen therapy
- Intradermal acupuncture
- Low frequency electrical stimulation
- Medication e.g. Mianserin/Lorazepam/Zopiclone
- Transcutaneous aricular vagus nerve stimulation
- Cognitive Behaviour Therapy (CBT) (including the individual components; Sleep Restriction Therapy, Stimulus Control, Cognitive Therapy and Relaxation Therapy, Paradoxical Intention Therapy, which each have an evidence base as single

component therapies but usually appear in multi-component CBT for Insomnia (CBT-I))

- Tiao Ren Tong Du needling
- Sleep hygiene
- Continuous Positive Airway Pressure
- Life style changes
- Blue Light therapy
- Mindfulness
- Breathing devices/surgery.

Scoping Search

A scoping search was conducted on 26.6.20 in preparation for submission. The first 200 papers were reviewed by title, and of those 83 abstracts were reviewed. Based on visual inspection, 15 papers appeared to include treatment data related to sleep disorder treatments post-stroke. This was prior to refinement of the search criteria, which at the time included 'fatigue' but has since been removed. Nevertheless, additional terms have been included so it is likely to increase the overall number. The final search terms will be part of an iterative process.

Search Terms*

Search Line	Search Terms	Filtered by
Line 1	Post-stroke OR (After-stroke OR after stroke) OR (Following stroke)	Title/Abstract
Line 2	Sleep* OR (Sleep disorder* OR sleep-disorder*)	Title/Abstract
Line 3	Treatment* OR (Rehab* OR Therap* OR Intervention*)	Title/Abstract
Line 4	Cognitive OR cognition	Title/Abstract
Line 5	Function*	Title/Abstract
Line 6	Emotion*	Title/Abstract

These search times are subject to change. Medical Subject Headings (MeSH), truncated words and wild cards will be used to ensure the search is comprehensive.

Types of studies to be included

- Randomised control trials
- Controlled trials
- Cross-sectional studies
- Cohort studies
- Case controlled studies

- Existing systematic reviews
- Existing meta-analyses.
- Open trials e.g. pre/post studies

Search Strategy

The databases named above will be searched in January 2021 using the key words and phrases used in the 'Search Term's' section. The search will look for relevant articles since inception. The search results will initially be screened by title and abstract. The lead author (JB) will review all full texts for consideration against inclusion/exclusion criteria. A second reviewer (TBC) will also review the search results to ensure that all relevant studies have been selected. Reasons for exclusion will be recorded and added to the PRISMA flow chart, see Appendix B.

Information Source

The following databases will be searched: Medline, PsychINFO, CINAHL, PubMed, OVID, Science Direct, Embase and CENTRAL. Manual searches in Google Scholar will also be carried out to identify any additional relevant papers.

The search plan will be checked with UEA Library colleagues trained in systematic reviews to ensure that the search is as effective and thorough as possible.

Data Collection Process

Articles identified from the search will be transferred to Endnote to ensure that accurate records of each step of selection is saved. Duplicates will be removed before the titles and abstracts are reviewed.

Data Extraction

The following information will be extracted and presented in table format:

- Study (inc. lead author and year)
- Country of study
- Sample Size
- Percentage female
- Type of stroke (ischemic or haemorrhagic)
- Location of stroke in the brain
- Type of intervention i.e. sleep disorder treatment
- Length of treatment
- Format e.g. clinician-led or self-directed
- Comparator, if used
- Primary Outcome Measure
- Secondary Outcome measure
- Means (pre and post)
- Standard deviations (pre and post)
- Quality Rating

Quality Assessment and Risk of Bias

All studies will be subject to a structured quality assessment to investigate risk of bias, using the Effective Public Health Practice Project (EPHPP) Quality Assessment Tool for Quantitative Studies (Evans, Lasen & Tsey, 2015). See Appendix C. This tool was chosen as it is a comprehensive assessment specifically designed for quantitative studies.

The Tool includes the following sections which are to be rated as ‘strong, moderate or weak’; selection bias, study design, confounders, blinding, data collection methods,

withdrawals and dropouts, intervention integrity and analysis. The tool is accompanied by a comprehensive dictionary to assist the author in selecting the correct ratings (Thomas, Ciliska, Dobbins & Micucci, 2008).

Studies will be reviewed by a second reviewer, another trainee clinical psychologist, to assess the quality of each study. This is to ensure inter-rater reliability, which will be measured with the kappa statistic. Any difference in ratings between the reviewers will be discussed and a consensus agreed. If a consensus cannot be agreed, a third reviewer will be sought to assist in making a decision. This will be part of a discussion with both supervisors to ensure collective agreement.

If it transpires that the majority of selected studies used non-randomised samples, then the Risk of bias in non-randomized studies of interventions (ROBINS-I) (Sterne et al 2016; Juni et al 2016) will be considered as an alternative quality assessment tool. See Appendix D.

Planned Analyses

1. Analyses between breathing related and non-breathing related study outcomes could be conducted if the necessary data are available
2. If sufficient data for 3 or more treatments are found, a network meta-analysis could be conducted by comparing the interventions (Rouse, Chaimai & Li, 2017)
3. If there is insufficient data to conduct meaningful meta-analyses, or sensitivity analyses, a narrative synthesis (Melendez-Torres et al, 2015) of the data could be conducted.
4. If there are enough treatment studies identified, a cumulative meta-analysis (Clarke, Brice & Chalmers, 2014) could be conducted i.e. adding studies by date of publication and presenting the results as each new study is added to observe how the overall estimate changes.

5. To consider a comparison of effectiveness between psychological and non-psychological treatment interventions
6. Where there is more than one treatment for a particular sleep disorder, the aim will be to analyse the data to identify the most effective of the available treatments.
7. Sensitivity analyses will be conducted to assess whether certain decisions have affected the outcome of the meta-analysis e.g. exclude all studies rated as 'weak'
8. Moderator analyses could be conducted to assess whether factors such as gender or location of stroke have an impact on the results.

Data Analyses

The study data will be collected and inputted into CSV. File e.g. SPSS or excel. RevMan, which is a free online resource, will be used to conduct the meta-analyses (Xu, Tang, & Chen, 2009). A random effects model will be used with 95% confidence intervals, which is expected within the field of clinical psychology (Borenstein, Hedges, Higgins & Rothstein, 2010).

Forest plots will be produced to display the results of the meta-analysis. The plots will be visually analysed for heterogeneity and outliers. Q-tests will also be used to assess heterogeneity (as long as this test can be sufficiently powered to ensure an accurate result). A significant Q-Test shows that the observed effect sizes are significantly different to a larger degree than would be expected due to chance. Heterogeneity will then be quantified as a percentage using i2 (25% low, 50% moderate, 75% high), with confidence intervals (Higgins et al, 2003). If heterogeneity is identified, the causes will be examined and discussed e.g. outliers, subgroup analyses and meta-regression analyses. Heterogeneity is likely to be high for this review due to the wide range of interventions being considered. Further subgroup analyses will be considered, as well as a narrative synthesis if the samples are too small.

Data will be extracted from studies which include intervention groups compared to the following:

- Treatment as usual
- Waitlist
- Placebo
- Control group
- Other comparator

Data will be included from self-reported scales as well as clinician rated measures. Continuous data e.g. number of hours sleep, and dichotomous data will be considered e.g. yes/no categories and clinically significant change. Follow up data will be considered where available.

Effect Size

Cohen's d will be used to calculate the effect sizes for continuous data. For studies where there is a treatment group and control group, the difference between the means and standard deviations will be extracted. They will be divided by the pooled standard deviations of the intervention and control groups. Effect sizes will be weighted i.e. larger studies will carry more weight than smaller studies (Ellis, 2010). The pooled effect sizes will be calculated, which is the weighted average of study level effect sizes.

Where sample sizes are small, Hedges g will be used to calculate the pooled standard deviations. Hedges g is understood to be a more accurate calculation for small sample sizes compared to Cohens d. If dichotomous data are used, Relative Risk or Odds Ratio will be used as effect sizes (Haddoc, Rindskopf & Shadish, 1998).

Publication Bias

Funnel plots will be completed to identify the potential for publication bias. If evident, this may be due to file drawer effects (Sharpe, 1997; Rothstein, Sutton & Borenstein, 2005) and will be discussed in the main paper.

Missing Data

If data essential to the meta-analysis e.g. group means and standard deviations are missing from any identified papers, JB will endeavour to contact the corresponding author by email to request the data. The Cochrane principles for handling missing data will also be followed (Higgins, Deeks, & Altman, 2009).

Budget

This project will not require financial support.

Ethics

This summary will be submitted to the University of East Anglia's ethics committee for approval as is standard procedure for trainee proposals. This review will only use data from existing published studies in which informed consent has already been provided by participants of each respective study's primary investigators.

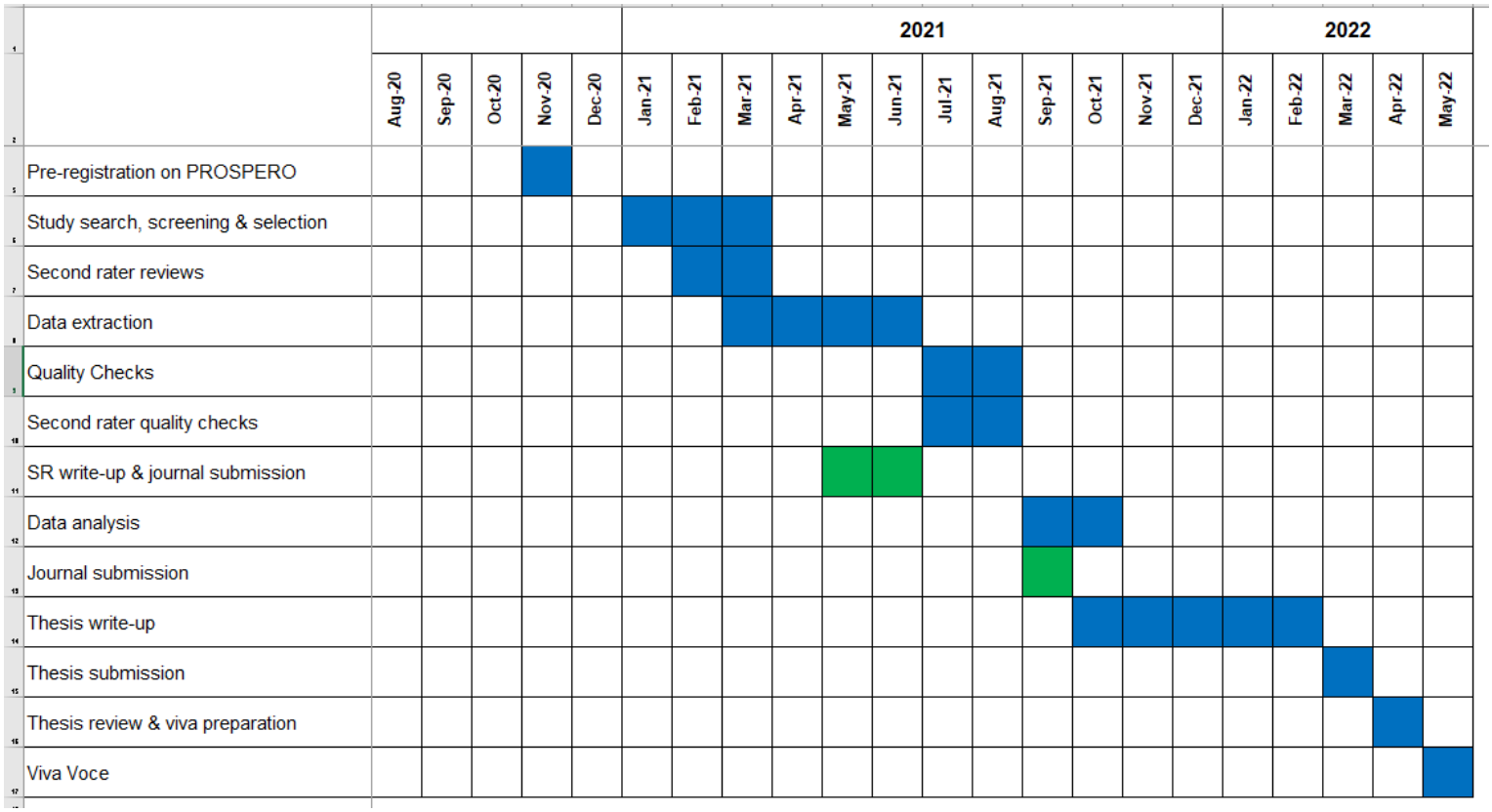
Dissemination

A manuscript will be prepared for publication in a peer-reviewed journal. The systematic review and meta-analyses may be published separately and together. The results may be presented at conferences and shared with stroke rehabilitation services locally and nationally. The research paper will be added to ResearchGate and shared on social media platforms to enhance its reach.

GANTT Chart

Anticipated Start Date: 01.2021

Anticipated End Date: 03.2022



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Appendix A: PRISMA Checklist

PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	

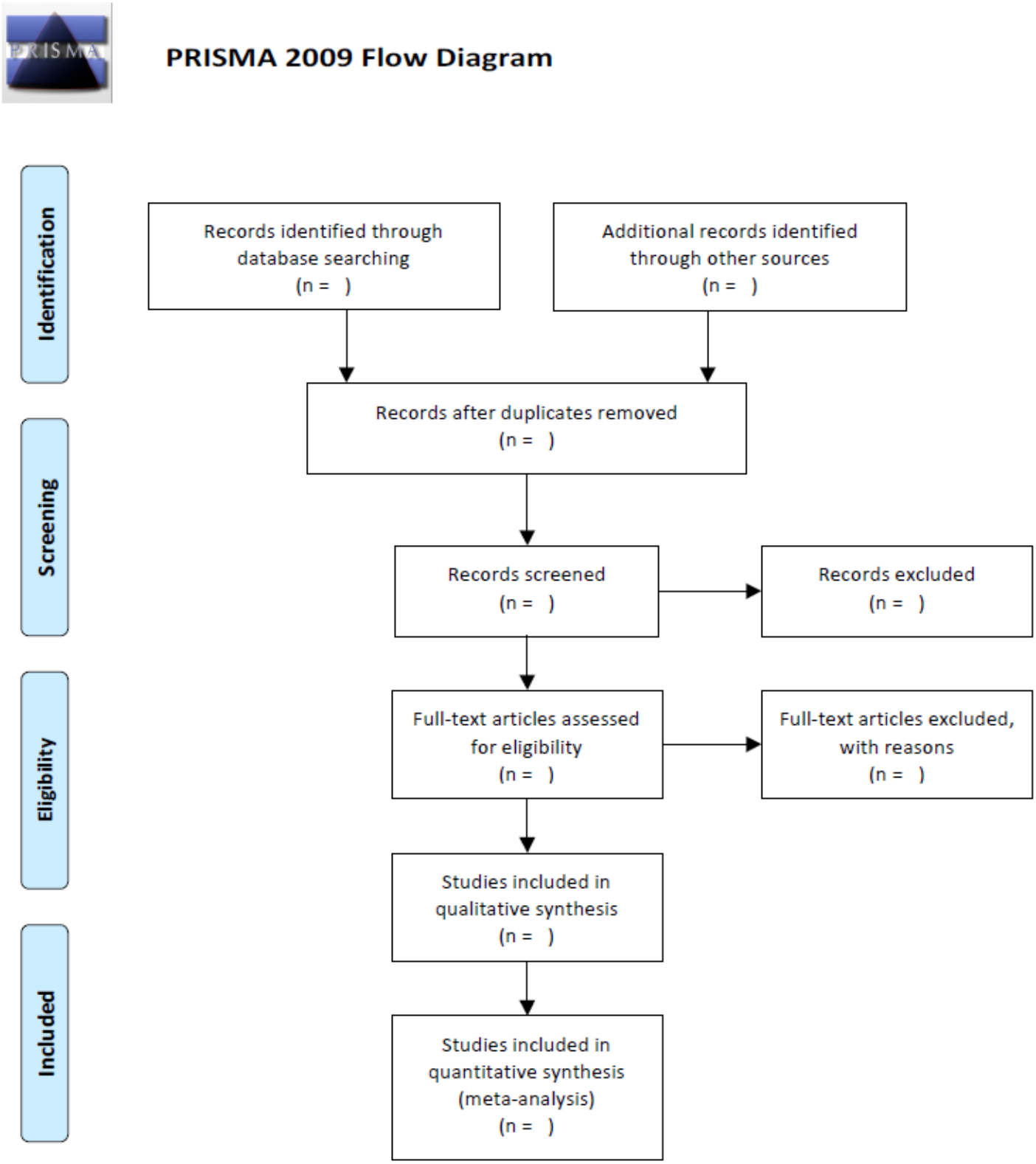
PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit: www.prisma-statement.org.

Appendix B: PRISMA Flowchart



Appendix C: EPHPP Quality Assessment Tool

46 Appendix A: Effective Public Health Practice Project (EPHPP) Quality Assessment Tool. . .

QUALITY ASSESSMENT TOOL FOR QUANTITATIVE STUDIES

COMPONENT RATINGS

A) SELECTION BIAS

(Q1) Are the individuals selected to participate in the study likely to be representative of the target population?

1 Very likely
2 Somewhat likely
3 Not likely
4 Can't tell

(Q2) What percentage of selected individuals agreed to participate?

1 80 - 100% agreement
2 60 – 79% agreement
3 less than 60% agreement
4 Not applicable
5 Can't tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

B) STUDY DESIGN

Indicate the study design

1 Randomized controlled trial
2 Controlled clinical trial
3 Cohort analytic (two group pre + post)
4 Case-control
5 Cohort (one group pre + post (before and after))
6 Interrupted time series
7 Other specify _____
8 Can't tell

Was the study described as randomized? If NO, go to Component C.

No Yes

If Yes, was the method of randomization described? (See dictionary)

No Yes

If Yes, was the method appropriate? (See dictionary)

No Yes

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

Appendix A: Effective Public Health Practice Project (EPHPP) Quality Assessment Tool. . . 47

C) CONFOUNDERS

(Q1) Were there important differences between groups prior to the intervention?

1 Yes
2 No
3 Can't tell

The following are examples of confounders:

1 Race
2 Sex
3 Marital status/family
4 Age
5 SES (income or class)
6 Education
7 Health status
8 Pre-intervention score on outcome measure

(Q2) If yes, indicate the percentage of relevant confounders that were controlled (either in the design (e.g. stratification, matching) or analysis)?

1 80 – 100% (most)
2 60 – 79% (some)
3 Less than 60% (few or none)
4 Can't Tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

D) BLINDING

(Q1) Was (were) the outcome assessor(s) aware of the intervention or exposure status of participants?

1 Yes
2 No
3 Can't tell

(Q2) Were the study participants aware of the research question?

1 Yes
2 No
3 Can't tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

E) DATA COLLECTION METHODS

(Q1) Were data collection tools shown to be valid?

1 Yes
2 No
3 Can't tell

(Q2) Were data collection tools shown to be reliable?

1 Yes
2 No
3 Can't tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

48 Appendix A: Effective Public Health Practice Project (EPHPP) Quality Assessment Tool...

F) WITHDRAWALS AND DROP-OUTS

(Q1) Were withdrawals and drop-outs reported in terms of numbers and/or reasons per group?

1 Yes
2 No
3 Can't tell
4 Not Applicable (i.e. one time surveys or interviews)

(Q2) Indicate the percentage of participants completing the study. (If the percentage differs by groups, record the lowest).

1 80 -100%
2 60 - 79%
3 less than 60%
4 Can't tell
5 Not Applicable (i.e. Retrospective case-control)

RATE THIS SECTION	STRONG	MODERATE	WEAK	
See dictionary	1	2	3	Not Applicable

G) INTERVENTION INTEGRITY

(Q1) What percentage of participants received the allocated intervention or exposure of interest?

1 80 -100%
2 60 - 79%
3 less than 60%
4 Can't tell

(Q2) Was the consistency of the intervention measured?

1 Yes
2 No
3 Can't tell

(Q3) Is it likely that subjects received an unintended intervention (contamination or co-intervention) that may influence the results?

4 Yes
5 No
6 Can't tell

H) ANALYSES

(Q1) Indicate the unit of allocation (circle one)

community organization/institution practice/office individual

(Q2) Indicate the unit of analysis (circle one)

community organization/institution practice/office individual

(Q3) Are the statistical methods appropriate for the study design?

1 Yes
2 No
3 Can't tell

(Q4) Is the analysis performed by intervention allocation status (i.e. intention to treat) rather than the actual intervention received?

1 Yes
2 No
3 Can't tell

Appendix A: Effective Public Health Practice Project (EPHPP) Quality Assessment Tool. . . 49

GLOBAL RATING

COMPONENT RATINGS

Please transcribe the information from the gray boxes on pages 1-4 onto this page. See dictionary on how to rate this section.

A	**SELECTION BIAS**	**STRONG**	**MODERATE**	**WEAK**	
		1	2	3	
B	**STUDY DESIGN**	**STRONG**	**MODERATE**	**WEAK**	
		1	2	3	
C	**CONFOUNDERS**	**STRONG**	**MODERATE**	**WEAK**	
		1	2	3	
D	**BLINDING**	**STRONG**	**MODERATE**	**WEAK**	
		1	2	3	
E	**DATA COLLECTION METHOD**	**STRONG**	**MODERATE**	**WEAK**	
		1	2	3	
F	**WITHDRAWALS AND DROPOUTS**	**STRONG**	**MODERATE**	**WEAK**	
		1	2	3	Not Applicable

GLOBAL RATING FOR THIS PAPER (circle one):

1	STRONG	(no WEAK ratings)
2	MODERATE	(one WEAK rating)
3	WEAK	(two or more WEAK ratings)

With both reviewers discussing the ratings:

Is there a discrepancy between the two reviewers with respect to the component (A-F) ratings?

No Yes

If yes, indicate the reason for the discrepancy

1	Oversight
2	Differences in interpretation of criteria
3	Differences in interpretation of study

Final decision of both reviewers (circle one):

1	**STRONG**
2	**MODERATE**
3	**WEAK**

Appendix D: Risk of bias in non-randomised studies of interventions (ROBINS-I)

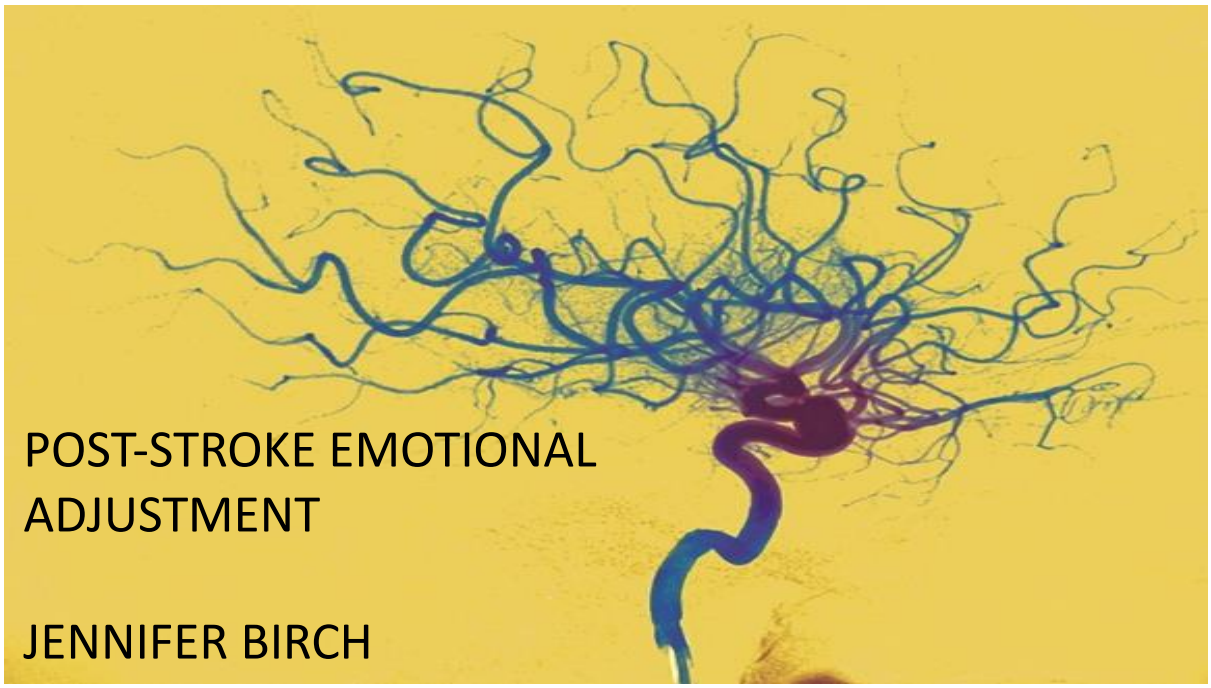
Bias arising from the randomization process	1.1 Was the allocation sequence random?	Y / PY / PN / N / NI	[Description]
	1.2 Was the allocation sequence concealed until participants were recruited and assigned to interventions?	Y / PY / PN / N / NI	[Description]
	1.3 Were there baseline imbalances that suggest a problem with the randomization process?	Y / PY / PN / N / NI	[Description]
	Risk of bias judgement	Low / High / Some concerns	[Support]
	Optional: What is the predicted direction of bias arising from the randomization process?		[Rationale]
Bias due to deviations from intended interventions	2.1. Were participants aware of their assigned intervention during the trial?	Y / PY / PN / N / NI	[Description]
	2.2. Were carers and trial personnel aware of participants' assigned intervention during the trial?	Y / PY / PN / N / NI	[Description]
	2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention beyond what would be expected in usual practice?	NA / Y / PY / PN / N / NI	[Description]
	2.4. If Y/PY to 2.3: Were these deviations from intended intervention unbalanced between groups *and* likely to have affected the outcome?	NA / Y / PY / PN / N / NI	[Description]
	2.5 Were any participants analysed in a group different from the one to which they were assigned?	Y / PY / PN / N / NI	[Description]
	2.6 If Y/PY/NI to 2.5: Was there potential for a substantial impact (on the estimated effect of intervention) of analysing participants in the wrong group?	NA / Y / PY / PN / N / NI	[Description]
	Risk of bias judgement	Low / High / Some concerns	[Support]
	Optional: What is the predicted direction of bias due to deviations from intended interventions?		[Rationale]
Bias due to missing outcome data	3.1 Were outcome data available for all, or nearly all, participants randomized?	Y / PY / PN / N / NI	[Description]
	3.2 If N/PN/NI to 3.1: Are the proportions of missing outcome data and reasons for missing outcome data similar across intervention groups?	NA / Y / PY / PN / N / NI	[Description]
	3.3 If N/PN/NI to 3.1: Is there evidence that results were robust to the presence of missing outcome data?	NA / Y / PY / PN / N / NI	[Description]
	Risk of bias judgement	Low / High / Some concerns	[Support]
	Optional: What is the predicted direction of bias due to missing outcome data?		[Rationale]
Bias in measurement of the outcome	4.1 Were outcome assessors aware of the intervention received by study participants?	Y / PY / PN / N / NI	[Description]
	4.2 If Y/PY/NI to 4.1: Was the assessment of the outcome likely to be influenced by knowledge of intervention received?	NA / Y / PY / PN / N / NI	[Description]
	Risk of bias judgement	Low / High / Some concerns	[Support]
	Optional: What is the predicted direction of bias due to measurement of the outcome?		[Rationale]
Bias in selection of the reported result	Are the reported outcome data likely to have been selected, on the basis of the results, from...		
	5.1. ... multiple outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	Y / PY / PN / N / NI	[Description]
	5.2 ... multiple analyses of the data?	Y / PY / PN / N / NI	[Description]
	Risk of bias judgement	Low / High / Some concerns	[Support]
	Optional: What is the predicted direction of bias due to selection of the reported result?		[Rationale]
Overall bias	**Risk of bias judgement**	Low / High / Some concerns	[Support]
	Optional: What is the overall predicted direction of bias for this outcome?		[Rationale]

Y = Yes, PY = Probable Yes, PN = Probably No, N = No, NI = No information

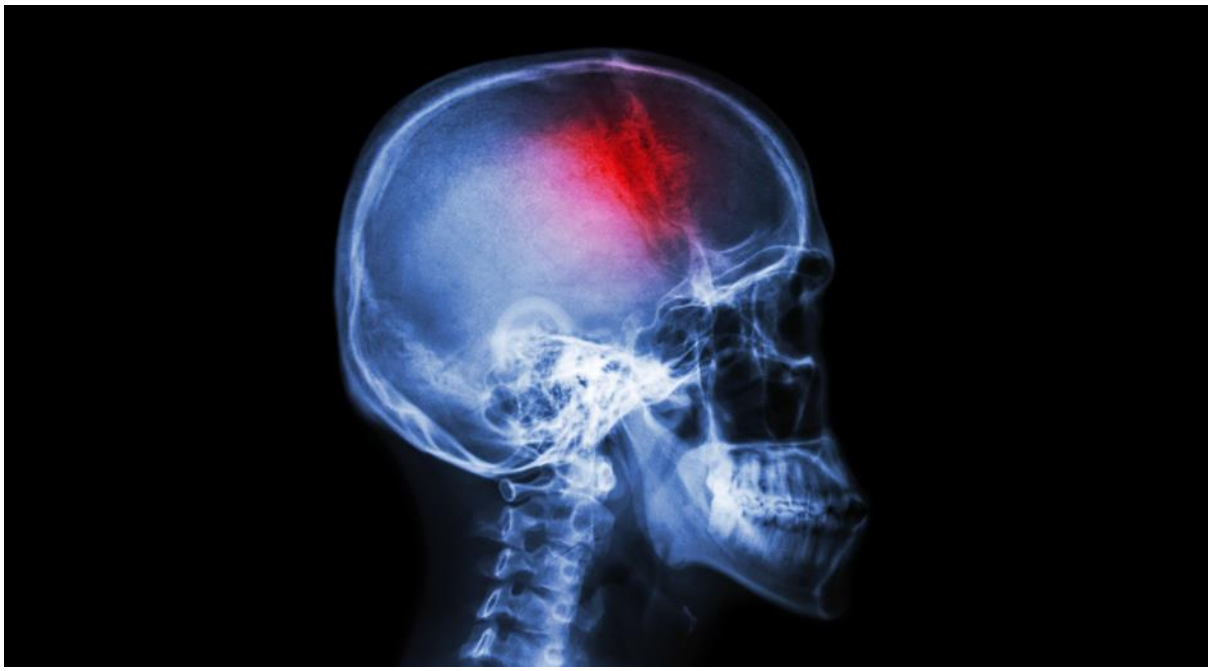
Appendix K

Pecha Kucha Slides with prompts

SLIDE ONE – TITLE



SLIDE 2



There are around 100,000 strokes every year in the UK, which works out at about one stroke every 5 minutes. Stroke causes 38,000 deaths which makes it the leading cause of death and disability. There are over 1.2million stroke survivors and two-thirds will leave hospital with some sort of disability. The average age for having a stroke is decreasing, with one-third of strokes in adults aged between 40-69.

SLIDE 3

75% will have some sort of cognitive impairment including: memory, attention, language, perception. Aphasia in particular is also common and cognitive-communication difficulties present a real challenge to therapists – as these considerations aren't readily built into current delivery.

Psychological mood disturbance, most commonly anxiety and depression, is associated with higher rates of long term disability, suicide, higher carer burden and higher dependency on outpatient services. Typically, it can take between 6-24 months to emotionally adjust to having had a stroke.

30% will suffer depression post-stroke, and ¼ will suffer anxiety. This inhibits patients progress in their rehabilitation (cognitively, functionally and physically). Current recommendations from NICE is to follow stepped care approach (threshold, mild/mod and severe) and offer CBT for anxiety and depression.

SLIDE 4

Evidence for CBT in stroke populations is inconclusive. One RCT in 2003 found CBT to be 'ineffective'. Need to consider session numbers. Studies suggest optimum number is between 15-18 sessions. But some suggest as low as 7. There is no reason why CBT shouldn't work – we just haven't worked out how to deliver CBT in the most effective way for this client group.

SLIDE 5

So this is where my research will hopefully come in. The idea is to create a research project which will facilitate psychological adjustment and augment psychological therapies post-stroke. There is very little research in this area, so it is wide open.

These case studies will have greater impact if they utilise more robust designs such as those with multiple baselines, more regular mood ratings and long-term follow up. They will also inform the development of manuals for future randomised controlled trials and help identify who is likely to benefit from modified CBT after stroke

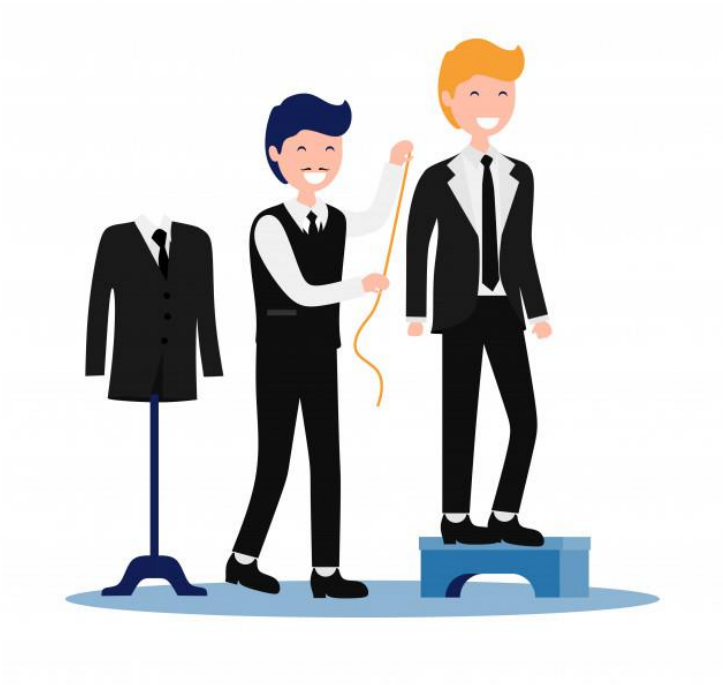
SLIDE 6

My plan at this stage is to consider doing a single-case experimental design to deliver specific brief interventions – but with elements of CBT therapy adjusted, or with elements added in, in line with recommendations made by a few key papers. I'd be looking to recruit ~5 patients from the local Norwich area. I will be doing this with adults (age range, gender, ethnicity etc... to be decided). I will need to decide on a time frame post-stroke for inclusion/exclusion criteria.

Other options include doing an experiment where I compare people who receive current treatment, vs those who will get an augmented version of CBT.

Another option is to design a group intervention and for me to facilitate this for 5-6 people.

SLIDE 7



Researchers suggest that CBT needs to be tailored to each individual

SLIDE 8

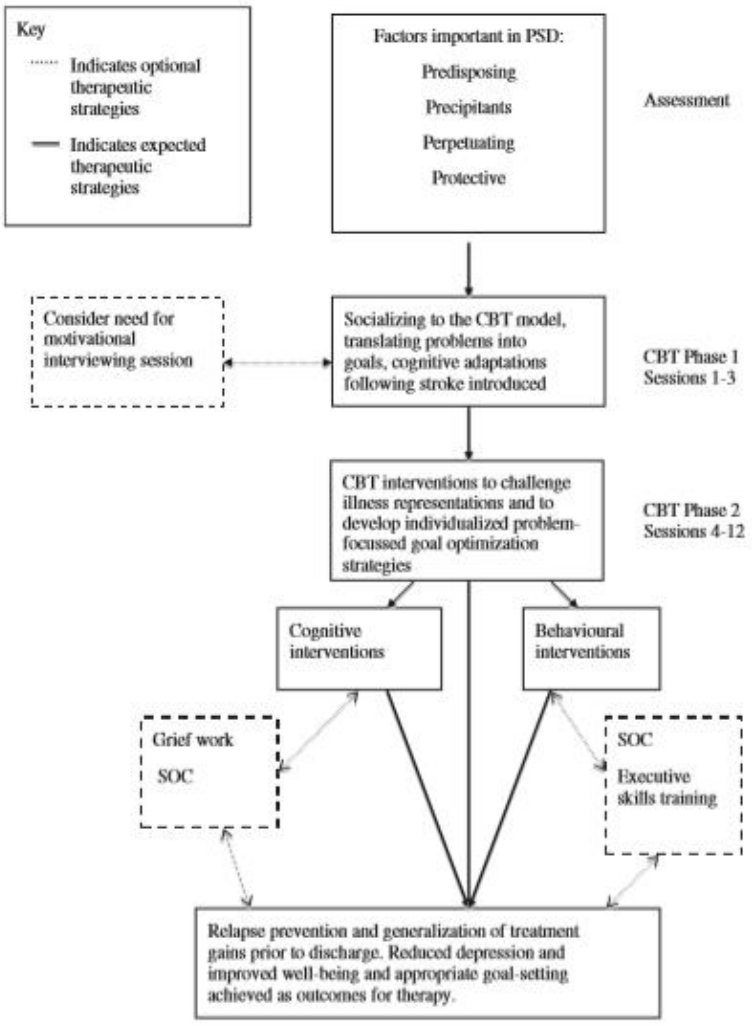
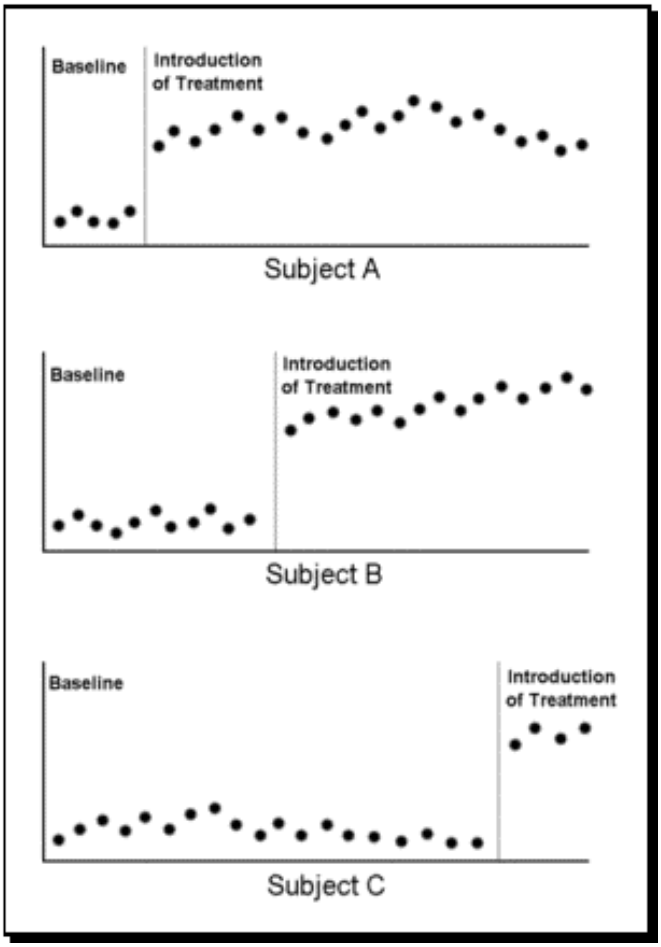


Figure 2. Illustrating augmented, individually tailored CBT for PSD
PSD = post-stroke depression. CBT = cognitive behavioural therapy. SOC = selective optimization with compensation.

There is a need to take into account the trauma, acute onset and loss elements. 5 components: Motivational interviewing, grief resolution, selective optimisation compensation, cognitive adaptations and executive skills training.

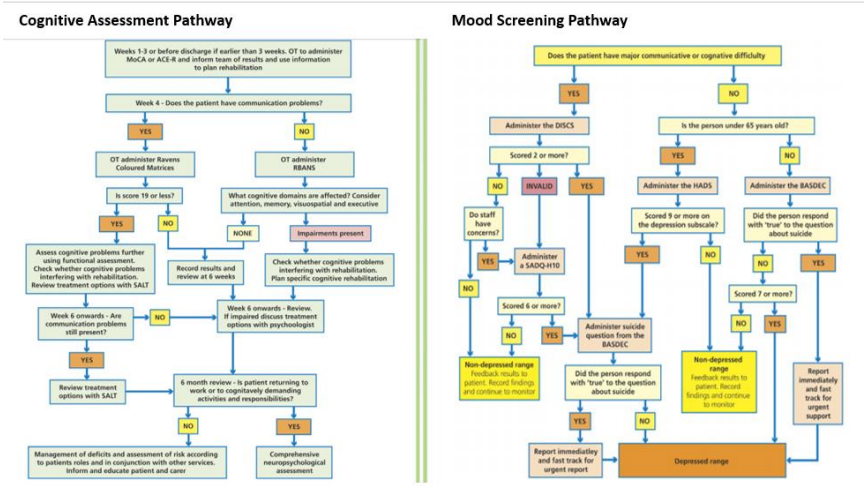
SLIDE 9



One method I'm looking into is Multiple Baseline. One thing I'm aware of is the need to think very carefully about the timescale i.e. if I have X weeks baseline, X number of sessions and X follow up.

Some previous studies have used AB designs where participants have acted as their own controls…but I need to understand more about why multiple baseline would be better.

SLIDE 10



In terms of recruitment – I have not yet decided if I will focus on anxiety, depression or both.

No studies have measures acceptability of interventions with patients so I'm keen to embed that if I can.

SLIDE 11

CLINICAL REHABILITATION

Article

An augmented cognitive behavioural therapy for treating post-stroke depression: description of a treatment protocol

Joyce A Kootker[1], Sascha MC Rasquin[2,3], Peter Smits[4], Alexander C Geurts[1], Caroline M van Heugten[5,6] and Luciano Fasotti[7,8]

Clinical Rehabilitation 2015, Vol. 29(9) 831–843 © The Author(s) 2014 Reprints and permissions: sagepub.co.uk/journalsPermissions.nav DOI: 10.1177/0269215514559987 cre.sagepub.com

SAGE

This series of articles for rehabilitation in practice aims to cover a knowledge element of the rehabilitation medicine curriculum. Nevertheless they ... competency addressed in this article ... physicians working in rehabilitation ...

Abstract

Aim: Currently, no evidence-based ... new psychological intervention ...

Method of protocol development ... and was shown feasible in a pilot ... both sensori-motor, cognitive, and ... resolution, and psycho-education. ... of the patients (i.e. be concrete, ... augmented the psychologist-admi ... therapist aimed at facilitating par ... hour sessions with a psychologis ... therapist. Currently, the effectiv ...

Discussion: The proposed ... behavioural therapy in a strok ... occupational or movement th ...

Update article

Single-case experimental designs to assess intervention effectiveness in rehabilitation: A practical guide

CrossMark

Agata Krasny-Pacini[a,b,c,*], Jonathan Evans[d]

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ARTICLE INFO

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Keywords:
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Single-case
Multiple baseline
Alternating treatment
Rehabilitation

ABSTRACT

Single-case experimental designs (SCED) are experimental designs aiming at testing the effect of an intervention using a small number of patients (typically one to three), using repeated measurements, sequential (± randomized) introduction of an intervention and method-specific data analysis, including visual analysis and specific statistics. The aim of this paper is to familiarise professionals working in different fields of rehabilitation with SCEDs and provide practical advice on how to design and implement a SCED in clinical rehabilitation practice. Research questions suitable for SCEDs and the different types of SCEDs (e.g., alternating treatment designs, introduction/withdrawal designs and multiple baseline designs) are reviewed. Practical steps in preparing a SCED design are outlined. Examples from different rehabilitation domains are provided throughout the paper. Challenging issues such as the choice of the repeated measure, assessment of generalisation, randomization, procedural fidelity, replication and generalizability of findings are discussed. Simple rules and resources for data analysis are presented. The utility of SCEDs in physical and rehabilitation medicine (PRM) are discussed.

Neuropsychological Rehabilitation, 2013
Vol. 23, No. 6, 798–810, http://dx.doi.org/10.1080/09602011.2013.820135

Routledge

Treating anxiety after stroke using cognitive-behaviour therapy: Two cases

Ian I. Kneebone[1,2], and Fiona W. Jeffries[3]

[1]Virgin Care, Department of Psychology, Farnham, Surrey, UK
[2]University of Western Sydney, School of Social Sciences and Psychology, Penrith, NSW, Australia
[3]University of Surrey, School of Psychology, Guildford, Surrey, UK

(Received 9 April 2013; ...

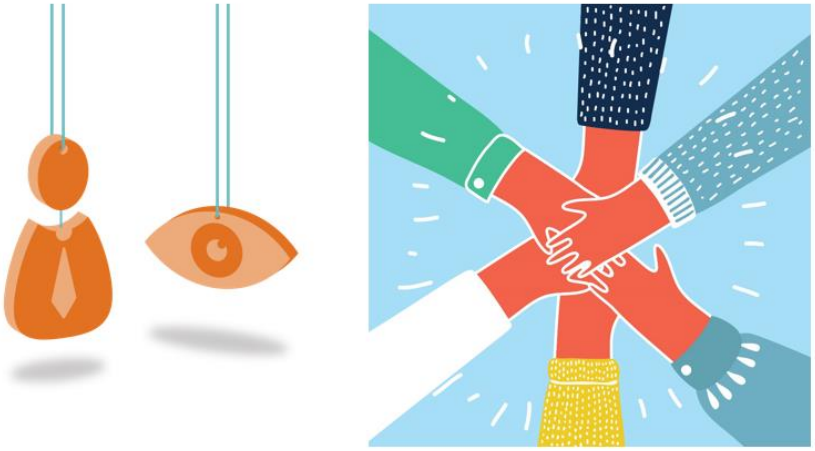
... However, information on how to ... lation is highly limited. Modified ... potential to assist. Two cases of ... iety after stroke are presented. ... icits in executive and memory ... communication difficulties in ... wer seven and nine sessions, ... wing the intervention, and ... follow-ups. Further case- ... ed to support and develop ...

... apy; Single case design.

Protocols for delivering adjusted CBT interventions are out there – Kootker combines anxiety and depression, but not executive element! Also Niall's Modified Social Cognitive Transition Model – theory of understanding post-stroke emotional adjustment.

SLIDE 12

SUPERVISION AND COLLABORATION



Niall explained that he has not yet supervised a single case experimental design study before, so we think it would be helpful to have a second supervisor – potentially Fergus. Niall has also floated the idea of having John Evans (Glasgow) to assist with the statistical/analysis side, and Professor Kneebone who is the main researcher in the field. Clinical supervision may be provided by Tom Steverson who will hopefully be able to help with recruitment.

SLIDE 13

Next steps: To meet with Niall, to keep reading more to hone in my ideas/questions, to think about meeting with Stroke Groups who could give insight and help me to finalise my ideas.