Investigating the Feasibility and Acceptability of Technology-Based Cognitive Rehabilitation after Stroke

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Thesis Portfolio Abstract

Purpose: The primary aim of this thesis was to evaluate the feasibility and acceptability of technology-based cognitive rehabilitation interventions in stroke. Related objectives were to better understand the challenges faced by trials in this area, as well as to summarise the technology-based cognitive rehabilitation interventions that have been tested in stroke.

Design: The portfolio contains the following sections: a) an introduction to the thesis portfolio, b) a systematic review of the feasibility and acceptability of technology-based cognitive rehabilitation in stroke, c) a bridging chapter highlighting the gaps identified by the systematic review that the empirical paper aimed to address, d) an empirical paper of a feasibility randomised-controlled trial of two online asynchronous psychological interventions for stroke survivors, one targeting executive functioning and problem-solving and the other providing psychoeducation about stroke and neuroanatomy, e) an additional methodology chapter for the empirical paper, and f) an overall discussion and critical evaluation.

Findings: The systematic review provides preliminary evidence that technology-based cognitive rehabilitation interventions are feasible and acceptable to research in a stroke population. Feasibility indicators aggregated across the identified studies suggest that research in technology-based cognitive rehabilitation interventions in stroke faces similar challenges to that of other forms of cognitive rehabilitation, especially recruitment inefficiency. Acceptability indicators were found to be positive where reported, although the majority of studies did not report the relevant data, making the findings difficult to generalise. The empirical paper found that a full trial of the two interventions we developed would be feasible, and that the interventions were acceptable to the stroke survivors recruited.

Originality/value: The systematic review and empirical research project presented in this thesis portfolio provide novel contributions to the literature on the feasibility and acceptability of technology-based cognitive rehabilitation in stroke, as well as highlight the potential role of these interventions in wider service provision. The portfolio has implications for future research conducted in this field, as well as for the ongoing initiatives to integrate technology-based interventions in standard post-stroke rehabilitation.

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Chapter One: Introduction to the Thesis Portfolio

Stroke is a leading cause of disability in industrialised nations, and the largest cause of complex and long-term disability in the United Kingdom (Stroke Association, 2018). Over 113,000 individuals in the United Kingdom suffer a stroke each year, with numbers projected to increase by as much as 60% between 2015 and 2035 (Rothwell et al., 2004; King et al., 2020).

Stroke is defined as "a neurological deficit attributed to an acute focal injury of the central nervous system by a vascular cause" (Sacco et al., 2013). There are two main types of stroke, depending on whether the disruption in blood supply is caused by a blockage (ischaemic stroke) or a rupture (haemorrhagic stroke) in a blood vessel within the Central Nervous System. Ischaemia and haemorrhage trigger blood supply disruptions that result in a cascade of pathophysiological responses, leading to cell death (Sekerdag et al., 2018). Ischaemic strokes are more common, accounting for approximately 62.4% of all stroke events (Feigin et al., 2021).

Despite the potential severity of having a stroke, advances in medical treatment have halved stroke-related mortality in the last two decades (NHS Digital, 2018), with the majority of stroke survivors in the UK being discharged back to the community (SSNAP, 2016). However, up to two thirds of stroke survivors are discharged from hospital with physical, cognitive, and emotional stroke-related impairments, which they have to manage at home (Adamson, 2004; Lutz et al., 2011). The increase in survival rate, in the context of an aging population, means that there is an increase in the number of stroke survivors who may benefit from community-based post-stroke rehabilitation. Additionally, first-time strokes are occurring at an earlier age compared to a decade ago, with over a quarter of strokes occurring to people of working age (Stroke Association, 2019). Post-stroke impairments can impede return to or ability to remain in employment (Balasooriya-Smeekens et al., 2016), posing additional financial pressures, both at the individual and societal level. In line with this, the NHS Long-Term Plan (NHS, 2019) aims to implement and further develop higher intensity rehabilitation provided to patients out of hospital. The National Stroke Service Model (NHS, 2022) proposes an Integrated Community Stroke Service to extend access to post-stroke rehabilitation, ensuring that all stroke patients are seen by an integrated multidisciplinary team and that rehabilitation is provided in line with the patient's need, with the option for rereferral after discharge.

Cognitive deficits can occur in the acute and chronic phases after stroke and include problems with memory, perception, language, attention, executive functioning, depending on the location of the stroke (Patel et al., 2003; Tatemichi et al., 1994). A review of studies involving nearly 300,000 people found that cognitive impairment can be detected in as many as 80% of stroke survivors (Sun, Tan & Yu, 2014). This is important because cognitive impairment has been found to be a critical determinant of overall neurorehabilitation outcome in stroke. The presence of cognitive impairments affects everyday functioning and wellbeing post-stroke over and above physical impairments caused by stroke (Claesson, 2005). Cognitive and emotional impairments have also been described as causing the most strain on the stroke survivor's social system (Anderson, Linto & Stewart-Wynne, 1995; van den Heuvel et al., 2001).

Rehabilitation is one of the most important elements of post-stroke care, leading to better recovery and higher levels of independence (National Institute for Health and Care Excellence, 2013; NICE). Cognitive rehabilitation is an umbrella term for a wide range of theory-based interventions that aim to reduce dysfunction through reinforcing, strengthening, or re-establishing previously learned patterns of behaviour or alternatively, establishing new patterns of cognitive activity or compensatory mechanisms and strategies (Mantovani et al., 2020). There is evidence of widespread unmet need for cognitive rehabilitation post-stroke, with a survey of 1,424 stroke survivors conducted by the Stroke Association (2016) concluding that nearly one in two were unhappy with the support they received for memory problems and fatigue. This was echoed by a recent consensus that highlighted cognitive function post-stroke as an area of unmet need (McDonald et al., 2019), as well as the Stroke Association Priority Setting Partnership (Watson et al., 2021) ranking the evaluation of cognitive dysfunction and interventions to reduce it as one of the highest priorities for stroke research, only second to the assessment of the impact of psychological effects and interventions to reduce them.

Executive functions (EF) are a heterogenous, inter-related group of higher-level cognitive processes which include inhibition, planning, problem-solving, task-switching, attention, self-monitoring, that give rise to top-down, goal-directed behaviour (Godefroy & Stuss, 2007; Pluck et al., 2020). They are primarily associated with the frontal lobe, more specifically the prefrontal cortex, but also to white matter connections and other brain regions such as subcortical structures (Poulin et al., 2012; Sereno & Bolding, 2009). It is commonly argued that frontal lobe functions are necessary when tasks are complex, novel, or require

considerable attentional resources (Stuss et al., 2011). Research suggests that frontal lobe functions can be differentiated into several domains (Cicerone et al., 2006; Stuss, 2007). 'Executive cognitive functions' are theorised to comprise the "cold" functions involved in the control of more automatic processes, such as those associated with memory and attention, as opposed to "hot" components, such as those involved in minute-to-minute regulation of social behaviour or decision-making involving emotional information (Grafman & Litvan, 1999). The model proposed by Diamond (2013) provides a similar delineation between 'core' EF components including working memory, inhibitory control, and cognitive flexibility, and 'higher-order' components, including reasoning, problem-solving, and planning. One model proposed by Stuss (2011) integrates these two categories and argues that there are five key frontal processes: task setting, monitoring, energization, (behavioural/emotional) selfregulation, and metacognition. The model argues that executive cognitive functions (i.e., task setting and monitoring) represent only one cognitive domain subserved by the frontal lobes. Similarly, Barkley's model (2012) describes five key frontal functions that mediate goaldirected behaviour: time management, organisation and problem-solving, exercising restraint, self-motivation, and emotion regulation.

Executive dysfunction is a common consequence of stroke estimated to affect up to 75% of stroke survivors (Lesniak et al., 2008; Zinn et al., 2007). As EFs are implicated in most aspects of human life, the disruption of these processes can have devastating consequences for quality of life, restricting the ability to perform daily functional activities (Poulin et al., 2012). Walker and colleagues (2004) investigated the impact of executive dysfunction on stroke rehabilitation and found that people who had both executive and motor impairments were unable to regain the ability to put on a polo shirt, whereas those with deficits in only one of those areas were able to regain independence in this task. This highlights the way in which executive dysfunction interacts with other deficits and hinders rehabilitation and regaining independence in activities of daily living. Other consequences of executive impairments after stroke include impulsivity, decision-making difficulties, cognitive inflexibility, and deficits in attentional control (Povroznik et al., 2018). More broadly, this means that people are less likely to engage in rehabilitation, return to work, and engage in social participation (Poulin et al., 2012). Maintaining goal-directed behaviour is theorised to heavily depend on executive functions (Duncan, 1986), and is a common difficulty post-stroke (Levine et al., 2000). According to Duncan (1986), much of the

disorganized behaviour seen in patients with frontal systems dysfunction can be attributed to impairments in the ability to construct and use goal lists to direct their behaviour.

As EF deficits interact with other stroke-related impairments, EF interventions may have the potential to augment stroke rehabilitation for other deficits, as well. Given that EF skills, which overlap significantly with general adaptive coping skills, are needed when faced with novel, complex, or stressful situations, EF skills training might be helpful to anyone post-stroke, as it would support them thinking about goals, problem-solving and getting organised, all key aspects of optimising stroke rehabilitation, and it should be particularly useful for people who have EF deficits (Williams & Thyer, 2009).

Different intervention approaches have been suggested for dysexecutive problems, including targeted remediation and retraining of specific EFs, teaching people to use internal strategies to compensate for deficits (e.g., learning to "stop and think" before acting), and using external compensatory mechanisms (e.g., learning to use checklists or phone reminders; Chung et al., 2013; Cicerone et al., 2019; 2000). Treating EF difficulties has been recommended by the National Clinical Guideline for Stroke (Intercollegiate Stroke Working Party, 2016). Systematic reviews of problem-solving training strategies suggest that they are effective in reducing executive dysfunction after a traumatic brain injury (Cicerone et al., 2000; Kennedy et al., 2008). However, this is not sufficient evidence to also recommend these interventions post-stroke, as differences in treatment effects have been documented between traumatic brain injury and stroke patients (Poulin et al., 2012). Goal Management Training (GMT; Levine et al., 2000; Levine et al., 2011; Robertson, 1996) is a standardised EF rehabilitation approach based on Duncan's (1986) model of disorganised behaviour due to frontal lobe lesions. It includes psychoeducation, attention training, and self-monitoring, and has been found to lead to improvements in EF measures in a variety of populations including adults with acquired brain injury and older adults (Stamenova & Levine, 2018). A trial of a brief GMT intervention reported improvement in the achievement of daily intentions in adults with acquired brain injury, indicating its potential usefulness, even when offered briefly (Gracey et al., 2017). However, there is not enough evidence for this intervention for EF rehabilitation in stroke patients (Chung et al., 2013).

Systematic reviews by Chung and colleagues (2013) and Poulin and colleagues (2019) state that current evidence is insufficient to reach generalised conclusions supporting the effectiveness of specific stroke EF rehabilitation interventions and highlight the need for high quality Randomised-Controlled Trials (RCTs) on the efficacy of EF rehabilitation

interventions. Current NICE (2013) stroke rehabilitation guidelines for adults do not mention EF at all, again reflecting the lack of robust evidence in this area.

Due to the Covid-19 pandemic, many rehabilitation approaches can now be delivered remotely to protect the safety of patients, or where in-person rehabilitation would not be feasible, such as in large rural areas, or areas with poor transport links. While cognitive rehabilitation is traditionally conducted face-to-face using paper-and-pencil tools, computer programs, or more recently virtual reality, can also be used to deliver these interventions. Technology-based delivery may be a way to make cognitive rehabilitation more easily accessible to stroke patients. The delivery of synchronous or asynchronous remote rehabilitation interventions is commonly known as telerehabilitation, a branch of telehealth that uses information and communication technologies across distance or time (Brennan et al., 2009; Stephenson et al., 2022). With stroke survivors frequently reporting insufficient support and rehabilitation following discharge from hospital (Pindus et al., 2018), telerehabilitation may provide an accessible, cost-effective and scalable way to increase provision of evidence-based interventions. Telerehabilitation has several advantages over face-to-face delivery of interventions, including greater access to specialized care, reduced transport and mobility-related barriers, permitting higher frequency of sessions, as well as enhanced monitoring of outcomes (English et al., 2022). However, its reliance on technological equipment and internet access may make it difficult to access for some people. Recent reviews have compared stroke telerehabilitation to in-person care finding that it can be as effective as usual care for motor function, activities of daily living, independence, and satisfaction/ quality of life (Appleby et al., 2019; Laver et al., 2020). However, the current evidence is mostly limited to case management and advice, or motor retraining (English et al., 2022).

A subtype of technology-based cognitive rehabilitation that has shown promise in some areas of cognition such as memory and executive functioning (van de Ven, 2016) is computer-assisted cognitive rehabilitation (CACR). This refers to standardised and structured training software delivered on computers or touch-screen devices that aim to restore specific cognitive functions such as memory or attention and adjust their difficulty in line with the individual's performance (Baltaduoniene et al., 2019). However, similar to other areas of research in stroke cognitive rehabilitation, systematic reviews have highlighted the paucity of high-quality evidence (Mingming et al., 2020), and at this point in time is it not possible to recommend CACR as a viable alternative to traditional cognitive post-stroke rehabilitation. As highlighted by systematic reviews, it is essential that more high-quality research is conducted in the area of stroke cognitive telerehabilitation. Randomized-controlled trials (RCTs) are widely regarded as the most rigorous design to determine the efficacy of new interventions, as they allow for causality to be established and limit biases that may lead to systematic differences between intervention groups (Ahn & Ahn, 2010). NICE guidelines, as well as Cochrane reviews, are predominantly based on RCT evidence, and it is therefore essential for further high-quality evidence to be available for consideration in guidance.

Groups conducting stroke RCTs face several barriers, a significant one being recruitment challenges, with numerous trials failing to achieve their target sample size, which affect the validity of the results. A recent systematic review reported that recruitment efficiency in stroke trials decreased over the last 25 years, with the majority of stroke trials reporting a low recruitment yield (Feldman, Kim & Chiong, 2017). Other challenges include patient-specific issues, with stroke-related pain, fatigue, or other symptoms making it difficult for stroke survivors to engage with research, as well as staffing issues, with research teams sometimes inadequately staffed to manage trials (Sheehy, 2020). To pre-empt such challenges, there has been increasing emphasis on conducting preliminary research prior to large-scale trials that require significant investment (Whitehead, Sully, & Campbell, 2014). Feasibility and pilot studies therefore play a key role in stroke research, supporting the development and refinement of study procedures, and reducing the likelihood of a full subsequent RCT experiencing unforeseen challenges (Pearson et al., 2020).

There is no universally accepted definition of feasibility studies. Sometimes the terms feasibility and pilot trials are used interchangeably in the literature, whereas others define them as separate concepts (Whitehead, Sully & Campbell, 2014). The National Institute for Health and Care Research (NIHR) states that "A feasibility study asks whether something can be done, should we proceed with it, and if so, how" (Eldridge et al., 2016). Randomised pilot studies are a subset of feasibility research, conducted to check whether study processes (including recruitment, randomisation, treatment, etc.) all run smoothly (Pearson et al., 2020). Conducting feasibility studies prior to embarking in a full trial is important and has practical, as well as ethical considerations, as it is critical that a trial can provide valid results. The Medical Research Council (MRC) guidelines on developing complex interventions (Skivington et al., 2021) outlines four distinct stages in the development and implementation of complex interventions: (1) development; (2) feasibility/piloting; (3) evaluation; and (4)

implementation, highlighting the role of feasibility and pilot trials within the process of researching the efficacy of treatments.

The primary aim of this thesis was to evaluate the feasibility and acceptability of technology-based cognitive rehabilitation interventions in stroke. Due to the potential of technology-based interventions to make cognitive rehabilitation more accessible to stroke survivors, we focussed on interventions delivered using computers, tablets and mobile phones as the most commonly available devices. Related objectives were to better understand the challenges faced by trials in this area, as well as to summarise the technology-based cognitive rehabilitation interventions that have been tested in stroke. Chapter 2 presents a systematic review on the feasibility and acceptability of technology-based cognitive rehabilitation interventions in stroke. Chapter 3 highlights the gaps identified by the systematic review that the empirical paper aimed to address. Chapter 4 presents a novel feasibility RCT of two online asynchronous psychological interventions for stroke survivors, one targeting executive functioning and problem-solving, and the other providing psychoeducation about stroke and neuroanatomy. Chapter 5 provides more information relation to the implementation of the RCT, focusing on aspects relating to NHS recruitment. The Thesis Portfolio closes with Chapter 6, where the findings of the systematic review and feasibility RCT are discussed, with reference to their implications for further research and clinical practice.

Chapter Two: Systematic Review

Prepared for submission to *Neuropsychological Rehabilitation (see Appendix A for author guidelines)*

The Feasibility and Acceptability of Technology-Based Cognitive Rehabilitation Interventions after Stroke: a Systematic Review

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Abstract

Background: The provision of post-stroke cognitive rehabilitation is variable despite the high prevalence and impact of cognitive impairments after stroke. Technology-based interventions may increase accessibility of cognitive rehabilitation for some stroke survivors, but reviews highlight a lack of relevant high-quality efficacy trials. Methodological issues faced by research in this field indicate a need to understand the feasibility of researching technology-based cognitive rehabilitation interventions, and their acceptability for stroke survivors, prior to full-scale efficacy trials.

Methods: Five electronic databases (MEDLINE, EMBASE, Web of Science, PsychINFO, NeuroBITE) were searched on 18th October 2022 for studies of technology-based cognitive rehabilitation in stroke. Data were extracted on participant, study, and intervention characteristics. Study quality was evaluated using the Joanna Briggs Institute Critical Appraisal Checklist and a narrative synthesis was used to summarise evidence relating to the feasibility and acceptability of the studies.

Results: Thirty-eight studies with a total of 2261 participants were included. There is preliminary evidence to support technology-based cognitive rehabilitation as a feasible to research and acceptable method to provide cognitive rehabilitation interventions to stroke patients. Studies generally reported low drop-out rates, low refusal rates, and positive feedback from participants, where this was sought. One challenge was slow recruitment. Key acceptability indicators were not adequately reported by the majority of the trials.

Conclusion: There is preliminary evidence that trials of technology-based cognitive rehabilitation are feasible and acceptable in stroke, but more attention is needed to routine, consistent reporting of feasibility and acceptability indicators in this field.

Keywords: Stroke; Cognitive Rehabilitation; Telerehabilitation

Prospero Registration: CRD42022359188

Introduction

Cognitive impairments, for example in memory, attention, or executive functioning, affect as many as 80% of stroke survivors (Sun, Tan & Yu, 2014). They are an important target for post-stroke rehabilitation, particularly as they may interfere with the ability to engage with other forms of rehabilitation (McDonald et al., 2019) and are associated with poorer outcomes including lower quality of life and reduced ability to perform activities of daily living (Claesson, 2005).

National Clinical Guidelines recommend the treatment and follow-up of cognitive dysfunction after stroke (Intercollegiate Stroke Working Party, 2016), but the provision of cognitive rehabilitation is variable, with some patients able to access this and others not. For example, in the UK, a recent survey found that as many as 77% of stroke survivors reported cognitive difficulties, with nearly 50% of them rating the support they received for this as poor (Stroke Association, 2016). This suggests that there is a need for wider and more easily accessible provision of cognitive rehabilitation post-stroke.

One method that could increase provision and intensity of post-stroke cognitive rehabilitation in a flexible, scalable, and cost-effective way is telerehabilitation, a branch of telehealth that uses information and communication technologies across distance or time (Brennan et al., 2009; Stephenson et al., 2022). More stroke survivors have access to personal digital devices such as laptops and smartphones than ever before and the Covid-19 pandemic led to a wider adoption of remotely delivered interventions. Cognitive telerehabilitation can be delivered both synchronously and asynchronously, using devices such as computers, telephones or other touch-screen devices, and, more recently, virtual reality. A subtype of technology-based cognitive rehabilitation that has shown promise in areas of cognitive rehabilitation (CACR). This provides rehabilitation for cognitive deficits using standardised and structured training software delivered on computers or touch-screen devices with task difficulty calibrated according to individual performance (Baltaduonienė, Kubilius & Mingaila, 2018).

The use of computer-assisted interventions is recommended by the UK National Clinical Guideline for Stroke (Intercollegiate Stroke Working Party, 2016), but due to limited evidence no specific interventions can be recommended. Recent systematic reviews of the efficacy of CACR in stroke also highlight the paucity of high-quality clinical trials in this area, with studies having small sample sizes, methodological issues, or not providing all the key information (Baltaduonienė, Kubilius & Mingaila, 2018; Loescher et al., 2019; Zhou et al., 2019).

Is it essential that factors influencing the feasibility of technology-based cognitive rehabilitation trials, as well as the acceptability of this type of interventions in a stroke population, are understood prior to the commencement of full-scale efficacy trials, as this will ensure that they run smoothly and provide high-quality efficacy data. Feasibility relates to whether the study design, procedures, and intervention can be carried out, whereas acceptability relates to whether they are appropriate from the participant's perspective (Office for Health Improvement and Disparities, 2020). The feasibility and acceptability of studies researching technology-based cognitive rehabilitation have not been evaluated to date, and therefore the barriers are not well understood. Although commonalities have been documented between stroke and TBI, they differ in their aetiology, incidence age, and lesion location, and therefore there may be differences in the degree, characteristics, and course of recovery in cognitive impairment between these two populations (Arciniegas, Held & Wagner, 2002). Due to these potential differences, findings from research conducted on TBI patients may not generalise to stroke patients.

This systematic review aims to (1) systematically search published literature to identify technologies used to provide cognitive rehabilitation after stroke, and (2) assess the evidence for their acceptability and feasibility, to support the identification of barriers to their adoption. It focuses on studies of interventions that would typically fall within the remit of clinical neuropsychology, such as interventions for acquired deficits affecting perception, processing speed, attention, memory, or executive functioning.

Methods

This review complies with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (Page et al., 2021; see Appendix C). A protocol for this review was registered with the PROSPERO systematic review protocol registry (CRD42022359188).

Search Strategy and Study Selection

Five electronic bibliographic databases (MEDLINE, EMBASE, Web of Science, PsychINFO, and NeuroBITE) were searched on 18th October 2022. The search strategy aimed to identify all published trials of technology-based cognitive rehabilitation interventions for stroke survivors. The PICOS framework (Schardt et al., 2007; see Figure 2.1) was used to define the research question and formulate eligibility criteria. Combinations of search terms were used to identify relevant articles, such as: "Cognitive rehabilitation", "Computer" and "Stroke" (see Appendix B for full search strategy).

Figure 2.1.

PICOS tool.

Population:	Stroke (Adult)
Intervention:	(Technology-based/ Online / Remote) Cognitive Rehabilitation
Comparison:	Another Intervention / Waitlist / No comparison
Outcomes:	Acceptability and Feasibility
	Acceptability = patient's willingness to use the technology. Measured through reporting of expressed refusal, adherence to treatment, user satisfaction.
	Feasibility = can the study design, procedures, and intervention be carried out. Measured through recruitment and drop-out rates.
Study:	Randomised-Controlled Trials and Cohort Studies (controlled and uncontrolled)

Articles were included if they were published in or after 2000, in English, and provide primary data from adults (over 18 years old) with a history of stroke, receiving any form of technology-based cognitive rehabilitation intervention. The year 2000 was used as the cut-off after an initial scoping search revealed that no relevant articles were likely to have been published prior to this date. We included any interventions delivered through a digital device such as a computer, mobile phone, or tablet that were intended to assist or provide cognitive rehabilitation after stroke, irrespective of the setting of the study. Cognitive rehabilitation was defined as an intervention that aims to restore or compensate for cognitive deficits (Anderson et al., 2010; Cicerone, 2000). Virtual-reality cognitive rehabilitation interventions and other brain-computer interface systems were considered to be distinct from other technology-based interventions, due to their immersive nature, and were thus not included in this review. One study (Akinwutan et al., 2010) using a driving simulator was included, as the participants interacted with the intervention via a computer screen rather than though immersive technology. Controlled and uncontrolled cohort studies, and randomized controlled trials were included. Studies were included if they had control conditions in which participants did

not receive technologies intended for remote cognitive rehabilitation. Studies where there was a mixed population (e.g., people with stroke or traumatic brain injury) were included where the stroke population was reported separately. There were no exclusion criteria dependent upon time after stroke when the intervention was delivered.

The identified papers were retrieved and imported into two reference managers (Endnote and Rayyan) and were individually screened by title and abstract. Any duplicate articles were removed. Relevant information was extracted from the final selection of full text articles.

The main outcomes of interest were:

- Qualitative and quantitative measures of acceptability of relevant technologies measured through reporting of expressed refusal, adherence to treatment, or user satisfaction (patient surveys and questionnaires).
- Measures of feasibility of the trial of relevant technologies including recruitment and drop-out rates.
- Intervention characteristics.

Data Extraction

Following study identification, data were extracted by one reviewer (CE) into a prepiloted, standardized form created on a spreadsheet software. The data extracted were: title; author; publication year; study design; patient characteristics (age, gender, number, type of stroke, timing of stroke before intervention); descriptions of types/design of the intervention: setting; targeted cognitive domain of the intervention; delivery technology, type of intervention delivered and its duration; indicators of intervention acceptability (refusal to participate, participant satisfaction ratings, adherence to intervention); measures of feasibility (recruitment and study completion rates). Where studies did not have a control comparison, this information was extracted. Intervention characteristics were extracted using the Template for Intervention Description and Replication (TIDieR) framework for the description of intervention components in trials (Hoffmann et al., 2014).

Quality Assessment

Study quality was evaluated using the Joanna Briggs Institute Critical Appraisal Checklist for RCTs (The Johanna Briggs Institute, 2017). This consists of 13 items, with each item labelled "Yes", "No", "Unclear", or "Unsuitable", as appropriate. The elements of the rating system include randomisation, blinding, the reliability of outcome measurement, and the appropriateness of the statistical analysis methods used. Study quality was assessed for all studies by one reviewer (CE) and a random subset (25%) were independently reviewed by a second reviewer (GO). Any discrepancies in the results between the two reviewers were resolved by discussion.

Narrative Synthesis

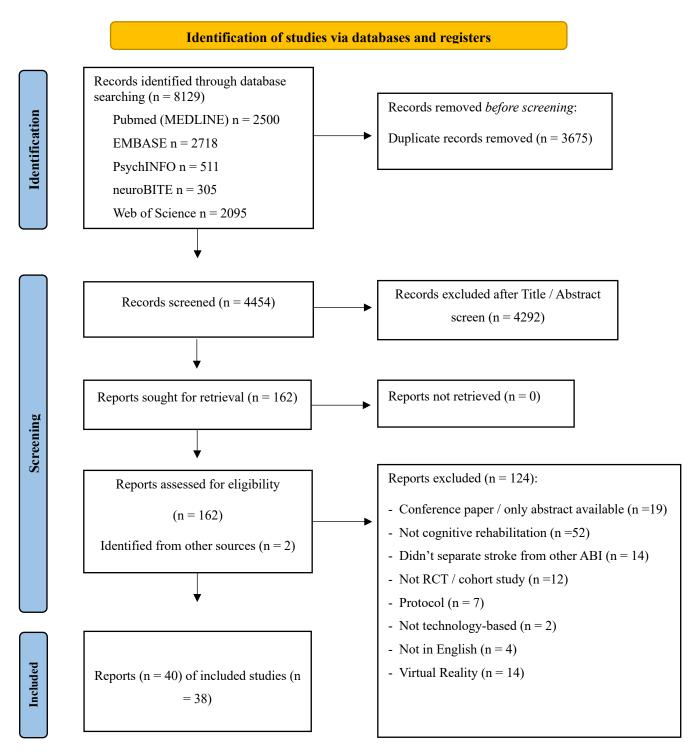
A narrative synthesis of relevant quantitative and qualitative data from the included studies was conducted, and followed the guidance by Popay and colleagues (2006). Descriptive statistics were used to summarise quantitative findings. Study characteristics, types of technological interventions (e.g., delivered via computerised programs) and their acceptability and feasibility of use were summarised. The key areas of acceptability that were synthesised were refusal to participate, participant satisfaction with the intervention, and participant adherence to the intervention protocol. The key areas of feasibility were dropout rates and ease of recruitment.

Results

The number of papers remaining after each identification and screening phase is represented in Figure 2.2.

Figure 1.2.

Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Study Selection.



Overview of Included Studies

Study characteristics are shown in Table 2.1. Thirty-eight studies described across 40 published papers were included, with 2261 participants in total. Of these, 30 were randomised-controlled trials (Akinwuntan et al., 2010; Baltaduoniene et al., 2019; Bo et al., 2019; Cho et al., 2015; Cho et al., 2016; Choi et al., 2015; Chu et al., 2022; De Luca et al., 2018; Jiang et al.; 2016, Jung et al., 2020; Lin et al., 2014; Liu et al., 2018; Navarro et al., 2020; Park et al., 2015a; Park et al., 2015b; Peers et al., 2021; Prokopenko et al., 2013; Prokopenko et al., 2019; Sihuykang et al., 2009; Tarantino et al., 2021; Van de Ven et al., 2017; Veisi-Pirkooji et al., 2019; Wentink et al., 2016; Westerberg et al., 2007; Yeh et al., 2019; Yeh et al., 2022; Yoo et al., 2015; Youze et al., 2021; Zhou et al., 2018; Zucchella et al., 2014), one was a non-randomised cohort study (Lawson et al., 2020), three were feasibility trials (Peers et al., 2020; Poulin et al., 2017; Svaerke et al., 2019), one was a cross-over cohort study (Nyberg et al., 2018), one was an uncontrolled cohort study (Zagavec et al., 2015), and two were cohort studies comparing two clinical populations (Stroke and Alzheimer's Disease patients or other Acquired Brain Injury) receiving the same intervention (Jung et al., 2021; Reissner et al., 2013). Follow-up reports on two of the trials were also identified, one (Wentink et al., 2018), exploring factors affecting adherence to treatment in a previous trial (Wentink et al., 2016), and another (Lawson et al., 2022) exploring the acceptability of an intervention delivered in a previous trial (Lawson et al., 2020).

The earliest included study was Westerberg et al., (2007), and the most recent was Chu et al., (2022). Thirteen studies (Bo et al., 2019; Jiang et al., 2016; Jung et al., 2020; Lawson et al., 2020; Navarro et al., 2020; Peers et al., 2021; Poulin et al., 2017; Sihyukang et al., 2019; Van de Ven et al., 2019; Wentink et al., 2016; Yeh et al., 2021; Youze et al., 2021; Zuccella et al., 2014) included trial flow diagrams such as Consolidated Standards of Reporting Trials (CONSORT) charts as part of their methodology, and one included a flow diagram without participant screening numbers (Baltaduoniene et al., 2019).

Nine studies were conducted in the Republic of Korea (Cho et al., 2015; Cho et al., 2016; Choi et al., 2015; Jung et al., 2020; Jung et al., 2020; Park et al 2015a; Park et al., 2015b; Sihuynkang et al., 2009; Yoo et al., 2015), nine in China (Bo et al., 2019; Chu et al., 2022; Jiang et al., 2016; Lin et al., 2014; Liu et al., 2018; Yeh at al., 2019; Yeh et al., 2022; Youze et al., 2021, Zhou et al., 2018), three in Italy (DeLuca et al., 2018; Tarantino et al., 2021; Zucchella et al., 2014), two in Russia (Prokopenko et al., 2013; Prokopenko et al., 2019), two in the Netherlands (Van de Ven et al., 2017; Wentink et al., 2016), two in the

United Kingdom (Peers et al., 2020; Peers et al., 2021), and there was one each in Australia (Lawson et al., 2020), Belgium (Akinwuntan et al., 2010), Canada (Poulin et al., 2017), the Czech Republic (Reissnet et al., 2013), Denmark (Svaerke et al., 2019), Iran (Veisi-Pirkooji et al., 2019), Lithuania (Baltaduoniene et al., 2019), Norway (Nyberg et al., 2018), Slovenia (Zagavec et al., 2015), Spain (Navarro et al., 2020), and Sweden (Westerberg et al., 2007).

Data relating to the participant gender were not reported by six studies (Jiang et al., 2016; Nyberg et al., 2018; Peers et al., 2020; Peers et al., 2021; Sihyunkang et al., 2009; Zagavec et al., 2015). In the remaining 32 studies, gender distribution of participants ranged from 20% female (Poulin et al., 2017) to 86.2% female (Jung et al., 2020). Across studies the mean percentage of female participants was 42.22%.

One study reported age range but not mean participant age (Park et al., 2015). In the remaining 37 studies, mean participant age ranged from 40.3 years (Zagavec et al. 2015) to 72.69 years (Jung et al., 2020), with an overall mean age of 59.36 years across studies.

Twenty-two papers did not report type of stroke of the participants (Baltaduoniene et al., 2019; Bo et al., 2019; Cho et al., 2015; Cho et al., 2016; Jiang et al., 2016; Jung et al., 2021; Lin et al., 2014; Nyberg et al., 2018; Park et al., 2015b; Peers et al., 2020; Peers et al., 2021; Prokopenko et al., 2013; Prokopenko et al., 2019; Reissner et al., 2013; Sihyunkang et al., 2009; Svaerke et al., 2019; Van de Ven et al., 2017; Veisi-Pirkooji et al., 2019; Yeh at al., 2019; Yoo et al., 2015; Zagavec et al., 2015; Zhou et al., 2018). The remaining 16 papers included individuals with both ischaemic and haemorrhagic stroke, with the percentage of haemorrhagic stroke ranging from 17.38% (Jung et al., 2020), to 50.96% (Navarro et al., 2020). The mean percentage of participants with haemorrhagic stroke across studies was 32.88%.

Eleven studies did not report the amount of time between the stroke occurrence and the intervention. In the remaining studies, the mean time between stroke and intervention ranged from 0.7 months (Svaerke et al., 2019) to 102 months (Peers et al., 2020). The mean time at which participants entered the trial was 16.14 months post-stroke.

The baseline cognitive status was part of the inclusion criteria in the majority of the studies and was most often assessed using the Mini Mental State Examination (MMSE). Five studies specified both a lower and upper limit (Cho et al., 2015; Cho et al., 2016; Choi et al., 2015; De Luca et al., 2018; Youze et al., 2021) nine only had a lower limit (Baltaduoniene et al., 2019; Jiang et al., 2016; Jung et al., 2020; Jung et al., 2021; Navarro et al., 2022;

Propokenko et al., 2013; Westerberg et al., 2007; Yeh et al., 2022; Zucchella et al., 2014) and eight only had an upper limit (Bo et al., 2019; Chu et al., 2022; Lin et al., 2014; Park et al., 2015a; Park et al., 2015b; Poulin et al., 2017; Sihyukang et al., 2009; Yeh et al., 2019). Three studies did not report their exclusion criteria (Peers et al., 2020; Reissner et al., 2013; Yoo et al., 2015) and the remainder did not include cognitive status as an inclusion criterion.

Table 2.1.

Participant Characteristics in Included Studies.

Study ID	Number of Participants		Age (years) Mean (SD)		Sex		Type of Stroke		Mean (SD) Time Post-Stroke	
	Experimental	Control	Experimental	Control	Experimental	Control	Experimental	Control	Experimental	Control
Akinwuntan	$CACR^{a} n = 33$	Pen-and-paper	55 (12)	54 (11)	24 M ^b 9 F ^c	31 M 5	24 I ^d 9 H ^e	29 I 7	-	-
(2010)		cognitive rehab n =				F		Н		
		36								
Baltaduonienė	2 groups: : OT ^f	Pen-and-paper	T2 = 73.67	74.33	T2 = 10 M 31	18 M 22	-	-	T2 = 24 > 4	$17 \leq 4$ hours,
(2019)	+ CACR (T2) n	cognitive rehab n =	(10.10) T3 =	(10.27)	F, T3 = 19 M	F			hours, 17 < 4	23 > 4 hours
	= 41; OT + VR ^g	40	69.71 (11.67)		21 F				hours; T3 =	
	(T3) n = 40								26 > 4 hours,	
									14 < 4 hours	
Bo (2019)	2 groups:	Control (usual care	TT = 66.68	Control =	TT = 19 F 25	Control	-	-	<6 months	<6 months
	physical	+ watching	(2.44), CACR	64.36	M, CT = 21 F	= 20 F				
	exercise +	documentaries) n =	= 67.51 (2.24)	(2.31), PE	24 M	27 M,				
	CACR (TT) n =	47, physical		= 65.12		PE = 19				
	44, CACR n =	exercise (PE) $n = 42$		(2.56)		F 23 M				
	45									

Cho (2015)	CACR + OT + physical therapy n = 12	OT and physical therapy n = 13	60 (4.7)	64.7 (6.3)	7M 5 F	9M 4 F	-	-	5.3 (2.3) months	6 (2.2) months
Cho (2016)	2 groups: neurofeedback (NFB) n = 14, CACR n = 14	OT and physical therapy n = 16	NFB = 62.2(6.2), CACR = 63 (5.4)	64 (8.8)	NFB = 8M 6 F, CACR = 9M 5 F	7M 9 F	-	-	NFB = 5.9 (2.2); CACR = 5.1 (2.2) months	6.5 (1.5) months
Choi (2015)	CACR + physical therapy n = 10	Physical therapy + balance training n = 10	64.8 (10.5)	54.6 (11.8)	6M 4 F	6M 4 F	7 I 3 H	5 I 5 H	22.9 (8.9) days	23.2 (9.7) days
Chu (2022)	2 groups: Intermittent theta burst stimulation + CACR (iTBS) n = 21), transcranial direct current stimulation + CACR (tDCS) n = 19	CACR n = 20	iTBS = 57.24 (14.03) tDCS = 61.58 (14.18)	66.75 (12.23)	iTBS = 18 M 3 F, tDCS = 14 M 5 F	13 M 7 F	iTBS = 13 I 8 H, tDCS = 14 I 5 H	12 I 8 H	iTBS = 4 (5) months, tDCS = 2 (3) months	6 (4) months

De Luca (2018)	CACR + paper- and pencil cognitive rehab n = 20	Paper-and-pencil cognitive rehab n = 15	43.9 (16.6)	42.1(17.7)	11 M 9 F	7 M 8 F	15 I 5 H	9 I 6 H	3 (1) months	4 (1) months
Jiang (2016)	3 groups: acupuncture (AC) $n = 52$, CACR = 51, AC + CACR $n = 52$	OT + physical therapy n = 49	AC = 57.75 (13.74), CACR = 59.56 (10.1), AC + CACR = 57.88 (9.45)	56.18 (11.86)	-	-	-	-	AC = 42.75 (20.14); CACR = 40.56 (18.88); CACR + AC = 41.75 (20.56) days	40.27 (19.17) days
Jung (2021)	CACR n = 20 stroke patients (intervention was the same it compared effect on stroke vs other traumatic brain injury)	CACR n = 22 traumatic brain injury patients	57.78 (16.66)	59.03 (17.22)	22 M 12 F	22 M 8 F	-	-	61.13 (35.46) days	74.03 (43.59) days
Jung (2020)	CACR $n = 14$	Standard medical care $n = 15$	72.71 (9.86)	72.67 (12.64)	2 M 12 F	2 M 13 F	11 I 3 H	13 I 2 H	-	-

Lawson (2020) and Lawson (2022)	Group cognitive rehabilitation delivered remotely n = 28	Group cognitive rehabilitation delivered face-to- face n = 18	53.36 (11)	61 (14.69)	15 M 13 F	11 M 11 F	18 I 6 H	10 I 2 Н	-	-
Lin (2014)	CACR $n = 16$	Standard medical care n = 18	62.4 (6)	63.2 (5.7)	10 M 6 F	10 M 8 F	-	-	227.5 (24) days	228.1 (18.4) days
Liu (2018)	CACR + standard rehabilitation n = 62	Standard rehabilitation n = 62	61.5 (12.34)	63.35 (10.34)	40 M 22 F	46 M 20 F	48 I 14 H	50 I 16 H	-	-
Navarro (2020)	Competitive group CACR n = 22	Non-Competitive group CACR n = 21	51.7 (18.1)	52.9 (10.6)	11 M 11 F	13 M 8 F	12 I 9 H	9 I 13 H	433.6 (258.5) days	374.3 (229.9) days
Nyberg (2018)	CACR $n = 22$	Waitlist n = 26	51.9 (1.2)	52.6 (10.3)	-	-	-	-	43 (13.9) months	41.9 (13.6) months
Park (2015)a	CACR + standard care n = 10	Standard care n = 10	-	-	5 M 5 F	4 M 6 F	4 I 6 H	8 I 2 H	-	-
Park (2015)b	CACR $n = 15$	Paper-and-pencil cognitive rehabilitation n = 15	64.7 (8.9)	65.2 (8)	6 M 9 F	8 M 7 F	-	-	1.5 (0.5) months	1.8 (0.6) months

Peers (2020)	n = 23, they	-	59 (10.6)	-	-	-	-	-	8.5 (4.7)	-
	don't report how								years	
	this was									
	allocated									
Peers (2021)	2 groups:	Waitlist $n = 27$	SAT = 58	61 (13.8)	-	-	-	-	SAT 2.33	3.1 (4.35)
	selective		(15.4), WMT						(3.56) years,	years
	attention		= 62 (12.2)						WMT = 3.85	
	training (SAT) n								(5.92) years	
	= 39, working									
	memory									
	training,									
	(WMT) n = 38									
Poulin (2017)	CACR $n = 4$	OT n = 5	57.5	49	4 M no F	3 M 2 F	4 I 0 H	1 I 4 H	6.36 months	6.1 months
Prokopenko	CACR $n = 24$	Standard	61	66	13 M 11 F	10 M 9	-	-	-	-
(2013)		rehabilitation n =19				F				
Prokopenko	CACR $n = 23$	Distracting	59	58	13 M 10 F	12 M 7	-	-	-	-
(2019)		computer programs				W				
		n = 19								

n = 19

30

Reissner (2013)	CACR Stroke group $n = 21$	CACR Alzheimer's group n = 15	60.5	71.5	15 M 6 F	7 M 8 F	-	-	-	-
Sihyunkang, (2009)	CACR n = 8	CACR n = 8	59.5 (10.7)	62.5 (9.6)	-	-	-	-	64.3 (37.4) days	58.1 (29.9) days
Svaerke (2019)	Early intervention CACR n = 7	Late intervention CACR n = 7	60 (12.15)	69 (10.53)	3 M 4 F	4 M 3 F	-	-	19 (13.11) days	23 (13.48) days
Tarantino	CACR $n = 18$	Standard care n =	64.6 (12.7)	64.9 (12.7)	12 M 6 F	14 M 5	13 I 6 H	12 I 6	3.1 (2.4)	4.2 (3.4)
(2021)		19				F		Н	months	months
Van de Ven	CACR $n = 38$	2 groups: active	57.0 (9.1)	active	24 M 14 F	active	-	-	28.3 (16.4)	active control
(2017)		control $n = 35$,		control =		control			months	= 28.3 (14.4);
		waitlist control n =		60.9 (7.5),		= 23 M				waitlist = 29.1
		24		waitlist =		12 F,				(17)
				61.2 (9)		waitlist				
						= 19 M				
						5 F				
Veisi-Pirkooji	CACR $n = 25$	Standard care n =	52.92 (10.44)	58.8	15 M 10 F	13 M 12	-	-	-	-
(2019)		25		(13.32)		F				
Wentink	CACR $n = 53$	Stroke education n	59	59	34 M 19 F	35 M 22	29 I 24 H	44 I 13	26 (9.1)	25 (7.4)
(2016) and		= 57				F		Н	months	months

Wentink

(2018)

Westerberg (2007)	CACR $n = 9$	Standard care $n = 9$	55 (8)	53.6 (8)	8 M 1 F	4 M 5 F	3 I 6 H	7 I 2 H	19.3 (6.2) months	20.8 (6.2) months
Yeh (2022)	2 groups:	AE $n = 18$	CACR =	57.36	CACR = 13	13 M 5	CACR = 8 I	12 I 5	-	-
	CACR $n = 18$,		60.17 (12.12)	(12.17)	M 5 F, AE +	F	10 H, AE +	Η		
	aerobic training		AE + CACR		CACR = 12		CACR = 8 I			
	(AE) + CACR n		= 53.05		M 8 F		12 H			
	= 20		(14.53)							
Yeh (2019)	CACR + AE n = 15	AE n = 15	50.63 (3.99)	60.21 (3.10)	8 M 7 F	13 M 2 F	-	-	47.8 (11.49) months	94.43 (30.8) months
V_{22} (2015)		Standard sons n -	52 2 (9 9)		9 M 12 F					
Yoo (2015)	CACR $n = 23$	Standard care n = 23	53.2 (8.8)	56.3 (7.9)	8 M 13 F	9 M 14 F	-	-	11.8 (7.5) months	10.7 (6.2) months
Youze (2021)	2 groups:	Paper-and-pencil	CA-SRL 57,	58	CA-SRL = 19	19 M 6	CA-SRL = 15	17 I 8	CA-SRl = 2	1 month
	computer aided	cognitive	DL 57		M 6 F, DL =	F	I 10 H, DL =	Н	moths, DL =	
	training (CA-	rehabilitation = 25			18 M 7 F		18 I 7 H		2 months	
	SRL) $n = 23$,									
	demonstration									
	learning (DL) n									
	-24									

= 24

Zagavec (2015)	CACR n = 11	-	40.3 (11.2)	-	-	-	-	-	4.2 (1.5) months	-
Zucchella (2014)	CACR $n = 42$	Sham intervention, no further detail n = 45	64	70	23 M 19 F	23 M 22 F	31 I 11 H	34 I H 11	-	-
Zhou (2018)	2 groups: an inpatient training group (ITG) n = 10, discharge training group (DTG) n = 10	2 groups: inpatient control group (ICG) n = 10, discharge control group (DCG) n = 10	ITG = 58.6 (11.44), DTG = 59.8 (11.26)	ICG = 56.1 (17.29), DCG = 56.5 (14.34)	ITG = 7 M 3 F, DTG = 7 M 3 F	ICG = 7 M 3 F, DCG = 5 M 4 F	-	-	ITG = 34.8 (20.65) days, DTG = 31 (17.06)) days	ICG = 29.9 (19.73) days, DCG = 32.8 (19.89) days

^aCACR: Computer Assisted Cognitive Rehabilitation

^bM: male

^cF: female

^dI: ischaemic stroke

^eH: haemorrhagic stroke

^fOT: Occupational Therapy

^gVR: Virtual Reality

Intervention Characteristics

Each of the 38 studies aimed to influence cognitive functioning in at least one domain, using commercially available CACR or interventions developed in-house (see Table 2.2). Sixty-six percent of the interventions adapted to the patient's performance; it was not specified whether this was the case for the remainder.

The duration of interventions ranged from a 30-minute single session intervention (Yeh et al., 2019), to 60 hours of input (Lin et al., 2014). The meanduration of training was 16.11 hours, with the number of weeks of it being delivered ranging from one (Yeh et al., 2019) to 12 weeks (Bo et al., 2019; Jiang et al., 2016; Jung 2020 et al., 2020; Reissner et al., 2013; Van de Ven et al., 2017; Yeh et al., 2022; Zagavec et al., 2015) and the mean number of weeks across studies being 6.13.

Sixteen of the studies were conducted in hospital settings (Baltaduoniene et al., 2019; Cho et al., 2015; Cho et al., 2016; Chu et al., 2022; Jiang et al., 2016; Jung et al., 2020; Liu et al, 2018; Navarro et al., 2020; Park et al, 2015a; Park et al., 2015b; Prokopenko et al., 2013; Reissner et al., 2013; Sihuynkang et al., 2009; Svaerke et al., 2019; Tarantino et al., 2021; Yoo et al., 2015), twelve in community rehabilitation centres (Akinwuntan et al., 2010; Bo et al., 2019; Choi et al., 2015; Jung et al., 2021; Lin et al., 2014; Prokopenko et al., 2019; Veisi-Pirkooji et al., 2019; Yeh et al., 2019; Yeh et al., 2022; Youze et al., 2021; Zagavec et al., 2015; Zuchella et al., 2014,), seven in the patient's home (Lawson et al., 2020; Peers et al., 2020; Peers et al., 2021; Poulin et al., 2017; Van de Ven et al., 2017; Wentink et al., 2016; Westerberg et al., 2007,), two in University research laboratories (DeLuca et al., 2018; Nyberg et al., 2018), and one both in hospital and in the patient's home (Zhou et al., 2018).

In fifteen studies, the interventions were self-directed, while for 14 others they were tailored and facilitated by various professionals (e.g., medical doctor, neuropsychologist, occupational therapist, physical therapist, or members of the research team). Nine of the studies did not state whether the intervention was self-directed or delivered with the support of a professional (Cho et al., 2016; Cho et al., 2015; Jiang et al., 2016; Jung et al., 2021; Nyberg et al., 2018; Park et al., 2015a; Park et al., 2015b; Prokopenko et al., 2013; Yoo et al., 2015).

There was a variety of controls for the interventions. The majority of studies used waitlist or usual care controls (Cho et al., 2015; Cho et al., 2016; Choi et al., 2015; Jiang et al., 2016; Jung et al., 2020; Lin et al., 2014; Liu et al., 2018; Nyberg et al., 2018; Park et al.,

2015a; Peers et al., 2020; Peers et al., 2021; Prokopenko et al., 2013; Tarantino et al., 2021; Veisi-Pirkooji et al., 2019; Yoo et al., 2015 and Westerberg et al., 2007), eight used a sham intervention (Bo et al., 2019; Prokopenko et al., 2019; Ven de Ven et al., 2017; Wentink et al., 2016; Yeh et al., 2019; Zhou et al., 2018; Zucchella et al., 2014), seven used traditional face-to-face cognitive rehabilitation (Akinwuntan et al., 2010; Baltaduoniene et al., 2019; DeLuca et al., 2018; Lawson et al., 2020; Park et al., 2015b; Poulin et al., 2017; Youze et al., 2021). Two studies did not have a control group but tested the same intervention in a different population (Jung et al., 2021, other acquired brain injury; Reissner et al., 2013, Alzheimer's Disease), one tested two different technology-based interventions (Sihuynkang et al., 2020), one used CACR without the addition of brain stimulation as the control (Chu et al., 2022), and one used the same intervention but with a different objective (Navarro et al., 2020). One study had an early and late intervention group using the same CACR program (Svaerke et al., 2019). One study did not employ a comparative or control intervention (Zagavec et al., 2015).

Digital Technologies

Most studies delivered the intervention via a laptop or computer (Baltaduoniene et al., 2019; Cho et al., 2015; Cho et al., 2016; Chu et al., 2022; DeLuca et al., 2018; Jiang et al., 2016; Jung et al., 2021; Lawson et al., 2020; Lin et al., 2014; Liu et al., 2018; Nyberg et al., 2018; Peers et al., 2020; Peers et al., 2021; Poulin et al., 2017; Prokopenko et al., 2013; Prokopenko et al., 2019; Reissner et al., 2013; Svaerke et al., 2019; Tarantino et al., 2021; Van de Ven et al., 2017; Veisi-Pirkooji et al., 2019; Wentink et al., 2016; Westerberg et al., 2007; Yeh et al., 2019; Yoo et al., 2015; Youze et al., 2021; Zagavec et al., 2015; Zhou et al., 2018; Zhou et al., 2018; Zucchella et al., 2014). One study employed an interactive computerised driving simulator (Akinwuntan et al., 2010), another used a joystick in addition to computer equipment (Park et al., 2015b), two also employed a motion tracking systems, acquiring motion data by monitoring the participant's movements through sensors (Choi et al., 2015; Sihuynkang et al., 2009). One study delivered the intervention via Zoom meetings (Lawson et al., 2020). In one study, the intervention was delivered in a group setting, employing touchscreens embedded in a conventional table, which provided visual and auditory feedback (Navarro et al., 2020). Touchscreen devices in the form of smartphones, tablets, or touchscreen laptops were employed in five other studies (Bo et al., 2019; Jung et al., 2020; Park et al., 2015a; Yeh et al., 2019; Yeh et al., 2022).

Five studies reported providing additional support to facilitate the intervention, in the form of weekly phone calls (Peers et al., 2020; Peers et al., 2021; Svaerke et al., 2019; Van de Ven et al., 2017; Westerberg et al., 2007).

Table 2.2.

Technology-Based Cognitive Rehabilitation Interventions Used in Included Studies.

Study ID	Targeted cognitive domains of the intervention	Intervention name and description	Was training adaptive / tailored?	Intervention duration (Frequency)	Total hours
Akinwuntan (2010)	attention (divided and selective); processing speed.	Driving simulator with interactive driving scenarios generated on a computer screen.	Not stated	3 x 60-minute sessions / week for 5 weeks.	15
Baltaduonienė (2019)	attention, concentration, memory, problem- solving, spatial perception.	PssCogRehab (2012) modules Foundations I/ II, Memory I/ II, Problem Solving I/ II, Visuospatial I/ II).	Yes	5 x 45-minute sessions / week for 32 days.	16
Bo (2019)	attention, executive functioning, memory, processing speed.	COGPACK programme, 12 exercises	Not stated	3 x 60-minute cognitive training sessions / week for 12 weeks	36
Cho (2015)	attention and concentration	RehaCom	Yes	30 minutes 5 times/week for 6 weeks	15

Cho (2016)	attention, concentration, memory	RehaCom using the attention, concentration, and memory	Not stated	30 minutes / period (2/week for 6 weeks)	6
		programms			
Choi (2015)	attention, concentration,	BioRescue	Yes	30 minutes per day, 5	10
	memory			days per week for 4	
				weeks	
Chu (2022)	attention, calculation,	After each iTBS/ tDCS treatment, the	Not stated	30 minutes for each	15
	executive function,	therapist conducted computer-assisted		session, 5 times a week	
	memory, reasoning	cognitive rehabilitation.		for 6 weeks (30 sessions	
	ability			total)	
De Luca	attention, executive	Erica (an Italian computer	Yes	24 sessions of 45	36
(2018)	functions (verbal and	rehabilitation program)		minutes each, 3 times a	
	nonverbal) memory,			week for 8 weeks	
	spatial cognition				
Jiang (2016)	attention, executive	RehaCom. Five programs, each has 1	Not stated	30 minutes per day, 5	30
	functions, memory, the	to 4 different tasks from which		days per week, for a total	
	visual field	participants choose during each		of 60 sessions over 3	
		therapy session.		months.	
Jung (2020)	attention (selective,	Com-Cog. 10 training activities: 2	Not stated	24 30-minute sessions.	12
	emotional), working	auditory processing tasks, 2 visual		Twice per week for 12	

	memory, recall memory,	processing tasks, 2 selective attention		weeks. Each session	
	processing (auditory and	tasks, 3 working memory tasks, and 1		lasted for 30 min per	
	visual),	emotional attention task		time.	
Jung (2021)	attention (selective),	Neuro-World—a set of six 'serious	Yes	30 min / day, twice a	15
	memory (short-term)	games' for cognitive training on		week for 12 weeks - 5	
		mobile devices.		minutes on each of the 6	
				games in each session	
Lawson	Memory	The intervention was a modified	Yes	Weekly two-hour	14
(2020)		version of the Monash Memory Skills		sessions for six weeks,	
		Group program and included		and a booster session	
		psychoeducation regarding memory			
		functioning, practical training in			
		internal and external compensatory			
		memory strategies, and information			
		about relevant impacts of lifestyle			
		factors Interactive in-session			
		exercises and between-session			
		homework tasks were included.			
Lin (2014)	executive function,	RehaCom	Not stated	six 1h sessions/week for	60
	memory			10 weeks (60h total)	

Liu (2018)	abstraction ability, attention, executive function, language, memory (delay), vision	A special computer-aided cognitive training program is developed by a professional doctor for each patient based on the patient's scores rated	Yes	30 minutes/ day 6 days/week for 4 weeks	12
Navarro (2020)	and space orientation attention (sustained and selective), inhibition, processing speed	with MOCA. Interactive computerized multi-touch exercises with eight games providing go/no-go, timed multi-choice, and cancellation tasks, framed as different sports, Olympic events, and scenarios, with each game focusing on a specific combination of attentional and other cognitive skills.	Yes	20 one-hour sessions, administered in groups of three or four participants, 3 days a week. All sessions combined 30 min of conventional exercises with 30 min of interactive computerized	10
Nyberg (2018)	working memory	Cogmed, an online working memory training program. Four exercises were used for calculation of improvement in trained tasks, as they were present	Not stated	multi-touch exercises. 25 sessions, typically to be completed in five weeks. The active time	16

40

		in all training sessions: "Grid" (visuospatial working memory); "Numbers" (verbal and visuospatial working memory); "Cube" (visuospatial working memory) and "Hidden numbers" (verbal working memory).		spent per session is approximately 40 min.	
Park (2015)a	memory, spatiotemporal perception, problem- solving	Cogrehab	Not clear	20 min a day 3 times a week for 4 weeks	4
Park (2015)b	object recognition, object constancy, figure- ground organization, visual discrimination, and visual organization.	CoTras	Yes	20 sessions (30 minute daily 5 days/week) over 4 weeks.	10
Peers (2020)		Two home-based online interventions. Two interventions, T1=	Yes	20 days each intervention (20	13

	attention, working	Selective Attention Training		sessions). WMT Cogmed	
	memory	consisting of five tasks developed to		- one session lasts about	
		shape participants' ability to rapidly		30-50 mins. SAT	
		attentionally sift through onscreen		training around 15 min /	
		stimuli for goal-relevant information.		session.	
		This was developed by the team. T2=			
		WMT battery, Cogmed.			
Peers (2021)	attention, working	Both interventions included a series	Yes	Both took	7
	memory	of 3–5 min time-limited "games".		approximatively 20 min	
		SAT tasks involved attending to		to complete / day,	
		increasing amounts of simultaneously		participants completed	
		presented on-screen information with		20 sessions over 4 weeks	
		minimal requirement for holding			
		information "in mind.". WMT			
		emphasized taking in and recalling			
		incrementally increasing strings of			
		sequentially presented information.			
Poulin (2017)	attention (divided),	The CACR program (NeuroActive)	Yes	16 one-hour sessions,	16
	cognitive flexibility,	developed for this study. Each		twice a week, for eight	
		training session consisted of three to		weeks	
		four computer activities targeting			

	inhibition, working	different EF processes. There were		
	memory	three divided attention tasks from the		
		Attentional software (Le Reseau		
		Psychotech Inc) as well as two		
		computerised tasks designed for		
		inhibition training and dual-task		
		training; nine different computer		
		activities.		
Prokopenko	attention (sustained,	Computerized Schulte's tables.	Yes	Daily, 30 min per day, 2

(2013)

selective, divided, alternating), memory (visual and spatial)

Training of visual and spatial gnosis with the use of the computer-based "figure-background" test. Training of visual and spatial memory aimed to the remembering of the position of images with gradually increasing number of objects (images of books) in cells of a five-by-five square

-

weeks

6

7

optical-spatial gnostic training using a computerized version of the "figurebackground" test; visuospatial memory training using tests based on remembering the position of a card; training of attention using computerized Schulte tables, training of visual memory using tests for remembering sequences of symbols which are difficult to verbalize, training to optical-spatial gnosis using a clock hands position test, a program to correct impulsivity and the concentration of attention, and a program for training to count.

Daily for 10 days, each session lasting 30–40 min.

concentration, executive NEUR functioning, planning, verb memory shapes

Prokopenko

(2019)

Reissner

(2013)

NEUROP-4 multimodal pack. Nonverbal tasks such as assembling shapes or figures, getting through a labyrinth, memorizing cards and shapes. Tasks focused on planning 1.5 h each week for 3 18 months

and strategic thinking for executive functions training, e.g. London Tower, Hanoi Tower, etc.

Sihyunkang (2009)	visual perception	CAMSHIFT, a computerized visual perception rehab programme with interactive computer interface for visual perception training.	Yes	12 sessions, three sessions per week for 30 minutes per session.	6
Zagavec (2015)	attention	the task Selective attention – Cross- modal on the rehabilitation software modules for computer-assisted cognitive rehabilitation CogniPlus was used	Yes	four times weekly for 30 min daily for 3 months	24
Svaerke (2019)	attention (visual), visuospatial abilities	The Danish version of the French CACR program "Scientific brain training PRO" was used. 5 exercises	Yes	30-45 minutes every second day for 3 weeks	5

	were selected from the domains of "visuospatial abilities" and "visual attention"		during the intervention period.	
	attention .			
executive functioning	Working Memory (WM), Interference Control and Inhibition (ICI), Task-Switching tasks, targeting Working Memory (WM), Interference Control and Inhibition (ICI), Task-	Yes	10 sessions, one hour each, over 2 weeks	10
	(TS), and Monitoring (M).		58 half-hour sessions 5	29
attention, memory, reasoning	A website (www.braingymmer.com) tailored to older adults as well as stroke survivors. `Tasks were presented in a predefined order and feedback was provided immediately after each task and at the end of each session. The cognitive flexibility training consisted of nine tasks.	Yes	times / week over 12 weeks	
	attention, memory,	 "visuospatial abilities" and "visual attention". executive functioning Working Memory (WM), Interference Control and Inhibition (ICI), Task-Switching tasks, targeting Working Memory (WM), Interference Control and Inhibition (ICI), Task-(TS), and Monitoring (M). attention, memory, reasoning A website (www.braingymmer.com) tailored to older adults as well as stroke survivors. 'Tasks were presented in a predefined order and feedback was provided immediately after each task and at the end of each session. The cognitive flexibility 	"visuospatial abilities" and "visual attention"."Yesexecutive functioningWorking Memory (WM), Interference Control and Inhibition (ICI), Task-Switching tasks, targeting Working Memory (WM), Interference Control and Inhibition (ICI), Task- (TS), and Monitoring (M).Yesattention, memory, reasoningA website (www.braingymmer.com) tailored to older adults as well as stroke survivors. 'Tasks were presented in a predefined order and feedback was provided immediately after each task and at the end of each session. The cognitive flexibility	"visuospatial abilities" and "visual attention". period. executive functioning Working Memory (WM), Yes 10 sessions, one hour cach, over 2 weeks Interference Control and Inhibition cach, over 2 weeks (ICI), Task-Switching tasks, targeting Working Memory tasks, targeting Working Memory (WM), Interference Control and Inhibition (ICI), Task-Switching tasks, targeting Working Memory (WM), Interference Control and Inhibition (ICI), Task-(TS), and Monitoring (M). attention, memory, reasoning A website (www.braingymmer.com) Yes tailored to older adults as well as stroke survivors. 'Tasks were tailored to older and feedback was provided immediately after each task and at the end of each session. The cognitive flexibility session. The cognitive flexibility

Veisi-Pirkooji	attention and response	RehaCom software.	Yes	10 sessions, 2 / week for	7.5
(2019)	control (inhibition)			5 weeks, each session 45	
				min	
Wentink	attention, flexibility,	Lumosity, sixteen "games".	Yes	8 weeks, 5 days/week	12
(2016)	memory, problem- solving, speed			15-20 minutes/day	
Westerberg	working memory	RoboMemo (Cogmed) - battery of	-	The training plan	17
(2007)		visuo-spatial and auditory working		specified that	
		memory tasks. All tasks involved: (i)		participants must	
		maintenance of multiple stimuli at the		complete 90 trials each	
		same time, (ii) short delays during		day (taking about 40	
		which the representation of stimuli		minutes), five days a	
		should be held in WM, (iii) unique		week for five weeks.	
		sequencing of stimuli order in each			
		trail, (iv) the difficulty level adapting			
		as a function of individual			
		performance.			

Yeh (2019)	attention, calculation,	BrainHQ, interactive computer	Yes	Cognitive group 60	0.5
	executive function,	programs that target various cognitive		minutes, COG + AE 30	
	colour and shape	functions		min AE then 30 minutes	
	identification, memory,			COG training.3	
	recognition, visual			days/week for 12 weeks	
	perception, visuospatial				
	processing				
Yeh (2022)	attention, calculation, executive function, colour and shape identification, memory, recognition, visual perception, visuospatial processing	BrainHQ, interactive computer programs that target various cognitive functions	Yes	30 minutes, one-off	36
Yoo (2015)	attention, focus, memory, spatial imagination, visual	RehaCom	Not stated	30 min 5 times/week for 5 weeks	12.5

impairment, and visuomotor coordination.

Youze (2021)

attention, memory, problem-solving

The cognitive module addressed simple reaction time, visual perception, visual attention, visual choice, sustained attention, working memory, a maze, one mind for two purposes, psychological rotation and auditory choice, which aimed to improve specific cognitive functions. The cognitive application module consisted of four parts: computer application training, memory application training, logic ability training and attention application training. 3 weeks in parallel with other intervention, 30 min each session 5 times / week

7.5

49

16

Yes

Zucchella (2014)	attention (visual), executive functions, memory, orientation (time, spatial), reasoning, memory	Standardised rehabilitation program, two exercise packs targeting various cognitive functions		45 minutes / session, 16 hours total over 4 weeks	
Zhou (2018)	attention, executive function, memory	The program was adopted from the Wispirit Inc. (66nao.com). It included both a speech-language module and a cognitive training module. Specific training paradigms included a paired- associate recall task, go-no go task, Stroop task, Flanker task, switching task, attention span task and n-back working memory task.	Yes	Twice / day for 30 minutes for 30 days	30

Quality Assessment

A summary of the Joanna Briggs quality assessment for RCTs is presented in Table 2.3. None of the studies adopted blinding of both the intervention and outcome evaluation. The mean score across studies was 9.39 out of a total of 13. All included studies, apart from one with no control group (Zagavec et al., 2015), analysed baseline participant characteristics to ensure that the experimental and control groups were similar pre-intervention. Randomisation was used in all but four studies (Jung et al., 2021; Nyberg et al., 2018; Reissner et al., 2013; Zagavec et al., 2015). Groups were treated identically apart from the intervention of interest in the majority of the studies, with the exception of Choi et al. (2015), where a subset of participants from both groups also received cognitive-behavioural therapy.

Table 2.3.

The Joanna Briggs Quality Assessment Tool

Study ID	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q13	Total
														"yes"
Akinwuntan (2010)	Yes	Unclear	Yes	Unclear	Unclear	Unclear	Yes	Yes	Yes	Yes	Yes	Yes	Yes	9
Baltaduonienė (2019)	Yes	Unclear	Yes	Yes	No	Unclear	Yes	Yes	Yes	Yes	Yes	Yes	Yes	10
Bo (2019)	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	12
Cho (2015)	Yes	Unclear	Yes	Unclear	Unclear	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	10
Cho (2016)	Yes	Unclear	Yes	No	No	Unclear	Yes	Yes	Yes	Yes	Yes	Yes	Yes	9
Choi (2015)	Yes	Unclear	Yes	Yes	No	Unclear	No	Yes	Yes	Yes	Yes	Yes	Yes	9
Chu (2022)	yes	Unclear	Yes	Unclear	Unclear	Unclear	Yes	Yes	Yes	Yes	Yes	Yes	Yes	9
De Luca (2018)	Yes	Unclear	Yes	Unclear	Unclear	Unclear	Yes	Yes	Yes	Yes	Yes	Yes	Yes	9
Jiang (2016)	Yes	Unclear	Yes	Unclear	Unclear	Unclear	Yes	Yes	Yes	Yes	Yes	Yes	Yes	9
Jung (2021)	Yes	Unclear	Yes	Unclear	Unclear	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	10
Jung (2020)	No	N/A	No	N/A	N/A	N/A	Yes	Yes	Yes	Yes	Yes	Yes	Yes	7
Lawson (2020)	No	N/A	Yes	N/A	No	Yes	Unclear	Yes	Yes	Yes	Yes	Yes	Yes	7
Lin (2014)	Yes	Unclear	Yes	Unclear	Unclear	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	10

Liu (2018)	Yes	Unclear	Yes	Unclear	Unclear	Unclear	yes	Yes	Yes	Yes	Yes	Yes	Yes	9
Navarro (2020)	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	11
Nyberg (2018)	No	No	N/A	Unclear	Unclear	Unclear	Yes	Yes	Yes	Yes	Yes	Yes	yes	7
Park (2015)a	Yes	Unclear	Yes	Yes	Unclear	Unclear	Yes	Yes	Yes	Yes	Yes	Yes	Yes	10
Park (2015)b	Yes	Unclear	Yes	Unclear	Unclear	Unclear	Yes	Yes	Yes	Yes	Yes	Yes	Yes	9
Peers (2020)	Yes	Unclear	Unclear	Unclear	Unclear	Unclear	Yes	Yes	Yes	Yes	Yes	Yes	Yes	8
Peers (2021)	Yes	Yes	Yes	Unclear	Unclear	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	10
Poulin (2017)	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	12
Prokopenko (2013)	Yes	Yes	Yes	Unclear	Unclear	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	9
Prokopenko (2019)	Yes	Unclear	Yes	Unclear	Unclear	Unclear	Yes	Yes	Yes	Yes	Yes	Yes	Yes	9
Reissner (2013)	No	N/A	No	N/A	N/A	N/A	Yes	Yes	Yes	Yes	Yes	Yes	Yes	7
Sihyunkang (2009)	Yes	Yes	Yes	No	No	yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	11
Zagavec (2015)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Yes	Unclear	N/A	1
Svaerke (2019)	Yes	Yes	Yes	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	10
Tarantino (2021)	Yes	Unclear	Yes	Yes	Yes	Unclear	Yes	Yes	Yes	Yes	Yes	Yes	Yes	10
Van de Ven (2017)	Yes	Unclear	Yes	Yes	Unsure	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	11

Veisi-Pirkooji (2019)	Yes	Unclear	Yes	Unclear	Unclear	Unclear	Yes	9						
Wentink (2016)	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	12
Westerberg (2007)	Yes	Yes	Yes	Yes	No	No	Yes	11						
Yeh (2022)	Yes	Unclear	Yes	Unclear	Unclear	yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	10
Yeh (2019)	Yes	Unclear	Yes	Unclear	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	10
Yoo (2015)	Yes	Unclear	Yes	Unclear	Unclear	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	10
Youze (2021)	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	11
Zucchella (2014)	Yes	Unclear	Yes	Unclear	Unclear	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	10
Zhou (2018)	Yes	Unclear	Yes	Unclear	Unclear	Unclear	Yes	9						

Note: Q1: randomization; Q2: allocation concealment; Q3: similar baseline; Q4: participant blindness; Q5:blindness of intervention implement; Q6: blindness of outcome assessment; Q7: groups treated identically other than the intervention of interest; Q8: complete follow-up or strategies to address incomplete follow-up; Q9: participants analysed in the groups to which they were randomized; Q10: outcomes measured in the same way for all groups; Q11: outcomes measured reliably; Q12: appropriate statistical analysis; Q13: appropriate trial design

Acceptability and Feasibility of the Intervention

Acceptability

Refusal to Participate. Twelve studies reported the number of participants who refused to take part or could no longer be contacted after being identified as eligible (Bo et al., 2019; Jung et al., 2020; Lawson et al., 2020; Navarro et al., 2020; Peers et al., 2021; Sihuykang et al., 2009; Tarantino et al., 2021; Van de Ven et al., 2017; Wentink et al., 2016; Westerberg et al., 2007; Yeh et al., 2022; Zucchella et al., 2014). The rate of refusal ranged from 0% (Jung et al., 2020, Wentink et al., 2016), to 72.5% (Peers et al., 2021), with a meanrate of 12.25%. Stated reasons for refusal were lack of interest, lack of time, lack of motivation, or participants no longer being contactable.

Participant Satisfaction with the Intervention. Most studies failed to report either quantitative or qualitative measures of participant satisfaction. Lawson et al., (2022) conducted follow-up interviews with participants in their study and found that participants were overwhelmingly positive about their experience of telerehabilitation. This study was a synchronous one-on-one intervention delivered using videoconferencing technology, and the individualised nature of the intervention was noted as a strong contributor to the high participant satisfaction levels. Navarro et al. (2020) stated that participants in the intervention group reported greater enjoyment than those in the control group, but did not find group differences in perceived competence, pressure/tension, or value/usefulness. Peers et al. (2021) found that reports of enjoyableness and helpfulness tended to improve as the sessions progressed. They also found that participants completing selective attention training (SAT) consistently rated their training as more helpful and enjoyable than those completing working memory training (WMT). Of the SAT intervention participants, 76% thought the intervention had helped them, 15% were unsure and 9% felt it had not helped. For WMT, 66% felt it had helped, 17% were unsure, and 17% felt the intervention had not helped. Finally, 100% of SAT and 90% of WMT participants rated their training as manageable in terms of session duration, frequency, technical demands. Poulin et al. (2017) stated that all participants reported being very satisfied with the interventions, except for one participant in each group who indicated they were 'neither satisfied nor dissatisfied'. Prokopenko et al. (2013) reported that all participants in the CACR intervention group reported "considerable improvement", whereas the majority of those in the control group reported an "absence of improvements". Lastly, Sihyukang et al. (2009) found that the group receiving an experimental, interactive, technology-based intervention group expressed significantly more interest than the control

group, which completed a standardised CACR intervention pack, when evaluated on an interest scale.

Participant Adherence to the Intervention Protocol. Most studies did not report metrics relating to adherence to the intervention protocol, apart from reporting the total number of participants who completed the intervention. Where this information was provided, it indicated high levels of adherence. There was no clear link between the intervention duration and levels of adherence. Jung et al., (2020) reported that all participants completed all 24 sessions of the CACR, and Lawson et al., (2020) similarly reported that there was full treatment adherence apart from a participant who dropped out due to stroke recurrence. Nyberg et al., (2018) reported that 22 out of 26 participants finished at least 70% of the training sessions (25 sessions total). Peers et al., (2020) reported that on average the working memory CACR group completed 19.8 of the intended 20 sessions whilst the selective attention CACR group completed 20.2 of the intended 23 sessions, with 86% of patients completing the training in the intended 4–5 weeks. Similarly, Peers et al., (2021) reported that 92% of participants in the attention CACR and 82% of those in the working memory CACR continued with the study to the follow-up sessions. Poulin et al., (2017) reported that all nine participants completed all 16 training sessions, as well as postintervention and follow-up assessments. Wentink et al., (2016) and Wentink et al., (2018) reported that out of the intended 600 minutes, the median engagement time in the CACR intervention group was 528 min (range 63–1264; 88%) vs. 193 min (range 27–2162; 32%) in the control group.

Feasibility

Dropout Rates. All studies provided information relating to drop-out rates. The meanoverall drop-out rate was 5.62%, ranging from 0% (Cho et al., 2015; Cho et al., 2016; Choi et al., 2015; De Luca et al., 2018; Jung et al., 2021; Lin et al., 2014; Liu et al., 2018; Park et al., 2015a; Park et al., 2015b; Prokopenko et al., 2013; Prokopenko et al., 2019; Reissner et al., 2013; Sihyukang et all., 2009; Van de Ven et al., 2017; Veisi-Pirkooji et al., 2019; Westerberg et al., 2007; Yeh et al., 2019; Yeh et al., 2019; Yoo et al., 2015; Zagavec et al., 2015) to 22% (Svaerke et al., 2019). Drop-out rates for groups receiving CACR interventions ranged from 0% (Cho et al., 2015; Cho et al., 2016; Choi et al., 2015; De Luca et al., 2018; Jung et al., 2021; Lin et al., 2014; Liu et al., 2018; Park et al., 2015a; Park et al., 2015; Prokopenko et al., 2015; Cho et al., 2017; Veisi-Pirkooji et al., 2015b; Prokopenko et al., 2015; Cho et al., 2017; Veisi-Pirkooji et al., 2015b; Prokopenko et al., 2015; Cho et al., 2017; Veisi-Pirkooji et al., 2015; De Luca et al., 2018; Jung et al., 2021; Lin et al., 2014; Liu et al., 2018; Park et al., 2015a; Park et al., 2015b; Prokopenko et al., 2015; Van de Ven et al., 2017; Veisi-Pirkooji et al., 2015; Sihyukang et all., 2009; Zagavec et al., 2015; Van de Ven et al., 2017; Veisi-Pirkooji et al., 2019;

Westerberg et al., 2007; Yeh et al., 2019; Yeh et al., 2019; Yoo et al., 2015) to 22.2% (Svaerke et al., 2019). Drop-out rates for the intervention group were not reported by Peers et al., (2020). Sixteen of the studies specified the reasons for drop-out: hospital discharge, medical complications, death, stroke-related difficulties, personal reasons, technology difficulties, and not wishing to continue participation. The most frequent reasons for discontinuation were medical complications and hospital discharge, mentioned in nine of the sixteen studies.

Ease of Recruitment. Recruitment was defined as the number of people enrolled in a study divided by the number screened for potential involvement. Several studies did not report the number of identified eligible participants and only reported the total number who entered the study (Chu et al., 2022; DeLuca et al., 2018; Lin et al., 2014; Liu et al., 2018; Peers et al., 2020; Prokopenko et al., 2013; Prokopenko et al., 2019; Reissner et al., 2013; Svaerke et al., 2019; Tarantino et al., 2021; Veisi-Pirkooji et al., 2019; Yoo et al., 2015; Zagavec et al., 2015; Zhou et al., 2018). The median number of randomised participants per study was 45. The percentage of participants who entered the study among those identified as eligible ranged from 42% (Navarro et al., 2020; Youze et al., 2021), to 100% (Baltaduonienė et al., 2019; Bo et al., 2018; Cho et al., 2015; Cho et al., 2016; Choi et al., 2015; Jiang et al., 2016; Jung et al., 2020; Park et al., 2015a; Park et al., 2015b; Peers et al., 2021; Sihuykang et al., 2009; Yeh et al., 2019; Yoo et al., 2015), with a meanrecruitment rate of 90%. Fifteen studies also reported the total number of potential participants that were screened. The number of participants screened ranged from 56 (Jung et al., 2020), to 1020 (Jiang et al., 2016), with the mean being 276.8 participants screened per study. The proportion of eligible participants from the total number of those screened ranged from 11% (Jung et al., 2021) to 89% (Jung et al., 2020), with a mean of 51.49%.

There was no clear link between the stringency of eligibility criteria and the rate at which eligible participants were identified through screening. For instance, the study with the lowest rate, 11% (Jung et al., 2021), had relatively few inclusion and exclusion criteria, whereas studies selecting specific subgroups of stroke patients, such as those diagnosed within specific timeframes or without specific impairments, reported much higher rates. For instance, Bo and colleagues (2019) only included medically stable stroke survivors that were less than six months post-stroke, had no severe somatic or mental illness, had no visual or auditory disturbances, and met criteria for cognitive impairment, while excluding those with motor deficits, non-stroke-related neurological impairments, or had been deemed unsafe for

physical activity, and nevertheless reported a rate of 87% of individuals among those screened being eligible to take part.

Thirty studies recruited participants exclusively through healthcare records or referral by healthcare providers, one used a combination of healthcare referrals and contact with patient societies (Van de Ven et al., 2017), another used a combination of referral by healthcare providers, university research database contact, and recruitment through local stroke charities (Peers et al., 2021), one recruited through online stroke support forums, newsletters, as well as by contacting clinicians to refer patients and by inviting participants who had been ineligible for another study (Lawson et al., 2020) and another recruited exclusively through a university research database (Peers et al., 2020). Three studies did not report their methodology for identifying potential participants (De Luca et al., 2018; Reissner et al., 2013; Yeh et al., 2019). Recruitment time was reported by seventeen studies, ranging from one month (Jung et al., 2020) to 69 months (Jung et al., 2021), with a mean of 20.53 months. Based on the data reported, the median recruitment rate was of 2.92 participants per month, ranging from 0.9 (Jung et al., 2021) to 12.22 (Wentink et al., 2016). There did not appear to be a link between a wider variety of recruitment sources and a higher recruitment rate, as the study that used the widest range of recruitment sources (Peers et al., 2021) had a marginally below-average recruitment rate (2.36 participants per month), and the other study who recruited through two sources (Van de Ven et al., 2017), did not have a much higherthan-average recruitment rate (4.22 participants per month). Recruitment rate was not available for the study with the widest range of recruitment sources (Lawson et al., 2020).

Discussion

This systematic review summarises evidence concerning the feasibility and acceptability of technology-based post-stroke cognitive rehabilitation trials. We aimed to identify the challenges faced in research in this field, following evidence that many trials encounter difficulties, including failing to reach recruitment targets, exceeding planned study timeframes, and early termination (McGill et al., 2020). Given the potential for telerehabilitation to increase availability of cognitive rehabilitation, it is important to understand whether trials researching the effectiveness of these interventions are feasible to conduct, and whether stroke survivors view the interventions as acceptable treatments.

A total of 40 articles reporting 38 studies were included in the review, most of which are randomised-controlled trials. Overall, the studies included provide preliminary evidence

that technology-based cognitive rehabilitation is feasible to research and an acceptable way to deliver cognitive rehabilitation interventions to stroke patients, with studies generally reporting low drop-out rates, low refusal rates, and positive feedback from participants, where this was sought. One challenge faced by most studies was recruitment, with low recruitment rates and studies being conducted over long periods of time. Although the purpose of this review was not to assess efficacy, a quality assessment was conducted as a tool to assess the feasibility of implementing techniques that reduce risk of bias. The majority of studies were rated as medium quality. Blinding of outcome assessment was consistently reported and likely to have been facilitated by digital data collection. Allocation concealment, participant blinding, and blinding of the person delivering the intervention, however, were frequently missing or unclear in many studies, highlighting these methodological aspects as the most difficult to implement.

Acceptability

Participant and intervention characteristics were often described in the included studies, but key acceptability indicators (reasons for refusal, measures of participant satisfaction, adherence to intervention) were not adequately reported for most trials. The acceptability of technology-based cognitive rehabilitation interventions for stroke survivors was supported when reported, but most studies failed to report acceptability indicators, limiting the generalisability of this finding. Importantly, none of the studies reported Participant and Public Involvement (PPI) strategies that informed their trial design, which may have affected acceptability. There is evidence that PPI has a positive effect on the feasibility of clinical trials, improving participant enrolment (Crocker et al., 2018) and increasing likelihood of achieving recruitment targets (Ennis & Wykes, 2016). Similarly, the transparency of feasibility indicators relating to recruitment and retention was limited by the fact that only a third of studies included CONSORT flow diagrams.

Refusal to Participate. The included studies indicate that participants are willing to receive technology-based post-stroke cognitive rehabilitation as an alternative to traditional cognitive rehabilitation or other types of support. The studies report low proportions of eligible participants declining to be enrolled, at 12.25%. However, information about the reasons for declining to participate was missing or incomplete for many of the studies. This makes it difficult to pinpoint whether individuals refused due to reasons related to the technology, or other factors. None of the studies reported factors specific to technology-based interventions as reasons for declining to participate, although general lack of interest, time

constraints, and lack of motivation were cited. This is a significant gap in evidence concerning acceptability. Identifying barriers to recruitment in cognitive telerehabilitation trials may facilitate targeted recruitment strategies and increase trial efficiency. It may also highlight specific subgroups of stroke survivors more likely to refuse to take part in trials of this type of interventions, and potential threats to the generalisability of results.

Adherence to Intervention. Most studies did not report the number of times participants engaged with the intervention relative to what was intended. The findings of seven studies that reported this information suggest high levels of adherence to the intervention protocol, between 70-100%. However, this information cannot be generalised, as it derives from only a minority of the studies. A qualitative study found that stroke survivors report several barriers to engaging with CACR, including difficulties finding the time, using the technology, initiating and persisting with the training (Connor & Standen, 2013). Similar barriers have been identified in other populations, including people diagnosed with HIV and schizophrenia (Ferreira-Correia et al., 2018). It is important to investigate these potential barriers in trial settings, and ways to mediate them, such as implementation of regular checkin contacts with participants. In line with this, studies that reported high levels of adherence tended to have provided individualised support, either in the form of the intervention being facilitated by a therapist (Poulin et al., 2017; Lawson et al., 2020), the research team providing initial training on how to use the program and additional technology support where required (Wentink et al., 2016), or regular check-in calls (Nyberg et al., 2018; Peers et al., 2020; Peers et al., 2021). It is possible that additional support facilitates adherence and engagement with the intervention. For example, Westerberg and colleagues (2007) provided additional weekly calls and reported a zero drop-out rate. Another study providing weekly calls recorded a drop-out rate of 22% (Svaerke et al., 2019) however, suggesting there may also be other key factors influencing attrition. Six of the seven studies that provided additional support were also conducted in participants' homes, with the seventh study not specifying the intervention setting (Nyberg et al., 2018). It is possible that additional support is particularly important for participants on technology-based cognitive rehabilitation trials outside healthcare settings, but further adherence data is needed to clarify this potential link.

Participant Satisfaction. Satisfaction ratings were generally high. Participants receiving technology-based cognitive rehabilitation provided higher ratings than those in the control groups in all studies where this was reported. Peers et al., (2021), found that satisfaction ratings tended to improve over time, possibly as participants became increasingly

familiar with the technology used. They also found that participants consistently rated an attention CACR as more helpful and enjoyable than another designed to improve working memory. There was no further participant feedback reported to clarify the reasons for the discrepancy, but this suggests the possibility that there could be differences in the acceptability of CACR interventions targeting different cognitive domains. The vast majority of studies in this review targeted more than one cognitive domain, and therefore it was not possible to ascertain if drop-out or participant satisfaction related to interventions for a specific domain, as detailed participant feedback was not available. Poulin et al., (2017) noted that one participant felt that the intervention did not provide enough emphasis on applying the cognitive skills to daily life situations, suggesting that introducing elements relating to activities of daily living may complement CACR training. No other information on potential helpful modifications or adaptations was noted by the studies. A previous qualitative study found that stroke survivors would benefit from CACR programs allowing more time to account for visual neglect and navigating a keyboard one-handed, as well as the option to omit tasks that the participant feels are too challenging (Connor & Standen, 2013). These adaptations may be particularly relevant where commercially available standardised interventions which had not been originally developed for a stroke population are used.

Feasibility

Dropout Rates. Overall, drop-out rates were low, with over half of the studies reporting no dropouts. The overall average drop-out rate of 5.62% is in line with findings from previous systematic reviews of stroke rehabilitation trials (McGill et al., 2020). There were no clear associations apparent between the number of participants recruited and proportion of dropouts, or between dropout rates and study settings (hospital vs community). However, a larger proportion of studies conducted in Asia reported no drop-outs relative to those conducted in Western countries, with 72.22% of studies conducted in Asia reporting no dropouts contrasted to 40% of those conducted outside of Asia. It is possible that cultural differences may contribute to this effect, with participants in Asian countries being motivated more by societal collectivism when compared to western societies (Delhey et al., 2018; Greif, 1994). In line with collectivistic beliefs, stroke survivors in an Asian context may be more willing to continue research participation due to the potential societal benefit of the studies. Another factor may be differences in the dynamic between staff and patients, as there is evidence that medical staff in South-Asian countries tend to be more directive, which may

have made it more likely for participants to continue taking part in the trial (Claramita et al., 2013; Hou & Xiao, 2012).

Ease of Recruitment. The median number of 45 participants randomised per trial was slightly higher than that of 34 participants reported in a previous systematic review (McGill et al., 2020). Similarly, the median recruitment rate of 2.92 participants per month observed in this review was higher than that of 1.5 participants per month reported in a previous review (McGill et al., 2020). As most studies used a similar strategy of recruitment through healthcare records or referrals, the effect of different recruitment strategies could not be determined. Recruitment of participants is a recognised significant challenge in clinical trials (Feldman, Kim & Chiong, 2017; Toerien et al., 2009), and the findings of this review also suggest that, overall, the trials included experienced slow recruitment. Although on average nine out of ten eligible stroke survivors entered each trial, the average proportion of eligible participants among those screened was just under one in two, highlighting the significant effort required in identifying eligible participants in order to reach recruitment targets.

Clinical Implications and Research Recommendations

The findings of this systematic review suggest that studies researching technologybased cognitive rehabilitation are able to recruit and retain stroke survivors, although low recruitment rates need to be considered when determining timelines for future studies. The available acceptability data are encouraging, suggesting that stroke survivors engaged with the technology-based interventions and found them acceptable, which may suggest that their implementation in clinical settings as part of full trials may be appropriate. We recommend that future trials report their data according to international guidance such as the CONSORT guideline (Moher et al., 2010) and routinely collect information relating to the willingness of stroke survivors to use technology-based cognitive rehabilitation, as well as their experience of participating in the trial. Data relating to adherence to treatment are also important to collect and report, as they would permit analyses of dose-response effects. It is also recommended to incorporate PPI at all stages, to maximise the acceptability of the trial design. The limited information relating to participant satisfaction from the included studies suggests that one clinical implication of this review is that it may be beneficial to include elements of activities of daily living to complement technology-based interventions, or highlight to participants how the intervention relates to day-to-day activities. It would be important that future research attends to a wider range of outcome domains, including collecting more detailed information relating to participant satisfaction, as this is an essential element of the rehabilitation

process and there is evidence that higher satisfaction ratings predict higher levels of treatment compliance (Schönberger, Humle, & Teasdale, 2006). Additionally, it is recommended to collect outcome data from multiple sources, including 'subjective' cognitive outcomes reports, as well as through psychometric evaluation and informant report

Strengths and Limitations

This is the first systematic review of feasibility and acceptability factors in this area. A systematic and inclusive search methodology was used, maximising the likelihood of identifying relevant studies. The ability to include studies not published in English may have permitted more feasibility and acceptability data to be included. The small number of studies, combined with the lack of consistent reporting of feasibility and acceptability indicators did not permit statistical analyses that were protected against Type 1 and 2 errors, and therefore this report only includes preliminary descriptive data.

Conclusions

There is preliminary evidence that technology-based cognitive rehabilitation interventions are feasible to research in stroke populations and are viewed as acceptable by stroke survivors. Understanding the feasibility and acceptability of these interventions is essential for ensuring that clinical trials can provide valid and generalisable results, which can then inform clinical guidance and practice. This review has highlighted that studies of technology-based cognitive rehabilitation do not routinely report measures of acceptability. Recruitment indicators, particularly those relating to screening, are also not routinely reported. In order to better understand the factors affecting the feasibility and acceptability of these interventions which were considered in this systematic review should be reported.

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Chapter Three: Bridging Chapter

The systematic review identified a range of technology-based interventions for poststroke cognitive rehabilitation and found that although there is preliminary support for the feasibility of trials in this area, they face challenges similar to other stroke rehabilitation trials, most notably slow recruitment and small samples. There is also preliminary support for the acceptability of technology-based cognitive rehabilitation for stroke survivors who participate in research, although there were frequent inconsistencies and omissions in the reporting of acceptability indicators, with most studies in this area failing to report data relating to declining to participate, intervention adherence, and participant satisfaction. This highlights the importance of future studies reporting acceptability and feasibility indicators.

Feasibility and pilot studies focus on acceptability and feasibility indicators rather than efficacy outcomes and can therefore be particularly effective in helping us understand which factors affect the feasibility of technology-based cognitive rehabilitation trials, and ensure interventions are likely to be acceptable to stroke survivors. As technology-based cognitive rehabilitation interventions are still relatively novel, feasibility and acceptability findings may significantly facilitate the planning of full-scale RCTs and overcome barriers that could otherwise impede the completion of costly trials. Research on usability and acceptability of these interventions is also essential to enhance their uptake in clinical services.

The majority of interventions considered in the systematic review consisted of repeated computerised exercises intended to target specific cognitive domains. One of the studies (Poulin et al., 2017), targeted executive functioning in a holistic manner, and provided significant input from a therapist, 16 hours per participant. There is a gap in the literature on technology-based cognitive rehabilitation simulating face-to-face interactions between patients and health professionals. One study (Lawson et al., 2020) delivered an intervention targeting memory via Zoom, which was originally developed for a face-to-face group. While this delivery may address the accessibility issues some stroke survivors encounter, it is not cost-effective, as it requires the same amount of clinical input as a face-to-face intervention. Additionally, if the intervention is synchronous then it may face several accessibility issues for stroke survivors who have returned to work, have carer responsibilities, or face severe restrictions due to post-stroke fatigue, to name a few.

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Technology-based cognitive rehabilitation can be developed to be delivered synchronously, with real-time interaction between the clinician and patient, asynchronously, where the intervention is conducted independently by the patient, or using a mixed approach (Stephenson et al., 2022). With asynchronous rehabilitation, also known as "store and forward" technology, there is a delay between when the intervention is sent and when it is conducted (Fiani, Siddiqi & Dhillon, 2020). Asynchronous interventions have certain advantages, as they can be conducted at the patient's convenience, as many times as wished, and require fewer provider resources relative to synchronous interventions. Additionally, the patient has more control over the intensity of the intervention and is able to interact with the same material multiple times.

The research study that follows in Chapter Four addresses a significant gap in the literature by examining the feasibility and acceptability of a brief and low-cost technologybased cognitive rehabilitation intervention that can be delivered asynchronously. It differs from previous technology-based cognitive rehabilitation studies in that the feasibility trial was conducted fully online. As no similar studies were identified in the systematic review, it was important to establish whether the study procedures were feasible and the asynchronous online intervention acceptable to stroke survivors.

Chapter Four: Empirical Paper

Prepared for submission to *Neuropsychological Rehabilitation (see Appendix A for author guidelines)*

A Feasibility Randomised-Controlled Trial of an Online Executive Functioning Rehabilitation Intervention for Stroke Survivors

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Abstract

Background: Executive dysfunction affects the majority of people post-stroke and can limit the individual's ability to engage with other forms of rehabilitation and adapt to life poststroke. Although executive functioning rehabilitation is recommended by clinical guidelines, there is a lack of robust efficacy evidence supporting specific interventions.

Aims: We aimed to investigate the feasibility and acceptability of delivering a theory- and evidence-based online post-stroke executive functioning intervention and a control psychoeducation intervention in a clinical trial setting.

Methods: This was a mixed-methods feasibility randomised-controlled trial conducted fully remotely. Participants were adult stroke survivors with no major comorbid conditions. Impaired executive functioning was not required for participants to be eligible, as the intervention focused on goal-setting and other general adaptive skills which may be beneficial to all stroke survivors. Both the executive functioning and stroke psychoeducation interventions were delivered asynchronously online. Each lasted two weeks and consisted of two 30-minute video recordings, with two accompanying homework tasks. All materials were internet-based. Validated outcome measures assessing executive functioning, wellbeing, and self-efficacy were completed at baseline, post-intervention, and at one-month follow-up. Qualitative and quantitative feedback was sought on both interventions.

Results: Nineteen of 22 randomised participants completed the trial: 10 were randomised to the Executive Functioning group and 9 to the Stroke Psychoeducation group. The recruitment rate was 3.67 participants per month and the drop-out rate was 13.64%. Both interventions were rated similarly for relevance, usefulness, and ease of use, and qualitative data indicated that both were acceptable and regarded as useful by participants. No harms or adverse effects were reported.

Conclusion: Our asynchronous online post-stroke executive functioning rehabilitation and stroke psychoeducation interventions appear feasible and acceptable to research in a full trial. An appropriately powered RCT is needed to determine the efficacy of the executive functioning intervention in comparison to other treatment options and natural recovery. Although NHS recruitment yielded a low number of participants, it would be important for a future trial to retain this recruitment avenue to maximise the sociodemographic diversity and representativeness of the sample.

Keywords: Stroke; Cognitive Rehabilitation; Telerehabilitation; Feasibility; Dysexecutive Problems; Pilot

ClinicalTrials Registration: NCT05461937

Introduction

Executive dysfunction affects as many as 75% of stroke survivors (Lesniak et al., 2008; Zinn et al., 2007), with persistent deficits frequently observed (Rasgin et al., 2013). As executive functions (EF) are thought to underpin goal-directed behaviour, with impairments affecting a wide range of abilities (e.g. planning, problem-solving, initiation, sequencing, monitoring, divided attention, flexibility, working memory and inhibition; Anderson, 2008; Godefroy & Stuss, 2007), post-stroke EF impairments have the potential to interfere with both performance of familiar tasks and the management of novel situations. This is important because it means that executive dysfunction may disrupt stroke rehabilitation and the process of adapting to other stroke-related impairments, such as mobility or language difficulties. Conversely, there is preliminary evidence that training specific EF skills generalises to improvements in activities of daily living after stroke (Poulin et al., 2017; Stablum et al., 2000), suggesting that EF rehabilitation might facilitate adaptation to life after stroke more generally. EF rehabilitation post-stroke is also recommended in clinical guidelines (Intercollegiate Stroke Working Party, 2016). Systematic reviews of post-stroke EF rehabilitation, however, highlight the lack of robust efficacy evidence supporting specific EF rehabilitation interventions (Chung et al., 2013, Cicerone et al., 2019, Poulin et al., 2012).

Stroke survivors can face challenges accessing cognitive rehabilitation interventions. A recent survey found that nearly one in two stroke survivors were not able to access the level of support they needed for memory and fatigue (Stroke Association, 2016), and cognitive dysfunction post-stroke has been highlighted as an area of unmet need by a recent consensus (McDonald et al., 2019). Making post-discharge rehabilitation more widely available is part of the NHS Long Term Plan (NHS, 2019). Telerehabilitation has emerged in the last two decades as a potential, more cost-effective, way to provide interventions to stroke survivors. Similarly to cognitive rehabilitation trials more generally, there is insufficient evidence relating to the effectiveness, as well as feasibility and acceptability of technology-based cognitive rehabilitation (Baldatuoniene & Mingailia, 2018; Loescher et al., 2019; Zhou et al., 2022). Although telerehabilitation has not been found to be superior to traditional forms of therapy, the fact that no systematic reviews found that it may lead to inferior outcomes (Laver, Walker, Ward, 2022) points towards the potential of implementing technology-based interventions to help bridge the accessibility gap of cognitive rehabilitation in the community.

Goal Management Training (GMT; Levine et al., 2000; Levine et al., 2021) is one of the leading rehabilitation approaches for patients with executive dysfunction. Goal setting is an integral part of all post-stroke rehabilitation (Sugavanam et al., 2011; Wade, 2009) and is recommended in clinical guidelines (Intercollegiate Stroke Working Party, 2016), but relies on EFs that may be disrupted by stroke. Theoretical accounts of EF highlight goal-setting and problem-solving as potential targets for treating executive dysfunction post-stroke. Duncan's (1986) theory of goal neglect proposes that a common feature of frontal lobe damage is the inability to perform actions, in spite of understanding task requirements. The model proposed by Diamond (2013) distinguishes between 'core' EF components including working memory, inhibitory control, and cognitive flexibility, and 'higher-order' components, including reasoning, problem-solving, and planning. Stuss' model (2011) proposes task-setting and monitoring as the key executive functions subserved by the frontal lobes. Barkley's model (2012) further differentiates five functions that mediate goal-directed behaviour: time management, organisation and problem-solving, exercising restraint, self-motivation, and emotion regulation. Goal-setting and problem-solving skills are common targets in psychological interventions for other populations where these skills are a recognised difficulty, such as individuals with depression (Stewart et al., 2022; Zhang, Park, Sullivan, Jing, 2018), as well as key elements of cognitive-behavioural therapy (Rohde, Feeny, Robins, 2005). The transdiagnostic applicability of enhancing problem-solving and goal-setting skills, combined with the strong theoretical rationale of these skills being essential components of EF, as well as preliminary evidence that enhancing EF skills can have a positive impact on readaptation to life post-stroke, points towards the relevance of interventions targeting them. The above models of EF informed the intervention we developed for this study, and the elements of problem-solving, goal setting, planning, and monitoring, which were recurrent across models, were incorporated. Duncan's (1986) theory of goal neglect and the model proposed by Stuss (2011), were particularly important for the development of the intervention.

One way to address the challenge of designing and conducting high-quality clinical trials of stroke rehabilitation interventions that can produce findings to inform guidance is to conduct feasibility studies prior to commencing a full trial, in order to pre-empt issues that may limit the validity and generalisability of the results, such as not meeting recruitment targets, or issues delivering the intervention in line with the protocol (Pearson et al., 2020).

The overarching aims of this research were to explore the feasibility and acceptability of delivering a theory- and evidence-based online post-stroke EF intervention targeting goal management and a control psychoeducation intervention to stroke survivors, as well as their

preliminary efficacy, to inform the protocol for a future definitive trial (see Table 4.1 for the study questions).

Table 4.1.

The study feasibility and acceptability questions.

Is the intervention trial **feasible**?

- Are the data parametric?
- What are stroke survivor recruitment, retention, and attrition rates?
- What is the completion rate of pre- and post- outcome measures?
- What are the levels of adherence to the intervention and control?
- What is the magnitude and variability of change in outcome measures post-intervention (effect sizes, standard deviations)?
- Is the change in outcome measure scores indicative of improvement?

Are the intervention and trial procedures acceptable?

- Are randomisation and blinding of participants to the two conditions acceptable?
- How acceptable are the outcome measures (average time required, ease of completion)?
- Is the online format acceptable (willingness of participants to do the intervention online, ratings of appropriateness and ease of use)?
- What is the participant's experience of the intervention, its perceived usefulness, and areas of improvement?

Methods

This report complies with the Consolidated Standards of Reporting Trials (CONSORT; see appendix D) guidelines (Eldridge et al., 2016).

Design

This was a mixed-methods feasibility study, incorporating a blinded parallel-group randomised controlled feasibility trial (EF vs Stroke Psychoeducation, 1:1 allocation ratio). Ethical approval was obtained from faculty (ETH2122-1680; see Appendix E) and local NHS ethics committees (22/EE/0094; see Appendix F).

Setting

The study was conducted fully remotely (online, and participant screening over the phone). Recruitment was conducted through three early supported discharge NHS services in

the East Anglia region, three Third-Sector National Charities, and a university database of stroke survivors who have consented to be invited to participate in research.

Participants

To be eligible for the study, participants needed to have a diagnosis of stroke, which was confirmed during the screening call, be over 18 years old, be able to provide capacitous consent to participate, and have access to a computer or tablet, the internet, and an email address. The presence of executive dysfunction was not an inclusion criterion, as the intervention focuses on goal setting and other general adaptive skills which are potentially useful for all stroke survivors. However, not having executive dysfunction as an inclusion criterion may impact results in a subsequent full trial by creating a ceiling effect. It may facilitate recruitment in the current feasibility trial, through there is also the possibility that participants may be less motivated to engage if they feel the intervention is not required to address an identified deficit. Exclusion criteria were having another significant mental or physical health condition, current involvement in another research trial, severe depression, indicated by a score of over 20 on the Patient-Health Questionnaire-9 (PHQ-9; Kroenke, Spitzer & Williams, 2001), being unable to read or understand English, having visual, auditory, or motor difficulties of a severity limiting the person's ability to attend to the content of the interventions, read the Participant Information Sheet, or complete the consent form and outcome measures, and not being registered with a General Practitioner (GP) or being unable to provide GP information (for reporting suicidal ideation concerns and scores of over 20 on the PHQ-9). Severe depression was an exclusion criterion to minimise potential risks and adverse effects due to the remote nature of the study. Recent draft guidance (NICE, 2023) also comments on the importance of considering depression in remote telerehabilitation, as there is tentative evidence it may lead to an increase in symptoms.

Recruitment

Participants were recruited through the NHS, Third Sector charities, and a university database. Potential participants were identified by staff from participating NHS stroke services, who provided the study Participant Information Sheet (see Appendix G). Potential participants had the option to consent for their contact details to be shared with the research team or to contact the team directly via email or phone. Three national stroke charities advertised the opportunity to take part in this study to their network of stroke survivors by posting the study poster which included study eligibility information and the contact email for the research team. Participants were also recruited from an ethically approved university

database of contacts of brain injury survivors managed by one of the faculty members. Participants were sent the study participant information sheet via email and post.

Interventions

Both interventions were designed to be delivered online, asynchronously. Each lasted two weeks and consisted of two 30-minute video recordings being made available each week, along with two homework tasks. All materials were provided by email. The videos were presentations developed by the research team, with information presented in both written form as well as verbally by a member of the research team. The homework tasks were explained at the end of each video, and handouts were provided to support their completion. Participants were given the option of a reminder to complete each module once or twice a week via their preferred contact method (email or text message).

Executive Functioning Intervention

An online asynchronous intervention was developed to target skills relevant for setting goals, self-monitoring, and problem solving (Berkley, 2012; Stuss, 2011; see Appendix H for content summary and slide examples). We adapted pre-existing tasks used in executive functioning rehabilitation. The content is closely related to Goal Management Training (GMT; Levine et al., 2000; Levine et al., 2011) and the Goal Management Training Framework (Miotto et al., 2009; Wilson et al., 2009). Findings from the systematic reviews conducted by Chung and colleagues (2013), Cicerone and colleagues (2019), and Poulin and colleagues (2019), alongside theoretical models of executive functioning (Barkley 2012; Stuss, 2011) were also considered when mapping the intervention content. As the aim was to improve goal management, the focus was on cognitive executive functions (i.e., problem solving, task-setting, monitoring), rather than emotion regulation. Additionally, each module included psychoeducation relevant to each skill.

Stroke Psychoeducation

Participants in the control group received a matched asynchronous stroke psychoeducation control intervention. Psychoeducation was deemed preferable to a waitlist condition to maximise retention rates, whilst being distinct in content from the EF intervention, as well as matching the level of input provided by the active intervention. The information provided covered definitions and descriptions of different types of stroke, areas of the brain, impact of strokes affecting different parts of the brain and the role of different professionals (see Appendix I for content summary and slide examples).

Randomisation

Randomisation occurred after baseline assessment. It was conducted on a 1:1 basis using a computer-generated randomisation sequence (www.randomization.com). It was not possible for the person providing access to the intervention and control recordings and materials and collecting the data to be blinded to group allocation. However, questionnaire data were gathered anonymously through an online survey platform (JISC surveys). Participants were blinded to intervention; the Participant Information Sheet stated that two interventions were being compared (one concerning goal-management and problem-solving skills and the other providing information about stroke) but remained neutral regarding any specific hypotheses.

Outcome Measures

Validated outcome measures were completed at baseline, after completion of the twoweek intervention, and at one-month follow-up. The PHQ-9 was completed as part of the screening process to assess eligibility. As this is a feasibility study, no primary outcome measure was identified. A variety of self-report measures were used to assess executive functioning (Revised Dysexecutive Questionnaire; DEX-R; Simblett, 2017), health-related quality of life (ICEpop CAPability measure for Adults; ICECAP-A; Al-Janabi, Flynn & Coast, 2012), wellbeing (Short Warwick-Edinburgh Mental Wellbeing Scale; SWEMWS; Ng Fat et al., 2017), and self-efficacy (The Stroke Self-Efficacy scale; SSE; Jones, Partridge & Reid, 2008). The DEX-R (Simblett, 2017) is a 37-item questionnaire, with items such as 'I act without thinking, doing the first thing that comes to mind' being rated on a five-point scale, ranging from 'Never' (0) to 'Very Often' (4). Higher scores indicate greater reports of dysexecutive problems. The ICECAP-A (Al-Janabi, Flynn & Coast, 2012) is a five-item questionnaire, with participants being asked to choose one of four options for each item (e.g. 'I am able to feel settled and secure in all areas of my life'(4), 'I am able to feel settled and secure in many areas of my life' (3), 'I am able to feel settled and secure in a few areas of my life' (2), and 'I am unable to feel settled and secure in any areas of my life' (1)). Higher scores indicate greater quality of life. The SWEMWS (Ng Fat et al., 2017) is a seven-item questionnaire with items such as 'I've been feeling optimistic about the future' being rated on a five-point scale ranging from 'None of the time' (1) to 'All of the time' (5). Higher scores indicate higher psychological wellbeing. The SSE (Jones, Partridge & Reid, 2008), is a 13item questionnaire, with items such as 'How confident are you now that you can cope with the frustration of not being able to do some things because of your stroke?' being rated on a

4-point scale ranging from 'Not at all confident' (0) to 'Very confident' (3). Higher scores indicate higher self-efficacy. During screening we also collected information about stroke rehabilitation interventions already received, sociodemographic information relating to age, gender, ethnicity, and stroke-related information such as site and type of stroke. A feedback survey (13 questions) utilising a mixture of open-ended (free text response) and closed (Likert type response) questions was administered to participants after completing the intervention in order to further assess acceptability.

Process Measures

The following data were collected to evaluate monthly recruitment rate:

- Number of invitations to take part sent by NHS services and proportion of patients who responded.
- Retention rates at each study timepoint (each assessment point and follow-up).
- Completion rates per intervention; in the feedback survey, participants were asked whether they had watched the videos and completed the homework tasks).
- Outcome measure completion rate.
- Number of questionnaire reminders sent.
- Number of participants requiring support to complete questionnaires.
- Patterns of missing data.

Procedure

Prospective participants who expressed interest in participating in the study were screened for eligibility by the primary researcher via a 15-minute phone call. They were asked to provide their GP details before completing the PHQ-9 and were made aware that the research team will contact their GP with their consent if the result is indicative of severe depression or suicidal ideation. If they met the eligibility criteria, prospective participants were given at least 48 hours to consider whether they wanted to participate, following which they were asked to complete an online consent form.

Informed consent was obtained online using MS Forms (see Appendix J). Participants were then assigned a code, in line with the randomisation sequence, and emailed URLs to access and complete baseline outcome measures. They were then sent emails containing the URL for the video and an attachment with the homework task, in line with their group allocation over the course of two weeks. Two emails were sent on the Monday of each week. They were sent reminder email messages according to their preference (once or twice each

week), if requested. Following the two sessions, they were emailed the outcome measures and feedback survey URLs. One month after completing the study the participants were emailed URLs with the final set of outcome measures.

If participants had not completed questionnaires at any of the three timepoints, they were emailed a reminder message a week after the initial link was sent, asking them to complete them. After completing these stages participants were given the option to be emailed the materials from the intervention they did not complete (i.e., participants in the control group were sent the materials of the executive functioning intervention and viceversa).

Data Analysis

Diagnostic plots were visually inspected to identify departures from normality in the distribution of variables/residuals, as well as to identify outliers (>3 standard deviations above the mean). Baseline data were analysed using chi-square tests of independence for categorical variables and independent samples t-tests for continuous ones, to check for between-group differences. The dataset was inspected for patterns of missing data. Descriptive statistics (with 95% confidence intervals) were used to summarise data relevant to recruitment, attrition, questionnaire completion rates and completion of sessions.

Suitability and magnitude of change in outcome measures was examined using analyses of variance (ANOVA). The analysis was conducted on a per protocol basis and was presented using summary statistics. Standard deviations (with 95% confidence intervals) of potential primary outcome measures were estimated, to inform power and sample size calculations for a future RCT and determine the appropriateness of the outcome measures selected.

Quantitative data from the feedback survey were summarised using descriptive statistics (means and standard deviations). Open text responses concerning participants' responses to the intervention and involvement in the study were content analysed through the process outlined by Erlingsson and Brysiewicz (2017) to determine the frequency of positive and negative words participants use to describe their experiences, as well as group similar feedback points into themes. The steps taken were gaining a general understanding of the written feedback, dividing the text into smaller meaning units, coding the meaning units, and lastly grouping the codes into categories.

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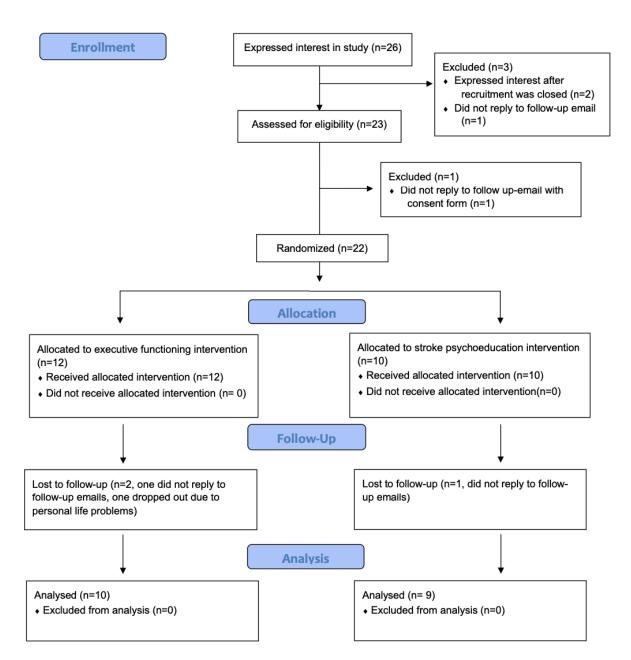
Results

Recruitment and Adherence

The first participant entered the study on 12 June 2022, the last one on 23 November 2022, and the final follow-up measure was completed on 16 January 2023. The flow of participants through the study can be seen in the CONSORT diagram (Figure 4.1). The study recruitment rate was 3.67 participants per month. Two of the three NHS Trusts that were participant identification centres recorded the number of participants they had approached with information about the study, with 93 stroke survivors being offered the opportunity to take part. In total, 4 potential participants were identified through NHS recruitment, one of whom could not be contacted after the screen call, and three of whom entered the study. Ten participants were identified through a university research database, and nine through two national stroke charities. Therefore, 95.83% of screened individuals were randomised.

Figure 4.1.

CONSORT flow diagram of participants included in each phase of the study.



Rates of compliance were high, with 84% of participants in the EF group and 90% of participants in the stroke psychoeducation group completing the study and outcome measures at baseline, post-intervention, and follow-up, and an overall drop-out rate of 13.64%. All participants who completed the intervention reported that they had watched both videos. Two participants, one from each group, reported not completing either of the two homework tasks. Six of nine participants in the stroke psychoeducation group and seven of ten participants in the executive functioning group requested to receive the materials from the other

intervention, as well. Participants completed the post-intervention questionnaires an average of 27.21 (SD = 16.49) days after baseline, though the intended completion time was 14 days post baseline. The one-month follow-up questionnaires were completed in line with the intended timeline, with participants completing them on average 32.42 (SD = 20.34) days post-intervention. There were no significant group differences in the number of days between completing baseline and post-intervention questionnaires [t(17) = -1.096, p = .289)], with participants in the EF group completing the post-intervention questionnaires an average of 23.3 (SD = 8.03) days after completing the baseline. There was a significant outlier in the psychoeducation group, who completed the post questionnaires 89 days after baseline. There was a significant group difference in the number of days between completing the post-intervention and follow-up questionnaires [t(17) = 2.254, p = .047], with participants in the EF group completion the number of days between completing the post-intervention and follow-up questionnaires an average of 41.1 (SD = 24.7) days after completing the post-intervention group, an average of 22.78 (SD = 6.70) days after the post-intervention questionnaires.

Support Requirements to Complete Outcome Measures

Consistent with the protocol, up to two reminders were sent to participants per questionnaire set. Fifteen of the 22 participants (68%) required at least one reminder. In total, 11 reminders were sent for the baseline measures, 11 for the post-intervention measures, and 9 for the follow-up measures. All participants were offered the option of receiving one or two reminders a week to watch the videos and complete the tasks, but only two participants accepted the offer. One participant needed more support to complete the questionnaires and was sent separate emails with links for each questionnaire rather than all links together in one email.

None of the participants required individual support to complete the questionnaires. The average completion times for the questionnaires were 95 seconds (SD = 115) for the SWEMWS, 258 seconds (SD = 216) for the SSE, 66 seconds (SD = 81) for the ICECAP-A, 376 seconds (SD = 257) for the DEX-R, and 314 seconds (SD = 200) for the feedback questionnaire. Therefore, the average amount of time spent completing the full set of questionnaires per timepoint was 18.48 minutes.

Baseline Demographics

The screening data could not be retrieved for one participant in the stroke psychoeducation group. Baseline background measures were analysed for the remaining 18 participants who completed the study, whereas the baseline questionnaire data were analysed for all 19 participants. No significant baseline group differences were found (see Table 4.2).

Table 4.2.

Differences between baseline characteristics of participants in the two treatment arms, separately.

Variable	Executive Functioning	Stroke psychoeducation	Group differences
Ν	10	8	
Female, n (%)	3 (30%)	4 (50%)	X^{2}_{1} = .748, p=.387
Age, mean (SD)	56.5 (15.76)	57 (18.87)	t(16)=061, p=.952, d=029
Time since stroke, months (SD)	86.80 (127.66)	53.13 (66.29)	t(16)=.721, p=.483, d = .320
Type of stroke	7 I 3 H	5 I 3 H	
Ethnicity	9 White British, 1 Pakistani	7 White British, 1 Indian	
Education (% with university degree)	70%	100%	

Feedback Data

There were no significant group differences in satisfaction ratings with the intervention and homework tasks. No harms or adverse effects were reported by participants in either group. The average rating for the relevance of the presentation content was 3.4 for the EF intervention and 4 for the Stroke Psychoeducation Intervention (0 being 'not relevant at all', and 5 being 'very relevant'). The average rating for the ease of engagement with the presentation was 4.2 for the EF intervention and 4 for the Stroke Psychoeducation

Intervention (0 being 'not easy at all', and 5 being 'very easy). Lastly, the average rating for the usefulness of the presentations was 3.4 for the EF intervention and 3.88 for the Stroke Psychoeducation Intervention (0 being 'not useful at all', and 5 being 'very useful). The average satisfaction rating for intervention length in the EF group was 3.2 (0 being too short, 5 being too long), and 2.56 in the psychoeducation group. Participants in the EF group reported that homework took them an average of 48.67 minutes to complete, whereas those in the psychoeducation group reported an average of 23.13 minutes. One participant in the EF group provided scores of '0' (on a scale of 0-5) for the usefulness and relevance of the intervention and homework task and provided feedback that the homework took too long to complete. One participant in the psychoeducation group rated the intervention as 2 out of 5, and the homework tasks as 0.67 out of 5, and provided feedback that although the videos offered lots of relevant and informative information, which helped them properly understand and could relate to the content, they were unable to execute the homework task because they found it difficult to talk about stroke and felt that it would cause them distress, due to the recency of the event. Another participant in the psychoeducation group rated both the intervention and homework as 2 out of 5, but provided feedback that they had found it extremely interesting and stated that there was nothing they did not like about the intervention.

Eight participants in the EF group provided qualitative feedback about the intervention. Two reported liking that the concepts were familiar (e.g. "Reinforced the mechanisms I have adopted since my stroke"), three fed back that the content was relevant (e.g. "I can see how it is useful to use the techniques and the suggestions were all good"), two that the content was practical (e.g. "Clear instructions and sensible, practical things to try out"), two that it was structured (e.g. "Break down into steps. Similar to writing computer code"), and one that they liked the level of detail ("I liked the level of detail required of us to create and implement our goals"). Four participants also provided feedback about what they did not like. Two people noted that the recommendations may be too ambitious or require skills that are too difficult for stroke survivors (e.g., strategies to manage concentration or use task chunking). One person felt that the format was too similar to a lecture, and another stated that the window size for the video was too small.

All nine participants in the stroke psychoeducation group provided written feedback. Three noted that the information presented was relevant (e.g. "Lots of relevant informative information helped me to properly understand / relate"), clearly presented (e.g. "Clear presentation of the brain and the function of its different parts"), two noted that it was useful to be able to share the facts to help others, one person liked that the information was on the presentation, as well as covered by a speaker, two felt that it normalised their experience (e.g., "I felt the intervention took into account what had happened to me"), one felt that the homework task was relevant ("The homework allows the learning to bed in"), and one noted that the content was interesting. Two participants provided feedback on what they did not like, as well. One person noted that they struggled to find someone to talk about the information with, which was part of the homework task, although the alternative of writing out notes for themselves had been offered. The other person noted that talking about stroke with others felt difficult, as it brought up memories of the traumatic experience.

Outcome Measures Descriptive Statistics

Normality assumptions were met for the DEX-R, ICECAP-A, SWEMWS, and SSE. Preliminary analyses indicated a significant Time x Group interaction [F(2,34)=4.224, p=.023, $\eta 2= 0.097$] for the DEX-R. No other main effects were significant. Table 4.3 presents descriptive statistics for the four outcome measures at three timepoints across both groups, with confidence intervals and effect size estimates for the group main effect. A larger sample of participants is needed to establish reliable magnitudes of change or measure group differences. All four effect size indicators suggest a small effect size.

Table 4.3.

The Dysexecutive Questionnaire Revised (DEX-R)							
Time	Executive Functioning			Stroke Psychoeducation			
	N	Mean	95% CI	Ν	Mean (SD)	95% CI	Group η2
		(SD)					
Pre	10	42.8	24.878-60.722	9	40.22	21.331-59.114	0.010
		(27.80)			(25.76)		
Post	10	34.5	19.466-49.534	9	40.11	24.264-55.958	
		(21.97)			(23.14)		
Follow-	10	34.5	19.861-49.139	9	44.56	29.124-59.987	
up		(18.03)			(25.63)		

Descriptive statistics for the four repeated measures at the three time points.

	N	Mean	95% CI	N	Mean (SD)	95% CI	Group η2
		(SD)					
Pre	10	31.2	27.351-35.048	9	31.33 (4.72)	27.277-35.390	0.033
		(6.56)					
Post	10	32.4	28.178-36.622	9	29.44 (6.86)	24.995-33.894	
		(5.82)					
Follow-	10	33.8	29.357-38.243	9	32.26 (6.68)	25.872-35.239	
up		(4.61)					
		ICE	pop Capability measu	e for A	dults (ICECAP	P-A)	
	N	Mean	95% CI	N	Mean (SD)	95% CI	Group η2
		(SD)					
Pre	10	15.9	14.021-17.779	9	15.67 (3.04)	13.686-17.648	0.002
		(2.6)					
Post	10	16.5	14.487-18.513	9	16.56 (2.88)	14.434-18.677	
		(3.14)					
Follow-	10	16.4	14.209-18.591	9	15.89 (3.37)	13.580-18.198	
up		(3.2)					
		Short War	wick-Edinburgh Ment	tal Well	being Scale (SV	WEMWS)	
	N	Mean	95% CI	N	Mean (SD)	95% CI	Group η2
		(SD)					
Pre	10	26.7	23.744-29.656	9	25.22 (4.32)	22.107-28.338	0.010
		(4.52)					
Post	10	26.1	22.741-29.459	9	25 (5.22)	21.459-28.541	
		(4.86)					
Follow-	10	25.9	22.640-29.160	9	25.89 (5.33)	22.453-29.325	
up		(4.46)			. ,		

The Stroke Self-Efficacy Questionnaire (SSE)

Discussion

We aimed investigate the feasibility and acceptability of a randomised controlled trial (RCT) of a brief asynchronous online goal management intervention compared to an asynchronous online psychoeducation active control.

Feasibility Indicators

Our findings provide support for the feasibility of investigating the test and control conditions. There was good adherence to most aspects of the trial protocol and procedures, apart from questionnaire data being returned with larger delays than anticipated. The recruitment rate was acceptable, though differed markedly between recruitment sites, with most participants identified through a university database. Recruitment through NHS services yielded a low number of participants. This may reflect features of the peri-pandemic context. During the Covid-19 pandemic services moved to hybrid delivery limiting staff access to printers and ability to provide printed study information to patients. Additionally, staff reported limited capacity to provide information about the study to patients due to needing to prioritise other aspects of clinical care which meant that the majority of information sheets were sent in bulk with administrative letters, possibly affecting interest in participation.

The screening process was highly efficient, with all participants who were screened being found eligible for participation. This may reflect the use of broad eligibility criteria and explicit information about these criteria in all study materials, leading only individuals likely to be eligible to express interest in taking part. All participants who were randomised were provided intervention resources in line with their allocation. All nineteen participants who completed the feedback questionnaire confirmed that they could access the resources they were emailed. The drop-out rate of 13.64% was slightly higher than the median of 6% reported by a systematic review of stroke rehabilitation trials (McGill et al., 2020), but there was no indication that participants dropped out due to factors relating to the interventions. However, two of the three participants who dropped out did not reply to follow-up contact attempts, and therefore factors relating to the intervention cannot be ruled out as a reason for drop-out in this study.

All participants completing the feasibility trial provided full datasets with no missing outcome measure data, suggesting that collecting data through online questionnaires was highly feasible and acceptable for the stroke survivors who took part. All participants were able to access online outcome measures, although the post-intervention questionnaires were returned later than planned on average. A large number of reminders were emailed to facilitate outcome measure completion. Reminder systems are established in this population and well-received (Fors et al., 2019), and likely to be an important element in a full trial. Our protocol specified one reminder a week, but more frequent reminders may have reduced delays in outcome measure completion.

As is customary for a feasibility trial, the small sample size does not permit conclusions to be drawn in relation to intervention efficacy. An interaction was observed between group and time on the DEX-R self-report measure of executive functioning. This might suggest positive change for participants in the executive functioning group, though the small effect size and wide confidence interval indicates the need to replicate the finding in a fully powered trial.

Acceptability Indicators

Positive quantitative ratings of usefulness, relevance, and ease of use for the executive functioning and stroke psychoeducation conditions suggest that the content was well-received by participants. Qualitative feedback was also consistent with this. Our findings are consistent with other studies in finding that most participants in technology-based cognitive rehabilitation intervention trials report finding these interventions acceptable (Peers et al., 2021; Poulin et al., 2017). One participant in each group reported not completing the homework tasks, suggesting that for some people the videos were perceived as more relevant or important than the associated homework, or possibly that completing the tasks was perceived as more time-consuming or effortful, compared to watching the videos. This, combined with the two participants feeding back that they found it difficult to discuss the information with other people, may suggest the homework tasks could be modified to be simpler and more flexible. The alternative of writing the information down as opposed to talking to someone else about it was offered, but it is possible that this was not made sufficiently explicit in the instructions.

Our study recruited a large proportion of participants with university degrees, and it would be important for future research to ensure generalisability to the wider stroke population. The median age of participants across groups in our study was 60 years, which is relatively young compared to the median age for a first stroke of 68 for men and 73 for women in the UK (Public Health England, 2018). This could point towards our sample being unrepresentative of the wider target population. However, it is also possible that this is a

representative sample of a specific subgroup of stroke survivors who might engage with and benefit from this type of intervention, as higher education and younger age are key predictors for experience with technology and attitudes toward computers (Czaja et al., 2006; Doo, Bonk, Heo, 2021). One fourth of strokes in the UK occur in people of working age (Public Health England, 2018). As cognitive dysfunction can significantly impair return to work (La Torre et al., 2022), and executive functioning rehabilitation plays a key role in re-adaptation to daily life, exploring the extent to which working-age stroke survivors benefit from this intervention would be important.

Using online outcome measures was a straightforward way to achieve blinding of outcome collection. For blinding in a full trial, it will also be important to ensure that data analysis is performed by a member of the research team not involved in recruitment, intervention delivery, or data collection.

Providing intervention materials for both interventions on request at the end of the study may have contributed to participant engagement with randomisation. There was little difference in dropout rate across groups. Two participants dropped out from the executive functioning group and one from the stroke psychoeducation group suggesting that participants were not more likely to discontinue one condition than the other. This is further corroborated by similar participant satisfaction ratings for both interventions. Most participants requested the materials from the other condition, suggesting good engagement with the material and finding it useful.

Limitations

One limitation of the current study is that it exclusively used self-report outcome measures. The post-intervention questionnaire data was also collected, on average, later than intended in the protocol. Another limitation is that the interventions are relatively brief, although the fact that the participants could watch the recordings multiple times may have compensated, to a degree. Preliminary evidence from a review of a small number of studies suggests that there is a link between the time and intensity of stroke computerised cognitive rehabilitation and the degree to which cognitive benefits are observed (Fava-Felix et al., 2022). We also only included participants who had access to the necessary technological equipment (computer or tablet, as well as access to the internet). Although there is evidence that as many as 94% of people in the UK now have access to the internet (Ofcom, 2022), 21% of them only do so via a smartphone, which due to the small screen size would not have

been suitable for our intervention. Therefore, it may have been beneficial to have the option of providing the necessary equipment to potential participants.

Future Research and Conclusions

Our results suggest that the brief asynchronous online executive functioning intervention and stroke psychoeducation control would be feasible and acceptable to research in a full trial. Future research, in an appropriately powered RCT, is needed to determine the efficacy of the executive functioning intervention over and above alternative treatment options and natural recovery. A full trial would need to account for slow recruitment rates, as well as use a variety of recruitment sources. The use of a research database of stroke survivors yielded a relatively high number of participants, and therefore it is recommended that a full future trial utilises this recruitment source. Although NHS recruitment yielded a low number of participants, it would be important to retain this recruitment avenue in a full trial, in order to maximise the representativeness of the study sample. As this intervention requires a level of computer literacy, it will be important to test the intervention on a more representative sample of stroke survivors, to identify specific subgroups most likely to engage with and benefit from the intervention. It is possible that the Covid-19 pandemic impacted NHS recruitment, as the staff from the services which acted as Participant Identification Centres were working in a hybrid format, which limited their access to printers. This meant that information about the study was provided to participants through less individualised avenues (e.g. along with appointment letters), which may have understandably impacted the willingness of potential participants to take part, resulting in a low conversion rate. In a full trial it may be beneficial to supply NHS staff with printed copies of the Participant Information Sheet, as well as have a member of the research team be physically present in the services, to answer any questions from staff, as well as speak with potential participants. Research has underlined the importance of highlighting the contributions of trial recruiters by updating them through regular newsletters and the research team having a presence at research sites (McGill et al., 2020), and therefore it will be important to prioritise this when recruiting through the NHS in a future trial. One limitation of the current study is that it exclusively used self-report outcome measures. It would be useful to consider supplementing self-report questionnaires with clinician-administered and informant outcome measures in a full trial. As the intervention targets EF, the use of neuropsychological tests such as the Trail Making Test Form B (Reitan, 1956), the Stroop Test (Stroop, 1935), and Digit Span (Blackburn & Benton, 1957) should be considered, to improve the validity of the

results. More frequent reminders (two or three per week) should be employed to hasten questionnaire completion times.

This research has important clinical implications, as the provision of a remote, asynchronous EF intervention could allow stroke survivors to access cognitive rehabilitation that may have otherwise not been available to them. As this intervention focuses on adaptive skills, should it be found to be effective in a full trial, it could help stroke survivors re-adapt to life in the community and facilitate their recovery.

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Chapter Five: Extended Methodology

This extended methodology chapter provides supplementary information regarding the timeline of the feasibility randomised controlled trial described in Chapter Four and the process of obtaining ethical approval.

Initial Consultations and Participant and Public Involvement (PPI)

Liaison with Stroke Survivors

Stroke survivors support groups were informally approached for PPI. Two stroke survivors and their informal carers were consulted in relation to the use of a control group, the format of the intervention, and randomisation. PPI influenced the study protocol by highlighting the importance of the content of the interventions being presented in multiple formats (i.e. on PowerPoint, as well as verbally) to make it more engaging, the use of frequent email reminders to improve adherence, as well as suggesting that a matched control is preferable to a waiting list one, especially one that involved psychoeducation.

Liaison with NHS clinicians

Eight clinicians from six potential Participant Identification Centres (PIC) in local NHS services were invited to discuss possible study recruitment and comment on the study protocol. After reading the study protocol, clinicians from four of the six services agreed to support participant recruitment for our study in principle, pending approvals from local Trust Research and Development (R&D) departments, the Health Research Authority (HRA) and a Research Ethics Committee (REC). Clinicians from one service declined to support recruitment due to concerns about the similarity between the executive functioning intervention to be trialled and existing interventions provided by the service. Another service declined to take part due to lack of capacity to support research at the time.

Liaison with Trust R&D Departments

After in-principle agreement to support the study was obtained from clinicians, NHS Trust R&D departments were approached. Three R&D departments agreed to facilitate the study set-up once HRA and REC approval was obtained. One R&D department advised that they were only able to support studies adopted onto the NIHR Portfolio, and we were therefore unable to proceed.

Ethical Approval

HRA and REC Approval

An application using the Integrated Research Application System was submitted on April 13th, 2022, naming three NHS Trusts as Participant Identification Centres. Following the attendance of a REC meeting on May 12th, 2022, a response requesting further information was received on 27th May 2022 and after this request was addressed, HRA and REC approval were issued on June 15th, 2022.

University Research Ethics Committee Approval

Due to delays obtaining HRA and REC approval and subsequent 'green light' to begin recruitment at NHS Participant Identification Centres, ethical approval was also sought from the University Faculty Research Ethics Committee, to permit recruitment through third sector agencies and a University research database of stroke survivors. An application for ethical approval was submitted on April 8th, 2022, and after a request for amendments on May 13th, 2022 was addressed, ethical approval was received on May 14th, 2022.

NHS Trust PIC agreement following HRA and REC approval

NHS Trust R&D departments were contacted as soon as HRA and REC approval was obtained to finalise and sign the PIC agreements. Signed PIC agreements were received on July 5th, 2022, July 8th, 2022 and September 16th 2022 from the three NHS Trust R&D Departments involved.

Chapter Six: General Discussion and Critical Review

The aim of the thesis portfolio was to investigate the feasibility and acceptability of technology-based cognitive rehabilitation interventions in stroke. Both the systematic review and empirical paper contribute to the literature on the feasibility and acceptability of technology-based cognitive rehabilitation in stroke. They extend our understanding of current cognitive rehabilitation technologies and characteristics of studies that have researched these interventions, and highlight the common barriers faced and gaps in our knowledge in relation to the feasibility of this area of research, and the acceptability of technology-based cognitive rehabilitation for stroke survivors. This final chapter of the thesis portfolio summarises and appraises the main findings of the systematic review and feasibility randomised controlled trial and summarises key clinical and research implications of the portfolio and overall conclusions.

Summary of Main Findings

The systematic review identified a body of literature consisting mostly of investigating the efficacy of a range of CACR designed to rehabilitate specific cognitive deficits, although other, more holistic, interventions were also found. Feasibility indicators aggregated across the identified studies suggest that research on technology-based cognitive rehabilitation interventions in stroke face similar challenges to those identified in trials of other forms of cognitive rehabilitation, especially recruitment inefficiency (McGill et al., 2020). The systematic review also highlighted that studies do not consistently report feasibility indicators and show poor reporting of acceptability indicators. The majority of studies included did not report information relating to participant experience of using technology-based cognitive rehabilitation interventions, levels of treatment adherence, or detailed information relating to people declining to take part. This limited the ability to draw conclusions about the acceptability of cognitive telerehabilitation for stroke survivors.

The empirical paper sought to contribute to the literature by providing a feasibility randomised controlled trial of an asynchronous, online, theory-informed telerehabilitation intervention targeting executive functioning and a psychoeducation control condition in stroke. The findings suggest that a full trial of the interventions would be feasible to conduct, and that both conditions were acceptable to participants. Based on the study results, a future full-scale trial protocol would need to account for slow recruitment rates, and to optimise outcome measure collection to ensure stricter adherence to collection timepoints. The

asynchronous delivery of the intervention provides several important advantages, as it is very flexible in terms of time and location, and participants can rewatch the material at their discretion, which may improve retention. There are also several disadvantages of the intervention, including reduced opportunities for social connection compared to standard face-to-face cognitive rehabilitation, difficulties ensuring that content was understood, and the need for additional input to resolve technology-related issues.

Clinical Implications and Appraisal of Results

As the majority of the trials identified by the systematic review were of CACR interventions, the data obtained in our feasibility RCT provides feasibility and acceptability data for a different format of cognitive telerehabilitation, that could be delivered either as a stand-alone, or in combination with CACR or other rehabilitation interventions. Indeed, many of the technology-based cognitive rehabilitation trials identified in the systematic review tested these interventions as an addition to usual care provided by occupational therapists or physiotherapists. This suggests that technology-based cognitive rehabilitation, especially when delivered asynchronously, may not necessarily replace face-to-face or standard care, but rather complement it by providing more input to stroke survivors in a scalable, costeffective, and accessible way. As psychological input is often limited in stroke services, the provision of technology-based cognitive rehabilitation could be a way to bridge the gap and make the information available to stroke survivors as they receive input from other professionals, such as occupational therapists or physiotherapists, as well as after the input from stroke services ceases. However, it would be important to ensure that the technologybased cognitive rehabilitation provided is appropriate to the individual needs and circumstances of each stroke survivor, and that the patient's engagement with it is monitored and reviewed (Intercollegiate Stroke Working Party, 2023).

A significant discrepancy between our intervention and those identified in the systematic review was that, on average, other interventions were delivered more intensively, over longer periods of time. Our intervention consisted of a total of 1 hour of input, delivered over two weeks, with the addition of an average of 48.67 minutes of homework per week for the EF group and 23.13 minutes of homework per week for the Stroke Psychoeducation group, according to participant self-report. The systematic review found that, on average, technology-based cognitive rehabilitation interventions provided an average of 16.11 hours of input, delivered over an average of 6.13 weeks. Preliminary evidence from a review of a small number of studies suggests that the time and intensity of cognitive training influence

the degree of cognitive benefits of computerised cognitive rehabilitation in stroke (Fava-Felix et al., 2022). Research of computerised cognitive training in other populations also suggests that intensity may be important. Karlene and colleagues (2013) found that there was a continuous relationship between the number of sessions of a processing speed training and improved outcomes in a sample of healthy older adults, with the effects being maintained over five years. Bamidis and colleagues (2015) found a dose-response effect on global cognition for a combined physical training and computerised cognitive training in a sample of healthy older adults. It will be important for the dose-response relationship to be explored in studies of technology-based cognitive rehabilitation in stroke as well, as this could inform decisions regarding the retention of the current two-session intervention format or development of a more intensive intervention for any future efficacy trial. None of the studies included in the systematic review commented on a dose-response relationship, focusing instead on experimental-control group differences.

One of the questions raised by the demographic characteristics of participants in the main study was whether the sample was representative, as the median participant age was 60 years old. This is relatively young compared to the median age for a first stroke in the UK, which is 68 for men and 73 for women in the UK (Public Health England, 2018). However, the average participant age across the studies included in the systematic review was 59.36 years, very much in line with our sample demographic. This suggests that it is possible that technology-based cognitive rehabilitation may be particularly appropriate or is more likely to appeal to a subgroup of stroke survivors, those that are more computer-literate or who hold more positive views of technology. While current research indicates that younger age correlates with these factors (Czaja et al., 2006; Doo, Bonk, Heo, 2021), as technology becomes more ubiquitous in the future this may change, and technology-based intervention may be more suitable for older individuals, as well. Importantly, recent demographic data indicates that more middle-aged people are having strokes than before, with over a third of first-time strokes happening in middle-aged adults (Public Health England, 2018). As return to work can be impeded by cognitive disability post-stroke (La Torre et al., 2022), this form of intervention may be particularly useful for this demographic of younger stroke survivors, who may require extra flexibility around other commitments.

Strengths, Limitations, and Considerations for Future Research

One strength of systematic review is that it identified more relevant papers than previous systematic reviews in this field. Our systematic review identified 30 relevant RCTs,

whereas previous reviews by Zhou and colleagues (2019) and Mingming and colleagues (2022) identified 10 and 17 studies respectively. This suggests that a follow-up SR examining the efficacy of technology-based interventions, with a possible meta-analysis on the CACR subset of studies may be warranted, as it would likely include studies not previously included in other systematic reviews. This is a rapidly expanding area of research, and it is important to frequently synthesise relevant evidence and incorporate new studies.

One limitation of the systematic review is that this only included peer-reviewed papers. Grey literature, or evidence not published in commercial publications, can include doctoral theses and research dissertations, conference papers and posters, among others (Paez, 2017). A future systematic review may consider including the identification of grey literature as part of the search strategy, to minimise the impact of publication bias and provide a more balanced summary of the evidence. There is evidence that much research is not disseminated through peer-reviewed publications, with some estimates suggesting that as many as half of all clinical trial results are not being published in journals (Riveros et al., 2013). Including grey literature would benefit the synthesis of feasibility and acceptability data, and it would particularly pertinent when synthesising efficacy results, as there is there is strong evidence that research with positive findings is more likely to be published than those with negative or null results (Hopewell et al., 2009), making estimates of pooled effect size likely to be exaggerated (Murad et al., 2018).

A full trial of the interventions developed for the main study needs to be conducted. One finding of the systematic review was that the majority of the studies that were conducted in the patient's home or remotely, employed regular check-ins with the participant, over and above the interventions offered. It may be helpful to incorporate a check-in element, in addition to the team being available to contact via email, in a full trial version of our study, to facilitate participant adherence to the intervention. The check-ins could also be used as an opportunity to collect acceptability data from participants.

Although assessing efficacy was beyond the scope of the main study, a potential limitation of a full trial version of our study is the exclusive use of self-report questionnaires as outcome measures. Most studies identified in the systematic review used cliniciandelivered assessments, and it may be helpful to incorporate relevant clinician-rated outcome measures in addition to the self-report questionnaires to assess executive functioning, or objective testing of EF. While self-report measures may provide useful information, there is evidence that there is a poor correlation between self-report scores and objective measures of EF in non-clinical samples, and that they may be influenced by personality factors (Buchanan, 2016; Laws et al., 2008). Incorporating objective testing of EF would improve the validity of the findings. Potential candidate neuropsychological tests include the Trail Making Test Form B (Reitan, 1956), the Stroop Test (Stroop, 1935), and Digit Span (Blackburn & Benton, 1957), as these are the most frequently used instruments to assess executive dysfunction for individuals with stroke and have acceptable internal consistency and high test-retest reliability (Conti et al., 2015).

Conclusions

The systematic review and empirical research project presented in this thesis portfolio provide novel contributions to the literature on the feasibility and acceptability of technologybased cognitive rehabilitation in stroke. The findings provide evidence supporting the feasibility of research on technology-based cognitive rehabilitation in a stroke population, and the acceptability of technology-based cognitive rehabilitation interventions to stroke survivors. Future research is needed, most notably to explore the acceptability of technologybased cognitive rehabilitation in stroke, as the systematic review highlighted the lack of consistent reporting of acceptability indicators. The data collected through our feasibility randomised controlled trial suggest that the interventions developed for this thesis portfolio are acceptable for stroke survivors, and a full-scale RCT would be feasible. In light of estimates that stroke incidence will increase in the next decade, developing cost-effective and flexible delivery methods for evidence-based cognitive rehabilitation to stroke survivors will be important, and technology-based cognitive rehabilitation could provide one potential solution to bridge gaps in service provision.

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Appendices

Appendix A: Author Guidelines for Neuropsychological Rehabilitation

Instructions for authors

Thank you for choosing to submit your paper to us. These instructions will ensure we have everything required so your paper can move through peer review, production and publication smoothly. Please take the time to read and follow them as closely as possible, as doing so will ensure your paper matches the journal's requirements.

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	1	stroke.ti.	188916	Advanced	Display Results More		Contract	
	2	cerebrovascular accident.ti.	925	Advanced	Display Results More	Q		
	3	cva.6.	304	Advanced	Display Results More	Q		
	4	ischaemic stroke.tijab.	13560	Advanced	Display Results More	Q		
	5	haemorrhagic stroke.ti,ab.	2335	Advanced	Display Results More	Q		
	6	1 or 2 or 3 or 4 or 5	194985	Advanced	Display Results More	Q		
	7	rehab*.li,ab.	278086	Advanced	Display Results More			
	8	cognition.ti,ab.	117946	Advanced	Display Results More	Q		
	9	cognitive dysfunction.ti,ab.	25264	Advanced	Display Results More	Q		
	10	neurological rehabilitation.ti,ab.	1483	Advanced	Display Results More	0		
	11	neuropsychological rehabilitation.ti,ab.	595	Advanced	Display Results More	0		
	12	cognitive rehabilitation.ti,ab.	3068	Advanced	Display Results More	0		
	13	telerehab*.ti,ab.	1577	Advanced	Display Results More	0		
	14	tele-rehab*.ti,ab.	377	Advanced	Display Results More	0		
	15	remote rehab*.ti,ab.	90	Advanced	Display Results More	Ô		
	16	virtual rehab*.ti,ab.	218	Advanced	Display Results More	0		
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	18	computer*.ti,ab.	404624	Advanced	Display Results More	O		
	19	computer assisted.ti,ab.	32725	Advanced	Display Results More	ō		
	20	cognitive training.ti.ab.	4575	Advanced	Display Results More	Q		
	21	brain training.ti,ab.	310	Advanced	Display Results More	Q		
	22	computerized cognitive training.tl.ab.	426	Advanced	Display Results More	Q		
	23	technology-based cognitive training.ti.ab.	1	Advanced	Display Results More	0		
	24	technology- based.ti,ab.	5891	Advanced	Display Results More	Ģ		
	25	online.ti,ab.	255645	Advanced	Display Results More	0		

Appendix B: Systematic Review Search Strategy

https://ovidsp-dc1-ovid-com.uea.idm.oclc.org/ovid-b/ovidweb.cgi

3/22					Display Results	Ovid: Se More		
1	27	ehealth.ti,ab.	4238	Advanced	Display Results		0	
1	28	telemedicine.ti,ab.	23238	Advanced	Display Results		Q	
1	29	telehealth.ti,ab.	12187	Advanced	Display Results		0	
1	30	remote.ti,ab.	107789	Advanced	Display Results		Ō	
1	31	virtual.ti,ab.	107306	Advanced			0	
		app.ti.ab.	47499		Display Results			
	32			Advanced	Display Results		0	
	33	telephone.ti,ab.	94844	Advanced	Display Results	More	Q	
	34	phone.ti,ab.	50643	Advanced	Display Results	More	Q	
	35	smartphone.ti,ab.	20413	Advanced	Display Results	More	Q	
]	36	telecare.ti,ab.	881	Advanced	Display Results	More	Q	
	37	18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36	1045110	Advanced	Display Results	More	O	
1	38	6 and 17 and 37	2778	Advanced	Display Results	More	Q	
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Appendix C: PRISMA Checklist

Section and Topic	ltem #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	15
ABSTRACT	<u>.</u>		
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	16
INTRODUCTION	<u>.</u>		
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	17 and 18
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	18
METHODS	•		
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	19 and 20
Information	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the	18
sources		date when each source was last searched or consulted.	
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	Appendix C
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record	20
		and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	
Data collection	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked	20
process		independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each	20

Section and Topic	ltem #	Checklist item	Location where item is reported
		study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	20
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	20 and 21
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	N/A
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	N/A
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	N/A
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	N/A
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	21
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	N/A
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	N/A
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	N/A
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	N/A
RESULTS	1		
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in	22

Section and Topic	ltem #	Checklist item	Location where item is reported
		the review, ideally using a flow diagram.	
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	22
Study characteristics	17	Cite each included study and present its characteristics.	23-33
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	52-54
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	N/A
Results of	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	N/A
syntheses	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	N/A
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	55-58
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	N/A
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	N/A
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	55-58
DISCUSSION	<u>.</u>		
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	58-63
	23b	Discuss any limitations of the evidence included in the review.	63
	23c	Discuss any limitations of the review processes used.	63

Section and Topic	ltem #	Checklist item	Location where item is reported
	23d	Discuss implications of the results for practice, policy, and future research.	62-63
OTHER INFORMA	TION		
Registration and	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	16
protocol	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	16
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	N/A
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	N/A
Competing interests	26	Declare any competing interests of review authors.	N/A
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	N/A

Appendix D: CONSORT Checklist

Section/Topic	ltem	Checklist Item	Reported on Page No
	No		
Title and abstrac	t		
	1a	Identification as a pilot or feasibility randomised trial in title	75
	1b	Structured summary of pilot trial design, methods, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	76
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	77-79
	2b	Specific objectives or research questions for pilot trial	79
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	79-80
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	80
	4b	Settings and locations where data were collected	80
	4c	How participants were identified and consented	80-81

Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were administered	81
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	82-83
	6b	Any changes to pilot trial assessments or measurements after pilot trial commenced, with reasons	N/A
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	N/A
Sample Size	7a	Rationale for numbers in the pilot trial	N/A
	7b	When applicable, explanation for any interim analyses and stopping guidelines	N/A
Randomisation			<u> </u>
Sequence	8a	Method used to generate the random allocation sequence	81
generation	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	81
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	N/A
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	82
Blinding	11a	If done, who was blinded after assignment to interventions (for example participants, care providers, those assessing outcomes) and how	82

	11b	If relevant, description of the similarity of the interventions	81
Statistical	12	Methods used to assess each pilot trial objective whether qualitative or quantitative	82-83
methods			
Results			
Participant flow (a	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility,	86
diagram is		randomly assigned, received intended treatment, and were assigned for each objective	
strongly recommended	13b	For each group, losses and exclusions after randomisation, together with reasons	86
Recruitment	14a	Dates defining the periods of recruitment and follow-up	85
	14b	Why the pilot trial ended or was stopped	N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	88
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant,these numbers should be by randomised group	90
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval)for any estimates. If relevant, these results should be by randomised group	90-91
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	N/A
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	88
	19a	If relevant, other important unintended consequences	N/A

Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	94-95
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	92-94
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	92-94
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	95-96
Other informatio	'n		
Registration	23	Registration number for pilot trial and name of trial registry	76
Protocol	24	Where the pilot trial protocol can be accessed, if available	76
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	N/A
	26	Ethical approval or approval by research review committee, confirmed with reference number	79

University of East Anglia

Study title: A Feasibility Randomised-Controlled trial of two online psychological interventions for stroke survivors

Application ID: ETH2122-1680

Dear Crina,

Your application was considered on 14th May 2022 by the FMH S-REC (Faculty of Medicine and Health Sciences Research Ethics Subcommittee).

The decision is: **approved**.

You are therefore able to start your project subject to any other necessary approvals being given.

If your study involves NHS staff and facilities, you will require Health Research Authority (HRA) governance approval before you can start this project (even though you did not require NHS-REC ethics approval). Please consult the HRA webpage about the application required, which is submitted through the <u>IRAS</u> system.

This approval will expire on 15th September 2023.

Please note that your project is granted ethics approval only for the length of time identified above. Any extension to a project must obtain ethics approval by the FMH S-REC (Faculty of Medicine and Health Sciences Research Ethics Subcommittee) before continuing.

It is a requirement of this ethics approval that you should report any adverse events which occur during your project to the FMH S-REC (Faculty of Medicine and Health Sciences Research Ethics Subcommittee) as soon as possible. An adverse event is one which was not anticipated in the research design, and which could potentially cause risk or harm to the participants or the researcher, or which reveals potential risks in the treatment under evaluation. For research involving animals, it may be the unintended death of an animal after trapping or carrying out a procedure.

Any amendments to your submitted project in terms of design, sample, data collection, focus etc. should be notified to the FMH S-REC (Faculty of Medicine and Health Sciences Research Ethics Subcommittee) in advance to ensure ethical compliance. If the amendments are substantial a new application may be required.

Approval by the FMH S-REC (Faculty of Medicine and Health Sciences Research Ethics Subcommittee) should not be taken as evidence that your study is compliant with the UK General Data Protection Regulation (UK GDPR) and the Data Protection Act 2018. If you need guidance on how to make your study UK GDPR compliant, please contact the UEA Data Protection Officer (dataprotection@uea.ac.uk).

Please can you send your report once your project is completed to the FMH S-REC (<u>fmh.ethics@uea.ac.uk</u>).

I would like to wish you every success with your project.

On behalf of the FMH S-REC (Faculty of Medicine and Health Sciences Research Ethics Subcommittee)

Yours sincerely,

Paul Linsley

Ethics ETH2122-1680: Ms Crina Ene

Appendix F: Cambridge Research Ethics Committee and HRA Approval

Health Research Authority

East of England - Cambridge Central Research Ethics Committee

Equinox House City Link Nottingham NG2 4LA

Telephone: 0207 104 8388

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

15 June 2022

Dr Catherine Ford Faculty of Medicine and Health Sciences University of East Anglia Norwich NR4 7TJ

Dear Dr Ford

Chudu title

Study title:	A Feasibility Randomised-Controlled trial of two online psychological interventions for stroke survivors
REC reference:	22/EE/0094
Protocol number:	005
IRAS project ID:	305848

Thank you for your letter of 09 June 2022, responding to the Research Ethics Committee's (REC) request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair and Lead Reviewer.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Good practice principles and responsibilities

The <u>UK Policy Framework for Health and Social Care Research</u> sets out principles of good practice in the management and conduct of health and social care research. It also outlines the responsibilities of individuals and organisations, including those related to the four elements of research transparency:

- 1. registering research studies
- 2. reporting results
- 3. informing participants
- 4. sharing study data and tissue

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

<u>Confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS</u> <u>management permission (in Scotland) should be sought from all NHS organisations involved in</u> <u>the study in accordance with NHS research governance arrangements.</u> Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations

Registration of Clinical Trials

All research should be registered in a publicly accessible database and we expect all researchers, research sponsors and others to meet this fundamental best practice standard. It is a condition of the REC favourable opinion that **all clinical trials are registered** on a publicly accessible database within six weeks of recruiting the first research participant. For this purpose, 'clinical trials' are defined as:

- · clinical trial of an investigational medicinal product
- clinical investigation or other study of a medical device
- combined trial of an investigational medicinal product and an investigational medical device
- other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice.

Failure to register a clinical trial is a breach of these approval conditions, unless a deferral has been agreed by the HRA (for more information on registration and requesting a deferral see: <u>Research registration and research project identifiers</u>).

If you have not already included registration details in your IRAS application form you should notify the REC of the registration details as soon as possible.

Publication of Your Research Summary

We will publish your research summary for the above study on the research summaries section of our website, together with your contact details, no earlier than three months from the date of this favourable opinion letter.

Should you wish to provide a substitute contact point, make a request to defer, or require further information, please visit: https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/

N.B. If your study is related to COVID-19 we will aim to publish your research summary within 3 days rather than three months.

During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you haven't already done so, please register your study on a public registry as soon as possible and provide the REC with the registration detail, which will be posted alongside other information relating to your project. We are also asking sponsors not to request deferral of publication of research summary for any projects relating to COVID-19. In addition, to facilitate finding and extracting studies related to COVID-19 from public databases, please enter the WHO official acronym for the coronavirus disease (COVID-19) in the full title of your study. Approved COVID-19 studies can be found at: https://www.hra.nhs.uk/covid-19-research/approved-covid-19-research/

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

After ethical review: Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study, including early termination of the study
- Final report
- Reporting results

The latest guidance on these topics can be found at https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/.

Ethical review of research sites

NHS/HSC sites

The favourable opinion applies to all NHS/HSC sites taking part in the study, subject to confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or management permission (in Scotland) being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS/HSC sites

I am pleased to confirm that the favourable opinion applies to any non-NHS/HSC sites listed in the application, subject to site management permission being obtained prior to the start of the study at the site.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	Version	Date
Copies of materials calling attention of potential participants to the research [Poster]	2	13 May 2022
Covering letter on headed paper [Covering letter]	1	27 May 2022
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Sponsor insurance evidence]	1	13 April 2022
IRAS Application Form [IRAS_Form_13042022]	1.121	13 April 2022
Letter from sponsor [Sponsor letter]	1	13 April 2022
Non-validated questionnaire [Screening quesionnnaire]	1	05 April 2022
Non-validated questionnaire [Intervention feedback]	1	05 April 2022
Participant consent form [Participant Consent form]	2	27 May 2022
Participant consent form [Participant consent to contact]	2	27 May 2022
Participant information sheet (PIS) [Neurolab Participant Information Sheet]	1	13 April 2022
Participant information sheet (PIS) [Participant Information Sheet]	2	13 May 2022
Referee's report or other scientific critique report [Thesis proposal feedback]		25 March 2022

Research protocol or project proposal [Protocol]	6	27 May 2022
Sample diary card/patient card [Executive functioning intervention slides session 2]	1	13 April 2022
Sample diary card/patient card [EF handout session 1]	1	13 April 2022
Sample diary card/patient card [EF handout session 2]	1	13 April 2022
Sample diary card/patient card [Stoke psychoeducation intervention slides session 1]	1	13 April 2022
Sample diary card/patient card [Stoke psychoeducation intervention slides session 2]	1	13 April 2022
Sample diary card/patient card [Stroke psychoeducation handout session 1]	1	13 April 2022
Sample diary card/patient card [Stroke psychoeducation handout session 2]	1	13 April 2022
Summary CV for Chief Investigator (CI) [CV Catherine Ford]	1	11 March 2022
Summary CV for student [CV Crina Ene]	1	14 March 2022
Summary CV for supervisor (student research) [CV Fergus Gracey]	1	29 March 2022
Validated questionnaire [DEX-R]	1	13 April 2022
Validated questionnaire [ICECAP-A]	1	13 April 2022
Validated questionnaire [PHQ-9]	1	13 April 2022
Validated questionnaire [SSEQ]	1	13 April 2022
Validated questionnaire [SWEMWBS]		13 April 2022

Statement of compliance

This Committee is recognised by the United Kingdom Ethics Committee Authority under the Medicines for Human Use (Clinical Trials) Regulations 2004, and is authorised to carry out the ethical review of clinical trials of investigational medicinal products.

The Committee is fully compliant with the Regulations as they relate to ethics committees and the conditions and principles of good clinical practice.

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: <u>http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/</u>

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities- see details at: https://www.hra.nhs.uk/planning-and-improving-research/learning/

IRAS project ID: 305848 Please quote this number on all correspondence

With the Committee's best wishes for the success of this project.

Yours sincerely

James Thomas

On Behalf Of Miss Stephanie Ellis Chair





Dr Catherine Ford Faculty of Medicine and Health Sciences University of East Anglia Norwich NR4 7TJ

Email: approvals@hra.nhs.uk

15 June 2022

Dear Dr Ford

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:

IRAS project ID: Protocol number: REC reference: Sponsor A Feasibility Randomised-Controlled trial of two online psychological interventions for stroke survivors 305848 005 22/EE/0094 University of East Anglia

I am pleased to confirm that <u>HRA and Health and Care Research Wales (HCRW) Approval</u> has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?

HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?

HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?

The standard conditions document "After Ethical Review – guidance for sponsors and investigators", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- · Notifying the end of the study

The <u>HRA website</u> also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

Who should I contact for further information?

Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is 305848. Please quote this on all correspondence.

Yours sincerely,

prope

Mark Sidaway Approvals Specialist Email: <u>approvals@hra.nhs.uk</u>

Copy to: Polly Harrison

List of Documents

The final document set assessed and approved by HRA and HCRW Approval is listed below.

Document	Version	Date
Copies of materials calling attention of potential participants to the research [Poster]	2	13 May 2022
Covering letter on headed paper [Covering letter]	1	27 May 2022
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Summary CV for Chief Investigator (CI) [CV Catherine Ford]	1	11 March 2022
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Validated questionnaire [PHQ-9]	1	13 April 2022
Validated questionnaire [SSEQ]	1	13 April 2022
Validated questionnaire [SWEMWBS]		13 April 2022

Information to support study set up

The below provides all parties with information to support the arranging and confirming of capacity and capability with participating NHS organisations in England and Wales. This is intended to be an accurate reflection of the study at the time of issue of this letter.

Types of participating NHS organisation	Expectations related to confirmation of capacity and capability	Agreement to be used	Funding arrangements	Oversight expectations	HR Good Practice Resource Pack expectations
There are no NHS research sites in this study, only NHS Participant IdentificationCentres (PICs).	PIC activities should not commence until a PIC Agreement is in place.	We are currently liaising with the sponsor to confirm contracting arrangements forPICs.	No external study funding has been sought.	The Chief Investigator will be responsible for all study activities performed atPICs.	The sponsor has stated that local staff in participating organisations in Englandwho have a contractual relationship with the organisation will undertake theexpected activities. Therefore no honorary research contracts or letters ofaccess are expected for this study.

Other information to aid study set-up and delivery

This details any other information that may be helpful to sponsors and participating NHS organisations in England and Wales in study set-up.

The applicant has indicated they do not intend to apply for inclusion on the NIHRCRN Portfolio.

Appendix G. Participant Information Sheet



A Feasibility Randomised-Controlled trial of two online psychological interventions for stroke survivors Participant information sheet

The purpose of this leaflet is to explain the research and what will happen if you decide to take part.

We are inviting you to take part in a research study. It is important that you read and understand why this research is taking place and what it involves before you decide to take part. Please take your time to read the following information carefully and discuss with others if you wish. You can find contact details of the researchers at the end of this document. Please contact us if there is anything that is not clear or if you would like more information.

What is the research about?

We want to test two online interventions for stroke survivors. One is about skills considered important for managing goals and problem solving, the other provides information about stroke. We want to find out whether it would be feasible to research these interventions as part of a larger definite trial.

By taking part in this study, you will help us learn more about how we can research online interventions for stroke survivors. In the long run it may mean that more people will have access to rehabilitation interventions.

We are asking people to take part if they meet the following criteria:

You are a stroke survivor that:

- Is aged 18 years old or over
- Has access to a computer and the internet
- Has access to an email address
- Does not have current significant mental or physical health difficulties (in addition to stroke)

Who is undertaking the study?

The study is being undertaken by Crina Ene as part of her Doctorate in Clinical Psychology at the University of East Anglia.

Do you have to take part?

No! It is up to you if you wish to take part or not. You can stop being part of the study at any time, without giving a reason, and without your legal rights being affected. If you withdraw from the study we will ask you about the reason why, but you are not obliged to answer this.

How will we use information about you?

We will need to use information from you for this research project. This information will include your name and contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

What would I have to do?

If you agree to participate, a member of the research team will call you in order to check that you meet the study inclusion and exclusion criteria. The call will take approximatively 15 minutes. As part of this process we will ask you to fill in a questionnaire that measures low mood. The name of the questionnaire is the Patient Health Questionnaire-9 (PHQ-9). During this telephone call we will also ask you to provide us the details of your General Practitioner (GP), as we need to tell them if we think you are at risk of harm or if your score on the low mood questionnaire suggests severe depression. We will let you know if this was the case.

If you are eligible to take part you will be sent a link to an online consent form, which we will ask you to read and fill in. You will have at least 48 hours to do this, and you can ask the team any questions about the study before signing the form. After completing the consent form, you will be emailed a link to complete several questionnaires, which we would like you do to within a week. One of the team members will be available to complete the questionnaires together with you if you experience difficulties with this. The questionnaires are:

- ✓ ICEpop CAPability measure for Adults
- ✓ The Stroke Self-Efficacy Scale
- ✓ Warwick-Edinburgh Mental Wellbeing Scale
- ✓ The Revised Dysexecutive Questionnaire

After the questionnaires are completed, you will be randomly assigned to receive one of the two interventions. We are not able to tell you which intervention you are receiving while you are involved in the trial but we will tell you after you finish the study or withdraw. Both interventions last for two weeks, and every week I will send you a link to a 30-minute recording that I would like you to watch. Both interventions also involve a weekly task relevant to the topics in each of the recordings that we will ask you to do. We will send you reminders to watch the video, and you will have a choice for how often to receive them and your preferred contact method.

At the end of the two weeks, I will ask you to again complete the questionnaires that you filled in before you started the intervention, and you will also be asked to fill in a feedback form about the intervention that you received. I will ask you to complete the questionnaires a third

time one month after you finish the intervention. After you complete the study, you will receive more information about which of the two interventions you completed and will have the option to be sent the materials for the intervention that you have not yet received.

In line with our duty to safeguard, if you tell me that you are a risk to your safety or that of others, I will have to pass this on to the relevant authorities; I will discuss with you if this is the case.

If you stop replying to emails the research team will

a) send an additional email advising that it is completely fine to not want to be involved in the study anymore but we want to check that this is the case

b) if there is no contact after two follow-up emails we will assume that you withdrew from the study.

What are the possible benefits of taking part?

The main benefit is that you will have access to stroke intervention materials which you may find useful. Additionally, you will contribute to a research project which may be useful for stroke survivors. You will also receive a £5 Amazon voucher as thank you for taking part, even if you decide to withdraw from the study early.

What are the possible disadvantages and risks of taking part?

We do not anticipate there being any risks to you due to your involvement in this research project. Some of the questionnaires you will be asked to complete are about your mental health and wellbeing, including feelings of depression. Some might find it uncomfortable to be asked about these kinds of things. Their completion might also take a significant amount of time. This is why we are asking you to take your time and complete the whole survey within a week. So you may stop, have a rest, and continue to complete them whenever you wish within a week. Additionally, you may use the contact details provided to you, to contact the researcher and discuss your concerns at any time, before, during or after the completion of the questionnaires.

Who has reviewed the study?

The ethical conduct of this study has been approved by an NHS Health Research Authority and Trust Research and Development department.

Where can you find out more about how your information is used? You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- by sending an email to the research team [c.ene@uea.ac.uk]
- by ringing us on [07749 725 729].

What do I do next?

If you are willing to consider taking part in the study, please email, telephone, or send a text message to Crina Ene (email: c.ene@uea.ac.uk; mob: 07749 725 729). I will then contact you by email or telephone and would be happy to answer any questions you may have about the study.

If you have any questions

If you would like any further information on the research, please contact Crina Ene at c.ene@uea.ac.uk. If you have any concerns about the research you may contact Professor Niall Broomfield (Head of Department for the UEA Department of Clinical Psychology and Psychological Therapies) via telephone (01603 59 1217) or email (n.broomfield@uea.ac.uk). Alternatively, please contact The Patient Advice and Liaison Service (PALS) if you wish to make a complaint about the study. To contact PALS, please phone NHS 111 to obtain the details of your nearest PALS office.

If you would like more support, please consider contacting the charities listed below. If you have an urgent healthcare or mental healthcare need that is not a life-threatening situation please call 111.

- Stroke Association
 - Stroke Helpline on 0303 3033 100 or email <u>helpline@stroke.org.uk</u>.
- MIND
 - o Infoline on 0300 123 3393
 - Email info@mind.org.uk

Appendix H. Executive Functioning Intervention Content

Session 1 topics:

- Things we want to do but struggle to versus things we want to avoid doing but struggle to, and what can get in the way.
- What executive functioning is and why it is important.
- How executive dysfunction can present.
- Being on autopilot.
- Goal management steps: identify goals, weigh up pros and cons of different ways of achieving them, breaking things down into steps, putting a plan into action and monitoring.
- SMART goals.
- Two examples of goal management, one for making a hot drink and the other for meeting with a friend.
- Homework task: use diagram provided to write down a goal and identify different ways in which it would be achieved.

What is executive functioning and why is it important?

- Deciding what we want to do
- Thinking of how to do it
- Starting to do it
- Keeping track
- Stopping at the right time



Session 2 topics:

- Recap from previous session.
- Putting a plan in place.
- Stop and think.
- Two examples of putting together a plan, one for making a hot drink and the other for meeting with a friend.
- Tips to make it easier to stick with a plan.
- Reflecting on whether activity went according to plan.
- Summary.
- More tips on how to put goal management strategies into practice.
- Homework task: make a step-by-step plan for a goal identified in the previous homework task.

Putting a plan in place



Once you select an option, plan everything you will need to do step-bystep. This will help you stay on track.

Write / draw / audio record the steps in the order in which you will do them.



The plan needs to be detailed enough that someone else would be able to follow it just by reading the instructions.

Appendix I. Stroke Psychoeducation Intervention Content

Session 1 topics:

- What is stroke.
- Types of stroke.
- Symptoms of a stroke (F.A.S.T).
- Beyond F.A.S.T.
- Brain Scans.
- Treatments for ischaemic stroke.
- Treatments for haemorrhagic stroke.
- Swallow screening.
- The NHS stroke treatment pathway.
- Professionals within the stroke pathway.
- Stroke charities.
- Risk factors for stroke.
- Homework task: talk to someone else about the signs that someone might be having a stroke, or write a note about them using handout provided.

Symptoms of a stroke

Face – the face may have dropped on one side, the person may not be able to smile, or their mouth or eye may have dropped.

Arms – the person with suspected stroke may not be able to lift both arms and keep them there because of weakness or numbness in one arm.

Speech – their speech may be slurred or garbled, or the person may not be able to talk at all despite appearing to be awake; they may also have problems understanding what you're saying to them.

Time – it's time to dial 999 immediately if you see any of these signs or symptoms.

Session 2 topics:

- Brain anatomy overview.
- The reptilian brain, limbic brain, and neocortex.
- Two hemispheres of the brain.
- Brain lobes.
- Overlap between lobes.
- Common deficits associated with right and left brain injury.
- Homework task: have a conversation with someone about something that they found interesting in the session. Alternatively, write it down using handout provided.



Lizard Brain (Brain stem and Cerebellum)

Autopilot Fight & Flight



Mammal Brain (Limbic system)

> Emotions Memories Habits



Human Brain (Neocortex)

Language, thinking, imagination, consciousness, logic and reasoning **Appendix J: Consent Form**

University of East Anglia

CONSENT FORM

Title of Project: A Feasibility Randomised-Controlled trial of two online interventions for stroke survivors

Name of Researcher: Crina Ene

Please tick all boxes

1. I confirm that I have read and understand the information sheet dated 13/05/2022 (version 2) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. I understand that should I withdraw, the information collected so far cannot be erased and that this information may still be used in the project analysis.

3. I understand that the researchers at University of East Anglia will hold my contact details so that they can liaise with me about the study.

4. I understand that I will not be named in any research reports, and my personal information will remain confidential.

5. I understand that the findings will be used in future conference and journal paper publications.









6. I understand that the information collected in this study will be used to support other research in the future and may be shared anonymously with other researchers.

7. I understand that if the researcher thinks that I, or someone else, might be at risk of harm, they will have to contact the relevant authorities; however, they will try and talk to me first about the best course of action.

8. I agree to take part in this study

Name of Participant	Date	Signature
Name of Researcher	Date	Signature