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ABSTRACT

Objective: To describe the process of developing a cognitive rehabilitation intervention for patients with post-stroke cognitive impairment (PSCI) and to describe the intervention prior to evaluation in a pilot randomised controlled trial (RCT). **Method:** The Medical Research Council framework, 'Developing and evaluating complex interventions', was used to develop the cognitive rehabilitation intervention. We conducted a combined analysis of the existing evidence base for PSCI rehabilitation alongside qualitative exploration of the perspectives of stroke survivors, their families, and healthcare professionals providing stroke care, on the necessary components for a cognitive rehabilitation intervention for PSCI. The Template for Intervention Description and Replication checklist was used as a structural framework for the description of the intervention. **Results:** The intervention comprises a five-week intervention integrating group-based activities, supported by a clinical neuropsychologist, with home-based activities to encourage self-efficacy through the practice of adjustment and compensatory strategies learned in the group format to achieve the patients' identified goals in managing their PSCI. **Conclusion:** A cognitive rehabilitation intervention for patients with PSCI has been developed and described. We are in the process of developing a structured intervention manual to standardise the content and delivery of the intervention for further testing in a pilot RCT.

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Introduction

Stroke is the second leading cause of death and disability worldwide (Feigin et al., 2017). Cognitive impairment has been reported to have a prevalence of over 50% in patients six months post-stroke (Mellon et al., 2015), with 38% of stroke survivors presenting with a level of cognitive impairment one year after stroke that does not meet the criteria for dementia (Sexton et al., 2019). Furthermore, the risk of dementia substantially increases following stroke, with an incidence rate of 34% one year after a severe stroke (Pendlebury & Rothwell, 2009). While the rehabilitation of the physical consequences of stroke has received much research focus (Horgan et al., 2008; Saka et al., 2009), less attention has been given to the cognitive and psychological sequelae of stroke and their subsequent impact on stroke survivors' adjustment to their physical and social environments (Hall et al., 2016). Furthermore, the efficacy of cognitive rehabilitation of post-stroke cognitive impairment (PSCI) has yet to be established in the literature, particularly when each affected cognitive domain (i.e., attention, executive function, memory, spatial neglect) is targeted in isolation (Bowen et al., 2013; Chung et al., 2013; das Nair et al., 2016; Loetscher & Lincoln, 2013; Loetscher et al., 2019).

Recognition of the effect of the consequences of diseases on patients' outcomes has informed the development of the biopsychosocial model of illness (Engel, 1977; Wade, 2015; Wade & Halligan, 2017), on which the International Classification of Functioning, Disability, and Health (WHO ICF) is based (WHO, 2001). The WHO ICF focuses not only on body functions and impairment, but also on the impact of illness on an individual's activities and participation. These factors are viewed relative to the health condition as well as the individual's personal, social, and environmental contexts.

The StrokeCog study was established to model and modify the consequences of stroke-related cognitive impairment through intervention (Merriman et al., 2017). The overarching aims of the project are to profile cognitive function in stroke patients in both the short- and long-term, to develop and then assess the effectiveness of a cognitive intervention to address PSCI, and to examine the cost-effectiveness of delivering the intervention in a healthcare setting. The rehabilitation of cognitive and psychological consequences of stroke is considered a complex intervention, which encompasses multiple interacting components (Craig et al., 2008). For example, patient characteristics such as heterogeneous levels of fatigue, adjustment post-stroke (i.e., emotional well-being, stress, etc.), impairment awareness, and functioning are likely to interact with each other and impact upon the intervention design. Due to the complex nature of cognitive rehabilitation, both in terms of the intervention components and patient and system characteristics, it is essential that the development and design of such interventions are described transparently to enable replication and help with facilitating evidence-based care (Hoffmann & Walker, 2015). The Template for Intervention Description and Replication (TIDieR) checklist is a useful tool in this regard to ensure detailed description of the particular intervention components (Hoffmann et al., 2014; Schmidt et al., 2018). The TIDieR checklist was developed through a process of literature review, a Delphi survey of international experts and stakeholders,

and a face-to-face panel meeting and is an extension of the Consolidated Standards of Reporting Trials (CONSORT) 2010 statement (Schulz et al., 2010).

We systematically developed the StrokeCog cognitive rehabilitation intervention for management of the impact of PSCI on activities and participation, based on the WHO ICF (WHO, 2001), and using the Medical Research Council (MRC) framework for developing and evaluating complex interventions (Craig et al., 2008). We aim to describe the process of developing the intervention for patients with PSCI and supply a detailed description of the intervention prior to evaluation in a pilot randomised controlled trial (RCT).

Methods and results

Medical research council framework – phase 1: Intervention development

The StrokeCog cognitive rehabilitation intervention was developed systematically, using the MRC framework for developing and evaluating complex interventions (Craig et al., 2008). The development stage (Phase 1) of the MRC framework comprises three steps: (i) establishing the existing evidence base, (ii) identifying relevant theory, and (iii) modelling process and outcomes, respectively. Relevant stakeholders comprising stroke survivors, their family members, and healthcare professionals (HCPs) providing stroke care were involved in informing the development and design of the cognitive intervention (Merriman, Bruen, et al., 2019), particularly where there were gaps in the literature.

Establishing the evidence base

Five previous Cochrane reviews have been conducted on the topic of post-stroke cognitive rehabilitation. These reviews have focused on occupational therapy for cognitive impairment (Hoffmann et al., 2010) and cognitive rehabilitation targeting executive dysfunction (Chung et al., 2013), attention deficits (Loetscher & Lincoln, 2013; Loetscher et al., 2019), memory deficits (das Nair et al., 2016), and spatial neglect (Bowen et al., 2013) resulting from stroke. The conclusion of each review has been that the effectiveness of cognitive rehabilitation aimed at each of these domains separately has yet to be established. However, the pattern of PSCI suggests that deficits are rarely limited to one cognitive domain in isolation and may be manifested across all cognitive domains (Sachdev et al., 2004; Vasquez & Zakzanis, 2015), with the severity of the cognitive impairment across different domains after stroke predicted by the lesion location (Barker-Collo et al., 2012; Nys et al., 2005). A further systematic review of 22 trials (nine of which focused on non-core domains such as perception and language) found a small overall effect of cognitive rehabilitation for general cognitive impairment post-stroke at the impairment level of functioning (Rogers et al., 2018). Similarly, our research team's systematic review of non-RCTs of psychological interventions for PSCI found a small overall effect on global cognition at the impairment level (Merriman, Sexton, et al., 2019), although these studies exhibited a high risk of bias and were of low quality. To address global cognitive dysfunction, cognitive interventions need to address a broad range of cognitive processes, while also having the scope to be tailored to the specific needs of individual patients, including design

features relating to intervention target, mode, intensity, duration, and frequency (Hoffmann et al., 2014).

As these important intervention design features (i.e., intensity, duration, frequency, etc.) of cognitive rehabilitation interventions post-stroke have yet to be established in the literature (McDonald et al., 2019), we conducted qualitative interviews with stroke survivors, their family members, and HCPs who provide stroke care to gain their perspectives on what particular intervention components should be included in the design of a cognitive rehabilitation intervention (Merriman, Bruen, et al., 2019).

Identifying relevant theory

The overall goal of the StrokeCog cognitive rehabilitation intervention is to enable stroke survivors to enhance their self-efficacy and confidence in their ability to manage their cognitive impairments and is based on the theoretical foundation of the biopsychosocial model (Engel, 1977). The WHO ICF (WHO, 2001) applies the biopsychosocial model of illness by focusing on the main components of disability, namely impairment, activities, and participation viewed in the personal, physical, and social contexts of the individual (Wade, 2005). This framework highlights the importance of conducting a thorough clinical and cognitive assessment in terms of the stroke survivor's current level of functioning and how that relates to the person's premorbid function and context, while also determining what is important to them in order to optimise cognitive rehabilitation by making it relevant and meaningful to the person's goals and cognitive profile (Mateer, 2005).

Self-efficacy theory (Bandura, 1991), which proposes that successful performance of a target behaviour is predicted by the patient's confidence in achieving that behaviour, further lends itself to optimising the impact of cognitive rehabilitation. Previous research has shown that the development of self-efficacy in managing cognitive impairment following stroke may be facilitated by experiences of achievement i) in tasks that are tailored to the individual's goals and cognitive capabilities; ii) through comparisons with other stroke survivors via peer support activities; and iii) through verbal encouragement (Horne et al., 2014; Woodman et al., 2014). Furthermore, the ability of stroke survivors to regain confidence in their own capacity was a prevalent theme in our qualitative analysis (Merriman, Bruen, et al., 2019). Systematic review evidence has demonstrated that self-efficacy is associated with better quality of life and adjustment post-stroke (Jones & Riazi, 2011). Goal setting and action planning are means through which patients can actively engage with their rehabilitation and manage their cognitive impairment (Hevey et al., 2020; Parsons et al., 2018). Both the biopsychosocial model and self-efficacy theory emphasise the importance of learning and practicing new skills during one's everyday life in one's own environment. In this way, stroke survivors can achieve their rehabilitation goals with home activities, through practicing and applying cognitive strategies learned in the rehabilitation group to real-life situations. Practicing new skills in the context of their own environment will further serve to empower individual stroke survivors to problem-solve and manage their cognitive impairment (Merriman, Bruen, et al., 2019).

Modelling outcomes and processes

Intervention outcomes and processes were modelled as recommended (Buhse & Mühlhauser, 2015; Sermeus, 2015), based on the synthesis of the scientific literature and qualitative work with stakeholders to inform the choice and role of intervention components, and the most relevant outcome measures to evaluate the effect of the cognitive rehabilitation intervention. The chosen outcome measures comprise composite outcomes of cognitive function as measured by the National Institute of Neurological Disorders and Stroke battery of cognitive assessment (Hachinski et al., 2006) (to be conducted approximately six weeks post-stroke), patient relevant outcomes, such as activities of daily living and stroke severity, and patient-reported outcomes such as self-efficacy and confidence (Buhse & Mühlhauser, 2015; Horne et al., 2017).

The modelling of processes, also based on combining systematic review evidence with qualitative findings and clinical expertise, resulted in 36 clinical activities being grouped into eight key intervention components (see Table 1). These key components were incorporated across sessions within the cognitive rehabilitation intervention. Figure 1 outlines the process map of the StrokeCog cognitive rehabilitation intervention, with a brief description of each stage of the intervention.

Intervention description and rationale

The TIDieR checklist (Hoffmann et al., 2014) was used to structure and describe the cognitive rehabilitation intervention.

TIDieR item 1: Brief name

The StrokeCog study: a group-based cognitive rehabilitation intervention, coupled with individualised home-based activities for patients with PSCI.

TIDieR item 2: Why: describe rationale, theory, or goal of the elements essential to the intervention

This intervention contains eight essential elements, comprising 36 clinical activities, which were derived from existing cognitive rehabilitation and self-management materials, drawing from the traumatic brain injury evidence-base (Cicerone et al., 2005, 2011; Headway, 2018; Lorig et al., 2012; Powell, 2013; Velikonja et al., 2014) as well as expertise from clinicians trained in secondary stroke prevention and neuropsychology, respectively.

Clinical assessment of cognitive functioning is an essential facet of cognitive rehabilitation to ensure the intervention is tailored to the cognitive profile of the stroke survivor and to ensure the activities are aimed at goals that are meaningful to the individual (Mateer, 2005).

Psychoeducation, including information concerning knowledge and consequences of stroke and stroke secondary prevention (Parappilly et al., 2020) was identified by stakeholders as being a crucial component of cognitive rehabilitation (Merriman, Bruen, et al., 2019).

Table 1. The eight key components and the 36 clinical activities.

	Key component	Clinical activity
1	Clinical assessment	Neuropsychological assessment
		Self-reported cognitive functioning
2	Psychoeducation	Introduction to StrokeCog cognitive rehabilitation intervention
		Information about stroke types and impact of stroke
		Secondary prevention information
		Lifestyle and health
		Psychoeducation about adjustment post-stroke
		Common cognitive difficulties following stroke Introduction to executive function/ memory/ attention
		Information on brain areas involved in these cognitive functions
		Processes of planning and organising
		Memory processes
		Attentional processes
		Recap on stroke psychoeducation
3	Supports	Information about available supports post-stroke
		Involvement of family/relatives
		Weekly phone calls with assistant psychologist
4	Emotional Well-being/ Adjustment	Introduction to relaxation
		Introduction to mindfulness
5	Goal Setting	Introduction to action planning
		Developing individual action plans
		Incorporation of executive function strategies into action plan
		Incorporation of memory strategies into action plan
		Incorporation of attention strategies into action plan
		Future action planning beyond cognitive intervention
6	Managing cognitive impairment	Executive function/ memory/ attention strategies for environment changes
		Executive function/ memory/ attention strategies for compensatory aids (internal)
		Executive function/ memory/ attention strategies for compensatory aids (external)
		Helpful materials and tools
		Real-life experiences and problem-solving
7	Peer support and learning	Group discussion on each preceding session and repetition and rehearsal of cognitive strategies
		Group discussion on action plan progress and problem-solving
		Strengths and weaknesses of individual's own executive function/ memory/ attention strategies
		Group discussion on usefulness of newly learned strategies
8	Individual exercises	Action plan progress and problem-solving
		Implementation of learned strategies and feedback

Goal setting and action planning are key elements of stroke rehabilitation. Goals that are relevant to the everyday life of the stroke survivor and are decided upon collaboratively with HCPs can lead to better outcomes, performance and goal achievement, and engagement with the intervention (Sugavanam et al., 2013).

Supports, such as information available from charitable organisations such as Headway Ireland and the Irish Heart Foundation are important to sign post as potential avenues of ongoing support for both the stroke survivor and family member once the intervention has finished. The support and involvement of family members may also encourage engagement with the cognitive rehabilitation intervention and aid the
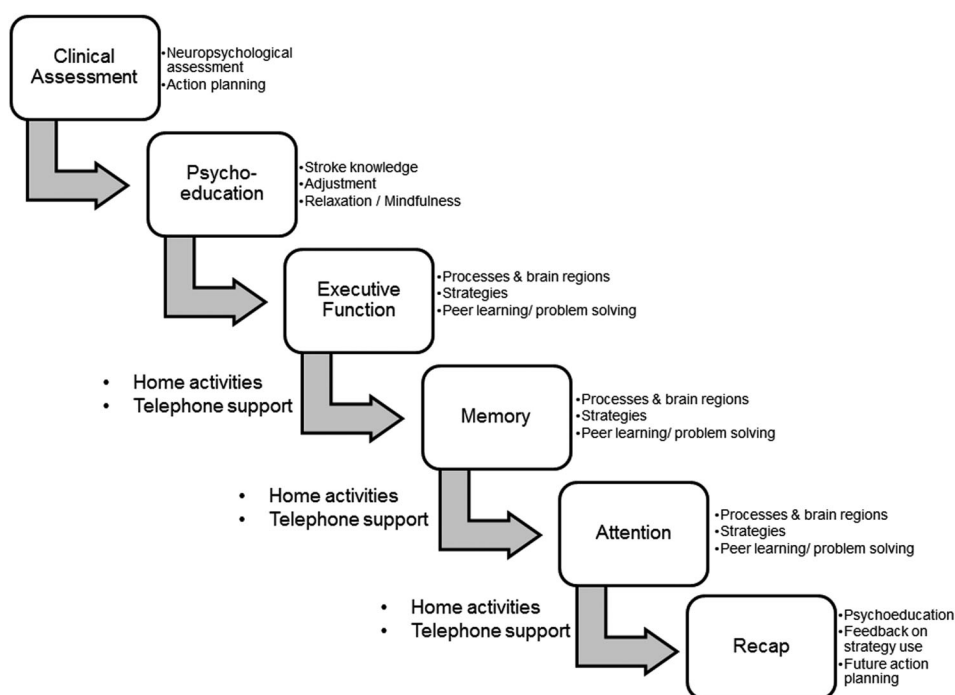
Figure 1. The StrokeCog cognitive rehabilitation intervention.

practicing of cognitive strategies in the home environment. Weekly phone support from the facilitator may assist with problem solving in achieving rehabilitation goals and serve as a prompt to continue practicing cognitive strategies in everyday activities (Behn et al., 2019).

Emotional well-being/adjustment can be affected post-stroke, with anxiety affecting 20% to 25% of stroke survivors (Knapp et al., 2020). Cognitive rehabilitation can incorporate interventions such as mindfulness and relaxation to help manage the stroke survivor's emotional distress, which may also impact cognitive dysfunction (Cicerone et al., 2000). Including a brief mindfulness and relaxation segment as an addition to cognitive rehabilitation, rather than the focus, may offer a beneficial coping strategy to stroke survivors (Jani et al., 2018).

Managing cognitive impairment is the crux of cognitive rehabilitation. The StrokeCog cognitive intervention includes various approaches based on the traumatic brain injury literature, including: a) restoration of previously learned behaviours or skills and cognitive function through repetition and reinforcement; b) the use of internal compensatory cognitive strategies to compensate for neuropsychological deficits; (c) the use of external cognitive strategies such as diary use, mobile phone reminders, or environmental structuring and support to compensate for neuropsychological deficits; and (d) enabling stroke survivors to manage their cognitive impairment in order to improve their overall level of functioning and quality of life (Cicerone et al., 2000).

Peer support and learning is facilitated through a group-based intervention, which creates opportunities for social interaction and facilitation of sharing

experiences of the impact of stroke and coping strategies, while also helping to nor-malise experiences following a stroke (Merriman, Bruen, et al., 2019). Group-based sessions also allow for the consolidation of learning through repetition and rehearsal of cognitive strategies.

Individualised exercises based on the stroke survivor's identified goals and tail-ored to their cognitive profile allow for the individual to practice cognitive skills and strategies outside of the rehabilitation group in their own home environment (Merriman, Bruen, et al., 2019).

TIDieR item 3: What (materials)

The intervention facilities include a tutorial room with laptop and projecting equipment on which the interactive learning and discussion material is presented by two facilitators.

A standardised booklet summarising the main points of each session is provided.

Materials such as hand-outs and worksheets to facilitate action planning for achievable goals that are relevant to the individual needs of the stroke survivor and their cognitive profile, based on managing PSCI, are provided. These materials include help-ful tools and tips for implementing compensatory strategies across the different cognitive deficits covered during group sessions.

Brief questionnaires regarding the stroke survivor's strengths and weaknesses with attention, executive function, and memory are provided to group members each week in preparation for the respective session covering these cognitive domains.

Stroke survivors are provided with a link to a website with exercises for mindfulness and relaxation (http://www.beaumont.ie/marc) and other self-help materials (Headway) (http://headway.ie/about-brain-injury/info-resources/).

Stroke survivors provide a telephone number to receive a phone call mid-week from the intervention facilitator.

TIDieR item 4: What (procedures)

Due to the limited information identified through examining the evidence-base in Phase 1 of the MRC framework (McDonald et al., 2019), decisions relating to intervention content, format, duration, dose, and delivery were informed by qualitative work with stroke HCPs, stroke survivors, and their family members/carers, .

In terms of intervention content, the qualitative findings recommended the inclusion of psychoeducation regarding the consequences of and adjustment to stroke. Several stroke survivors and family members highlighted a lack of clear communication regarding the impact of stroke on their return to pre-stroke lives and that cognitive rehabilitation should address this from the outset (Merriman, Bruen, et al., 2019). Interviewees indicated that cognitive rehabilitation content should be meaningful for the stroke survivor and relevant to what s/he wants to achieve (focusing on activity and participation levels of functioning, taking into account the individual's goals and context) and be cognisant of the moderating effect of a stroke survivor's capacity to engage with the intervention, considering potential fluctuating levels of fatigue, mood, and functioning. The focus on assisting the stroke survivor in making changes

that improve their function in areas that are relevant to their everyday lives is the cornerstone of cognitive rehabilitation (Cicerone et al., 2000).

The resulting cognitive rehabilitation intervention is a five-week group-based ($N = 4$) and largely interactive format, with short presentations relating to psychoeducation and adjustment to stroke-related deficits in the core cognitive domains of executive function, attention, and memory, respectively, and strategies addressing the activities and participation levels of functioning from the WHO ICF framework (WHO, 2001). Each session lasts approximately 2.5 h, with a break and refreshments in the middle. Based on the identification of relevant theory in the development of this complex intervention, home activities are included to encourage self-efficacy (Bandura, 1991) in tasks that are tailored to the individual's goals and cognitive capabilities, and the generalisation of skills and strategies learned, through the practice of skills learned in the group format to achieve these goals (Horne et al., 2014; Woodman et al., 2014).

Session 1 – Introduction and psychoeducation: The first session begins with welcoming the stroke survivors and outlining the content and process of the StrokeCog cognitive rehabilitation intervention. Topics include: discussion about causes and impact of different stroke types; secondary prevention and lifestyle; adjustment post-stroke; common mood and behavioural consequences of stroke; information about available supports; information for family members; introduction to action planning; introduction to emotional well-being/adjustment and mindfulness; and a self-report questionnaire on executive functioning for the following week's topic.

Session 2 – Executive Function: Topics include: discussion of the previous session and practice of home-based activities; introduction to processes and brain areas involved in executive function; common difficulties in planning and organising following stroke; different types of useful strategies (environment restructuring, internal and external compensatory aids); real-life experiences and problem solving; identification of three strategies to practice in the home setting; action planning; and a self-report questionnaire on memory for the following week's topic.

Session 3 – Memory: Topics include: discussion of the previous session and home-based activities; introduction to processes and brain areas involved in different types of memory; common difficulties in encoding, storing, and recalling information following stroke; different types of useful strategies (environmental restructuring, internal and external compensatory aids); real-life experiences and problem solving; identification of three strategies to practice in the home setting; action planning; and a self-report questionnaire on attention for the following week's topic.

Session 4 – Attention: Topics include: discussion of the previous session; introduction to processes and brain areas involved in different types of attention; common difficulties in attention and concentration following stroke; different types of useful strategies (environment restructuring, internal and external compensatory aids); collaboratively working through real-life experiences and problem solving difficulties; identification of three strategies to practice in the home setting; and action planning.

Session 5: Topics include: recap on stroke psychoeducation covered in Session 1; discussion about experience using the different types of strategies; making a plan to continue to employ the strategies learned and practiced during the rehabilitation intervention; and discussion of how to deal with future stroke-related challenges (see Figure 1).

TIDieR item 5: Who provided

In examining the evidence base, a range of different therapists were involved in delivering cognitive rehabilitation across previous studies (Merriman, Sexton, et al., 2019; Rogers et al., 2018). Our qualitative findings recommended that the cognitive rehabilitation intervention be delivered by a HCP trained in adjustment post-stroke. As the WHO ICF recommends a full clinical and cognitive assessment prior to cognitive rehabilitation to tailor the content to individual nuanced cognitive impairment (Mateer, 2005), the cognitive rehabilitation intervention groups are facilitated by a clinical neuropsychologist, supported by a stroke researcher and an assistant psychologist. The stroke researcher is involved in all aspects of assessment but not in intervention delivery; the assistant psychologist provides hands-on support in the setting up of group sessions, meeting and greeting patients (and family members, where relevant) and assisting the clinical neuropsychologist in running the sessions, as well as completing phone calls to participants to encourage self-efficacy, facilitate generalisation of skills, and trouble-shoot any difficulties encountered with home-based activities.

TIDieR item 6: How - modes of delivery

There was much heterogeneity in the literature regarding cognitive intervention delivery, with modes ranging from individualised computer-based sessions and pen-and-paper exercises to group-based interventions (Merriman, Sexton, et al., 2019; Rogers et al., 2018). Drawing on our qualitative findings, interviewees recommended the inclusion of both group-based and individualised components to incorporate peer support and tailored activities. This combination of delivery modes allows the stroke survivor to compare their achievements in completing their individualised activities and group-based activities with that of similarly affected group members, and to learn from their peers' own strategies in managing cognitive impairment (Horne et al., 2014; Woodman et al., 2014).

As the optimum timing of cognitive rehabilitation post-stroke is still unclear, recruitment of stroke survivors is from inpatient acute and rehabilitation settings. The cognitive rehabilitation intervention is delivered face-to-face in a group setting. To support stroke survivors between sessions in achieving their chosen action plans, a booklet summarising the main points of each session (see Item 3) and telephone calls are made weekly to participants by the assistant psychologist.

TIDieR item 7: Where - type of location

The group can be run in a tutorial room in a large tertiary referral hospital, or local hospital, or in community venues that are as convenient as possible for each group member.

TIDieR item 8: When and how much

The group sessions last approximately 2.5 h and run for five consecutive weeks, to facilitate participants in the implementation and practice of strategies learned in between sessions (see Figure 1). The dose and duration of sessions is informed by the qualitative findings and based on the organisational context (i.e., health system resources) in which the StrokeCog cognitive rehabilitation intervention takes place. The

intervention duration also takes into account challenges noted by family members and stroke survivors of continued engagement over a longer period of time, given other commitments (Merriman, Bruen, et al., 2019). Two hour group sessions are tolerated well by similar acquired brain injury populations (Behn et al., 2019).

TIDieR item 9: Tailoring
The cognitive rehabilitation intervention is partly standardised and partly patient-centred. Tailoring occurs through individual goal setting and through discussion topics within the group context.

Previous research has recommended that cognitive rehabilitation for stroke survivors be tailored to the individual's level of cognitive impairment (Cicerone et al., 2005), as some types of cognitive rehabilitation (e.g., internal compensatory strategies and metacognitive instruction strategies) are more effective for those with mild cognitive impairment compared to those with severe cognitive impairment. For this reason, intervention groups need to be stratified by level of cognitive impairment, as those with mild cognitive impairment will have different needs to those with moderate cognitive impairment (Mateer, 2005).

TIDieR item 10: Modifications during the course of the study
Modifications during the pilot RCT will be recorded through constant process evaluation and will be reported in the evaluation study.

TIDieR item 11: How well (planned)
Fidelity to the intervention protocol will be assessed in the pilot RCT. Attendance, attrition, and engagement (through attempting to achieve self-set goals through action planning) with the cognitive rehabilitation intervention will be recorded by the facilitators.

TIDieR item 12: How well (actual)
Attendance and intervention acceptability will be reported in the evaluation study.

Finalising the intervention

The resulting StrokeCog cognitive rehabilitation intervention consists of a five-week group-based cognitive intervention comprising psychoeducation, cognitive strategy training across cognitive domains consisting of executive function, memory, and attention, coupled with home-based exercises tailored to the patient's individual functional goals and cognitive profile.

To summarise the design and development stage of the intervention, the systematic review evidence thus far suggests a small effect of cognitive rehabilitation on global cognition, although the optimal timing, dose, frequency, and duration has yet to be established (Merriman, Sexton, et al., 2019). Based on the combined analysis of systematic review evidence and qualitative interviews with stroke survivors, their family members, and HCPs who provide stroke care, and the identification of the relevant theory underpinning the intervention design, we hypothesise that a group-based

cognitive intervention comprising psychoeducation regarding the consequences of stroke and adjustment, cognitive strategy training across cognitive domains, as described, coupled with home exercises tailored to the patient's individual goals and cognitive profile, will have an effect on stroke survivors' self-efficacy in managing their cognitive impairment.

We conducted initial feasibility and acceptability testing with two groups of stroke survivors: (1) a mild/moderate PSCI group with two participants (1 male, 1 female; aged 63 and 44, respectively; Montreal Cognitive Assessment (MoCA) score of 25 and 20, respectively); and (2) a severe PSCI group with two patients (2 males, aged 77 and 79 respectively, both with a MoCA score of 15), and two family members (one family member of each patient). The mild/moderate PSCI group found the intervention content, duration, and dose to be acceptable. However, while the family carers of the severely cognitively impaired stroke survivors reported finding the intervention content informative, the stroke survivors themselves reported being unable to engage with the intervention, even at a reduced session length of an hour with refreshment breaks. A pilot RCT will aim to compare the StrokeCog cognitive rehabilitation intervention to usual care for stroke survivors with mild to moderate PSCI. The primary focus of the pilot RCT is on recruitment and retention of patients in the intervention, and follow-up assessments. We will also investigate outcomes associated with the intervention and the anticipated effect size for powering a larger trial, with a focus on the feasibility of implementing the intervention in a future definitive RCT.

Discussion

A cognitive rehabilitation intervention for PSCI has been systematically developed based on the MRC guidelines for development and evaluation of complex interventions (Craig et al., 2008). In order to structure and manualise the intervention, the intervention was fully described using the TIDieR checklist (Hoffmann et al., 2014). The StrokeCog cognitive rehabilitation intervention is designed to incorporate both a group-based format, allowing for peer learning and support, with individual home exercises tailored to the goals and cognitive profile of each participant. Ascertaining the cognitive profile of stroke survivors to establish their cognitive strengths and weaknesses prior to implementing cognitive rehabilitation is critical to optimising cognitive rehabilitation (Mateer, 2005). The overall goal of the intervention is to enable stroke survivors to enhance their self-efficacy and confidence in their ability to manage the impact of their particular cognitive impairments on their everyday lives, and to achieve meaningful, functional goals.

There are a number of strengths associated with the design of this cognitive rehabilitation intervention. Firstly, the intervention was developed systematically and with transparency, following the MRC guidelines. Using this approach ensured that gaps in the evidence base were identified at the outset and augmented with substantial qualitative research. This in turn enabled the identification of the theoretical foundation on which to develop the intervention as well as identification of appropriate outcome measures that would be best used to evaluate the efficacy of the intervention. Furthermore, the detailed description and subsequent manualisation of the

intervention, including guidance on how best to tailor the content to different cognitive profiles, will enable implementation across health and community settings, with the potential for replication in other contexts beyond that of the pilot randomised study. The design of the intervention fully incorporated the views of relevant stakeholders, such as stroke survivors, their family members, and HCPs who provide stroke care. This allowed us to identify potential barriers and facilitators to implementing the intervention in a health/community setting, particularly as they relate to resources and expertise of facilitators. The ubiquity of cognitive impairment following stroke (approximately 38% in the first year after stroke (Sexton et al., 2019)) highlights the necessity of expanding the delivery of the cognitive rehabilitation intervention, if proven efficacious, beyond the pilot RCT. However, as healthcare resources differ across different geographical locations, both in the Republic of Ireland and internationally (McElwaine et al., 2015, 2016), this maybe a limitation to the further implementation of the cognitive rehabilitation intervention.

The design of the cognitive rehabilitation intervention may be limited by the nature of its complexity in terms of providing an evidence base for each individual clinical activity (Schmidt et al., 2018). To circumvent this limitation, we utilised expert clinical neuropsychological knowledge and experience in developing the minutiae of the individual intervention components. However, unlike the physical rehabilitation of function post-stroke (Pollock et al., 2007), the evidence-base for cognition-focused psychological interventions for cognitive impairment following stroke has yet to be established, due in part to a paucity of high quality randomised controlled studies (Merriman, Sexton, et al., 2019). This in itself is a limitation and highlights the need for well-designed studies aimed at improving cognitive function post-stroke. A barrier to conducting high quality studies is retention of stroke survivors to RCTs. A systematic review of the efficiency of recruitment to stroke rehabilitation found that only one third of eligible stroke survivors were randomised to rehabilitation trials, with approximately 5% of participants not completing the study (McGill et al., 2020). Another potential limitation to recruitment and retention may be related to stroke survivor characteristics, such as the severity of cognitive impairment. Initial feasibility testing of the StrokeCog cognitive rehabilitation intervention found that, while the intervention was feasible and acceptable to those with mild PSCI, it was not feasible to deliver the intervention to severely impaired stroke survivors. Group-based cognitive rehabilitation is recommended for those with mild to moderate PSCI as these individuals are more likely to have the capacity to engage with the intervention than those with severe cognitive impairment (Cicerone et al., 2011).

A future real-world implementation limitation relates to facilitation of the intervention by a clinical neuropsychologist. Currently, clinical neuropsychologists are rarely included as part of the stroke rehabilitation multidisciplinary team within the Irish health system (McElwaine et al., 2016) and many other countries (Clarke, 2013). However, if a pilot randomised trial of the StrokeCog cognitive rehabilitation intervention proves successful, it is hoped that the findings will provide robust evidence for more substantial involvement of psychological services in stroke care. The detailed description of the intervention is currently being manualised to facilitate further testing within a pilot RCT.

Disclosure statement

Funding

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Data availability statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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