



STUDY PROTOCOL

StrokeCog-R: Protocol for a Pilot Randomised Controlled Trial Evaluating the Feasibility and Acceptability of a Novel Cognitive Rehabilitation Intervention for Post-Stroke Cognitive Impairment

[version 1; peer review: 1 approved with reservations]

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Abstract

Background

Post-stroke cognitive impairment (PSCI) affects approximately 40% of stroke survivors within one year, yet cognitive rehabilitation is not routinely integrated into post-stroke care. This protocol outlines a

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pilot randomised controlled trial (RCT) to assess the feasibility, acceptability, and preliminary effectiveness of a structured cognitive rehabilitation programme, *StrokeCog-R*, for PSCI. A nested Study Within A Trial (SWAT) will evaluate the impact of follow-up communication methods on participant retention.

Any reports and responses or comments on the article can be found at the end of the article.

Methods

Sixty-four stroke survivors will be recruited and randomly assigned to either a StrokeCog-R intervention ($n=32$) or control (usual care; $n=32$) group. StrokeCog-R is a five-week, group-based cognitive rehabilitation/psychoeducation programme targeting executive function, memory, and attention, delivered by a clinical neuropsychologist. Primary outcomes include recruitment, retention, intervention acceptability, and cognition. Cognitive function will be assessed using the National Institute for Neurological Disorders and Stroke (NINDS) battery at baseline (six weeks post-stroke), immediately post-intervention/control period, and at a four-month follow-up. Secondary outcomes include self-efficacy, functional ability, mood, as well as carer-rated cognitive and behavioural changes and carer wellbeing. The SWAT will examine whether additional text messages during the follow-up period improve retention at the four-month assessment compared to telephone calls alone. Recruitment and retention rates will be reported with 95% confidence intervals. Effect size estimates from pre- to post-intervention changes in cognition will inform sample size calculations for a future definitive trial. Qualitative data will be analysed using a reflexive thematic approach, guided by the Consolidated Framework for Implementation Research (CFIR).

Results

This pilot RCT will assess the feasibility of conducting a full-scale definitive RCT, including recruitment and retention rates, and preliminary outcome trends. SWAT findings will guide future retention strategies.

Conclusions

Findings will inform the design of a larger RCT and, if feasible, support the potential integration of cognitive rehabilitation into routine post-stroke care to improve long-term cognitive outcomes.

Keywords

Attention, Cognitive rehabilitation, Executive function, Intervention studies, Memory, Outcome and process assessment, Pilot RCT, Post-stroke cognitive impairment, Protocol, Psychoeducation, Stroke

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Introduction

Stroke is the second leading cause of death globally, following ischaemic heart disease, and remains a major contributor to acquired disability^{1,2}. As global populations age, stroke has emerged as a critical public health challenge³. Although age-standardised stroke mortality rates have declined over the past two decades, the absolute number of stroke cases, survivors, and the overall global burden of stroke continue to rise^{1,4}. This increasing prevalence places substantial economic strain on healthcare systems and heightens demands for medical care, community support, and long-term rehabilitation services^{5,6}.

Stroke can lead to a wide range of physical, emotional, and cognitive impairments that significantly impact a survivor's quality of life. Indeed, post-stroke cognitive impairment (PSCI) is common, manifesting as either focal deficits (e.g., naming or hemi-spatial neglect) or global impairments affecting memory, attention, learning, decision-making, and problem-solving^{7,8}. Cognitive impairment is defined as self- or informant-reported cognitive complaints, objective deficits, preserved functional independence, and the absence of a dementia syndrome⁹. While most cases are mild-to-moderate in severity¹⁰, severe cognitive impairment can develop, particularly after recurrent strokes^{11,12}. Notably, over 50% of stroke survivors experience PSCI at six months post-stroke¹⁰, with 38% still affected at one year despite not meeting dementia criteria¹³. However, these estimates likely underrepresent the true burden due to practical challenges such as feasibility of testing and follow-up attrition¹¹.

Beyond cognitive decline, stroke survivors frequently experience emotional and psychological challenges^{14,15}, which can hinder their reintegration into social and occupational roles. These impairments often limit participation in meaningful daily activities^{16,17} and contribute to increased disability, reduced independence¹⁰, and long-term morbidity and mortality¹⁸. Additionally, cognitive impairment can interfere with adherence to medication and rehabilitation regimens¹⁸, emphasising the need for targeted cognitive interventions. Beyond its direct impact on stroke survivors, PSCI places substantial strain on caregivers, increasing disability and reducing overall quality of life¹⁹. There is also a strong correlation between cognitive impairment and the need for long-term care, particularly among individuals with severe post-stroke disabilities⁶.

Stroke and dementia exhibit a bidirectional relationship; experiencing a stroke elevates the risk of cognitive decline, while pre-existing dementia exacerbates the likelihood of stroke-related complications¹². Optimal acute stroke management and secondary prevention are therefore crucial in mitigating cognitive deficits and reducing the risk of recurrent stroke¹². A systematic review and meta-analysis found that 10% of patients had dementia before their first stroke, another 10% developed dementia within one-year post-stroke, and more than one-third developed dementia after recurrent stroke¹². More recent analyses estimate that approximately one in five stroke survivors develop dementia (type, unspecified), with the highest risk occurring within the first year, particularly following recurrent strokes¹¹. The Oxford Vascular Study further

elucidates this risk, demonstrating that the incidence of dementia within one year post-event was 34% for patients with severe stroke, 8% for those with minor stroke, and 5% following transient ischaemic attack²⁰. These findings indicate a significant increase in dementia risk even after less severe cerebrovascular events, compared to the general population, underscoring the need for interventions across all severities of stroke²⁰.

Variation in reported prevalence is largely due to methodological differences across studies, including whether pre-stroke dementia is accounted for, differing diagnostic criteria, and the heterogeneity of stroke and dementia subtypes, many of which are not clearly specified^{11,12,20}. Indeed, the term “poststroke dementia” is commonly applied to any dementia developing after a clinically evident stroke, without necessarily indicating a specific underlying neuropathological mechanism²¹. This practical convention acknowledges that cognitive impairment post-stroke often reflects a blend of vascular damage and neurodegenerative processes²².

Building upon this understanding, the convergence of an ageing population and increasing post-stroke survival rates suggests that the prevalence of post-stroke dementia is expected to rise, as both stroke and dementia risks escalate with advancing age^{23,24}. These findings underscore the critical need for effective secondary prevention strategies to reduce the burden of PSCI and dementia. As research increasingly focuses on modifiable risk factors for dementia, PSCI has emerged as a crucial target for preventive strategies²⁵. Indeed, addressing PSCI has been identified as a key priority for stroke survivors, caregivers, and healthcare professionals^{26–28}.

Cognitive rehabilitation for PSCI

While substantial research has been dedicated to physical rehabilitation post-stroke, leading to significant functional improvements²⁹, cognitive rehabilitation remains relatively underexplored by contrast, with evidence for its efficacy not well established³⁰. Cognitive rehabilitation involves systematic, functionally orientated therapeutic activities guided by cognitive assessment and an understanding of the relationship between brain injury and behaviour³¹. It addresses multiple cognitive domains, including attention, memory, perception, and executive functioning (e.g., cognitive flexibility, problem-solving, planning, and self-regulation). Despite its potential benefits, five Cochrane reviews examining post-stroke cognitive rehabilitation across these domains, focusing on occupational therapy for cognitive impairment⁸ and interventions targeting executive dysfunction³², attention deficits³³, memory deficits³⁴, and spatial neglect³⁵, concluded that evidence for its efficacy remains insufficient. Consequently, the effectiveness of cognitive rehabilitation interventions targeting isolated cognitive domains remains uncertain.

PSCI often manifests as deficits across multiple cognitive domains rather than being confined to a single function^{36,37}. The severity of cognitive impairment is further influenced by lesion location, which can affect multiple cognitive domains^{38,39}. A systematic review of 22 trials, including nine focusing on

non-core domains such as perception and language, found a small effect of cognitive rehabilitation on general cognitive impairment⁴⁰. Similarly, a review of non-randomised controlled trials assessing psychological interventions for PSCI reported a small effect on global cognition³⁰, though these studies exhibited low quality and high risk of bias. These findings highlight a significant lack of high-quality randomised controlled trials (RCTs) in this area, underscoring the need for further rigorous research to strengthen the evidence base.

In Ireland, the lack of cognitive rehabilitation and psychological support in standard stroke care has been flagged as a key issue in the National Stroke Strategy 2022–2027². The National Institute for Health and Care Excellence (NICE) guidelines recommend that all stroke patients be screened for cognitive impairment within two weeks of stroke onset, irrespective of severity, to identify initial cognitive deficits⁴¹. If impairment is detected, a full cognitive assessment should be conducted six weeks post-stroke^{41–43}. However, evidence suggests that cognitive assessments are not routinely conducted in Ireland or internationally. The 2022 National Stroke Audit⁴⁴ highlights a severe shortage of psychological services for patients with PSCI, a problem unchanged since the first audit in 2006–2007⁴⁵. While 93% of patients are assessed by physiotherapists, only 7% are assessed by psychologists⁴⁴, and just 21% of hospitals provide access to clinical psychologists as part of routine stroke unit care⁴⁶. The absence of structured cognitive rehabilitation programmes, coupled with the significant shortage of psychological services, highlights a crucial gap in post-stroke care, emphasising the urgent need for targeted interventions.

Development of the StrokeCog-R intervention

In response to this critical gap in post-stroke cognitive rehabilitation, the original StrokeCog study aimed to model and mitigate the impact of PSCI through targeted intervention, with a key objective of developing and evaluating an effective cognitive rehabilitation programme⁴⁷. The StrokeCog-R intervention was created using the Medical Research Council (MRC) framework for complex interventions^{48,49}. Given the multifaceted nature of cognitive rehabilitation (shaped by factors such as fatigue, emotional adjustment, impairment awareness, and functional capacity), a structured, evidence-based approach was essential. The intervention's design was informed by a systematic review, qualitative interviews with 44 stakeholders (including stroke survivors, carers, and healthcare professionals), and feasibility testing through n-of-1 studies to evaluate its real-world applicability^{28,30,50,51}.

Findings from this development phase highlighted the need for structured yet flexible interventions that addressed multiple cognitive domains while accommodating individual needs^{28,30,50}. Stroke survivors reported that cognitive deficits significantly impacted daily life, confidence, and self-efficacy, emphasising the importance of psychoeducation, fatigue management, adjustment strategies, and goal-oriented rehabilitation. Regaining confidence in cognitive and functional abilities emerged as a central theme²⁸, with research linking

confidence to self-efficacy⁵², a top priority for stroke survivors, caregivers, and healthcare professionals^{26,27}. As self-efficacy is a key predictor of rehabilitation success⁵³, it was made central to the StrokeCog-R intervention. Systematic reviews further reinforce self-efficacy's role in post-stroke adjustment⁵⁴, while goal-setting and action planning empower patients to manage cognitive challenges^{55,56}. Participants also expressed a strong preference for interventions tailored to cognitive severity, fatigue, mood fluctuations, and personal goals. To address this, StrokeCog-R integrates both group-based and individualised components, balancing peer support with personalised rehabilitation strategies to enhance self-efficacy, psychological adjustment, and long-term cognitive recovery. Another key recommendation from the development phase was that cognitive rehabilitation should be delivered by healthcare professionals trained in both cognitive rehabilitation and post-stroke adjustment. Clinical neuropsychologists, given their expertise, were identified as ideal facilitators. However, they remain underrepresented in stroke rehabilitation teams both nationally and internationally^{44,45}.

The resulting StrokeCog-R intervention consists of a five-week group-based programme led by a clinical neuropsychologist⁵⁰. Sessions, lasting 2.5 hours with a mid-session break, accommodate four patients and combine cognitive training with psychoeducation. Home-based activities are personalised to facilitate skill transfer into daily life. In addition to cognitive rehabilitation, the intervention prioritises psychological adjustment through stress management, fatigue management, and self-efficacy strategies. The intervention draws from evidence-based rehabilitation approaches in traumatic brain injury rehabilitation^{57–62} and incorporates expertise from clinicians specialising in neuropsychology and secondary stroke prevention. The intervention is grounded in a biopsychosocial model⁶³, recognising the interplay between cognitive impairment, daily activities, and social participation. The WHO International Classification of Functioning, Disability, and Health (ICF)⁶⁴ further informs its approach, emphasising the need to assess not just impairment but also its impact on meaningful activities and participation⁶⁵. A thorough clinical and cognitive assessment ensures that rehabilitation aligns with the individual's premorbid function, current needs, and personal goals⁶⁶.

Feasibility testing of StrokeCog-R

Feasibility testing employed an n-of-1 study design to assess the intervention's acceptability and practicality^{50,51}. Two groups participated: one with mild-to-moderate PSCI and another with severe PSCI alongside their caregivers. Each participant engaged in group-based rehabilitation supplemented by individualised home exercises. The study confirmed the intervention's suitability for individuals with mild-to-moderate PSCI, with participants reporting subjective improvements in cognitive function and self-efficacy. They found the intervention's content, duration, and dose acceptable. However, while caregivers of stroke survivors with severe PSCI found the content informative, the survivors themselves reported being unable to engage with the intervention, even at a reduced duration. Further, recruitment challenges emerged as a key

barrier, as clinical staff with existing workloads managed patient recruitment, leading to delays and participant withdrawals before intervention commencement. However, once initiated, retention was high. These findings informed refinements for the present pilot RCT methodology. To enhance recruitment efficiency, a dedicated research assistant will oversee patient enrolment, reducing the burden on clinical staff. The need for protected time for clinical neuropsychologists to deliver the intervention was also identified. Moreover, inclusion criteria were refined to focus on stroke survivors with mild-to-moderate PSCI.

The present study: aims and research questions

Pilot RCT: StrokeCog-R. This protocol outlines the pilot RCT which aims to assess the feasibility and acceptability of delivering the StrokeCog-R cognitive rehabilitation intervention for stroke survivors with mild-to-moderate cognitive impairment. Specifically, the primary focus is to evaluate the implementation of StrokeCog-R by examining recruitment, retention, follow-up processes, and cognitive outcomes. Additionally, the study will estimate the effect size (based on between-group changes in cognition over time) to inform the design of a future definitive trial comparing StrokeCog-R to usual post-stroke care in Ireland. This study aligns with Step 3 of the Medical Research Council (MRC) Framework for Developing and Evaluating Complex Interventions^{48,49}. A qualitative process evaluation will explore the acceptability of the intervention to patients and patient adherence to the study protocol, with findings used to refine the protocol for a larger trial.

Secondary objectives include exploratory analyses of self-efficacy outcomes. Additionally, a micro-costing analysis will examine material and consumable expenses, as well as staffing costs for recruitment, assessments, and intervention delivery. Healthcare utilisation costs recorded for both the intervention and control groups will also provide insights into the cost of usual care and intervention participation for the purpose of developing and costing a larger definitive trial.

Study Within a Trial (SWAT): Retention Strategies. As part of the pilot RCT, we will conduct a Study Within a Trial (SWAT) to evaluate the effectiveness of communication strategies in improving participant retention at follow-up. Retention remains a significant challenge in clinical trials, with a median loss-to-follow-up of 11% reported in UK trials⁶⁷, and it is a top priority for methodological research⁶⁸. The SWAT will investigate the effectiveness of different communication strategies in improving participant retention at follow-up. The primary research question is whether supplementing follow-up telephone calls with summary text messages enhances retention compared to telephone calls alone. Given the cognitive challenges faced by stroke survivors, written summaries may improve recall and engagement, ultimately reducing loss to follow-up. This study aligns with the PRioRiTy II research agenda, specifically addressing the question of how technology can optimise trial follow-up processes⁶⁹. Findings will contribute to trial methodology by informing best practices for participant retention in

post-stroke cognitive rehabilitation research and will support the design of a future definitive StrokeCog-R trial.

Protocol

Study design

This pilot RCT will evaluate a 5-week, group-based cognitive rehabilitation intervention. Sixty-four stroke survivors with mild-to-moderate cognitive impairment will be randomised to either a StrokeCog-R intervention or control group. The pilot RCT was registered at clinicaltrials.gov (NCT06021470) and ethical approval was granted by the Beaumont Hospital Research Ethics Committee (REC reference: 23/14), which has oversight over both recruitment settings (Beaumont Hospital and St. Joseph's Rehabilitation Hospital, Dublin, Ireland). Additionally, the SWAT will be conducted during the follow-up period of the pilot RCT. Participants within both intervention and control groups will undergo further randomisation to the SWAT intervention, allowing for additional evaluation of specific trial processes. The SWAT is registered in the SWAT repository at Queen's University Belfast (SWAT232;⁷⁰). We used the SPIRIT checklist when writing this report⁷¹.

Study setting

Recruitment will be conducted at Beaumont Hospital and St. Joseph's Rehabilitation Hospital in Dublin, Ireland, while assessments and interventions will take place at the Clinical Research Centre in Beaumont Hospital.

Participants

This pilot RCT aims to recruit 64 stroke survivors diagnosed with mild-to-moderate PSCI, with equal allocation to the intervention and control groups. While the study is not powered to detect a significant effect on the primary outcome (cognitive function, specified below), it will provide an estimate of the standard deviation (SD) necessary for calculating effect size in a future definitive trial. Additionally, whenever possible, a caregiver or family member will be invited to participate by completing questionnaires, with one respondent per participant (64 caregivers/family members). Additionally, the staff members involved in delivering the intervention will participate in a qualitative process evaluation following intervention delivery.

Sample size calculation

Sim *et al.*⁷² recommend a minimum of 50 participants to estimate SD with sufficient precision; with 64 participants, this study meets that threshold, ensuring reliable data for informing a larger trial. Additionally, a minimum sample of 60 participants is required to estimate a recruitment or retention rate of at least 50% with a precision of 12.7%. Recruitment feasibility is supported by stroke admission rates, with 433 admissions to the Beaumont Hospital stroke unit in 2022⁷³. Considering a 15–20% mortality rate and that 38% of surviving patients present with cognitive impairment¹³, a recruitment rate of six participants per month is expected. Based on prior research and national audit data, this enrolment rate would enable completion of study recruitment within 12 months. To support

participant adherence, recruitment and retention success is defined as retaining at least 90% of those randomised at the 4-month follow-up assessment.

Recruitment and eligibility screening

To ensure a rigorous selection process, recruitment will follow a structured, multi-stage eligibility procedure (see Figure 1).

Stage 1: Pre-screening. A research assistant (RA) will recruit consecutive stroke patients from both an acute hospital setting (Beaumont Hospital) and a post-acute rehabilitation facility (St. Joseph's Hospital). Patient identification will be facilitated through collaboration with a multidisciplinary stroke team. A pre-screening assessment, conducted in consultation with clinical staff, will establish overarching eligibility, ensuring that patients who do not meet inclusion criteria are not approached. Initial inclusion criteria include prospective participants who have experienced a first-ever ischaemic stroke, are aged 18 or older, reside in the community rather than in long-term care facilities, speak and understand English, and have the capacity to provide informed consent. Additionally, participants must have no history of neurodegenerative disorders or psychiatric conditions as defined by DSM-5 or ICD-11 criteria. Eligible patients will be introduced to the study by a clinical team member acting as a gatekeeper. The RA will then provide further details, including a participant information leaflet (PIL).

Stage 2: Bedside screening. Patients expressing interest in participation will provide written informed consent for screening. Adequate time will be given to review the PIL, ask questions, and sign the first consent form, which will apply solely to the screening process. Patients deemed eligible post-screening will undergo an additional consenting process before formal enrolment in the main trial. Participants will first be screened for delirium using the 4AT (Assessment Test for Delirium and Cognitive Impairment)⁷⁴, with a score below 4 indicating eligibility. If delirium is detected, screening will be halted. Next, participants will be screened for aphasia using the Frenchay Aphasia Screening Test (FAST)⁷⁵, with a minimum score of 13 required for eligibility. If no significant aphasia or delirium is present, participants will then complete the Montreal Cognitive Assessment (MoCA)⁷⁶, with a minimum score of 18 required for inclusion (permission for its use was obtained 20th September 2023, <https://mocacognition.com>). A score of 18 or above indicates either mild cognitive impairment (MCI) or normal cognitive performance⁷⁶. Those meeting this criterion will be initially included, with the understanding that a comprehensive neuropsychological assessment will be conducted six weeks post-stroke. This will help identify more subtle cognitive deficits that may not be apparent during the initial screening or account for cognitive fluctuations in the early period following a stroke⁷⁷. Patients failing to meet eligibility criteria due to more severe cognitive impairment, significant aphasia, or current delirium will be excluded from the study. These patients will be

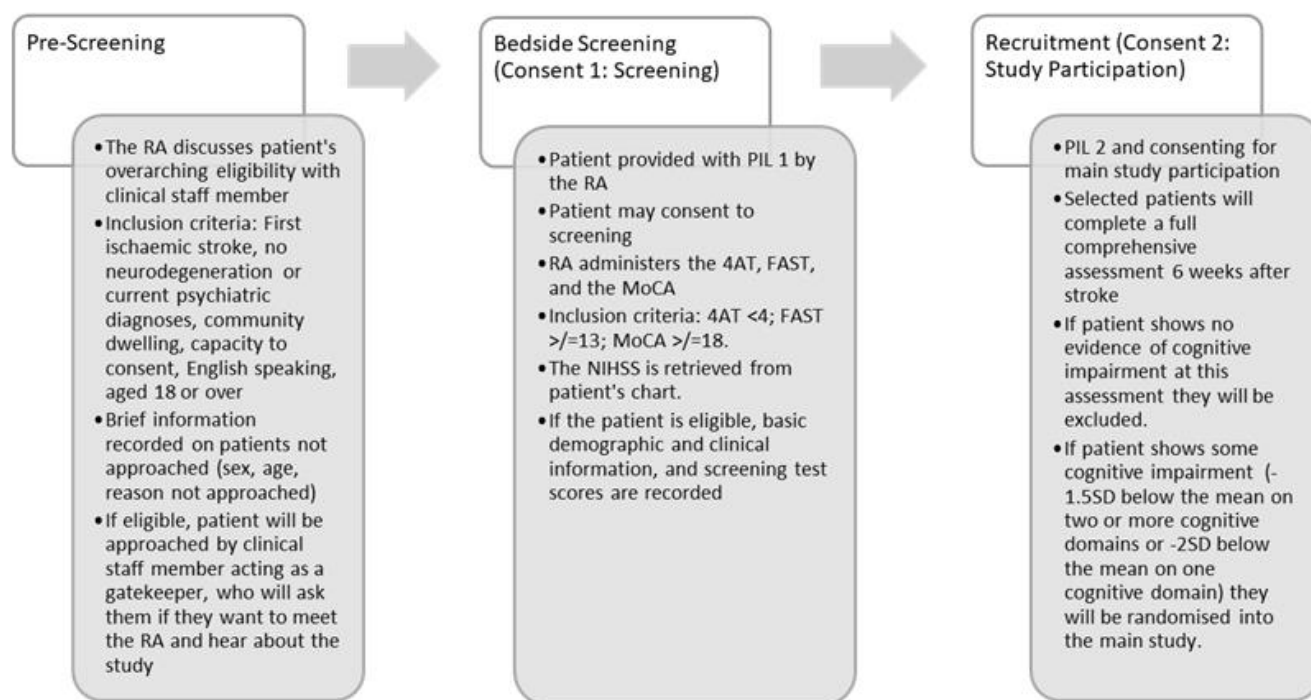


Figure 1. A flow diagram of the multi-step participant recruitment and screening eligibility processes. Note. Abbreviations: 4AT, Assessment Test for Delirium and Cognitive Impairment; FAST, Frenchay Aphasia Screening Test; MoCA, Montreal Cognitive Assessment; NIHSS: National Institutes of Health Stroke Scale; PIL, participant information leaflet; RA, research assistant; SD, standard deviation.

informed of the outcome and thanked for their participation. Those patients meeting all screening requirements will be invited to proceed with participation.

Baseline data will be collected for all screened participants, including demographic information such as age, sex, highest level of education, and employment status. Clinical details will also be extracted from the patient's medical records, including stroke history, early intervention information, multimorbidity, clinical frailty, and stroke severity as measured by the National Institutes of Health Stroke Scale (NIHSS;⁷⁸). All screening scores and patient data will be recorded using a pseudonymous alphanumeric code to maintain confidentiality. For individuals found to be ineligible following screening, the reason for exclusion will be documented.

Stage 3: Baseline neuropsychological assessment. Participants will undergo a full neuropsychological evaluation six weeks post-stroke, in line with NICE recommendations, which recommend that cognitive screening be followed by a detailed assessment using valid and reliable tools before initiating a treatment plan⁴¹⁻⁴³. For participants discharged from the hospital, assessments will take place at a Clinical Research Centre, with transport arranged by the study team. Home-based assessments will be offered for individuals with mobility challenges. Patients screened in the rehabilitation setting will undergo full neuropsychological assessments within one week of their bedside screening if they are six weeks or more post-stroke.

Before proceeding with the full baseline assessment, participants will complete a second informed consent process specific to their enrolment in the main pilot RCT. They will then undergo a comprehensive 60-minute neuropsychological battery based on the National Institute of Neurological Disorders and Stroke (NINDS) cognitive assessment battery⁷⁹ and some additional measures (see §*Outcome Measures*). This assessment will evaluate core cognitive domains, including memory, attention, executive function, and information processing speed. Norm-referenced test scores, using norms from the test publishers, will determine final eligibility. Participants will be included if they score at least 1.5SD below the mean in two or more cognitive domains or at least 2SD below the mean in one cognitive domain, consistent with established criteria used in other MCI and post-stroke cognitive studies^{80,81}. Those with no detectable cognitive impairment following this assessment will be excluded from further study participation and will be thanked for their time. Participants meeting the cognitive impairment criteria will proceed to randomisation.

For each eligible patient participant, a family member or caregiver will be invited to take part in the study. The patient will be asked if they have a family member or carer who is interested in participating. If the individual expresses interest in participating, they will receive a PIL and provide written consent, which can be returned via a pre-stamped, addressed envelope. If the family member or caregiver is available in person, they will sign the consent form on-site. Standardised questionnaire

measures will then be sent by post, and can either be returned using a separate pre-stamped, addressed envelope or brought to the participant's subsequent testing session.

Finally, staff members involved in delivering the intervention will be invited to participate in a qualitative process evaluation. They will be provided with a PIL and will give written informed consent if they choose to take part.

Randomisation and blinding

Following the baseline assessment, eligible participants will be randomly assigned to either the intervention or usual care group by the RA. A total of 64 stroke survivors will be randomised, with equal allocation to the intervention ($n= 32$) and control ($n= 32$) groups using a computer-generated randomisation sequence. Randomisation will be conducted by an independent statistician (KB) to ensure allocation concealment. The randomisation sequence will be generated using the envelope randomisation⁸² to create a block randomisation list for the 1:1 randomisation to intervention or control group using block sizes 4, 6, and 8. In addition, within the intervention and control arms, a further randomisation sequence will be generated for the allocation to the SWAT group in a 1:1 ratio, using blocked randomisation with block sizes 4, 6 and 8. To ensure the concealment of the allocation, the randomisation sequence will only be available to the researcher who is involved in recruiting the participants into the study. The researcher conducting all post- and follow-up neuropsychological assessments will remain blinded and will not be involved in the intervention delivery. Since participants cannot be blinded to their group assignment, objective cognitive measures will be used to minimise response bias. To further preserve blinding, participants will be instructed not to disclose their allocation during post-assessments. The clinical neuropsychologist delivering the intervention will have no role in assessments. All participant data will be pseudonymised initially using unique alphanumeric identifiers for pre-, post-, and follow-up assessment analyses, until eventual irrevocable anonymisation following study completion.

Interventions protocol

StrokeCog-R intervention group. The intervention will be delivered in small groups of four participants at Beaumont Hospital, Dublin, Ireland by a clinical neuropsychologist. The 5-week programme combines psychoeducation with compensatory cognitive strategies to target executive function, memory, and attention. Each session lasts approximately 2.5 hours, including a break of 30 minutes with refreshments, and incorporates both rehearsal-based and compensatory-based strategies to enhance cognitive functioning. Sessions include brief presentations on stroke-related cognitive deficits, along with discussion and practical strategies for managing these challenges. Between sessions, participants engage in tailored home activities designed to reinforce skill application, promote self-efficacy, and support the achievement of personally identified goals. To maintain engagement, a research team member conducts weekly follow-up phone calls to assess

participation, self-efficacy, and general well-being, as well as providing additional support for home activities where necessary. The content of each session is outlined below.

Session 1 – Introduction and Psychoeducation: This first session welcomes participants and provides an overview of the StrokeCog-R cognitive rehabilitation programme. Key topics include the causes and impact of different stroke types, secondary prevention and lifestyle modifications, post-stroke adjustment, common mood and behavioural changes including fatigue, and available support resources. The session also introduces action planning, emotional well-being strategies, and mindfulness. Additionally, participants complete a self-report questionnaire on executive functioning in preparation for the next session.

Session 2 – Executive Function: This session begins with a review of the previous week's material and home-based activities. Participants learn about the brain regions involved in executive function and common difficulties with planning and organisation following stroke. Various compensatory strategies are introduced, including environmental modifications, internal cognitive techniques, and external memory aids. Participants share real-life experiences, engage in problem-solving activities, and identify two to three strategies to implement at home. A self-report questionnaire on memory is completed in preparation for the next session.

Session 3 – Memory: Following a review of the previous session, this session focuses on different types of memory and the brain areas involved in encoding, storing, and retrieving information. Participants learn about common memory deficits after stroke and explore strategies for improving recall, including environmental restructuring and the use of internal and external memory aids. Practical exercises and problem-solving discussions reinforce these strategies. Participants select two to three strategies to practice at home and complete a self-report questionnaire on attention for the next session.

Session 4 – Attention: This session covers the different types of attention, the brain regions responsible for attention control, and common attention and concentration difficulties following stroke. Participants are introduced to strategies for managing attentional deficits, including environmental adjustments and cognitive compensatory techniques. Real-life experiences are discussed, and problem-solving exercises are used to help participants integrate these strategies into their daily lives. Participants develop an action plan for continued practice at home.

Session 5 – Emotional Well-Being and Consolidation of Learning: The final session revisits stroke-related psychoeducation from Session 1 and reviews participants' experiences with the strategies introduced throughout the programme. The discussion focuses on the psychological impact of stroke, common mood changes, managing

fatigue, and strategies for emotional regulation and well-being. Participants develop a long-term plan to maintain and apply the cognitive strategies they have learned and discuss approaches to managing future stroke-related challenges.

Control group: usual care. Participants in the control group will receive their usual standard stroke rehabilitation care. The nature and intensity of usual care may vary between acute hospital and rehabilitation settings. To account for these variations and also to inform a micro-costing analysis, detailed information on healthcare utilisation will be recorded at each assessment session for both the intervention and control groups.

To maintain engagement, a member of the research team also makes weekly follow-up phone calls to the control group during the intervention/control period, coinciding with the timing of calls to those in the intervention group, to assess participation and check on general well-being. Upon study completion (i.e., once all intervention groups have concluded and control group participants have completed their follow-up assessments), individuals in the control group will receive a video-recorded version of the StrokeCog-R intervention along with all accompanying materials.

SWAT intervention group. During the four-month period between the post-intervention and follow-up assessments, participants in the SWAT intervention group will receive two follow-up telephone calls, each accompanied by a summary text message. The first call will take place one month after the immediate post-intervention assessment, while the second will occur one month prior to the final four-month follow-up assessment. These calls will follow a structured script that includes: (a) an expression of appreciation for their participation in the StrokeCog-R trial; (b) a reminder of the importance of continued involvement; (c) details of the next scheduled contact before the follow-up assessment; (d) information on the expected timeline for trial results and how they will be communicated; and (e) a reminder that participants can contact the StrokeCog team with any questions or concerns. Following each call, participants will receive a summary text message reiterating these key points.

SWAT control group. Participants in the SWAT control group will also receive two follow-up telephone calls at the same intervals as those in the intervention group. These calls will follow an identical scripted format; however, they will not receive any supplementary summary text messages.

Outcome measures

Patient assessment: primary and secondary outcome measures. Patients will undergo cognitive and behavioural evaluations at three time points: baseline (six weeks post-stroke, pre-intervention), immediately post-intervention (or equivalent control period), and at a 4-month follow-up to examine maintenance effects. The primary outcome is cognitive function and will be measured using a modified version of the

validated 60-minute NINDS cognitive battery⁷⁹. This comprehensive battery evaluates key cognitive domains, including memory, attention, executive function, and information processing. These assessments will include the Digit Span (Forward, Backward, and Sequencing trials), Verbal Fluency Test (Phonemic and Semantic), Colour Trail Tests (A & B), 30-Item Boston Naming Test, Symbol Digit Modalities Test, Rey Complex Figure Test (Copy, Immediate recall, Delayed Recall, and Recognition), and the Rey Auditory Verbal Learning Test (Immediate recall, Delayed Recall, and Recognition). To supplement these measures, participants will complete the Test of Premorbid Functioning (TOPF;⁸³) at baseline only, while the Wechsler Abbreviated Scale of Intelligence Second Edition (WASI-II⁸⁴) Vocabulary and Matrix Reasoning tests will be administered at every assessment. These assessments align with routine clinical practice in Beaumont Hospital's Department of Psychology and are well tolerated by patients.

A key secondary outcome is patient-reported self-efficacy in managing cognitive deficits, assessed using the Modified Stroke Self-Efficacy Scale (MSSES;⁸⁵). Additional measures will include demographic and clinical information. As per best practice²¹, cognitive testing will be complemented by functional assessments (WHO Disability Assessment Schedule, WHODAS-12;⁸⁶), Modified Rankin Scale (MRS;^{87,88}) and evaluations of frequently co-occurring neuropsychological issues, including mood (Generalized Anxiety Disorder 7-item assessment, GAD-7⁸⁹); Patient Health Questionnaire (PHQ-8⁹⁰), and fatigue (Fatigue Severity Scale, FSS⁹¹). Participants will also be asked to identify and prioritise their goals for subjective cognitive and psychological difficulties (Schedule for the Evaluation of Individual Quality of Life (SEIQoL)⁹²).

Family Member or Carer Assessment. Family members or carers who are available and willing to participate will complete structured evaluations to provide insight into the patient's cognitive and behavioural changes post-stroke. These assessments will include questionnaires on perceived cognitive decline and behavioural changes of the stroke survivor from the family member's perspective (Informant Questionnaire for Cognitive Decline in the Elderly (Short Form IQ-CODE)⁹³). Additionally, carers will complete validated assessments measuring their psychological well-being including the GAD-7, PHQ-8, Perceived Stress Scale (PSS;⁹⁴), caregiver burden (the 22-item Zarit Burden Interview⁹⁵), and vulnerability (Vulnerable Elders Survey (VES⁹⁶)). These data will help assess the broader impact of stroke-related cognitive impairments on both patients and their support systems.

Qualitative Process Evaluation. In line with MRC guidelines for evaluating complex interventions^{48,49}, qualitative focus group interviews with participants in the intervention group will assess the acceptability and feasibility of the intervention, as well as adherence. These discussions will explore their experiences, perceived benefits, and any challenges associated with the intervention. These sessions will take place at the conclusion of the final intervention session, prior to the

post-intervention assessment. Additionally, qualitative data will be collected from staff delivering the intervention to explore their perspectives on feasibility, usefulness, and any necessary refinements before scaling up to a definitive trial. To ensure protocol fidelity, the intervention will follow a manualised format delivered by a clinical neuropsychologist. Any deviations from the protocol, such as additional tailoring, will be documented. Process notes will be maintained to assess adherence and identify any areas for refinement.

Micro-Costing. A micro-costing exercise will be conducted throughout the trial to estimate the costs associated with scaling the intervention into a future definitive trial. This bottom-up approach involves systematically collecting data on resource utilisation, including the clinical neuropsychologist's time, educational materials, and participant-related expenses such as transportation. Additionally, at each testing session, we will record all participants' healthcare utilisation, informal care, and any social support expenses.

SWAT Outcome Measures. The SWAT primary outcomes include retention to the trial at the 4-month final post-intervention assessment, comparing participants who received additional text summaries with those who did not. Additionally, qualitative data, via self-report questionnaires, will be collected at the final assessment to assess the acceptability and perceived effectiveness of the additional text follow-up. The secondary outcomes are the cost per participant retained, and the proportion of participants withdrawing prior to the final assessment.

Data analysis and statistical plan

To address the primary research question regarding recruitment and retention, we will assess recruitment rates for all screened patients, presenting these rates by recruitment approach along with corresponding 95% confidence intervals (CIs). For participants who meet the inclusion criteria, we will calculate the proportions randomised and retained at each post-intervention assessment, also with 95% CIs. Patient characteristics will be analysed to identify factors associated with attrition. Descriptive analyses will be performed, and clinically meaningful changes in the primary outcome (cognitive function) from pre- to post-assessment will be indicated by standardised effect sizes ranging from 0.3 to 0.5, based on evidence from previous systematic reviews^{30,40}. Changes in cognitive outcomes between groups over time will be used to estimate effect sizes. As this is a pilot study, statistical significance will be considered exploratory, with findings primarily informing the estimation of the standard deviation (SD) needed to power a future definitive trial. Additionally, the cost of delivering the intervention will be calculated, with 95% CIs reported. All quantitative analyses will be performed using Stata software.

To evaluate intervention acceptability, we will transcribe and analyse qualitative data from the process evaluation involving patient participants in the intervention group and staff members responsible for delivering the intervention. Reflexive thematic analysis^{97,98} will be employed using an inductive,

reflective approach. The analysis will also be informed by the Consolidated Framework for Implementation Research (CFIR), which includes five domains: intervention characteristics, outer setting, inner setting, characteristics of individuals involved, and the implementation process⁹⁹, as well as the MRC framework for complex interventions^{48,49}. Thematic analysis will be conducted using NVivo software.

For the SWAT analysis, we will report the proportion of patients withdrawing before the 4-month post-intervention assessment as numbers and percentages. Statistical comparisons between the SWAT intervention and control groups will be made using chi-square analysis. Qualitative data from the questionnaire self-report process evaluation at the end of the final assessment will also contribute to the analysis. Secondary analysis will assess the cost per participant retained between the group receiving both telephone follow-up and text summary versus those receiving telephone calls alone. This will include an evaluation of costs associated with telephone calls, texts, and staff time spent administering the intervention.

For the purposes of data analysis related to adherence, recruitment and retention success is operationally defined as retaining at least 90% of randomised participants at the 4-month follow-up assessment. To evaluate strategies for improving adherence, the SWAT intervention⁷⁰ will examine the impact of enhanced communication methods delivered between the post-intervention assessment and the 4-month follow-up on participant retention rates. Complementing the quantitative analysis, a qualitative process evaluation will explore patterns of adherence to the study protocol and identify perceived barriers to continued participation.

Sex and Gender Data Analysis. There are known sex differences in stroke incidence and outcomes, with the incidence rising in older women and greater risk for poorer post-stroke recovery¹⁰⁰. Additionally, evidence from cardiac rehabilitation suggests lower uptake and poorer attendance rates in women, a trend that has not improved over time^{101,102}. To account for potential sex and gender differences, all data analysis and reporting will disaggregate findings by sex and gender, where feasible. The trial will explore any potential disparities in participation, retention, reasons for attrition, and outcomes, ensuring the research addresses the needs and experiences of all participants.

Patient and Public Involvement

Patient and Public Involvement (PPI) will play a central role in this study, with ongoing contributions from patients who have experienced stroke and PSCI, as well as their family members. Their involvement spans multiple stages of the trial, including the previous development and feasibility testing of the StrokeCog-R intervention, co-designing participant materials, offering input on the ethical approval process, interpreting results, and developing creative strategies for disseminating research findings⁵⁰. A key member of the Trial Steering Committee, who has lived with PSCI, has contributed to the development of this study, ensuring the perspectives

of those directly affected by stroke are integrated into every phase. PPI will also inform decisions such as tailoring the intervention to individual patient goals, reducing reliance on written information, and assessing the impact of telephone-based follow-up.

Ethical considerations

Ethical approval for the trial has been granted by the Beaumont Hospital Research Ethics Committee (REC reference: 23/14) and a data protection assessment has been approved by the Data Protection Officers at both RCSI University and Beaumont Hospital. Ethical considerations for this pilot trial have been carefully addressed to ensure participant protection and compliance with relevant laws and regulations. Participants will be assigned a pseudonymous alphanumeric ID to ensure confidentiality, and a master list linking participant names with IDs will be securely maintained and then deleted at the end of the study, whereupon data will be irrevocably anonymised. Data handling will comply with GDPR (Regulation (EU) 2016/679)¹⁰³ and the Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018)¹⁰⁴, with all electronic files encrypted and password-protected. Hard copies will be minimised; where necessary, documents will be scanned, stored digitally, encrypted, and then shredded. Participants will be fully informed about the study's objectives, procedures, and confidentiality measures, and their written consent will be obtained prior to screening and study enrolment, and re-confirmed orally before each testing session. In the event of cognitive impairment, participants will be presumed to have the capacity to consent unless demonstrated otherwise, in line with the Assisted Decision-Making Capacity Act (2015) Part 1, Section 3, Subsections 2–6¹⁰⁵ and the HSE National Policy for Consent in Health and Social Care Research¹⁰⁶.

Participants will have the right to withdraw at any time without consequence. In case of distress, participants will be referred to appropriate clinical support, and any necessary actions, such as informing their GP, will be taken with their consent. Discontinuation criteria for withdrawing a participant from the trial (but not stopping the overall trial) will include: withdrawal of consent by the participant; any condition that the research team or sponsor determines may jeopardise the participant's safety if she or he continues participating in the trial; ineligibility arising during the study (e.g., participant recovers cognitive function between screening and baseline assessments; or aphasia identified subsequent to screening); an adverse event which requires discontinuation from the trial (e.g., hospitalisation for disease progression; a new diagnosis that would affect cognition; mortality).

Furthermore, participants may access their data upon request until the point at which the data are permanently anonymised at the conclusion of the study. Full details of their rights are outlined in the PIL. In such cases, participants will also be offered the opportunity to discuss their test results with the clinical neuropsychologist. A comprehensive Data Management

Plan will ensure proper data collection, storage, and retention procedures, with anonymised data deposited in open-access repositories upon study completion. Data will be securely stored on an RCSI server, and only authorised personnel will have access. The safety and well-being of participants are paramount, and all trial procedures have been designed with minimal risk and previously feasibility tested.

Dissemination plan

The results of this pilot trial will be disseminated through a comprehensive strategy aimed at maximising outreach and impact. Information will be shared through local patient and family support meetings organised by the Irish Heart Foundation (IHF), the principal stroke charitable organisation in Ireland, as well as national conferences such as the IHF annual stroke survivor conference. Findings will also be presented at major stroke conferences, such as the UK Stroke Forum and the European Stroke Organisation conference, and published in peer-reviewed journals. To ensure accessibility, open access strategies will be employed, with research materials, including protocols, datasets, and study findings, made available through HRB Open, the Open Science Framework, and the RCSI repository. This comprehensive dissemination plan will contribute to informing clinical practice, policy, and the field of cognitive rehabilitation for stroke survivors.

Conclusions

In conclusion, this research aims to evaluate, through a pilot RCT, the feasibility and preliminary effectiveness of the StrokeCog-R intervention for PSCI, addressing a significant gap in current stroke rehabilitation. Given that cognitive impairment is a frequent consequence of stroke, this pilot trial will generate essential data on recruitment, retention, preliminary efficacy, and cost-effectiveness, to guide a future definitive trial. The potential benefits extend to patients, carers, health-care providers, and policy-makers by offering an evidence-based approach to cognitive rehabilitation, improving patient outcomes, and reducing long-term healthcare costs associated with cognitive decline and dementia. Ultimately, integrating cognitive rehabilitation into routine post-stroke care could transform stroke rehabilitation practices, enhancing quality of life for stroke survivors and yielding lasting societal benefits.

Statements and disclosures

Clinical trials registration

- clinicaltrials.gov: The NCT number is NCT06021470.
- Queen's University Belfast repository: SWAT232

Ethics and consent

Ethical approval was approved by Beaumont Hospital research ethics approval (REC reference: 23/14). Patients expressing interest in participation will provide written informed consent for screening.

Data (and software) availability

Underlying data

No data are associated with this article as this is a protocol.

Extended data

Open Science Framework: Extended data for StrokeCog-R: Protocol for a Pilot Randomised Controlled Trial Evaluating the Feasibility and Acceptability of a Novel Cognitive Rehabilitation Intervention for Post-Stroke Cognitive Impairment, <https://doi.org/10.17605/OSF.IO/CMKHT¹⁰⁷>

This project contains the following underlying data:

- [AppendixA_BH_26.9.23_PatientPIL1_Screen_V4.docx](#)
- [AppendixB_BH_PatientConsent1_Screen_V3.docx](#)
- [AppendixC_BH_PatientPIL2_26.9.23_V4.docx](#)
- [AppendixD_BH_PatientConsent\(2\)_V3.docx](#)
- [AppendixE_BH_21.6.23_CarerPIL_V3.docx](#)
- [AppendixF_BH_CarerConsent_V3.docx](#)
- [AppendixG_BH_21.6.23_StaffPIL_V3.docx](#)
- [AppendixH_BH_StaffConsent_V3.docx](#)
- [SPIRIT_checklist_Moran2025.docx](#)

Data is available under *CC-BY Attribution 4.0 International*.

Reporting guidelines

- SPIRIT checklist <https://doi.org/10.17605/OSF.IO/CMKHT¹⁰⁷>,

Trial Governance Composition, Roles and Responsibilities:

- **Coordinating centre:** RCSI University of Medicine and Health Sciences
- **Principal Investigator:**
 - Design and conduct of StrokeCog-R
 - Liaising with Sponsorship Office
 - Budget administration and contractual issues with recruitment centres
 - Preparation of protocol and revisions
 - Organising steering committee meetings
 - Publication of study findings
 - Chair of Trial Management Committee and Trial Steering Committee
- **Steering committee (SC)**
 - All trial co-applicants will be steering committee members (see title page for members)
 - Agreement of final protocol
 - Regular meetings to review progress of trial and, if necessary, agree changes to the protocol to facilitate the smooth running of the study.

- **Trial Management Committee (TMC)**

(Principal investigator, Post-Doctoral researcher, Research Assistants, Stroke Physician, Clinical Neuropsychologist, Trial Biostatistician)

Study planning

Trial data management and approval of trial data management and data analysis plans

Advice for lead investigators

- **Core Trial Management Group**

(Principal investigator, Post-Doctoral researcher, Research Assistants)

Study planning

Weekly trial management meetings

Organisation of steering committee meetings

Manage correspondence with research ethics committee and data protection officers

Preparation of protocol and revisions

Randomisation

Data management and development of a trial data management plan

Data verification

Publication and presentation of study findings

- **Trial Manager**

Creation and maintenance of trial data entry system and data entry

Data verification

Data Monitoring: Formal Committee:

- This study is a pilot trial involving a relatively small number of patients and a low-risk intervention. As such, an *a priori* decision was taken at the funding application stage that the data monitoring and safety monitoring functions of the trial will be managed by the Trial Steering Committee. The data monitoring function will involve monitoring data emerging from the trial with a particular view to identifying any safety issues, including issues that may need to be brought to the attention of the Sponsor and the trial participants. As part of the safety monitoring aspect of this trial, other potential adverse events will be monitored and recorded, including health outcomes that may be unrelated to the trial, such as hospital admissions, or other health events such as a new clinical diagnosis, and mortality.

Protocol Version 1: 29/04/25

References

- Feigin VL, Norrving B, Mensah GA: **Global Burden of stroke.** *Circ Res.* 2017; **120**(3): 439–48.
[PubMed Abstract](#) | [Publisher Full Text](#)
- Health Service Executive (HSE): **National Stroke Strategy 2022–2027.** Dublin, Ireland: Health Service Executive, 2023.
[Reference Source](#)
- Di Carlo A: **Human and economic burden of stroke.** *Age Ageing.* 2009; **38**(1): 4–5.
[PubMed Abstract](#) | [Publisher Full Text](#)
- GBD 2021 Stroke Risk Factor Collaborators: **Global, regional, and national burden of stroke and its risk factors, 1990–2021: a systematic analysis for the Global Burden of Disease study 2021.** *Lancet Neurol.* 2024; **23**(10): 973–1003.
[PubMed Abstract](#) | [Publisher Full Text](#)
- Strlicuc S, Grad DA, Radu C, et al.: **The economic burden of stroke: a systematic review of cost of illness studies.** *J Med Life.* 2021; **14**(5): 606–19.
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Smith S, Horgan F, Sexton E, et al.: **The cost of stroke and Transient Ischaemic Attack in Ireland: a prevalence-based estimate.** *Age Ageing.* 2012; **41**(3): 332–8.
[PubMed Abstract](#) | [Publisher Full Text](#)
- Barbay M, Diouf M, Roussel M, et al.: **Systematic review and meta-analysis of prevalence in post-stroke Neurocognitive Disorders in hospital-based studies.** *Dement Geriatr Cogn Disord.* 2018; **46**(5–6): 322–34.
[PubMed Abstract](#) | [Publisher Full Text](#)
- Gibson E, Koh CL, Eames S, et al.: **Occupational therapy for cognitive impairment in stroke patients.** *Cochrane Database Syst Rev.* 2022; **3**(3): Cd006430.
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Petersen RC, Caracciolo B, Brayne C, et al.: **Mild cognitive impairment: a concept in evolution.** *J Intern Med.* 2014; **275**(3): 214–28.
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Mellon L, Brewer L, Hall P, et al.: **Cognitive impairment six months after ischaemic stroke: a profile from the ASPIRE-S study.** *BMC Neurol.* 2015; **15**: 31.
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Craig L, Hoo ZL, Yan TZ, et al.: **Prevalence of dementia in ischaemic or mixed stroke populations: systematic review and meta-analysis.** *J Neurol Neurosurg Psychiatry.* 2022; **93**(2): 180–7.
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Pendlebury ST, Rothwell PM: **Prevalence, incidence, and factors associated with pre-stroke and post-stroke dementia: a systematic review and meta-analysis.** *Lancet Neurol.* 2009; **8**(11): 1006–18.
[PubMed Abstract](#) | [Publisher Full Text](#)
- Sexton E, McLoughlin A, Williams DJ, et al.: **Systematic review and meta-analysis of the prevalence of cognitive impairment no dementia in the first year post-stroke.** *Eur Stroke J.* 2019; **4**(2): 160–71.
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Williams OA, Demeyere N: **Association of depression and anxiety with cognitive impairment 6 months after stroke.** *Neurology.* 2021; **96**(15): e1966–e74.
[PubMed Abstract](#) | [Publisher Full Text](#)
- Hackett ML, Yapa C, Parag V, et al.: **Frequency of depression after stroke: a systematic review of observational studies.** *Stroke.* 2005; **36**(6): 1330–40.
[PubMed Abstract](#) | [Publisher Full Text](#)
- Stolwyk RJ, Mihaljcic T, Wong DK, et al.: **Poststroke cognitive impairment negatively impacts activity and participation outcomes: a systematic review and meta-analysis.** *Stroke.* 2021; **52**(2): 748–60.
[PubMed Abstract](#) | [Publisher Full Text](#)
- Adamit T, Maeir A, Ben Assayag E, et al.: **Impact of first-ever mild stroke on**

- participation at 3 and 6 month post-event: the TABASCO study. *Disabil Rehabil.* 2015; **37**(8): 667–73.
[PubMed Abstract](#) | [Publisher Full Text](#)
18. Rohde D, Gaynor E, Large M, et al.: Cognitive impairment and medication adherence post-stroke: a five-year follow-up of the ASPIRE-S cohort. *PLoS One.* 2019; **14**(10): e0223997.
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
 19. Blake H, Lincoln N: Cognitive impairments following a stroke: the strain on caregivers. *British J Ther Rehabil.* 2002; **9**(9): 334–7.
[Publisher Full Text](#)
 20. Pendlebury ST, Rothwell PM: Incidence and prevalence of dementia associated with Transient Ischaemic Attack and stroke: analysis of the population-based Oxford vascular study. *Lancet Neurol.* 2019; **18**(3): 248–58.
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
 21. Mijajlovic MD, Pavlovic A, Brainin M, et al.: Post-stroke dementia - a comprehensive review. *BMC Med.* 2017; **15**(1): 11.
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
 22. Brainin M, Tuomilehto J, Heiss WD, et al.: Post-stroke cognitive decline: an update and perspectives for clinical research. *Eur J Neurol.* 2015; **22**(2): 229–38, e13–6.
[PubMed Abstract](#) | [Publisher Full Text](#)
 23. Rothwell PM, Coull AJ, Giles MF, et al.: Change in stroke incidence, mortality, case-fatality, severity, and risk factors in Oxfordshire, UK from 1981 to 2004 (Oxford vascular study). *Lancet.* 2004; **363**(9425): 1925–33.
[PubMed Abstract](#) | [Publisher Full Text](#)
 24. Rothwell PM, Coull AJ, Silver LE, et al.: Population-based study of event-rate, incidence, case fatality, and mortality for all acute vascular events in all arterial territories (Oxford vascular study). *Lancet.* 2005; **366**(9499): 1773–83.
[PubMed Abstract](#) | [Publisher Full Text](#)
 25. Hachinski V, Einhäupl K, Ganten D, et al.: Preventing dementia by preventing stroke: the Berlin manifesto. *Alzheimers Dement.* 2019; **15**(7): 961–84.
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
 26. Pollock A, St George B, Fenton M, et al.: Top ten research priorities relating to life after stroke. *Lancet Neurol.* 2012; **11**(3): 209.
[PubMed Abstract](#) | [Publisher Full Text](#)
 27. Pollock A, St George B, Fenton M, et al.: Top 10 research priorities relating to life after stroke—consensus from stroke survivors, caregivers, and health professionals. *Int J Stroke.* 2014; **9**(3): 313–20.
[PubMed Abstract](#) | [Publisher Full Text](#)
 28. Merriman NA, Bruen C, Gorman A, et al.: “I’m just not a Sudoku person”: analysis of stroke survivor, carer, and healthcare professional perspectives for the design of a cognitive rehabilitation intervention. *Disabil Rehabil.* 2020; **42**(23): 3359–69.
[PubMed Abstract](#) | [Publisher Full Text](#)
 29. Van Peppen RPS, Kwakkel G, Wood-Dauphinee S, et al.: The impact of physical therapy on functional outcomes after stroke: what's the evidence? *Clin Rehabil.* 2004; **18**(8): 833–62.
[PubMed Abstract](#) | [Publisher Full Text](#)
 30. Merriman NA, Sexton E, McCabe G, et al.: Addressing cognitive impairment following stroke: systematic review and meta-analysis of non-randomised controlled studies of psychological interventions. *BMJ Open.* 2019; **9**(2): e024429.
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
 31. Cicerone KD, Dahlberg C, Kalmar K, et al.: Evidence-based cognitive rehabilitation: recommendations for clinical practice. *Arch Phys Med Rehabil.* 2000; **81**(12): 1596–615.
[PubMed Abstract](#) | [Publisher Full Text](#)
 32. Chung CS, Pollock A, Campbell T, et al.: Cognitive rehabilitation for executive dysfunction in adults with stroke or other adult non-progressive acquired brain damage. *Cochrane Database Syst Rev.* 2013; **2013**(4): Cd008391.
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
 33. Loetscher T, Potter KJ, Wong D, et al.: Cognitive rehabilitation for attention deficits following stroke. *Cochrane Database Syst Rev.* 2019; **2019**(11): CD002842.
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
 34. das Nair R, Cogger H, Worthington E, et al.: Cognitive rehabilitation for memory deficits after stroke. *Cochrane Database Syst Rev.* 2016; **9**(9): Cd002293.
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
 35. Longley V, Hazelton C, Heal C, et al.: Non-pharmacological interventions for spatial neglect or inattention following stroke and other non-progressive brain injury. *Cochrane Database Syst Rev.* 2021; **7**(7): Cd003586.
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
 36. Vasquez BP, Zakzanis KK: The neuropsychological profile of Vascular Cognitive Impairment Not Demented: a meta-analysis. *J Neuropsychol.* 2015; **9**(1): 109–36.
[PubMed Abstract](#) | [Publisher Full Text](#)
 37. Sachdev PS, Brodaty H, Valenzuela MJ, et al.: The neuropsychological profile of Vascular Cognitive Impairment in stroke and TIA patients. *Neurology.* 2004; **62**(6): 912–9.
[PubMed Abstract](#) | [Publisher Full Text](#)
 38. Barker-Collo S, Starkey N, Lawes CM, et al.: Neuropsychological profiles of 5-year ischemic stroke survivors by Oxfordshire stroke classification and hemisphere of lesion. *Stroke.* 2012; **43**(1): 50–5.
[PubMed Abstract](#) | [Publisher Full Text](#)
 39. Nys GM, Van Zandvoort MJ, De Kort PL, et al.: Domain-specific cognitive recovery after first-ever stroke: a follow-up study of 111 cases. *J Int Neuropsychol Soc.* 2005; **11**(7): 795–806.
[PubMed Abstract](#) | [Publisher Full Text](#)
 40. Rogers JM, Foord R, Stolwyk RJ, et al.: General and domain-specific effectiveness of Cognitive Remediation after stroke: systematic literature review and meta-analysis. *Neuropsychol Rev.* 2018; **28**(3): 285–309.
[PubMed Abstract](#) | [Publisher Full Text](#)
 41. National Institute for Health and Care Excellence (NICE): Stroke rehabilitation in adults. *Clinical Guideline 162.* 2013.
[Reference Source](#)
 42. Blackburn DJ, Bafadhel L, Randall M, et al.: Cognitive screening in the acute stroke setting. *Age Ageing.* 2013; **42**(1): 113–6.
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
 43. National Institute for Health and Care Excellence (NICE): Stroke rehabilitation in adults. *Nice Guideline, G236.* 2023.
[Reference Source](#)
 44. National Office of Clinical Audit: Irish national audit of stroke national report 2022. Dublin, 2023.
[Reference Source](#)
 45. Horgan F, Hickey A, McGee H, et al.: National Audit of Stroke Care. 2008.
[Reference Source](#)
 46. National Office of Clinical Audit: Irish national audit of stroke organisational audit report 2021. Dublin, 2022.
[Reference Source](#)
 47. Merriman NA, Sexton E, Donnelly NA, et al.: Overview of the strokeCog study: modelling and modifying the consequences of stroke-related cognitive impairment through intervention. *Eur Stroke J.* 2017; **2**: 363.
 48. Skivington K, Matthews L, Simpson SA, et al.: A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. *BMJ.* 2021; **374**: n2061.
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
 49. Craig P, Dieppe P, Macintyre S, et al.: Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ.* 2008; **337**: a1655.
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
 50. Merriman NA, Gillan D, Pender N, et al.: The StrokeCog study: development and description of a cognition-focused psychological intervention to address cognitive impairment following stroke. *Psychol Health.* 2021; **36**(7): 792–809.
[PubMed Abstract](#) | [Publisher Full Text](#)
 51. Merriman NA, Gillan D, Pender N, et al.: Acceptability of a cognitive rehabilitation intervention for Post-Stroke Cognitive Impairment. *Int J Stroke.* 2020; **15**(1_suppl): 265–6.
[Reference Source](#)
 52. Horne J, Lincoln NB, Preston J, et al.: What does confidence mean to people who have had a stroke? A qualitative interview study. *Clin Rehabil.* 2014; **28**(11): 1125–35.
[PubMed Abstract](#) | [Publisher Full Text](#)
 53. Gangwani R, Cain A, Collins A, et al.: Leveraging factors of self-efficacy and motivation to optimize stroke recovery. *Front Neurol.* 2022; **13**: 823202.
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
 54. Jones F, Riaz A: Self-efficacy and self-management after stroke: a systematic review. *Disabil Rehabil.* 2011; **33**(10): 797–810.
[PubMed Abstract](#) | [Publisher Full Text](#)
 55. Hevey D, Wilson O'Raghallaigh J, O'Doherty V, et al.: Pre-post effectiveness evaluation of Chronic Disease Self-Management Program (CDSMP) participation on health, well-being and health service utilization. *Chronic Illn.* 2020; **16**(2): 146–58.
[PubMed Abstract](#) | [Publisher Full Text](#)
 56. Parsons JGM, Plant SE, Slark J, et al.: How active are patients in setting goals during rehabilitation after stroke? A qualitative study of clinician perceptions. *Disabil Rehabil.* 2018; **40**(3): 309–16.
[PubMed Abstract](#) | [Publisher Full Text](#)
 57. Cicerone KD, Dahlberg C, Malec JF, et al.: Evidence-based cognitive rehabilitation: updated review of the literature from 1998 through 2002. *Arch Phys Med Rehabil.* 2005; **86**(8): 1681–92.
[PubMed Abstract](#) | [Publisher Full Text](#)
 58. Cicerone KD, Langenbahn DM, Braden C, et al.: Evidence-based cognitive rehabilitation: updated review of the literature from 2003 through 2008. *Arch Phys Med Rehabil.* 2011; **92**(4): 519–30.
[PubMed Abstract](#) | [Publisher Full Text](#)
 59. Velikonja D, Tate R, Ponsford J, et al.: INCOG recommendations for management of cognition following Traumatic Brain Injury, part V: memory. *J Head Trauma Rehabil.* 2014; **29**(4): 369–86.
[PubMed Abstract](#) | [Publisher Full Text](#)
 60. Headway Ireland: Living with a brain injury. 2018.
[Reference Source](#)
 61. Lorig K, Holman H, Sobel D, et al.: Living a healthy life with chronic conditions: self-management of heart disease, arthritis, diabetes, asthma,

- bronchitis, emphysema & others. 4 ed. Colorado, USA: Bull Publishing Company, 2012.
62. Powell T: **The brain injury workbook**. Oxfordshire, UK: Routledge, 2013. [Publisher Full Text](#)
 63. Engel GL: **The need for a new medical model: a challenge for biomedicine**. *Science*. 1977; **196**(4286): 129–36. [PubMed Abstract](#) | [Publisher Full Text](#)
 64. World Health Organisation: **International classification of functioning, disability, and health: ICF**. 2001. [Reference Source](#)
 65. Wade DT: **Applying the WHO ICF framework to the rehabilitation of patients with cognitive deficits**. In: Halligan PW, Wade DT, editors. *Effectiveness of rehabilitation for cognitive deficits*. UK: Oxford University Press, 2005; 31–42. [Publisher Full Text](#)
 66. Mateer CA: **Fundamentals of cognitive rehabilitation**. In: Halligan PW, Wade DT, editors. *Effectiveness of rehabilitation for cognitive deficits*. UK: Oxford University Press, 2005; 21–30. [Publisher Full Text](#)
 67. Walters SJ, Bonacho dos Anjos Henriques-Cadby I, Bortolami O, *et al.*: **Recruitment and retention of participants in randomised controlled trials: a review of trials funded and published by the United Kingdom health technology assessment programme**. *BMJ Open*. 2017; **7**(3): e015276. [PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
 68. Tudur Smith C, Hickey H, Clarke M, *et al.*: **The trials methodological research agenda: results from a priority setting exercise**. *Trials*. 2014; **15**(1): 32. [PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
 69. Brunsdon D, Biesty L, Brocklehurst P, *et al.*: **What are the most important unanswered research questions in trial retention? A James Lind Alliance Priority Setting Partnership: the PRioRiTy II (Prioritising Retention in Randomised Trials) study**. *Trials*. 2019; **20**(1): 593. [PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
 70. Hickey A, Bruen C, Moran C: **SWAT 232: Use of telephone follow-up with text or WhatsApp message summary versus telephone follow-up alone to trial participants to improve trial retention QUB SWAT Repository**. 2024. [Reference Source](#)
 71. Chan AW, Tetzlaff JM, Gøtzsche PC, *et al.*: **SPRIT 2013 explanation and elaboration: guidance for protocols of clinical trials**. *BMJ*. 2013; **346**: e7586. [PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
 72. Sim J, Lewis M: **The size of a pilot study for a clinical trial should be calculated in relation to considerations of precision and efficiency**. *J Clin Epidemiol*. 2012; **65**(3): 301–8. [PubMed Abstract](#) | [Publisher Full Text](#)
 73. National Office of Clinical Audit: **Irish national audit of stroke national report 2022 - Appendices**. Dublin, 2023. [Reference Source](#)
 74. MacLulich A: **4AT: rapid clinical test for delirium**. n.d. [Reference Source](#)
 75. Enderby PM, Wood VA, Wade DT, *et al.*: **The Frenchay Aphasia screening test: a short, simple test for aphasia appropriate for non-specialists**. *Int Rehabil Med*. 1986; **8**(4): 166–70. [PubMed Abstract](#) | [Publisher Full Text](#)
 76. Nasreddine ZS, Phillips NA, Bédirian V, *et al.*: **The Montreal Cognitive Assessment, MoCA: a brief screening tool for mild cognitive impairment**. *J Am Geriatr Soc*. 2005; **53**(4): 695–9. [PubMed Abstract](#) | [Publisher Full Text](#)
 77. El Hussein N, Katzan IL, Rost NS, *et al.*: **Cognitive impairment after Ischemic and Hemorrhagic Stroke: a scientific statement from the American Heart Association/American Stroke Association**. *Stroke*. 2023; **54**(6): e272–e91. [PubMed Abstract](#) | [Publisher Full Text](#)
 78. Brott T, Adams HJ, Olinger C, *et al.*: **National Institutes of Health Stroke Scale (NIHSS) [Database record]**. *APA PsycTests*. 1989.
 79. Hachinski V, Iadecola C, Petersen RC, *et al.*: **National Institute of Neurological Disorders and Stroke-Canadian Stroke Network vascular cognitive impairment harmonization standards**. *Stroke*. 2006; **37**(9): 2220–41. [PubMed Abstract](#) | [Publisher Full Text](#)
 80. Jak AJ, Bondi MW, Delano-Wood L, *et al.*: **Quantification of five neuropsychological approaches to defining mild cognitive impairment**. *Am J Geriatr Psychiatry*. 2009; **17**(5): 368–75. [PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
 81. Munthe-Kaas R, Aam S, Ihle-Hansen H, *et al.*: **Impact of different methods defining post-stroke neurocognitive disorder: the Nor-COAST study**. *Alzheimers Dement (N Y)*. 2020; **6**(1): e12000. [PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
 82. Sealed envelope Ltd. 2022. [Reference Source](#)
 83. The Psychological Corporation: **Test of premorbid functioning: advanced clinical solutions for use with WAIS-IV and WMS-IV San Antonio**. Texas: The Psychological Corporation, 2009.
 84. Wechsler D: **Wechsler abbreviated scale of intelligence - Second Edition**. San Antonio, TX: Pearson, 2011. [Reference Source](#)
 85. Jones F, Partridge C, Reid F: **The Stroke Self-Efficacy Questionnaire: measuring individual confidence in functional performance after stroke**. *J Clin Nurs*. 2008; **17**(7B): 244–52. [PubMed Abstract](#) | [Publisher Full Text](#)
 86. World Health Organisation: **Measuring health and disability: manual for WHO Disability Assessment Schedule (WHODAS 2.0)**. Geneva, Switzerland, 2010. [Reference Source](#)
 87. Rankin J: **Cerebral vascular accidents in patients over the age of 60. II. Prognosis**. *Scott Med J*. 1957; **2**(5): 200–15. [PubMed Abstract](#) | [Publisher Full Text](#)
 88. Bonita R, Beaglehole R: **Recovery of motor function after stroke**. *Stroke*. 1988; **19**(12): 1497–500. [PubMed Abstract](#) | [Publisher Full Text](#)
 89. Spitzer RL, Kroenke K, Williams JBW, *et al.*: **A brief measure for assessing Generalized Anxiety Disorder: the GAD-7**. *Arch Intern Med*. 2006; **166**(10): 1092–7. [PubMed Abstract](#) | [Publisher Full Text](#)
 90. Kroenke K, Strine TW, Spitzer RL, *et al.*: **The PHQ-8 as a measure of current depression in the general population**. *J Affect Disord*. 2009; **114**(1–3): 163–73. [PubMed Abstract](#) | [Publisher Full Text](#)
 91. Krupp L, LaRocca N, Muir-Nash J, *et al.*: **Fatigue Severity Scale (FSS) [Database record]**. *APA PsycTests*. 1989.
 92. Hickey AM, Bury G, O'Boyle CA, *et al.*: **A new short form individual quality of life measure (SEIQoL-DW): application in a cohort of individuals with HIV/AIDS**. *BMJ*. 1996; **313**(7048): 29–33. [PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
 93. Jorm AF: **A short form of the Informant Questionnaire on Cognitive Decline in the Elderly (IQCODE): development and cross-validation**. *Psychol Med*. 1994; **24**(1): 145–53. [PubMed Abstract](#) | [Publisher Full Text](#)
 94. Cohen S, Kamarck T, Mermelstein R: **Perceived Stress Scale [Database record]**. *APA PsycTests*. 1983. [Reference Source](#)
 95. Zarit SH, Orr NK, Zarit JM: **The hidden victims of Alzheimer's disease. Families under stress**. New York, NY USA: Nueva York University Press, 1985. [Reference Source](#)
 96. Saliba D, Elliott M, Rubenstein LZ, *et al.*: **The vulnerable elders survey: a tool for identifying vulnerable older people in the community**. *J Am Geriatr Soc*. 2001; **49**(12): 1691–9. [PubMed Abstract](#) | [Publisher Full Text](#)
 97. Braun V, Clarke V: **Reflecting on reflexive thematic analysis**. *Qual Res Sport Exerc Health*. 2019; **11**(4): 589–97. [Publisher Full Text](#)
 98. Braun V, Clarke V: **One size fits all? What counts as quality practice in (reflexive) thematic analysis?** *Qual Res Psychol*. 2021; **18**(3): 328–52. [Publisher Full Text](#)
 99. Damschroder LJ, Reardon CM, Widerquist MAQ, *et al.*: **The updated Consolidated Framework for Implementation Research based on user feedback**. *Implement Sci*. 2022; **17**(1): 75. [PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
 100. Rexrode KM, Madsen TE, Yu AYY, *et al.*: **The impact of sex and gender on stroke**. *Circ Res*. 2022; **130**(4): 512–28. [PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
 101. Beckie TM, Beckstead JW: **Predicting cardiac rehabilitation attendance in a gender-tailored randomized clinical trial**. *J Cardiopulm Rehabil Prev*. 2010; **30**(3): 147–56. [PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
 102. Mehrabi S, Harnett A, Saikaley M, *et al.*: **Female enrollment in rehabilitation trials: a systematic review of reporting sex and female participation in randomized controlled trials of poststroke upper extremity rehabilitation over 50 years**. *Arch Phys Med Rehabil*. 2024; **105**(7): 1399–406. [PubMed Abstract](#) | [Publisher Full Text](#)
 103. General Data Protection Regulation (GDPR) (EU): **Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation)**. 2016. [Reference Source](#)
 104. Department of Health: **Data Protection Act 2018 (Section 36(2)) (Health Research) (Amendment) Regulations 2021 (S.I. No. 18/2021)**. Irish Statute Book, 2021. [Reference Source](#)
 105. **Assisted decision-making (Capacity) Act 2015**. Stat. Section 3, page 15, 2015. [Reference Source](#)
 106. Health Service Executive (HSE): **National policy for consent in health and social care research Dublin**. Ireland: Health Service Executive, 2022. [Reference Source](#)
 107. Moran C, Pender N, Williams DJ, *et al.*: **Extended data for StrokeCog-R: protocol for a Pilot randomised controlled trial evaluating the feasibility and acceptability of a novel cognitive rehabilitation intervention for post-stroke cognitive impairment**. *Open Science Framework*. 2025.

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Many thanks for the opportunity to review this work. The burden of PCSI is well outlined by the authors and indeed is a priority among those living with stroke. The intervention has been foregrounded by sound development work including testing feasibility and acceptability. The outcome measures outlined are clear and map to the areas of concern and the recruitment process and strategies to enhance same are well articulated.

There were a number of areas I think could be clarified, to enhance transparency and replicability of this protocol.

- 1) Many of the topics covered in the intervention cross with interventions provided by other disciplines, particularly stroke nurses and occupational therapists or physiotherapists in terms of fatigue management - is there a requirement from the study creators that those randomised to the intervention arm do not have access to these professionals? If so, it would represent an ethical quandary. If not (and it is far more likely that they will meet a stroke nurse, physiotherapist or occupational therapist than another neuropsychologist, as the authors themselves have outlined) then how will these likely interactions influence on the intervention and subsequent outcomes be managed?
- 2) To that end, and in part as the authors have highlighted the extreme lack of neuropsychologists in rehabilitation compared to other professionals, is there a reason why this is not an interprofessional delivered intervention? It would be good to justify this, as it currently stands it seems unlikely that even if this intervention proves effective, that it can be implemented without extensive investment in neuropsychology in rehabilitation given current service structures and staffing - which is perhaps a driving interest here?
- 3) It would be good to be clear on what is meant by 'severe aphasia' - as assessed by whom and what steps are being taken during communication in written and oral discussions with possible participants to ensure supportive communication strategies.
- 4) If a family member is not available or not willing to take part, will they still be considered for this study? I assume so, but it would be good to be clear on same.
- 5) Managing blinding in assessors post such an intervention is very tricky - people try their best

but assessors are often unblinded accidentally. Recommend a line about reporting of unblinding at follow up assessment and management of same.

6) Must participants be less than 6 weeks post stroke at initial assessment? I assume so given the expected 6 week intensive assessments - but it needs to be clarified.

7) Will participants remain eligible if they are not discharged home by the time the intervention starts and/or are admitted for something other than stroke? (highly likely for some, given health complications)

8) In the design phase for this work, both group and individual sessions were mentioned - for this intervention, is the 'individual' component the phone calls in-between sessions? It was not obvious to me when/how individual interaction would occur otherwise in this protocol.

9) Finally, and this is true of many stroke studies, the fact that the population targeted has mild - moderate cognitive issues, are able to consent with ?no less than moderate aphasia and living at home, this population is more likely than many others to do well with any intervention - it could be acknowledged as such in this protocol, that amendments to this could be considered for those living with more complexity (as noted in development phase when those with more severe cognitive issues were unable to engage) in future work.

Is the rationale for, and objectives of, the study clearly described?

Yes

Is the study design appropriate for the research question?

Yes

Are sufficient details of the methods provided to allow replication by others?

No

Are the datasets clearly presented in a useable and accessible format?

Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Occupational therapy and Rehabilitation

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.
