

UNIVERSIDADE FEDERAL DE MINAS GERAIS
Escola de Educação Física, Fisioterapia e Terapia Ocupacional
Programa de Pós-graduação em Ciências da Reabilitação

Paula da Cruz Peniche

**COMPORTAMENTOS DE ESTILO DE VIDA SAUDÁVEL NO CONTEXTO DA
PREVENÇÃO SECUNDÁRIA DO ACIDENTE VASCULAR CEREBRAL**

Belo Horizonte

2025

Paula da Cruz Peniche

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PREVENÇÃO SECUNDÁRIA DO ACIDENTE VASCULAR CEREBRAL**

Tese apresentada ao Programa de Pós-graduação em Ciências da Reabilitação da Escola de Educação Física, Fisioterapia e Terapia Ocupacional da Universidade Federal de Minas Gerais, como requisito parcial para a obtenção do título de Doutor em Ciências da Reabilitação.

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Orientadora: Prof^a Dr^a Christina Danielli Coelho de Moraes Faria

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**COMPORTAMENTOS DE ESTILO DE VIDA SAUDÁVEL NO
CONTEXTO DA PREVENÇÃO SECUNDÁRIA DO ACIDENTE
VASCULAR CEREBRAL**

PAULA DA CRUZ PENICHE

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A Comissão considerou a tese:

☒ Aprovada

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*“O correr da vida embrulha
tudo, a vida é assim: esquentando e esfria, aperta e daí afrouxa,
sossega e depois desinquieta. O que ela quer da gente é coragem.”*

João Guimarães Rosa, Grande Sertão: Veredas (1956)

RESUMO

Países de baixa e média renda, como o Brasil, enfrentam elevada carga do acidente vascular cerebral (AVC) e do AVC recorrente, mas carecem de intervenções voltadas para incentivar a adoção de comportamentos de estilo de vida saudável para a prevenção secundária dessa condição de saúde. Assim, esta tese apresenta os resultados de cinco estudos que exploraram a adoção de comportamentos de estilo de vida saudável para a prevenção secundária do AVC. Recentemente, uma *overview* de revisões sistemáticas demonstrou a eficácia de intervenções presenciais de mudança de comportamento e autogerenciamento na prevenção secundária do AVC. Considerando a utilidade clínica da telessaúde no cuidado de indivíduos pós-AVC, o **Estudo 1** teve como objetivo avaliar criticamente e consolidar os achados das revisões sistemáticas existentes sobre a eficácia de intervenções de mudança de comportamento e autogerenciamento, implementadas por telessaúde, na redução do risco de recorrência do AVC, além de fornecer novas sínteses de estudos primários que aplicaram intervenções teoricamente informadas. Quinze revisões sistemáticas (Fase 1) e 14 ensaios clínicos aleatorizados (ECA) que aplicaram intervenções teoricamente informadas (Fase 2) mostraram que intervenções de telessaúde foram eficazes para melhorar a adesão à medicação, alimentação saudável, prática de atividade física, e controle da pressão arterial e do colesterol, com redução da pressão arterial sistólica (PAS). Contudo, identificou-se a escassez de estudos desenvolvidos em países de baixa e média renda, e nenhum havia sido conduzido no Brasil. Reconhecendo a importância da telessaúde na oferta de cuidados a indivíduos pós-AVC e o fato de a inatividade física representar o fator de risco para recorrência do AVC mais prevalente no Brasil, foi realizado o **Estudo 2** com o objetivo de desenvolver o protocolo de um estudo de viabilidade de uma intervenção teoricamente informada, combinando a intervenção breve dos 5As (Arguir, Aconselhar, Avaliar, Assistir e Acompanhar), do Pacote Técnico HEARTS (documento elaborado por organizações como a Organização Mundial do AVC e a Organização Mundial da Saúde), com o uso de monitor de atividade física, por telessaúde, para aumentar o nível de atividade física pós-AVC (grupo experimental, GE), enquanto o grupo controle (GC) não utilizou o monitor de atividade física. O **Estudo 3** teve como objetivo apresentar os resultados da condução do estudo anterior, confirmando a viabilidade em termos de recrutamento, implementação e mensuração, apesar das perdas de seguimento. Os principais custos para a condução do estudo estiveram relacionados ao transporte para avaliações presenciais. Os níveis de atividade física aumentaram clinicamente em ambos os grupos, com grande efeito intragrupo no GE (Cohen's $d=1,01$) e efeito moderado no GC (Cohen's $d=0,76$). A próxima fase do estudo deverá viabilizar avaliações remotas, a fim de reduzir perdas de seguimento e custos com transporte. O gerenciamento simultâneo de fatores de risco agrupados está associado a maior redução na ocorrência do AVC, o que reforça a relevância do controle de múltiplos fatores para prevenir a recorrência do AVC. Diante da ausência de uma intervenção estruturada para prevenção secundária do AVC no Brasil que envolva o gerenciamento simultâneo de múltiplos fatores de risco, a intervenção irlandesa “*iHELP Stroke: Improving Health and Lifestyle Programme*”, alinhada às recomendações de prevenção secundária do AVC, mostra-se promissora para aplicação no país. No entanto, diferenças socioeconômicas, geográficas e culturais justificam a necessidade de sua adaptação ao contexto brasileiro antes da implementação. Considerando o movimento atual de responsabilização e trabalho em parceria na pesquisa em saúde, princípios que fundamentam a recomendação de incluir a abordagem de Envolvimento Público e Paciente (EPP) em pesquisa, planejou-se envolver indivíduos pós-AVC como representantes do EPP na adaptação da intervenção irlandesa “*iHELP Stroke*” para o contexto brasileiro. Por isso, foi realizada uma revisão de escopo para identificar como o EPP tem sido implementado e relatado em pesquisas empíricas sobre AVC

(**Estudo 4**). Esse estudo evidenciou a escassez de pesquisas que utilizem o EPP em pesquisas sobre AVC, principalmente no contexto da prevenção secundária, e recomendou a ampliação dessa abordagem, especialmente em países de baixa e média renda. Além disso, considerando que a implementação de intervenções para prevenção secundária do AVC deve atender às necessidades e prioridades de indivíduos pós-AVC, torna-se igualmente relevante, para subsidiar o processo de adaptação da intervenção “*iHELP Stroke*” ao contexto brasileiro, compreender as semelhanças e diferenças entre indivíduos pós-AVC irlandeses e brasileiros quanto à priorização de componentes-chave a serem incluídos em intervenções voltadas ao incentivo à adoção de comportamentos de estilo de vida saudável. Nesse sentido, foi desenvolvido o **Estudo 5** com o objetivo de compreender as semelhanças e diferenças na forma como os indivíduos pós-AVC irlandeses e brasileiros, participantes de painéis de EPP na pesquisa, priorizam componentes-chave a serem incluídos em intervenções para incentivar a adoção de comportamentos de estilo de vida saudável. Foi identificada ampla convergência (a maioria dos componentes foi considerada “definitivamente importante” simultaneamente em ambos os países), embora diferenças tenham reforçado a necessidade de adaptações ao transferir intervenções de países de alta renda para contextos de média renda. Por fim, o **Estudo 6** teve como objetivo descrever o processo de adaptação da intervenção irlandesa “*iHELP Stroke*” para o contexto brasileiro, que incluiu a abordagem de EPP em pesquisa com uma representante pós-AVC como co-pesquisadora, resultando na “*iVIDAVC*: intervenção para melhorar a saúde e o estilo de vida pós-AVC”. Foram realizadas adaptações linguísticas, culturais e estruturais. A versão adaptada demonstrou viabilidade, com alta aceitabilidade e satisfação, além de bons níveis de retenção e frequência. As próximas fases do estudo devem contemplar os seguintes pontos: testar o programa com a oferta de um maior número de sessões (9-14 sessões), considerando os relatos de que o período de intervenção foi curto; garantir a participação contínua de profissionais convidados, já que esses componentes ultrapassaram o tempo de condução inicialmente planejado; incluir pelo menos quatro participantes por grupo, visto que a ausência de dois integrantes em um grupo formado por três comprometeu a realização das sessões em grupo; e aprimorar a avaliação dos desfechos clínicos, a fim de favorecer uma melhor compreensão dos fatores associados ao cumprimento das metas de mudança de comportamento estabelecidas. Além disso, considerando a relevância da telessaúde para viabilizar a oferta de intervenções a indivíduos pós-AVC no Brasil, é igualmente importante que futuros estudos investiguem a viabilidade de implementar a intervenção “*iVIDAVC*” nesse contexto. Os seis estudos desenvolvidos forneceram resultados com potencial de aplicação clínica para incentivar a adoção de comportamentos de estilo de vida saudável pós-AVC no Brasil, reforçando o valor de intervenções teoricamente informadas e apontando direções para pesquisas futuras.

Palavras-chave: acidente vascular cerebral; estilo de vida; prevenção secundária.

ABSTRACT

Low- and middle-income countries, such as Brazil, face a high burden of stroke and recurrent stroke but lack interventions aimed at encouraging the adoption of healthy lifestyle behaviors for the secondary prevention of this health condition. Thus, this thesis presents the results of five studies that explored the adoption of healthy lifestyle behaviors for stroke secondary prevention. Recently, an overview of systematic reviews demonstrated the effectiveness of face-to-face behavior change and self-management interventions for stroke secondary prevention. Considering the clinical utility of telehealth in the care of individuals post-stroke, **Study 1** aimed to critically assess and consolidate the findings of existing systematic reviews on the effectiveness of behavior change and self-management interventions, implemented via telehealth, in reducing the risk of stroke recurrence, as well as to provide new syntheses of primary studies that applied theoretically informed interventions. Fifteen systematic reviews (Phase 1) and 14 randomized controlled trials (RCT) that applied theoretically informed interventions (Phase 2) showed that telehealth interventions were effective in improving medication adherence, healthy eating, physical activity, and control of blood pressure and cholesterol, with a reduction in systolic blood pressure (SBP). However, a shortage of studies conducted in low- and middle-income countries was identified, and none had been conducted in Brazil. Recognizing the importance of telehealth in providing care to individuals post-stroke and the fact that physical inactivity represents the most prevalent risk factor for recurrent stroke in Brazil, **Study 2** was carried out with the objective of developing the protocol for a feasibility study of a theoretically informed intervention, combining the 5As brief intervention (Ask, Advise, Assess, Assist, and Arrange), from the HEARTS Technical Package (a document developed by organizations such as the World Stroke Organization and the World Health Organization), with the use of a physical activity monitor, via telehealth, to increase physical activity levels post-stroke (experimental group, EG), while the control group (CG) did not use the physical activity monitor. **Study 3** aimed to present the results of the previous study, confirming feasibility in terms of recruitment, implementation, and measurement, despite follow-up losses. The main costs for conducting the study were related to transportation for in-person assessments. Physical activity levels increased clinically in both groups, with a large within-group effect in the EG (Cohen's $d=1.01$) and a moderate effect in the CG (Cohen's $d=0.76$). The next phase of the study should enable the conduction of assessments remotely, in order to reduce follow-up losses and transportation costs. The simultaneous management of clustered risk factors is associated with a greater reduction in stroke occurrence, reinforcing the relevance of controlling multiple factors to prevent recurrence. Given the absence of a structured intervention for stroke secondary prevention in Brazil that involves the simultaneous management of multiple risk factors, the Irish intervention "iHELP Stroke: Improving Health and Lifestyle Programme," aligned with stroke secondary prevention recommendations, appears promising for application in the country. However, socioeconomic, geographic, and cultural differences justify the need for its adaptation to the Brazilian context prior to implementation. Considering the current movement toward shared responsibility and partnership in health research, principles that support the recommendation to include the Patient and Public Involvement (PPI) approach in research, individuals post-stroke were planned to be involved as PPI representatives in the adaptation of the Irish intervention "iHELP Stroke" to the Brazilian context. However, there is a scarcity of studies employing PPI in health research in low- and middle-income countries, such as Brazil. Therefore, a scoping review was conducted to identify how PPI has been implemented and reported in empirical stroke research (**Study 4**). This review highlighted the limited use of PPI in stroke research and recommended expanding this approach, particularly in low- and middle-income countries. In addition,

considering that the implementation of stroke secondary prevention interventions should meet the needs and priorities of individuals post-stroke, it is equally relevant, to support the process of adapting the “iHELP Stroke” intervention to the Brazilian context, to understand the similarities and differences between Irish and Brazilian individuals post-stroke regarding the prioritization of key components to be included in interventions aimed at encouraging the adoption of healthy lifestyle behaviors. In this sense, **Study 5** was developed with the objective of understanding the similarities and differences in the way Irish and Brazilian individuals post-stroke, participants of PPI research panels, prioritize key components to be included in interventions to encourage the adoption of healthy lifestyle behaviors. A broad convergence was identified (most components were considered “definitely important” simultaneously in both countries), although differences reinforced the need for adaptations when transferring interventions from high-income to middle-income contexts. Finally, **Study 6** aimed to describe the process of adapting the Irish “iHELP Stroke” intervention to the Brazilian context, which included the PPI approach in research with a representative post-stroke as a co-researcher, resulting in “*iVIDAVC: intervenção para melhorar a saúde e o estilo de vida pós-AVC*”. Linguistic, cultural, and structural adaptations were made. The adapted version demonstrated feasibility, with high acceptability and satisfaction, in addition to good levels of retention and attendance. The next phases of the study should address the following points: testing the program with a greater number of group sessions (in the present study, only a minimum of six sessions were offered), considering the reports that the intervention period was too short; ensuring the continuous participation of invited professionals, as these components exceeded the initially planned time; including at least four participants per group, since the absence of two members in a group of three compromised the group sessions; and improving the evaluation of clinical outcomes, in order to better understand the factors associated with meeting the established behavior change goals. Furthermore, considering the relevance of telehealth in enabling the delivery of interventions to individuals post-stroke in Brazil, it is also important that future studies investigate the feasibility of implementing the “iVIDAVC” intervention in this format. The six studies developed provided results with potential for clinical application to encourage the adoption of healthy lifestyle behaviors post-stroke in Brazil, reinforcing the value of theoretically informed interventions and pointing to directions for future research.

Keywords: stroke; lifestyle; secondary prevention.

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PREFÁCIO

A presente tese foi elaborada conforme a RESOLUÇÃO Nº 004/2018 (03 de abril de 2018) do Programa de Pós-Graduação em Ciências da Reabilitação (PPGCR) da Universidade Federal de Minas Gerais (UFMG), que estabelece a regulamentação para elaboração de dissertações e teses. O trabalho foi desenvolvido sob a orientação da Professora Doutora Christina Danielli Coelho de Moraes Faria, do Departamento de Fisioterapia da UFMG, e coorientação da Professora Doutora Olive Lennon, da *School of Public Health, Physiotherapy and Sports Science* da *University College Dublin* (UCD) (Irlanda). Além disso, em conformidade com a RESOLUÇÃO Nº 002/2018 (06 de fevereiro de 2018), que dispõe sobre a marcação de defesa de dissertação de mestrado e de tese de doutorado do PPGCR, a discente Paula da Cruz Peniche recebeu a anuência de sua orientadora e do colegiado do curso quanto às providências necessárias para a defesa. Ainda conforme a mesma resolução, a discente publicou pelo menos um artigo durante o doutorado e apresentou comprovação de submissão de outro artigo com dados de sua pesquisa a periódico científico classificado como B1 ou superior no Qualis da área de Educação Física da CAPES, ou em periódico com fator de impacto (ISI-JCR). De acordo com o Regulamento do PPGCR (versão março de 2018), a discente concluiu o total de 36 créditos exigidos pelo programa (ANEXO A) e foi aprovada no exame de qualificação (ANEXO A), realizado em 5 de junho de 2024.

A tese foi redigida em português. Considerando o formato opcional de apresentação, sua estrutura inclui os tópicos obrigatórios: capa, sumário, agradecimentos, resumo e *abstract*, prefácio, introdução e artigos provenientes dos estudos realizados apresentados em respectivos capítulos, considerações finais, referências bibliográficas, comprovação de aprovação dos estudos pelo Comitê de Ética em Pesquisa (ANEXO B e ANEXO C) e minicurrículo da discente. Em consonância com a RESOLUÇÃO Nº 004/2018 (03 de abril de 2018), os artigos dos estudos que compõem a tese foram formatados segundo as normas dos periódicos aos quais foram ou serão submetidos, motivo pelo qual todos foram redigidos em inglês.

O conteúdo da tese é exposto em seis capítulos, apresentados como artigos científicos (exceto o Capítulo 1, que corresponde à Introdução). Cada capítulo possui objetivos específicos, mas todos se articulam em torno do tema central: comportamentos de estilo de vida saudável no contexto da prevenção secundária do acidente vascular cerebral (AVC). Os artigos foram desenvolvidos ao longo dos quatro anos de doutorado da discente (2021-2025). No período de maio de 2023 a fevereiro de 2024, a discente realizou doutorado-sanduiche na UCD (Irlanda), com financiamentos da Coordenação de Aperfeiçoamento de Pessoal de Nível Superior

(Programa Print/CAPES) e *Worldwide Universities Network* (WUN). Durante esse período, a discente desenvolveu atividades diretamente relacionadas ao conteúdo desta tese ou que foram apresentadas em seu minicurrículo.

No Capítulo 1, apresenta-se a contextualização da temática, com ênfase na elevada carga global do AVC e do AVC recorrente, que impacta de forma mais acentuada países de baixa e média renda, como o Brasil. Destaca-se que, apesar da relevância da temática, ainda há a carência de estudos no país, o que resulta na falta de orientações práticas para os profissionais de saúde. Também são analisadas, discutidas e identificadas intervenções teoricamente informadas que atendem às recomendações de prevenção secundária do AVC e buscam incentivar a adoção de comportamentos de estilo de vida saudável. Por fim, o capítulo apresenta a justificativa e os objetivos da tese.

No Capítulo 2, apresenta-se uma *overview* de revisões sistemáticas que sintetizou os achados das revisões sistemáticas existentes e forneceu novas meta-análises sobre a efetividade de intervenções de mudança de comportamento e autogerenciamento, implementadas por telessaúde, para modificar desfechos relacionados à prevenção secundária do AVC. Esta *overview* foi realizada nos dois primeiros anos do doutorado (2021-2023) e publicada em 2024 na *Journal of Telemedicine and Telecare* (Percentil Scopus: 90%, CiteScore 2024: 11,4).

- Peniche PC, Faria CDCM, Hall P, Lennon O. Effectiveness of behavior change and self-management theoretically-informed telehealth interventions for stroke secondary prevention: An overview of systematic reviews. *J Telemed Telecare*. 2025;31(7):961-990. doi: 10.1177/1357633X241238779.

Os Capítulos 3 e 4 apresentam, respectivamente, o protocolo e a execução de um estudo de viabilidade de ensaio clínico aleatorizado (ECA) que implementou uma intervenção de mudança de comportamento teoricamente informada, via telessaúde, para aumentar o nível de atividade física pós-AVC. O estudo foi aprovado pelo Comitê de Ética em Pesquisa (ANEXO B). O artigo do estudo de protocolo apresentado no Capítulo 3 foi desenvolvido entre 2022 e 2024 e publicado em 2025 na *PLoS One* (Percentil Scopus: 86%, CiteScore 2024: 5,4). O artigo do estudo apresentado do Capítulo 4, desenvolvido em 2024 e 2025, será submetido à *Clinical Rehabilitation* (Percentil Scopus: 94%; CiteScore 2024: 6,2) após a defesa, com a incorporação das sugestões apresentadas pelos membros da banca.

- Peniche PC, Lennon O, Magalhães JP, Santos JM, Polese JC, Faria CDCM. Telehealth intervention involving the HEARTS Technical Package and the additional use of an activity monitor to increase physical activity level post-stroke: Protocol for a feasibility

randomized controlled trial. PLoS One. 2025;20(4):e0320026. doi: 10.1371/journal.pone.0320026.

- Peniche PC, Magalhães JP, Lennon O, Ferreira JMS, Polese JC, Faria CDCM. Telehealth intervention involving the HEARTS Technical Package and the additional use of an activity monitor to increase physical activity level post-stroke: a feasibility randomized controlled trial. A ser submetido à *Clinical Rehabilitation*.

No Capítulo 5, foi apresentada uma revisão de escopo cujo objetivo foi identificar como a abordagem de Envolvimento do Paciente e do Público (EPP) vem sendo implementada e relatada em pesquisas empíricas sobre AVC. Essa revisão de escopo foi realizada durante o período de doutorado-sanduíche (maio de 2023 a abril de 2024) e concluída após o retorno da discente Paula Peniche ao Brasil. O estudo foi posteriormente publicado em 2024 na *International Journal of Stroke* (Percentil Scopus: 97%; CiteScore 2024: 14.8).

- Peniche PC, Faria CDCM, Hall P, Fingleton C, McPhillips L, Gaetz R, Roche A, McCann L, O'Beaglaoich P, Murphy D, Hickey J, Lennon O. A scoping review of patient and public involvement in empirical stroke research. *Int J Stroke*. 2024;19(9):962-972. doi: 10.1177/17474930241262638.

O estudo apresentado no Capítulo 6 analisou as semelhanças e diferenças na forma como indivíduos pós-AVC, participantes de painéis de Envolvimento do Paciente e do Público (EPP) na Irlanda e no Brasil, priorizam os componentes a serem incluídos em uma intervenção voltada para incentivar a adoção de comportamentos de estilo de vida saudável. O estudo foi aprovado pelo Comitê de Ética em Pesquisa (ANEXO C). O artigo desse estudo foi desenvolvido de 2024 a 2025 e foi submetido ao *American Journal of Health Promotion* (Percentil Scopus: 79%; CiteScore 2024: 4,9).

- Peniche PC, Lennon O, Hall P, Ferreira JMS, Marques LF, Assunção GFSA, Rosa NAB, Martins BCA, Faria CDCM. Prioritizing components for a healthy lifestyle intervention post-stroke: A cross-country Patient and Public Involvement-based descriptive analysis. Submetido ao *American Journal of Health Promotion*.

O Capítulo 7 apresenta a adaptação da intervenção irlandesa ao contexto brasileiro, seguindo as etapas do *ADAPT guidance* (Moore *et al.*, 2021), que incluiu a investigação da sua viabilidade com indivíduos pós-AVC brasileiros. O artigo desse estudo foi desenvolvido no período de 2024 e 2025 e será submetido ao *International Journal of Stroke* (Percentil Scopus: 97%, CiteScore 2024: 14,8) após a defesa, com a incorporação das sugestões apresentadas pelos membros da banca.

- Peniche PC, Lennon O, Hall P, Lima LAA, Ferreira JMS, Faria CDCM. Healthy lifestyle participation after stroke: Brazilian adaptation and feasibility evaluation of an Irish intervention. A ser submetido ao *International Journal of Stroke*.

Por fim, seguindo a estrutura proposta, apresentam-se as considerações finais, as referências bibliográficas, anexos e minicurrículo da discente.

CAPÍTULO 1

INTRODUÇÃO

CAPÍTULO 1 - INTRODUÇÃO

1.1 Contextualização

Dentre as condições de saúde não transmissíveis, o acidente vascular cerebral (AVC) é a terceira principal causa de morte no mundo, superado apenas pelas doenças cardíacas isquêmicas e pela COVID-19, e constitui a quarta principal causa de anos de vida perdidos por incapacidade ou morte prematura (*GBD 2021 Stroke Risk Factor Collaborators*, 2024). A carga do AVC é especialmente elevada em países de baixa e média renda, responsáveis por cerca de 90% de todas as mortes e anos de vida ajustados por incapacidade atribuíveis ao AVC (Feigin *et al.*, 2025; Feigin *et al.*, 2023; *GBD 2019 Stroke Collaborators*, 2021). No Brasil, o cenário é semelhante: o AVC também representa a terceira principal causa de morte no país e responde pelo segundo maior número de internações clínicas e pelo maior custo associado a essas hospitalizações no Sistema Único de Saúde (SUS), ficando atrás apenas da insuficiência cardíaca (Oliveira *et al.*, 2024). Projeções indicam, ainda, que países de média renda, como o Brasil, estarão entre os mais impactados pela carga do AVC nas próximas décadas (Cheng *et al.*, 2024).

O AVC recorrente contribui de forma significativa para a elevada carga global do AVC (Mbalinda *et al.*, 2024; Feigin *et al.*, 2023; Samsa *et al.*, 1999). Em uma revisão sistemática, Mohan *et al.* (2011) estimaram um risco cumulativo combinado de recorrência do AVC de aproximadamente 25% em cinco anos e de quase 40% em dez anos. No Brasil, os dados epidemiológicos sobre o AVC recorrente ainda são limitados, mas um risco cumulativo de 15% após cinco anos foi identificado (Cabral *et al.*, 2019). O AVC recorrente está associado a piores desfechos clínicos (Ferrone *et al.*, 2022), maior risco de mortalidade (Skajaa *et al.*, 2022; Hardie *et al.*, 2004; Samsa *et al.*, 1999) e custos mais elevados em comparação ao primeiro evento (Ferrone *et al.*, 2022; Samsa *et al.*, 1999). Além disso, a recorrência do AVC é considerada a principal causa de readmissões hospitalares no primeiro ano após o evento inicial (Zhong *et al.*, 2016). Diante desse cenário, a prevenção secundária do AVC tem sido apontada como uma das estratégias prioritárias para reduzir a elevada carga global do AVC (Feigin *et al.*, 2023).

O objetivo da prevenção secundária vai além da redução do risco de recorrência, englobando também a melhora da saúde e do bem-estar cotidiano dos indivíduos pós-AVC (Lawrence *et al.*, 2019). Para isso, recomenda-se a utilização de intervenções e estratégias educacionais, teoricamente informadas, voltadas ao autogerenciamento de fatores de risco modificáveis relacionados ao estilo de vida, como tabagismo, inatividade física, consumo

nocivo de bebida alcoólica e alimentação não saudável (Chiangkhong *et al.*, 2023; Feigin *et al.*, 2023; Gladstone *et al.*, 2022; *GBD 2019 Stroke Collaborators*, 2021; Kleindorfer *et al.*, 2021; Lennon *et al.*, 2018). Além dos fatores de risco modificáveis relacionados ao estilo de vida, fatores cardiovasculares, como hipertensão, diabetes e dislipidemias, e fatores psicossociais, como estresse, ansiedade e depressão, também devem ser gerenciados (Chiangkhong *et al.*, 2023; Feigin *et al.*, 2023; Gladstone *et al.*, 2022; *GBD 2019 Stroke Collaborators*, 2021; Kleindorfer *et al.*, 2021; Lennon *et al.*, 2018). Por fim, destaca-se a importância de que as intervenções para prevenção secundária do AVC sejam adaptadas ao contexto de vida e individualizadas de acordo com as capacidades, necessidades e prioridades significativas dos indivíduos pós-AVC e de suas famílias (Lawrence *et al.*, 2019).

Recentemente, uma *overview* de revisões sistemáticas, conduzida em duas etapas, sintetizou a evidência disponível sobre intervenções de mudança de comportamento e autogerenciamento, implementadas de forma presencial, para a prevenção secundária do AVC (Hall *et al.*, 2024a; Hall *et al.*, 2024b). Na primeira etapa (Hall *et al.*, 2024a), foram analisadas revisões sistemáticas com o objetivo de reunir evidências de alto nível sobre tais intervenções. Os autores destacaram a necessidade de estratégias eficazes voltadas à modificação de comportamentos de estilo de vida pós-AVC, em complemento à prevenção farmacológica (Hall *et al.*, 2024a). Além disso, apontaram a relevância da inclusão de intervenções multimodais e terapias psicológicas, apoiadas por evidências de qualidade moderada (Hall *et al.*, 2024a). Contudo, a sobreposição entre estudos e teorias apontou a necessidade de pesquisas adicionais para definir as técnicas mais adequadas de mudança de comportamento (Hall *et al.*, 2024a). Na segunda etapa (Hall *et al.*, 2024b), foram analisados ensaios clínicos aleatorizados (ECA) identificados nas revisões incluídas na primeira fase, desde que tivessem implementado intervenções teoricamente informadas. Verificou-se que os ensaios de prevenção secundária permanecem escassos, reforçando a necessidade de futuros estudos (Hall *et al.*, 2024b). Entre os 19 ECA analisados, apenas dois foram conduzidos em países de média renda (ambos na China), e nenhum no Brasil (Hall *et al.*, 2024b). Importante ressaltar que os estudos avaliados contemplaram exclusivamente intervenções presenciais, sem considerar intervenções implementadas por telessaúde.

A telessaúde, definida como a prestação de serviços de saúde a distância por meio de tecnologias de informação e comunicação (Brennan; Mawson; Brownsell, 2009), tem se consolidado como um recurso promissor no cuidado a indivíduos pós-AVC, sobretudo após a pandemia de COVID-19 (Bloem; Dorsey; Okun, 2020). Revisões sistemáticas têm investigado seu efeito na prevenção secundária do AVC (Hwang; Park; Chang, 2021, Kraft *et al.*, 2017).

Hwang, Park e Chang (2021) não realizaram meta-análises e apresentaram os resultados de forma narrativa, indicando efeitos positivos no alcance das metas relacionadas ao autogerenciamento e ao manejo do estado emocional. Na revisão sistemática conduzida por Kraft *et al.* (2017), a pressão arterial sistólica (PAS) foi a única variável de desfecho que permitiu a realização de uma meta-análise. Foi identificado que as intervenções de telessaúde tiveram efeito significativo na redução da PAS (Kraft *et al.*, 2017). Além disso, os autores relataram que as intervenções foram majoritariamente conduzidas por telefone (Kraft *et al.*, 2017). Uma diretriz internacional também reconhece o uso da telessaúde para a oferta de intervenções para prevenção secundária do AVC, embora a qualidade das evidências ainda seja baixa (nível C) (Gladstone *et al.*, 2022). Considerando a existência de revisões sistemáticas sobre a temática, torna-se relevante sintetizá-las para oferecer direcionamento clínico aos profissionais de saúde e identificar as lacunas ainda presentes. Até o momento, não há uma síntese específica, como a fornecida por uma *overview* de revisões sistemáticas acerca de intervenções de mudança de comportamento e autogerenciamento para prevenção secundária do AVC ofertadas por telessaúde, o que reforça a necessidade de investigação nessa área.

O uso da telessaúde para ofertar intervenções de prevenção secundária do AVC constitui um recurso especialmente relevante no Brasil. Este país possui a quinta maior extensão territorial do mundo, o que, comumente, gera a necessidade de longos deslocamentos para acessar os serviços de saúde (Almeida *et al.*, 2022; Caetano *et al.*, 2020). Além disso, as políticas públicas não asseguram transporte adequado frente à dimensão continental e à heterogeneidade socioespacial do país, comprometendo o acesso da população aos serviços de saúde (Almeida *et al.*, 2022). Já foi relatado, também, que a dificuldade de transporte é uma barreira significativa para indivíduos pós-AVC terem acesso aos cuidados em saúde (Peniche *et al.*, 2022; Souza; Meneghin; Leme, 2022; Scianni; Teixeira-Salmela; Ada, 2012). No Brasil, também tem sido identificado que os custos com deslocamento tornam as consultas presenciais no sistema público mais onerosas do que as teleconsultas (Padilha *et al.*, 2024). Além disso, iniciativas de telessaúde já demonstraram viabilidade econômica e efetiva ampliação do acesso à atenção especializada na saúde pública (Alkmim *et al.*, 2012). Esses fatores reforçam a importância de explorar o uso da telessaúde no país para incentivar a adoção de comportamentos de estilo de vida saudável, especialmente considerando o perfil de estilo de vida dos indivíduos pós-AVC brasileiros.

Estudos sobre o perfil de adoção de comportamentos de estilo de vida em indivíduos pós-AVC brasileiros indicam que 15%-38% ainda fumam (Luz *et al.*, 2019; Marchioli, 2018; Cabral *et al.*, 2015; Muller, 2015; Ribeiro *et al.*, 2012; Moreira *et al.*, 2010) e 14%-29% mantêm

o consumo de bebida alcoólica (Luz *et al.*, 2019; Marchioli, 2018; Ribeiro *et al.*, 2012; Moreira *et al.*, 2010). Os dados sobre o perfil alimentar ainda são escassos. Entretanto, tem sido identificado que 93% consomem frutas, verduras e legumes, embora a maioria os inclua apenas no almoço (Trabaquini, 2015). Em relação à prática de atividade física, 38%-60% dos indivíduos pós-AVC são sedentários (Marchioli, 2018; Moreira *et al.*, 2010). De forma geral, cerca de 30% necessitam de atenção quanto ao tabagismo e consumo de bebida alcoólica. Embora muitos indivíduos consumam frutas e vegetais (Trabaquini, 2015), é essencial incentivar a adesão a uma dieta saudável, visando atingir, por exemplo, a recomendação mínima de cinco porções diárias de frutas e/ou vegetais (World Health Organization, 2003), incluindo também a redução do consumo de sódio e açúcares (Gladstone *et al.*, 2022; Kleindorfer *et al.*, 2021). Por fim, uma parcela considerável dos indivíduos pós-AVC, chegando a cerca de 60% (Marchioli, 2018; Moreira *et al.*, 2010), necessita de incentivo para maior participação em atividade física, o que reforça a importância de testar intervenções específicas voltadas para essa população.

Estudos de viabilidade que ofereceram intervenções e estratégias educacionais teoricamente informadas e individualizadas demonstraram efeitos promissores no aumento da participação em atividade física pós-AVC (Caetano *et al.*, 2023; Preston *et al.*, 2017). Preston *et al.* (2017) desenvolveram um programa de intervenção domiciliar de autogerenciamento destinado a indivíduos na fase aguda pós-AVC, composto por cinco sessões de 60 minutos, distribuídas ao longo de três meses. Inspirando-se nesse modelo, Caetano *et al.* (2023) implementaram um programa similar voltado para indivíduos pós-AVC na fase subaguda, com seis sessões de 60 minutos também ao longo de três meses. Nenhum dos estudos, entretanto, incluiu indivíduos na fase crônica pós-AVC, população que também apresenta baixos níveis de atividade física (Mendes *et al.*, 2022). Além disso, ambas as intervenções demandaram visitas domiciliares de profissionais de saúde para a condução das sessões (Caetano *et al.*, 2023; Preston *et al.*, 2017). Embora esse formato apresente a vantagem de reduzir os custos de transporte para indivíduos pós-AVC, o deslocamento dos profissionais pode gerar despesas elevadas e limitar a aplicabilidade clínica dessas estratégias. Nesse contexto, alternativas devem ser investigadas para viabilizar a oferta de intervenções teoricamente informadas que incentivem a participação em atividade física pós-AVC.

O uso da telessaúde poderia viabilizar a oferta dessas intervenções teoricamente informadas para incentivar a participação em atividade física com indivíduos pós-AVC, reduzindo os custos de transporte tanto para os indivíduos pós-AVC quanto para os profissionais responsáveis pela condução das sessões. English *et al.* (2024), em um estudo de

viabilidade, ofertaram uma intervenção por telessaúde a indivíduos pós-AVC, incluindo estratégias de incentivo para o aumento da prática de atividade física, e observaram resultados promissores quanto à melhora nos níveis de atividade física. No entanto, a intervenção utilizou *software* de videoconferência, exigindo dispositivos compatíveis e conexão estável à internet (English *et al.*, 2024), fatores que podem restringir sua aplicabilidade clínica. Como alternativa de menor custo, ligações telefônicas têm sido empregadas em intervenções de telessaúde para incentivar a adoção de comportamentos de estilo de vida saudáveis com indivíduos pós-AVC (Peniche *et al.*, 2025a; Kraft *et al.*, 2017), ampliando a viabilidade dessas intervenções.

Outro exemplo de tecnologia disponível também a preços acessíveis e que pode ser utilizada para incentivar indivíduos pós-AVC a se engajarem em atividade física, são os monitores de atividade física. *Smartwatches* de baixo custo, como o *Smartwatch Mi Band 7®*, apresentam maior viabilidade econômica em comparação a dispositivos como *Garmin Forerunner 920XT*, *BodyMedia SenseWear MF* e *Garmin Vivoactive* (Wahl *et al.*, 2017), e podem ser utilizados para auxiliar no aumento dos níveis de atividade física em indivíduos pós-AVC (Fini *et al.*, 2021; OPAS, 2019; Billinger *et al.*, 2014). Esses dispositivos funcionam como ferramentas motivacionais, que estimulam o engajamento em atividades físicas (Albergoni *et al.*, 2019; Hannan *et al.*, 2019; Izawa *et al.*, 2012; Furber *et al.*, 2010), e se relacionam com o construto de “Regulação Comportamental” da estrutura de domínios teóricos de mudança de comportamento, ao facilitar o automonitoramento por meio do rastreamento de passos (Atkins *et al.*, 2017). O uso dessa tecnologia é reconhecido em diretrizes e documentos que orientam a prática de atividade física pós-AVC (Fini *et al.*, 2021; OPAS, 2019; Billinger *et al.*, 2014). Entretanto, uma revisão sistemática apontou evidências limitadas quanto ao efeito desses dispositivos no aumento da atividade física em indivíduos pós-AVC (Lynch *et al.*, 2018). Os autores da revisão sugerem que estudos futuros combinem o uso de monitores de atividade física com intervenções multifacetadas de mudança de comportamento, a fim de avaliar de maneira mais robusta o potencial dessa tecnologia para incentivar a participação em atividade física pós-AVC (Lynch *et al.*, 2018).

Um exemplo de intervenção multifacetada para mudança de comportamento é a intervenção breve dos 5As (Arguir, Aconselhar, Avaliar, Assistir e Acompanhar) descrita no Pacote Técnico HEARTS (OPAS, 2019). Desenvolvido por organizações como a Organização Mundial do AVC, a Organização Mundial da Saúde (OMS) e a Organização Pan-Americana da Saúde (OPAS), o Pacote Técnico HEARTS é uma estratégia consolidada para a melhoria da saúde cardiovascular e está disponível em português-Brasil (OPAS, 2019). O documento é estruturado em seis módulos, correspondentes às letras da sigla HEARTS: H - “Hábitos

saudáveis: aconselhamento a pacientes”; E - “Evidências: protocolos baseados em evidências”; A - “Acesso a medicamentos e tecnologias essenciais”; R - “Risco: manejo das doenças cardiovasculares baseado no risco”; T - “Trabalho de equipe como base para a atenção”; e S - “Sistemas de monitoramento” (OPAS, 2019).

O módulo H - “Hábitos saudáveis: aconselhamento a pacientes” apresenta a intervenção breve dos 5As voltada para incentivar a prática de atividade física (OPAS, 2019). Essa abordagem combina planejamento, aconselhamento prático e suporte social (OPAS, 2019), contemplando sete domínios teóricos relacionados à mudança de comportamento: “Conhecimento”, “Intenções”, “Crenças sobre capacidades”, “Objetivos/Metas”, “Influências sociais”, “Contexto ambiental e recursos” e “Reforço” (Atkins *et al.*, 2017). A estratégia já foi aplicada tanto em indivíduos pós-AVC (Liljehult *et al.*, 2024; Amiri *et al.*, 2022; Pacheco *et al.*, 2021) quanto em outras populações, como indivíduos com diabetes, hipertensão e obesidade (Gulayin *et al.*, 2024; Welzel *et al.*, 2021; Moattari *et al.*, 2012), envolvendo o incentivo à adoção de comportamentos de estilo vida saudável. Paralelamente, estudos que investigaram o gerenciamento do risco cardiovascular (Ordunez *et al.*, 2024; Nsour *et al.*, 2023) identificaram o Pacote Técnico HEARTS (OPAS, 2019) como uma ferramenta viável de ser implementada em diferentes níveis, incluindo comunidades, pacientes, profissionais de saúde, gestores e financiadores. Mais recentemente, Liljehult *et al.* (2024) demonstraram que uma intervenção combinando a intervenção breve dos 5As, o uso de monitores de atividade física e acompanhamento por telefone é viável de ser implementada com indivíduos pós-AVC. Contudo, como o grupo controle (GC) nesse estudo (Liljehult *et al.*, 2024) recebeu apenas o cuidado usual, não foi possível determinar de forma isolada o impacto dos monitores de atividade física dentro da intervenção de mudança de comportamento utilizada. Assim, permanece a necessidade de integrar intervenções multifacetadas, como a intervenção breve dos 5As, ao uso dos monitores de atividade física para esclarecer seu potencial efeito adicional no aumento dos níveis de atividade física pós-AVC.

Apesar de, no Brasil, indivíduos pós-AVC necessitarem de maior incentivo para a prática de atividade física, considerando que cerca de 60% não adotam esse hábito (Marchioli, 2018; Moreira *et al.*, 2010), é fundamental ressaltar que eles devem ser estimulados a adotar simultaneamente todos os comportamentos de estilo de vida saudável, contemplando também o gerenciamento dos fatores de risco cardiovasculares e psicossociais no âmbito da prevenção secundária do AVC (Gladstone *et al.*, 2022; Kleindorfer *et al.*, 2021). Estima-se que dez fatores de risco potencialmente modificáveis estejam coletivamente associados a cerca de 90% do risco atribuível populacional para o AVC (O'Donnell *et al.*, 2016). Entre eles, destacam-se:

hipertensão arterial, participação regular em atividade física, perfil lipídico, qualidade da dieta, razão cintura-quadril, tabagismo, consumo de bebida alcoólica e diabetes mellitus (O'Donnell *et al.*, 2016). Em um estudo de coorte recente, envolvendo 22.661 adultos sem histórico de AVC no *baseline*, Liu *et al.* (2024) investigaram prospectivamente a associação entre fatores de estilo de vida saudável e o risco de AVC. Os resultados mostraram que a manutenção de múltiplos comportamentos saudáveis reduz significativamente a probabilidade de ocorrência do evento (Liu *et al.*, 2024). Observou-se ainda que, quanto maior o número de fatores de estilo de vida saudável adotados, menor o risco de AVC (Liu *et al.*, 2024). Embora esses achados estejam fundamentados no contexto da prevenção primária, eles fornecem embasamentos relevantes que reforçam a importância do gerenciamento de múltiplos fatores de risco associados ao AVC recorrente, visando reduzir a chance de um novo evento (Kleindorfer *et al.*, 2021). Assim, torna-se necessária uma intervenção mais abrangente, que contemple os diferentes fatores de risco modificáveis e esteja alinhada às recomendações atuais de prevenção secundária do AVC (Gladstone *et al.*, 2022; Kleindorfer *et al.*, 2021).

No Brasil, até o momento, não foi identificada uma intervenção estruturada para prevenção secundária do AVC especificamente voltada para incentivar a adoção de comportamentos de estilo de vida saudável. Embora as diretrizes clínicas brasileiras para o cuidado de indivíduos pós-AVC reconheçam a importância dessa adoção, ainda faltam orientações claras sobre quais intervenções devem ser implementadas (Minelli *et al.*, 2022a; Minelli *et al.*, 2022b; Brasil, 2020; Brasil, 2013). Em 2019, mais da metade das mortes registradas no país foi atribuída a doenças crônicas não transmissíveis (DCNT), como por exemplo, o AVC recorrente (Brasil, 2021). Paralelamente, o envelhecimento populacional tem contribuído para o aumento da prevalência de condições crônicas e para a elevação dos custos diretos em saúde (Zhao *et al.*, 2020). Diante desse cenário, o Brasil estabeleceu um plano de ações estratégicas para o enfrentamento das DCNT (Brasil, 2021). Esse documento enfatiza o controle dos fatores de risco comportamentais por meio da adoção de comportamentos de estilo de vida saudável como eixo central das recomendações (Brasil, 2021). Contudo, tais diretrizes permanecem genéricas e não apresentam uma intervenção específica destinada a apoiar a adoção de comportamentos de estilo de vida saudável (Brasil, 2021).

Na Irlanda, país de alta renda, foi desenvolvida, na *University College Dublin* (UCD), uma intervenção destinada a incentivar a adoção de comportamentos de estilo de vida saudável no contexto da prevenção secundária do AVC (Hall *et al.*, 2025). O trabalho foi conduzido por Patricia Hall, durante seu doutorado sob a supervisão da professora Olive Lennon (iPASTAR, 2025). A intervenção foi elaborada por meio de um processo de *co-design* fundamentado em

evidências e teorias, utilizando a abordagem *Design Thinking* (Ku; Lupton, 2020) e as orientações do *Medical Research Council* (MRC) para o desenvolvimento de intervenções de saúde complexas (Hall *et al.*, 2025; Skivington *et al.*, 2021). O programa, denominado “*iHELP Stroke: Improving Health and Lifestyle Programme*”, foi desenvolvido com a participação de pesquisadores, profissionais de saúde, representantes de organizações e indivíduos pós-AVC (Hall *et al.*, 2025). No desenvolvimento da intervenção “*iHELP Stroke*”, indivíduos pós-AVC também atuaram como co-pesquisadores, por meio da abordagem de Envolvimento do Paciente e do Público (EPP) (do inglês *Patient and Public Involvement*, PPI) em pesquisas, contribuindo para aprimorar a qualidade e a condução do estudo (Hall *et al.*, 2025). Em síntese, o EPP em pesquisa refere-se a realizar estudos “com” ou “por” membros do público, em vez de “para”, “sobre” ou “em relação a” eles (NIHR, 2024). A discente Paula Peniche e sua orientadora, Professora Christina Faria, acompanharam presencialmente, na Irlanda, o processo de desenvolvimento da intervenção “*iHELP Stroke*”. A estrutura desta intervenção engloba uma sessão inicial individualizada, seguida de encontros em grupo durante 6 a 12 semanas, envolvendo seis componentes principais: educação sobre o AVC, definição de metas baseadas em atividades, participação em atividade física, autorregulação emocional, treinamento em habilidades para adoção de comportamentos de estilo de vida saudável e apoio entre pares (Hall *et al.*, 2025). Além disso, durante o processo de desenvolvimento, os indivíduos pós-AVC destacaram a preferência de que a intervenção fosse implementada presencialmente. Além de ser teoricamente informada e baseada nas recomendações atuais para o desenvolvimento de intervenções de saúde complexas, a intervenção “*iHELP Stroke*” integra avaliação individualizada de riscos e estabelecimento de metas, atendendo às recomendações centrais para a prevenção secundária do AVC (Hall *et al.*, 2025). Considerando esses pontos relevantes, juntamente com o fato de a intervenção oferecer uma estrutura para abordar múltiplos fatores de risco e diante da ausência de programas específicos em países de baixa e média renda, a intervenção irlandesa “*iHELP Stroke*” (Hall *et al.*, 2025) apresenta elevado potencial de aplicação em contextos como o brasileiro.

A aplicação direta da intervenção irlandesa “*iHELP Stroke*” (Hall *et al.*, 2025) com indivíduos pós-AVC brasileiros enfrenta importantes desafios. A mudança de comportamento, elemento central da prevenção secundária do AVC, é influenciada por múltiplos fatores, incluindo os fatores individuais, sociais e ambientais (Atkins *et al.*, 2017). Além disso, intervenções para prevenção secundária do AVC devem ser ajustadas às capacidades, necessidades e prioridades significativas de cada indivíduo (Lawrence *et al.*, 2019). As diferenças contextuais entre os países (Irlanda e Brasil) também reforçam a necessidade de

adaptação da “*iHELP Stroke*” (Hall *et al.*, 2025). A Irlanda, país de alta renda, ocupa a 9ª posição no *Social Progress Index* (SPI=88,1), enquanto o Brasil, um país de média renda, está na 55ª posição (SPI=72,4), refletindo menor progresso social (SPI, 2024). Também existem contrastes relevantes entre os sistemas de saúde dos dois países. Na Irlanda, os serviços públicos podem envolver custos diretos, e aproximadamente metade da população possui seguro privado (*Health Insurance Authority*, 2024). Por outro lado, no Brasil, a maior parte da população depende do SUS, que oferece cobertura universal gratuita, com apenas cerca de 20% da população do país possuindo seguro privado (*International Trade Administration*, 2025; Tikkanen; Osborn, 2020). Características específicas do Brasil também devem ser consideradas: o país apresenta grande extensão territorial (sendo o 5ª maior país do mundo) e um sistema de saúde público do qual dependem majoritariamente pessoas de baixa renda, o que impõe barreiras adicionais à oferta equitativa de cuidados (Younger, 2016; Françoso; Boschma; Vonortas, 2024). Diante dessas diferenças socioeconômicas, culturais e estruturais, a intervenção irlandesa “*iHELP Stroke*” (Hall *et al.*, 2025) precisa ser devidamente adaptada antes de ser implementada no contexto brasileiro para indivíduos pós-AVC.

A adaptação de intervenções para diferentes contextos oferece a vantagem de economizar recursos humanos e financeiros que, de outra forma, seriam necessários para o desenvolvimento de novas intervenções em cada cenário (Movsisyan *et al.*, 2019). Além disso, ajustar intervenções às características da população-alvo tem mostrado maior engajamento e aceitabilidade por parte dos participantes, bem como a melhores desfechos clínicos (Rathod *et al.*, 2018; Steinka-Fry *et al.*, 2017; Bernal; Rodríguez, 2012). Para alcançar esses benefícios, é fundamental que o processo de adaptação seja conduzido de forma sistemática, utilizando estratégias e métodos estruturados (Stirman; Baumann; Miller, 2019; Baumann *et al.*, 2015; Stirman *et al.*, 2015; Baumann *et al.*, 2014; Glasziou *et al.*, 2014). Entretanto, observa-se que muitas adaptações realizadas em novos contextos deixam de contemplar etapas fundamentais, como a avaliação da viabilidade ou a realização de estudos piloto da intervenção adaptada, o que aponta a necessidade de um guia sistematizado para orientar este processo (Escoffery *et al.*, 2018). Além disso, poucos estudos têm relatado de forma explícita a utilização de uma estrutura teórica ou metodológica para orientar o processo de adaptação (Escoffery *et al.*, 2018).

O *ADAPT Guidance* fornece orientações para a adaptação e transferência de intervenções em saúde para novos contextos (Moore *et al.*, 2021). Esse guia foi elaborado a partir do reconhecimento de que a simples replicação de uma intervenção pode comprometer seus resultados, uma vez que fatores sociais, culturais, econômicos e organizacionais variam entre contextos (Moore *et al.*, 2021). O documento descreve quatro etapas principais: (1) avaliar

a justificativa para a intervenção e seu ajuste ao contexto; (2) planejar e realizar as adaptações necessárias; (3) planejar e conduzir estudos piloto e avaliações preliminares, a fim de testar a intervenção em pequena escala e gerar evidências iniciais; e (4) implementar e sustentar a intervenção adaptada em larga escala (Moore *et al.*, 2021). A ênfase recai sobre a tomada de decisões transparentes, a documentação clara das adaptações e o monitoramento contínuo, aspectos fundamentais para a sustentabilidade (Moore *et al.*, 2021). Assim, o *ADAPT Guidance* (Moore *et al.*, 2021) propõe um processo sistemático que busca equilibrar a fidelidade científica com a adequação ao contexto, favorecendo a transferência eficaz de intervenções para diferentes realidades.

Seguindo as orientações da Etapa 1 do *ADAPT Guidance* (Moore *et al.*, 2021), que envolve a avaliação da justificativa e da relevância contextual de uma intervenção, é importante destacar que países de baixa e média renda, como o Brasil, enfrentam uma carga desproporcionalmente elevada do AVC (Cheng *et al.*, 2024; Feigin *et al.*, 2025; Feigin *et al.*, 2023), incluindo casos de AVC recorrente, ao mesmo tempo em que o acesso a estratégias de prevenção secundária é limitado (Peniche *et al.*, 2025a; Hall *et al.*, 2024; Hall *et al.*, 2022). A intervenção irlandesa “*iHELP Stroke*” (Hall *et al.*, 2025) surge como uma candidata promissora para adaptação ao contexto brasileiro, uma vez que seu desenvolvimento seguiu as recomendações atuais para desenvolver intervenções de saúde complexas, e está alinhada às diretrizes de prevenção secundária do AVC, sendo teoricamente informada e contemplando o gerenciamento de múltiplos fatores de risco relacionados ao estilo de vida. Apesar dessas características, que fundamentam o potencial da “*iHELP Stroke*” (Hall *et al.*, 2025) para aplicação em indivíduos pós-AVC no Brasil, as diferenças entre a Irlanda e o Brasil reforçam a importância de realizar adaptações contextuais para que a estratégia seja efetiva no cenário brasileiro.

Visando acompanhar o movimento atual em direção ao trabalho em parceria e à maior corresponsabilização na pesquisa em saúde que fundamenta a recomendação em incluir a abordagem de EPP em pesquisas em saúde (NIHR, 2024), torna-se relevante incluir indivíduos pós-AVC como representantes do EPP, atuando como co-pesquisadores na equipe envolvida na adaptação da intervenção irlandesa “*iHELP Stroke*” (Hall *et al.*, 2025) para o contexto brasileiro. Uma revisão sistemática mostrou que a inclusão da abordagem de EPP em pesquisas de saúde ainda é limitada em países de baixa e média renda (Cook *et al.*, 2019), como o Brasil. O estudo também evidenciou que nenhum dos trabalhos incluídos foi conduzido no Brasil e que apenas um envolveu pesquisas sobre AVC (Cook *et al.*, 2019). Nesse sentido, não é possível identificar, a partir da literatura, estratégias viáveis e adequadas para incorporar o EPP em

pesquisas sobre AVC no Brasil. Assim, torna-se essencial compreender como o EPP tem sido incorporado em estudos sobre AVC, visando fundamentar o planejamento da inclusão efetiva dessa abordagem em pesquisas conduzidas no Brasil.

Por fim, deve-se ressaltar também que, ao implementar intervenções de prevenção secundária do AVC, é fundamental considerar as necessidades e prioridades significativas dos indivíduos pós-AVC (Lawrence *et al.*, 2019). Nesse sentido, investigar as perspectivas desses indivíduos em ambos os países sobre aspectos centrais a serem contemplados em uma intervenção voltada a incentivar a adoção de comportamentos de estilo de vida saudável contribuiria para reforçar a importância de realizar adaptações contextuais na intervenção irlandesa “iHELP Stroke” (Hall *et al.*, 2025), garantindo que a estratégia seja adequada ao contexto de indivíduos pós-AVC brasileiros. Considerando sua relevância e potencial de adaptação, e com o objetivo de conduzir e apresentar o processo de maneira sistematizada, é necessário prosseguir com as etapas subsequentes propostas pelo ADAPT *Guidance* (Moore *et al.*, 2021).

1.2 Justificativa

Países de baixa e média renda, como o Brasil, além de serem mais impactados pela elevada carga do AVC (Feigin *et al.*, 2025; Cheng *et al.*, 2024; Feigin *et al.*, 2023), e, consequentemente, também pela carga relacionada ao AVC recorrente, carecem de intervenções teoricamente informadas que sejam contextualmente adequadas para incentivar a adoção de comportamentos de estilo de vida saudável no contexto da prevenção secundária do AVC (Peniche *et al.*, 2025a; Hall *et al.*, 2024b). Recentemente, uma *overview* de revisões sistemáticas, conduzida em duas etapas, sintetizou os achados de revisões sistemáticas já publicadas e de estudos primários incluídos nessas revisões sobre intervenções de mudança de comportamento e autogerenciamento, implementadas de forma presencial, voltadas à prevenção secundária do AVC (Hall *et al.*, 2024a; Hall *et al.*, 2024b). Nessa *overview* (Hall *et al.*, 2024a; Hall *et al.*, 2024b), as intervenções implementadas por telessaúde não foram exploradas. O uso da telessaúde para a oferta de intervenções de prevenção secundária do AVC é particularmente relevante no Brasil: trata-se do quinto maior país em extensão territorial, o que implica longos deslocamentos para acessar serviços de saúde (Caetano *et al.*, 2023; Almeida *et al.*, 2022); as políticas públicas não asseguram transporte adequado frente à dimensão continental e à heterogeneidade socioespacial do país, comprometendo o acesso da população aos serviços (Almeida *et al.*, 2022); além disso, a dificuldade de transporte constitui

uma barreira para indivíduos pós-AVC acessarem cuidados de saúde (Peniche *et al.*, 2022; Souza; Meneghin; Leme, 2022; Scianni; Teixeira-Salmela; Ada, 2012). Esses fatores reforçam a importância de explorar a telessaúde no país para incentivar a adoção de comportamentos de estilo de vida saudável no contexto da prevenção secundária do AVC. Considerando a existência de revisões sistemáticas sobre o uso de intervenções para prevenção secundária do AVC no contexto da telessaúde (Hwang; Park; Chang, 2021; Kraft *et al.*, 2017), torna-se relevante sintetizar os achados das revisões sistemáticas existentes, bem como produzir novas sínteses, a fim de fornecer direcionamento clínico aos profissionais de saúde e identificar as lacunas ainda existentes. Diante disso, foi conduzida uma *overview* de revisões sistemáticas com o objetivo de avaliar e consolidar criticamente as evidências sobre intervenções de telessaúde na prevenção secundária do AVC (Capítulo 2) (Peniche *et al.*, 2025a).

Essa *overview* de revisões sistemáticas (Peniche *et al.*, 2025a) mostrou, entre outros achados, a necessidade de estudos voltados a incentivar a participação em atividade física pós-AVC, utilizando intervenções teoricamente informadas no contexto da telessaúde. A relevância desse tipo de investigação também é reforçada por estudos que analisaram o perfil de hábitos de vida de indivíduos pós-AVC no Brasil (Luz *et al.*, 2019; Marchioli, 2018; Cabral *et al.*, 2015; Muller, 2015; Trabaquini, 2015; Ribeiro *et al.*, 2012; Moreira *et al.*, 2010), mostrando que a inatividade física é o fator de risco relacionado ao estilo de vida mais prevalente para recorrência de AVC no país. A telessaúde constitui uma estratégia promissora para implementar intervenções teoricamente informadas que incentivem a prática de atividade física pós-AVC no Brasil, considerando os aspectos mencionados anteriormente (Caetano *et al.*, 2023; Almeida *et al.*, 2022). No entanto, é fundamental assegurar a viabilidade da intervenção por meio do uso de tecnologias de baixo custo, como ligações telefônicas e monitores de atividade física. Contudo, as evidências sobre a efetividade do uso de monitores de atividade física para estimular a prática de atividade física pós-AVC ainda são limitadas (Lynch *et al.*, 2018). Nesse sentido, recomenda-se investigar o uso combinado desses monitores com intervenções multimodais de mudança de comportamento, a fim de avaliar o efeito dessa tecnologia para incentivar a participação em atividade física pós-AVC (Lynch *et al.*, 2018). Um exemplo de intervenção multimodal e teoricamente informada é a intervenção breve dos 5As, apresentada no Pacote Técnico HEARTS (OPAS, 2019).

Como mencionado anteriormente, o Pacote Técnico HEARTS é uma estratégia consolidada para a melhoria da saúde cardiovascular, desenvolvido por organizações como a Organização Mundial do AVC, a OMS e a OPAS (OPAS, 2019). A associação entre o acompanhamento remoto por telefone e o uso de monitores de atividade física para ofertar a

intervenção breve dos 5As mostrou-se viável de ser implementada com indivíduos pós-AVC para incentivar a prática de atividade física (Liljehult *et al.*, 2024). No entanto, nesse estudo, o GC recebeu apenas cuidados usuais, o que impossibilita determinar o efeito adicional do uso dos monitores de atividade física associados a uma intervenção multimodal e teoricamente informada (Liljehult *et al.*, 2024). Diante disso, foi desenvolvido e publicado o protocolo de um estudo cujo objetivo foi investigar a viabilidade de implementar, por telessaúde, uma intervenção teoricamente informada que combinou a intervenção breve dos 5As, apresentada no Pacote Técnico HEARTS (OPAS, 2019), com o uso de monitor de atividade física para aumentar a participação em atividade física pós-AVC (Capítulo 3) (Peniche *et al.*, 2025b). A condução desse estudo e seus resultados são apresentados no Capítulo 4.

Apesar de a inatividade física ser o fator de risco relacionado ao estilo de vida mais prevalente para AVC recorrente no Brasil, conforme mostrado por estudos que analisaram o perfil de estilo de vida de indivíduos pós-AVC no país (Luz *et al.*, 2019; Marchioli, 2018; Cabral *et al.*, 2015; Muller, 2015; Trabaquini, 2015; Ribeiro *et al.*, 2012; Moreira *et al.*, 2010), é fundamental incentivar a adoção de todos os comportamentos de estilo de vida saudável, bem como incluir o gerenciamento de fatores de risco cardiovasculares e psicossociais (Gladstone *et al.*, 2022; Kleindorfer *et al.*, 2021). O estudo de coorte de Liu *et al.* (2024), com 22.661 adultos sem histórico de AVC, mostrou que quanto maior o número de fatores de estilo de vida saudável adotados, menor o risco de AVC. Embora esses achados se refiram à prevenção primária, eles fundamentam a importância do gerenciamento de múltiplos fatores de risco associados ao AVC recorrente, visando reduzir a probabilidade de um novo evento (Kleindorfer *et al.*, 2021). A escassez de estudos sobre essa temática em países de baixa e média renda, como o Brasil, somada à ausência de intervenções teoricamente informadas e alinhadas às recomendações de prevenção secundária do AVC no país (Hall *et al.*, 2024a; Hall *et al.*, 2024b, Peniche *et al.*, 2025a), torna necessária a importação de intervenções desenvolvidas em países de alta renda, como a Irlanda. Na Irlanda, onde a pesquisa em prevenção secundária do AVC recebe incentivo financeiro (iPASTAR, 2025; HRB, 2025a; HRB, 2025b; Horgan *et al.*, 2022), foi desenvolvida uma intervenção para incentivar a adoção de comportamentos de estilo de vida saudável pós-AVC: a “*iHELP Stroke*” (Hall *et al.*, 2025). Além de estar alinhada às recomendações de prevenção secundária, por ser teoricamente informada e contemplar o gerenciamento de múltiplos fatores de risco relacionados ao estilo de vida, a intervenção seguiu as recomendações atuais para o desenvolvimento de intervenções de saúde complexas (Hall *et al.*, 2025), o que a torna promissora para aplicação no Brasil. No entanto, as diferenças

socioeconômicas e culturais entre os países justificam a necessidade de adaptação prévia da intervenção ao contexto brasileiro.

Considerando a necessidade de acompanhar o movimento atual em direção ao trabalho em parceria e à maior corresponsabilização na pesquisa em saúde, princípios que fundamentam a recomendação de incluir a abordagem de EPP em pesquisas (NIHR, 2024), foi planejado envolver indivíduos pós-AVC como representantes do EPP, atuando como co-pesquisadores na equipe envolvida na adaptação da intervenção irlandesa “*iHELP Stroke*” para o contexto brasileiro (Hall *et al.*, 2025). No entanto, há escassez de estudos que incluam a abordagem de EPP em pesquisas em saúde em países de baixa e média renda (Cook *et al.*, 2019), como o Brasil, e, conseqüentemente, em pesquisas sobre AVC. Diante disso, foi conduzida uma revisão de escopo (Peniche *et al.*, 2024) com o objetivo de identificar e sintetizar como a abordagem de EPP tem sido implementada e relatada em pesquisas empíricas sobre AVC (Capítulo 5).

Por fim, para embasar esse processo, e considerando a importância de contextualizar a prevenção secundária do AVC de acordo com as necessidades e prioridades de indivíduos pós-AVC (Lawrence *et al.*, 2019), torna-se relevante compreender as semelhanças e diferenças entre indivíduos pós-AVC irlandeses e brasileiros quanto à priorização de componentes-chave a serem incluídos em intervenções voltadas a incentivar a adoção de comportamentos de estilo de vida saudável, tema investigado no estudo apresentado no Capítulo 6. Concluída essa etapa, procedeu-se à adaptação da “*iHELP Stroke*” para o contexto brasileiro, utilizando a estrutura padronizada do *ADAPT Guidance* (Moore *et al.*, 2021) (Capítulo 7). Esse processo incluiu também a investigação da viabilidade da intervenção adaptada com indivíduos pós-AVC brasileiros (Capítulo 6), etapa essencial, mas ainda pouco reportada em estudos sobre adaptação de intervenções (Escoffery *et al.*, 2018). Essa última etapa contemplou a abordagem de EPP em pesquisa.

A organização dos capítulos da tese é apresentada na Figura 1.

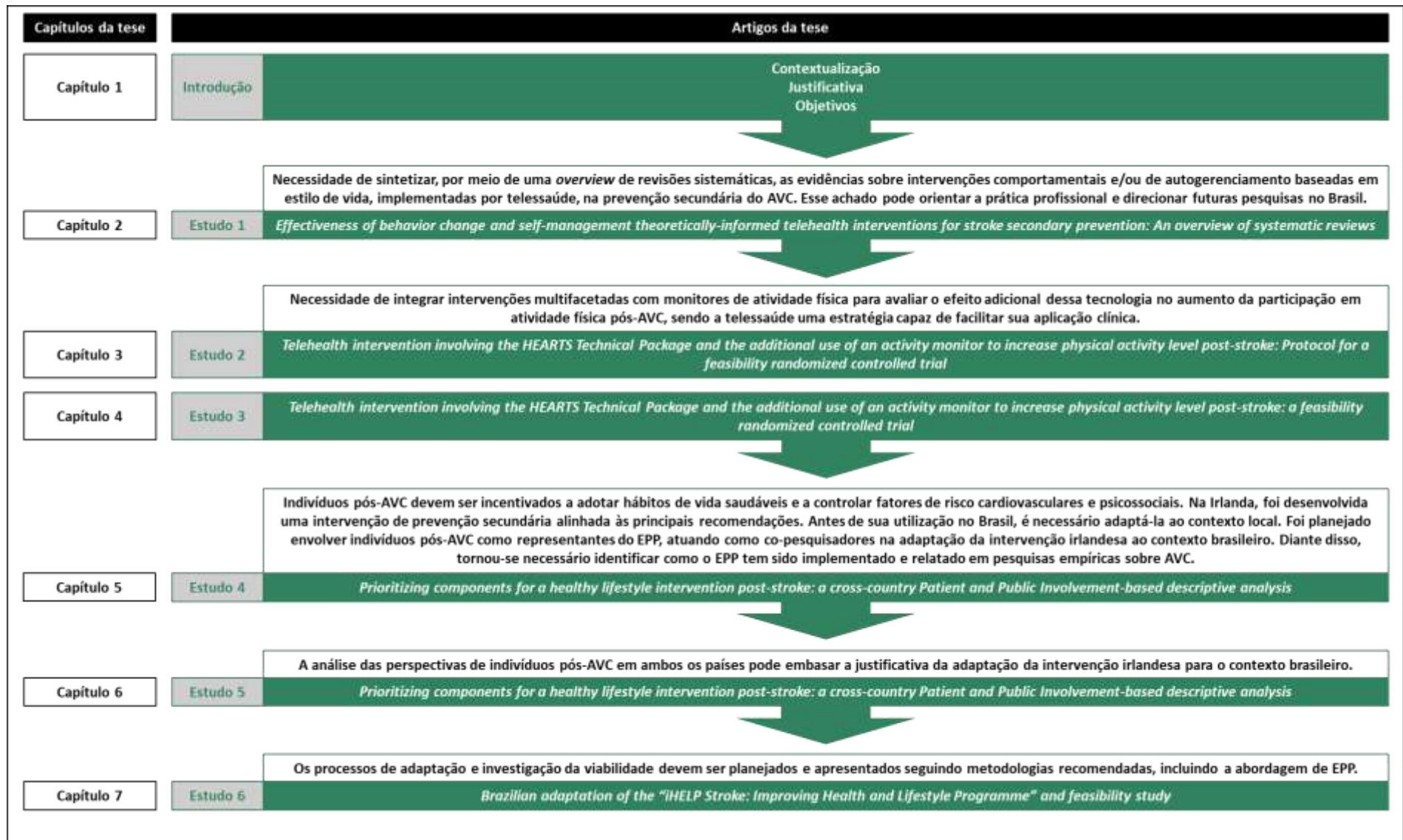


Figura 1. Fluxograma de organização da tese, considerando os estudos apresentados em cada capítulo. Legenda: AVC – acidente vascular cerebral; EPP - Envolvimento do Paciente e do Público

1.3 Objetivos

- Avaliar criticamente e consolidar evidências de revisões sistemáticas existentes sobre a eficácia de intervenções de mudança de comportamento e autogerenciamento, implementadas por telessaúde, na redução do risco de recorrência do AVC, e fornecer novas sínteses de estudos primários que implementaram intervenções teoricamente informadas (artigo do Estudo 1);
- Investigar a viabilidade de implementar uma intervenção teoricamente informada, realizada por telessaúde (via ligação telefônica), que combina a intervenção breve dos 5As, conforme descrita no Pacote Técnico HEARTS, com o uso de monitor de atividade física, em comparação a um GC que recebeu apenas a intervenção breve dos 5As (também por ligação telefônica), seguindo protocolo previamente desenvolvido (artigos dos Estudos 2 e 3);
- Identificar como a abordagem de EPP tem sido implementada e reportada em pesquisas empíricas sobre AVC (artigo do Estudo 4);
- Identificar semelhanças e diferenças na forma como indivíduos pós-AVC, participantes de painéis de Envolvimento do Paciente e do Público (EPP) em um país de alta renda (Irlanda) e em um país de média renda (Brasil), priorizam os componentes a serem incluídos em uma intervenção voltada ao incentivo da adoção de comportamentos de estilo de vida saudável durante *workshops* de *co-design* (artigo do Estudo 5);
- Adaptar a intervenção irlandesa “*iHELP Stroke*” ao contexto brasileiro (fase I) e investigar a viabilidade de implementar a versão adaptada com indivíduos pós-AVC no Brasil (fase II) (artigo do Estudo 6).

CAPÍTULO 2

ARTIGO 1

CAPÍTULO 2 – ESTUDO 1

O artigo do Estudo 1, intitulado “*Effectiveness of behavior change and self-management theoretically-informed telehealth interventions for stroke secondary prevention: An overview of systematic reviews*”, foi publicado em 2024 no periódico *Journal of Telemedicine and Telecare*.



Effectiveness of behavior change and self-management theoretically-informed telehealth interventions for stroke secondary prevention: An overview of systematic reviews

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Abstract

Introduction: Despite the increased use of telehealth interventions, low-level evidence supports their use for behavior change and self-management in stroke secondary prevention. Therefore, this overview of systematic reviews (SRs) critically appraises and consolidates the evidence about theoretically-informed telehealth interventions in stroke secondary prevention.

Methods: Two phases were conducted independently by two reviewers. Phase-1 included SRs contemplating randomized controlled trials (RCTs) implementing telehealth interventions with individuals post-stroke, targeting cardiovascular events, risk-reducing health behaviors or physiological risk factors. Phase-2 interrogated RCTs from these SRs that implemented theoretically-informed interventions. Best-evidence synthesis of published meta-analyses and new meta-analyses of theoretically-informed interventions were conducted. GRADE evidence was applied.

Results: In Phase-1 (15 SRs), best-evidence synthesis identified telehealth interventions as effective in reducing recurrent angina and recurrent stroke rates (both with very low GRADE), improving medication adherence (low GRADE), physical activity participation (very low GRADE), and blood pressure targets (very low GRADE), reducing systolic blood pressure (SBP) (moderate GRADE) and low-density lipoprotein levels (very low GRADE). In Phase-2 (14 RCTs), new meta-analyses identified theoretically-informed telehealth interventions as effective in improving medication adherence (SMD: 0.38; 95%CI: 0.13–0.64; I²: 72%, low GRADE) and healthy eating (SMD: 0.38; 95%CI: 0.15–0.60; I²: 38%, low GRADE), and decreasing SBP (MD: −9.19; 95%CI: −5.49 to −12.89; I²: 0%, moderate GRADE).

Discussion: Telehealth demonstrates utility in stroke secondary prevention, notably in SBP reduction. High-quality RCTs are required given the lack of current evidence supporting theoretically-informed telehealth interventions addressing primary outcomes of secondary prevention, and the low certainty evidence identified for health behavior change.

Keywords

Stroke, self-management, health behavior, telehealth, secondary prevention, systematic review

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Introduction

Stroke has a high burden worldwide and is the third leading cause of death and disability combined.^{1,2} Recurrent stroke contributes to the high burden of this disease, where recurrence rates vary between 7.7% and 39.7% from three months to 12 years after a first stroke.³ Recurrent strokes are associated with greater functional disability than first stroke episodes^{4,5} and are considered a leading cause of hospital readmissions during the first year post-stroke.⁶ Consequently, stroke secondary prevention has been identified as one of the top 10 priority research areas to reduce stroke burden by individuals post-stroke and other key stakeholders.⁷

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Data Availability Statement included at the end of the article

Stroke secondary prevention based on non-surgical and non-pharmacological (e.g., behavioral) interventions comprises the use of theoretically-informed interventions to address and self-manage lifestyle-related risk factors, contextualized and individualized to the needs of individuals post-stroke and their families.⁸ While stroke secondary prevention guidelines recommend the use of behavior change and self-management interventions to promote a healthy lifestyle including healthy eating, physical activity, cessation of smoking, safe alcohol consumption, and management of psychosocial stress, recommendations are often drawn from primary prevention study evidence.^{9–11} Better evidence supporting interventions delivered post-stroke is therefore required.¹⁰

Theoretically-informed behavioral interventions to self-manage lifestyle-related risk factors post-stroke⁸ can be provided remotely through telehealth.⁹ Telehealth refers to the provision of health care services using information and communication technologies (e.g., cellphones and internet) where patients and providers are separated by distance.¹² Telehealth interventions are becoming more frequent in health service delivery and were widely adopted during the Coronavirus pandemic.^{13,14} There is evidence by meta-analysis that their use in clinical populations is at least as good as usual care,¹⁵ alongside a growing body of research in stroke care.^{16,17} However, an updated practice guideline for stroke secondary prevention pointed that telehealth use in practice is yet supported by limited research evidence and low level evidence such as professional consensus.^{9,18} Therefore, better evidence supporting the effectiveness of theoretically-informed telehealth interventions in stroke secondary prevention is required.

In recent years, systematic reviews (SRs) of telehealth interventions targeting stroke secondary prevention outcomes have been published.^{19–21} However, some specifically addressed one outcome (e.g., medication adherence)^{19,22,23} while others did not specify stroke populations (e.g., included individuals with arterial occlusive events or cardiovascular disease).^{19,20} These methodological differences do not allow consolidated evidence about the effectiveness of telehealth interventions for stroke secondary prevention outcomes to be determined. The purpose of this overview, therefore, was to critically appraise and consolidate evidence from existing SRs on the effectiveness of behavior change and self-management telehealth interventions delivered to individuals for the purposes of reducing risk of recurrent stroke and to provide new synthesis from primary studies that were clearly informed by behavior change theory and/or techniques, as per best-practice recommendations.

Methods

Design and registration

An overview of SRs was conducted following the Cochrane Guidelines for Overviews of Reviews²⁴ and adhering to the

preferred reporting guideline for overviews of reviews of healthcare interventions (PRIOR) statement (checklist available in Supplementary Files).²⁵ This overview involved two phases: identification, screening, selection and synthesis of high-level evidence from eligible SRs of telehealth interventions addressing stroke secondary prevention outcomes (phase-1), and identification, screening, selection and synthesis of eligible primary studies that used specified behavior change theory and/or techniques from these SRs (phase-2). The protocol for this overview was previously published²⁶ as a public record of the review. The current overview describes telehealth interventions as distinct from interventions delivered face-to-face previously published.²⁷ Each step, in both overview phases, was conducted independently by two reviewers (PCP and CDCMF). A third reviewer (OL) was consulted where no consensus was initially reached through discussion.

Search methods

Electronic databases Embase, Epistemonikos, Medline and Cochrane were searched for published SRs (current to March 2023) using a comprehensive search strategy (available in Supplementary Files). Searches were supplemented by hand-searching reference lists of relevant SRs and reference lists of relevant guideline and policy documents.^{10,28,29} No language or time restriction for publications were applied. Given the multiplicity of terms often used to describe telehealth interventions (e.g., telemedicine, telerehabilitation, eHealth, mHealth) no search string was employed related to telehealth. Rather all SRs on stroke secondary prevention were screened against our inclusion criteria. Peer review of the electronic search strategy was conducted in line with best practice PRESS guidelines.³⁰

Phase-1: systematic reviews (SRs)

Selection criteria. Inclusion criteria were guided by the Population, Intervention, Comparator, Outcome and Study Type (PICOS) construct²⁴:

- Population: individuals post-stroke or transient ischemic attack (TIA), or cardiovascular disease populations where stroke was included as a discrete subpopulation;
- Intervention: telehealth interventions¹² targeting risk reduction by changing health behaviors and/or by self-management;
- Comparator: usual care or alternate active intervention;
- Outcomes:
 - Primary outcomes related to cardiovascular events: mortality (all cause and cardiovascular), recurrent stroke and other cardiovascular events;
 - Secondary outcomes related to risk-reducing health behaviors: medication adherence (anti-hypertensive

agents, cholesterol lowering agents, antiplatelet/anticoagulant agents), healthy eating, physical activity participation, smoking cessation, safe alcohol consumption and emotional self-regulation of psychosocial stress;

- Tertiary outcomes related to physiological risk factors: systolic blood pressure (SBP), diastolic blood pressure (DBP), lipid profiles and blood glucose.
- Study type: SRs pooling randomized controlled trials (RCTs) or cluster randomized controlled trials (CRCTs) of telehealth interventions to improve risk-reducing health behaviors post-stroke and reporting outcomes of interest. If reviews included other study designs, we included reviews from which it was possible to extract meta-analysis of RCTs or CRCTs data. For the study to be considered a systematic review, it was required to have identified itself as SRs, stated the objectives, named all databases searched, and detailed inclusion and exclusion criteria.³¹

SRs were excluded if they included only studies that aimed to change the behaviors of health professionals in secondary prevention practice or health systems interventions which aim to improve secondary prevention protocols.

Identification of SRs and data extraction. Identified published SRs were independently screened for inclusion by two reviewers. Data were extracted from included SRs independently by two reviewers using an agreed proforma. Graphical Representation of Overlap for OVERviews (GROOVE) tool was used to identify the degree of overlap between identified SRs.³² Telehealth interventions were classified according to the Center for Connected Health Policy's four domains of application: live videoconferencing (synchronous), store-and-forward (asynchronous), remote patient monitoring, and mobile health.^{33,34}

Quality appraisal of included SRs. Each SR was independently rated for quality by two reviewers using the risk of bias in SRs (ROBIS) tool.³⁵

Best-evidence synthesis of reported SRs results. A best-evidence synthesis was conducted for all published meta-analyses affecting significant change in pre-identified outcomes of interest. Grading of Recommendations Assessment, Development and Evaluation (GRADE) criteria³⁶ were applied to establish the certainty of evidence they provided. Judgement of GRADE quality for each comparison was agreed by consensus of all authors, with consideration of risk of bias of included studies,³⁷ inconsistency,³⁸ indirectness,³⁹ imprecision⁴⁰ and publication bias.⁴¹ Where two or more reviews reported meta-analysis for the same outcome and intervention, the

best-evidence was determined by consensus of authors, based on the quality appraisal of the SR of origin, the degree of overlapping studies and the timeframe in which the review was conducted. High-level evidence knowledge gaps relating to telehealth interventions for stroke secondary prevention were identified.

Phase-2: primary studies (RCTs or CRCTs)

Selection criteria and identification of the primary studies. Unique primary studies identified from included SRs during phase-1 were next screened independently by two reviewers. Initial screening used the study description provided by the SRs of origin and then full text review was conducted to ensure the identified primary studies met specific study-level inclusion criteria: an RCTs or CRCTs study design; stroke or TIA population; theoretically-informed telehealth interventions delivery only (e.g., that described the underpinning theory and/or referenced behavior change techniques)^{42,43}; and included primary, secondary or tertiary outcomes related to this overview. Studies which included interventions designed to alter care delivery processes or health professional education were excluded. Following screening, the interventions, as described in the included primary studies (and associated protocol paper, where relevant), were independently examined and extracted using domains 1 and 2 of TIDieR's 10 item checklist.⁴⁴

Data extraction from primary studies. Included primary studies had the following data items extracted independently by two reviewers: characteristics of the participants (e.g., number, age, sex, and time post-stroke), additional characteristics relating to the intervention (using domains 3–10 of the TIDieR checklist),⁴⁴ primary, secondary and tertiary outcomes, and results of between group comparisons. Telehealth interventions were again classified according to the Center for Connected Health Policy's four domains of application.^{33,34} Where any inconsistency between the information provided by the SR and the primary study was identified, the information provided by the primary study was considered.

Quality appraisal of primary studies. Two reviewers assessed the quality of each primary study using the Cochrane Risk of Bias Tool.⁴⁵

Data synthesis. Data from primary studies were grouped by technologies used to implement telehealth interventions and by outcomes of interest. Where data type and outcomes reported from two or more primary studies permitted, a meta-analysis was conducted. For continuous data, mean differences (MD) and 95% confidence intervals (95%CI) or standardized mean differences (SMD) were calculated from pooled data. For dichotomous variables, risk ratios

(RR) with 95%CI using the Mantel-Haenszel method were employed. The certainty of the evidence for each meta-analysis by outcome of interest was reported based on GRADE criteria.³⁶ Again, the judgement of GRADE certainty for each comparison was agreed by consensus of all authors.

Results

Search

Figure 1 depicts the flowchart for the screening and selection of eligible studies across the two overview phases. The initial search applied across the electronic databases identified 14,721 records. In phase-1, 15 SRs were included.^{19–23,46–55} In phase-2, 229 primary studies were identified from these SRs, of which only 14 could be included, as RCTs that employed specified behavior change theory and/or techniques in the telehealth intervention delivered for individuals post-stroke.^{56–69}

Phase-1: systematic reviews (SRs)

Table 1 details the 15 included SRs. They dated from 2016–2022 and they searched across 19 different databases. The most employed electronic databases in >10% of all included SRs were Medical Literature Analysis and Retrieval System Online (Medline) (16%), Cochrane (18%), Excerpta Medica Database (Embase) (16%), and Cumulative Index to Nursing and Allied Health Literature (CINAHL) (12%). Six (33%) SRs^{19,20,46,51,54,55} registered or published the review protocol in advance. Seven (47%) SRs^{20,46,48–50,52,54} reported adherence to the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) statement.⁷⁰

Telehealth intervention domains permitted in the inclusion criteria of these SRs were: all domains (videoconferencing, store-and-forward, remote patient monitoring, and mobile health),^{49–52,55} remote patient monitoring and mobile health,⁴⁷ and only mobile health.^{19–23,46,48,53,54} Eight (53%) SRs^{21–23,47,49,50,52,53} rated as at high risk of bias, primarily because of concerns related to study eligibility criteria.

Nine SRs (60%)^{20,21,23,46,48,50–52,54} conducted meta-analyses addressing outcomes of interest to this overview (available in Supplementary Files). For primary outcomes related to cardiovascular events, one SR pooled data addressing mortality, recurrent stroke and other cardiovascular events.⁴⁸ For secondary outcomes related to risk-reducing health behaviors: five SRs pooled data addressing medication adherence^{20,21,23,46,48}; two pooled data addressing physical activity participation^{48,54}; one pooled data addressing smoking cessation⁴⁸; one pooled data addressing emotional self-regulation of psychosocial stress (depressive symptoms)⁵¹; and none addressed healthy eating or safe alcohol consumption. For tertiary outcomes related to physiological risk factors: four SRs pooled data addressing blood pressure (recommended blood pressure targets, reduction in SBP and/or DBP)^{20,48,50,52}; two pooled data addressing lipid profile (lipid targets, total cholesterol and low density lipoprotein (LDL))^{20,48} and none addressed blood glucose.

Table 2 depicts the best-evidence synthesis supporting telehealth interventions by GRADE of evidence for each meta-analysis by outcome demonstrating statistically significant effect sizes. For outcomes related to cardiovascular events, very low GRADE certainty of evidence was identified for telehealth interventions to reduce rates of recurrent angina and recurrent stroke and/or TIA.⁴⁸ For outcomes related to risk-reducing health behaviors, low GRADE certainty of evidence was identified for telehealth interventions

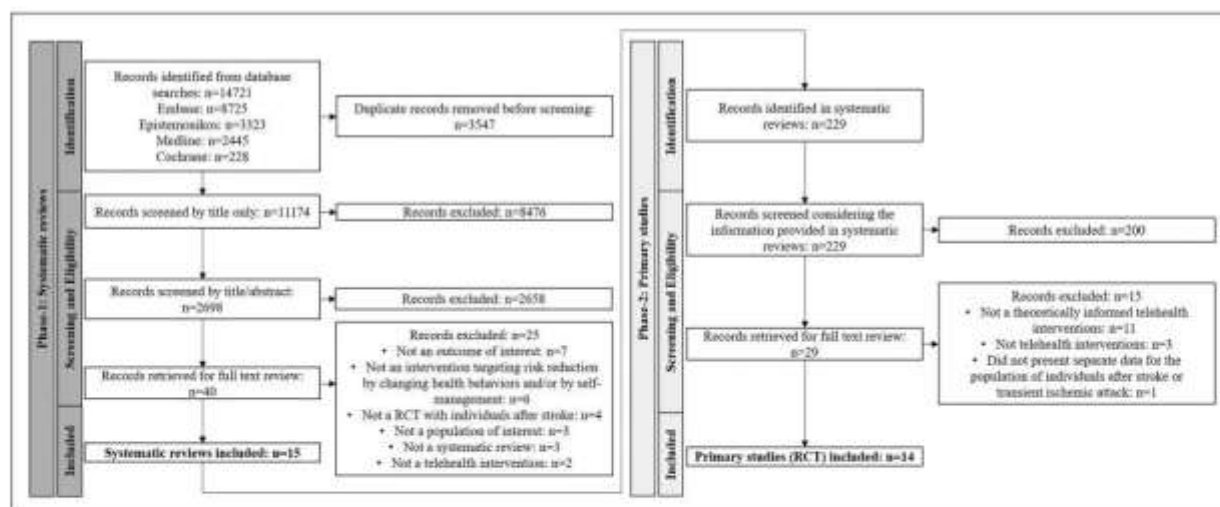


Figure 1. Flowchart of the identification, screening, and selection of eligible studies in the two phases of the overview.

Table 1. Description and methodological quality of systematic reviews included in the overview.

Systematic review	Main objective; population; telehealth application domain	Search range	Review: 1. registered in PROSPERO; 2. published protocol; 3. followed the PRISMA (yes or no)	Primary studies included: in the review; in the overview (n; %)	Outcomes of interest	Methodological quality ^a
Adler et al. ¹⁹	To determine whether mobile phone text messaging is effective in enhancing adherence to recommended medication Individuals with established arterial occlusive Mobile Health	Cochrane CPCI-S EMBASE MEDLINE Studies published until November 2016	1. No information 2. Yes 3. No information (only flow diagram)	7; 1 (14.3%)	Primary: medication adherence, fatal, non-fatal and combined cardiovascular events Secondary: surrogate outcomes for secondary prevention (e.g. blood pressure), adverse effects	Domain 1 Domain 2 Domain 3 Domain 4 Overall
Al-Arkee et al. ²⁰	To assess the effects of mobile health care apps on medication adherence and health-related outcomes Individuals with CVD Mobile Health	CINAHL Cochrane EMBASE Google Scholar MEDLINE PsycINFO Studies published until January 2020	1. Yes (CRD42019121385) 2. No information 3. Yes	16; 1 (6.3%)	Primary: medication adherence Secondary: SBP, DBP, TC, LDL	Domain 1 Domain 2 Domain 3 Domain 4 Overall
Armitage et al. ⁴⁶	To establish whether apps designed to support medication adherence demonstrate efficacy and to identify the intervention characteristics and BCT associated with efficacy Individuals with any health condition Mobile Health	CINAHL EMBASE MEDLINE PsycINFO Web of Science Studies published from 1990 to November 2018	1. Yes (CRD42017080150) 2. No information 3. Yes	9; 0 (0%)	Medication adherence	Domain 1 Domain 2 Domain 3 Domain 4 Overall
Freund et al. ⁴⁷	To examine the effectiveness of self-directed, information and communications technology-based interventions that aimed to improve outcomes Individuals after stroke or TIA Remote patient monitoring and mobile health	Cochrane EMBASE MEDLINE Studies published from January 2006 to June 2020	1. No information 2. No information 3. No information (only flow diagram)	19; 4 (21.1%)	Stroke outcomes (e.g., speech, hemiparesis, cognition), physical outcomes (e.g., blood pressure), behavioral outcomes (e.g., medication adherence, physical activity), psychosocial outcomes (e.g., depression, quality of life) and health service use	Domain 1 Domain 2 Domain 3 Domain 4 Overall

(continued)

Table 1. Continued

Systematic review	Main objective; population; telehealth application domain	Search range	Review: 1. registered in PROSPERO; 2. published the protocol; 3. followed the PRISMA (yes or no)	Primary studies included in the review; in the overview (n; %)	Outcomes of interest	Methodological quality ^a
Gandapur et al. ²²	To review the role of mobile health tools for improving medication adherence Individuals with CVD Mobile Health	MEDLINE Studies published from January 1966 to December 2015	1. No information 2. No information 3. No information	10; 1 (10.0%)	Medication adherence	Domain 1 Domain 2 Domain 3 Domain 4 Overall
Gandhi et al. ⁴⁸	To provide further insight as to whether mobile health technology can provide added benefit in the contemporary management of CVD Individuals with CVD Mobile Health	CINAHL CNKI Cochrane EMBASE MEDLINE PsycINFO WANFANG Studies published from 1950 to January 2016	1. No information 2. No information 3. Yes	27; 0 (0%)	Primary: medication adherence Secondary: adherence to either pharmacologic or nonpharmacologic recommendations, and the ability to meet secondary prevention targets (blood pressure, LDL, BMI, exercise, or smoking cessation) Tertiary: blood pressure, LDL, BMI, exercise, smoking cessation, and clinical events (e.g., TIA/stroke, myocardial infarction, and mortality)	Domain 1 Domain 2 Domain 3 Domain 4 Overall
Hwang et al. ⁴⁹	To identify the components the of telehealth-self-management Intervention's focus and self-management support components, the telehealth delivery type, and the telehealth-self-management support effects Individuals after stroke Videoconferencing, store-and-forward, remote patient monitoring, and mobile health	CINAHL EMBASE MEDLINE PsycINFO Web of Science Studies published from 2005 to 2020	1. No information 2. No information 3. Yes	10; 1 (10.0%)	Goal attainment, self-care, activities of daily living, self-efficacy, quality of life, lifestyle behavior, participation, function, psychosocial, disability, and adherence	Domain 1 Domain 2 Domain 3 Domain 4 Overall
Kassavou et al. ²³	To assess the effectiveness of interactive voice response and short message service interventions to support medication	CINAHL Cochrane EMBASE	1. No information 2. No information	17; 1 (5.9%)	Medication adherence	Domain 1 Domain 2

(continued)

Table 1. Continued

Systematic review	Main objective; population; telehealth application domain	Search range	Review: 1. registered in PROSPERO; 2. published the protocol; 3. followed the PRISMA (yes or no)	Primary studies included in the review; in the overview (n; %)	Outcomes of interest	Methodological quality ^a
	adherence, and to identify the BCT and other intervention characteristics that are positively associated with greater intervention effectiveness Individuals with diagnosis of or at risk of a cardio-metabolic condition Mobile Health	MEDLINE PsycINFO (from January 1992 to April 2016) Data related to the search date were not provided for the other databases	3. No information (only flow diagram)			Domain 3 Domain 4 Overall
Kraft et al. ⁵⁰	To systematically assess the principles of telemedical-supported strategies to improve secondary prevention after stroke or TIA currently used and to analyze the potential implications of telemedical support in terms of long-term outcome Individuals after stroke or TIA Videoconferencing, store-and-forward, remote patient monitoring, and mobile health	Cochrane Google Scholar MEDLINE Studies published until May 2016	1. No information 2. No information 3. Yes	13; 4 (30.8%)	Primary: SBP (e.g., adherence to SBP recommendations, achievement of health behavior targets) Secondary: consequences of the primary outcomes (e.g., mortality, recurrent events, laboratory or vital parameters, health service utilization, re-admission to hospital, and quality of life)	Domain 1 Domain 2 Domain 3 Domain 4 Overall
Laver et al. ⁵¹	To determine whether the use of telerehabilitation leads to improved ability to perform activities of daily living when compared with in-person rehabilitation or no rehabilitation or usual care Individuals after stroke Videoconferencing, store-and-forward, remote patient monitoring, and mobile health	AMED CINAHL Cochrane EBSCO EMBASE HTA MEDLINE OTseeker PEDro PsycBITE PsycINFO REHABDATA Studies published until June 2019	1. No information 2. Yes 3. No information	22; 2 (9.1%)	Primary: independence in activities of daily living Secondary: self-care and domestic life, mobility, balance, participant satisfaction with the intervention, self-reported health-related quality of life, depression	Domain 1 Domain 2 Domain 3 Domain 4 Overall

(continued)

Table 1. Continued

Systematic review	Main objective; population; telehealth application domain	Search range	Review: 1. registered in PROSPERO; 2. published the protocol; 3. followed the PRISMA (yes or no)	Primary studies included in the review; in the overview (n; %)	Outcomes of interest	Methodological quality*
Lv et al. ⁵²	To estimate the effects of telemedicine and mobile health interventions on the control of systolic blood pressure Individuals after stroke Videoconferencing, store-and-forward, remote patient monitoring, and mobile health	Cochrane EMBASE MEDLINE Web of Science Studies published until June 2020	1. No information 2. No information 3. Yes	9; 4 (44.4%)	SBP	Domain 1 Domain 2 Domain 3 Domain 4 Overall
Park et al. ⁵³	To identify the potential of mobile phones features to be used as effective interventions in the secondary prevention of CVD Individuals with CVD Mobile Health	CINAHL Cochrane MEDLINE PsycINFO Studies published from January 2002 to January 2016	1. No information 2. No information 3. No information	28; 1 (3.6%)	Secondary prevention of CVD	Domain 1 Domain 2 Domain 3 Domain 4 Overall
Patterson et al. ⁵⁴	To determine if smartphone applications are effective at changing physical activity and sedentary behavior Individuals with CVD Mobile Health	CINAHL Cochrane EMBASE MEDLINE SCOPUS Sports Discus Studies published from 2007 to October 2020	1. Yes (CRD42020189046) 2. No information 3. Yes	19; 0 (0%)	Primary: physical activity and sedentary behavior Secondary: participant characteristics (e.g., age, gender, diagnoses) and the factors which influence uptake (including requirement to own a smartphone), engagement and adherence to such interventions and retention rates	Domain 1 Domain 2 Domain 3 Domain 4 Overall
Rintala et al. ⁵⁵	To investigate the effectiveness of technology-based distance physical rehabilitation interventions on physical functioning compared to a combination of traditional treatments such as similar treatment, other treatment, and usual care Individuals after stroke Videoconferencing, store-and-forward, remote patient monitoring, and mobile health	CINAHL Cochrane EMBASE PEDro Web of Science Studies published from January 2000 to May 2018	1. Yes (CRD42017065918) 2. No information 3. No information	13; 1 (7.7%)	Measures of physical functioning	Domain 1 Domain 2 Domain 3 Domain 4 Overall

(continued)

Table 1. Continued

Systematic review	Main objective; population; telehealth application domain	Search range	Review: 1. registered in PROSPERO; 2. published the protocol; 3. followed the PRISMA (yes or no)	Primary studies included: in the review; in the overview (n; %)	Outcomes of interest	Methodological quality ^a
Zeng et al. ²¹	To evaluate the effects of mobile health and telehealth technology and usual care on medication adherence Individuals after stroke Mobile Health	Cochrane EMBASE MEDLINE Web of Science Studies published until September 2021	1. No information 2. No information 3. No information	10; 5 (50%)	Medication adherence	Domain 1 Domain 2 Domain 3 Domain 4 Overall

Legend: AMED - Allied and Complementary Medicine; BCT - behavior change technique; BMI - body mass index; CINAHL - Cumulative Index to Nursing and Allied Health Literature; CNKI - China National Knowledge Infrastructure; CPCI-S - Conference Proceedings Citation Index - Science; CVD - cardiovascular disease; DBP - diastolic blood pressure; EBSO - Business Source Complete; EMBASE - Excerpta Medica Database; HbA1c - glycated haemoglobin; HTA - Health Technology Assessment Database; INSPEC - ISI Web of Knowledge; LDL - low-density lipoprotein; MEDLINE - Medical Literature Analysis and Retrieval System Online; OTRseeker - Occupational Therapy System Evaluation of Evidence; PEDro - Physiotherapy Evidence Database; PRISMA - Preferred Reporting Items for Systematic Reviews and Meta-Analyses; PROSPERO - International Prospective Register of Systematic Reviews; PsycBITE - Psychological Database for Brain Impairment Treatment Efficacy; PsycINFO - Psychological Abstracts; SBP - systolic blood pressure; TC - total cholesterol; TIA - transient ischemic attack.

^aRisk of bias in systematic reviews ROBIS tool (Domain 1: study eligibility criteria; Domain 2: identification and selection of studies; Domain 3: data collection and study appraisal; Domain 4: synthesis and findings; Overall - Risk of bias in the review. Colors: green - low risk of bias; red - high risk of bias; yellow - unclear)

Table 2. GRADE of evidence supporting telehealth interventions with statistically significant effects (meta-analyses from the included systematic reviews).

Outcome	Systematic review	Interventions compared	Studies	N	Effect Estimate [95% CI]	I ²	Quality of evidence (GRADE)	Reasons for down-grade
Recurrent stroke/TIA	Gandhi et al. ⁴⁸	Mobile health intervention versus usual care	2	176	OR: 0.18 [0.08 to 0.41]	NR	⊕○○○ Very Low	ROB and imprecision; Inconsistency domain was not rated considering the absence of data
Angina	Gandhi et al. ⁴⁸	Mobile health intervention versus usual care	3	305	OR: 0.23 [0.08 to 0.64]	NR	⊕○○○ Very Low	ROB and imprecision; Inconsistency domain was not rated considering the absence of data
Medication adherence	Al-Arkee et al. ²⁰	App-based interventions versus usual care	6	820	MD: 0.90 [0.03 to 1.78]	93%	⊕○○○ Very Low	ROB, inconsistency, indirectness, and imprecision
	Armitage et al. ⁴⁶	App-based interventions versus usual care	9	988	OR: 2.12 [1.64 to 2.75]	9.8%	⊕⊕○○ Low	ROB and imprecision
	Gandhi et al. ⁴⁸	Mobile health interventions versus usual care	9	1355	OR: 4.51 [2.38 to 8.57]	61%	⊕○○○ Very Low	ROB and inconsistency
	Kassavou et al. ²³	Interactive voice response or SMS interventions versus usual care	17	25,101	OR: 1.89 [1.51 to 2.36]	89%	⊕○○○ Very Low	ROB and inconsistency
	Zeng et al. ²¹	Mobile health intervention versus usual care (scores)	4	498	SMD: 0.67 [0.49 to 0.85]	0%	⊕⊕○○ Low	ROB
		Mobile health intervention versus usual care (ratios)	6	1653	OR: 2.81 [1.35 to 5.85]	77%	⊕○○○ Very Low	ROB and inconsistency
Physical activity participation	Patterson et al. ⁵⁴	Smartphone apps interventions versus usual care (MVPA minutes/week)	7	600	MD: 40.35 [1.03 to 79.67]	51%	⊕○○○ Very Low	ROB, indirectness, and imprecision
		Smartphone apps interventions versus usual care (steps/day)	3	67	MD: 2390 [1006.9 to 3791.2]	0%	⊕○○○ Very Low	ROB, indirectness, and imprecision
Blood pressure targets	Gandhi et al. ⁴⁸	Mobile health interventions versus usual care	2	913	OR: 2.80 [2.04 to 3.86]	NR	⊕○○○ Very Low	ROB, inconsistency and publication bias; Inconsistency domain was not rated considering the absence of data
SBP	Kraft et al. ⁵⁰	Telemedical interventions versus control treatment without telemedical approach	4	840	MD: -6.14 [-10.41 to -1.87]	53%	⊕○○○ Very Low	ROB, inconsistency and imprecision
	Lu et al. ⁵²	Telemedicine and mobile health interventions versus usual care	9	1583	MD: -5.49 [-7.87 to -3.10]	24%	⊕⊕⊕○ Moderate	ROB
LDL	Al-Arkee et al. ²⁰	App-based interventions versus usual care	2	192	MD: -0.46 [-0.79 to -0.12]	0%	⊕○○○ Very Low	ROB, indirectness, imprecision, and publication bias

Legend: 95%CI - 95% confidence interval; DBP - diastolic blood pressure; GRADE - Grading of Recommendations Assessment, Development and Evaluation; LDL - low-density lipoprotein; MD - mean difference; NR - not reported; RCT - randomized controlled trial; ROB - Risk of bias; RR - Risk Ratio; SBP - systolic blood pressure; SMD - standardized mean difference; SMS - short message service.

to improve medication adherence^{21,46} and very low GRADE certainty of evidence to improve physical activity participation.⁵⁴ For outcomes related to physiological risk factors, very low GRADE certainty of evidence was identified for telehealth interventions to meet recommended blood pressure targets,⁴⁸ moderate GRADE certainty of evidence to reduce SBP⁵² and a very low GRADE certainty of evidence to control LDL levels.⁵⁰

Figure 2 depicts only slight overlap of primary studies between the 15 SRs identified, with a 2.15% degree of corrected covered area (CCA). The citation matrix for primary studies (available in Supplementary Files) identifies 6 (43%) key primary studies^{56,60,62,66-68} cited in more than one systematic review.

Phase-2: primary studies

Table 3 summarizes the 14 primary studies included following screening of RCTs. Included interventions were all broadly categorized under the Center for Connected Health Policy's domain^{33,34} of mobile health, with one study including both mobile health and remote patient monitoring.⁶⁶ No primary studies identified used the live videoconferencing (synchronous) or store-and-forward (asynchronous) telehealth domains. The interventions identified were implemented through telephone/cellphone for call-based delivery^{56,58,59,61,63,67} or utilized a combination of technologies: cellphone and internet for app use, alongside a home blood pressure monitor⁶⁶; cellphone/telephone for call-based delivery alongside a home blood pressure monitor⁶⁴; computer and internet for web-site access⁶²; computer and internet for web-site access combined with a cellphone/telephone for call-based delivery⁶⁵; computer and internet to support sending SMS combined with a cellphone to receive SMS/call.^{57,60,68,69}

The majority of primary studies (n=9, 64%) were conducted in high income countries (Australia, Canada, Denmark, Korea, United Kingdom, and United States), with 36% (n=5) performed in middle-income countries:

China,⁶⁷⁻⁶⁹ Ghana⁶⁶ and Pakistan.⁶⁰ Sample sizes in primary studies ranged from n=36⁶² to n=265.⁶⁵ Time post-stroke at trial entry ranged from less than one month^{56,59,66,67} to 188 months.^{56,61} Four studies did not provide information about time post-stroke.^{58,64,68,69}

Behavior change theories and/or techniques implemented varied across the studies. Many were implemented as a single strategy in the included studies: coaching,⁶¹ goal-setting,⁶⁷⁻⁶⁹ motivational interviewing,^{58,59} self-determination theory,⁶⁶ and social cognitive theory.⁶² Other primary studies implemented reported theories and techniques in combination: cognitive behavioral therapy and problem-solving approaches,⁶³ health belief model and social cognitive theory,⁶⁰ motivational interviewing, self-efficacy and self-managed care theories,⁶⁴ self-management support, community resources, and decision support,⁶⁵ social cognitive theory and motivational interviewing,⁵⁶ and social cognitive theory, information-motivation-behavioral theory and operant condition.⁵⁷

The professional delivering the telehealth interventions, where clearly identified (n=10, 71%), comprised: a nurse (n=7, 50%),^{61,63,64,66-69} doctor and nurse combination (n=1, 7%),⁶² a pharmacist (n=1, 7%)⁵⁹ and social workers (7%, n=1).⁶⁵ The length of identified interventions varied from one⁵⁷ to six months.^{56,59,64,69} The majority of studies (n=10, 71%) reported usual care as the control condition,^{56-60,62,63,65,68,69} although all control interventions reported were devoid of behavior change theory and/or techniques.

The methodological quality of RCTs included in phase-2 is summarized in Table 4. Domains with the highest risk of bias were noted to be blinding of participants and personnel (n=14, 100%) and blinding of outcome assessment (n=3, 21%).

Of the primary outcomes of interest, two studies reported recurrent stroke rates as an outcome.^{65,69} Secondary outcomes of interest reported included medication adherence (n=8),^{59,60,62,64,66-69} healthy eating (n=4),^{58,62,67,68} physical activity participation (n=6),^{56,58,61,62,67,68} smoking

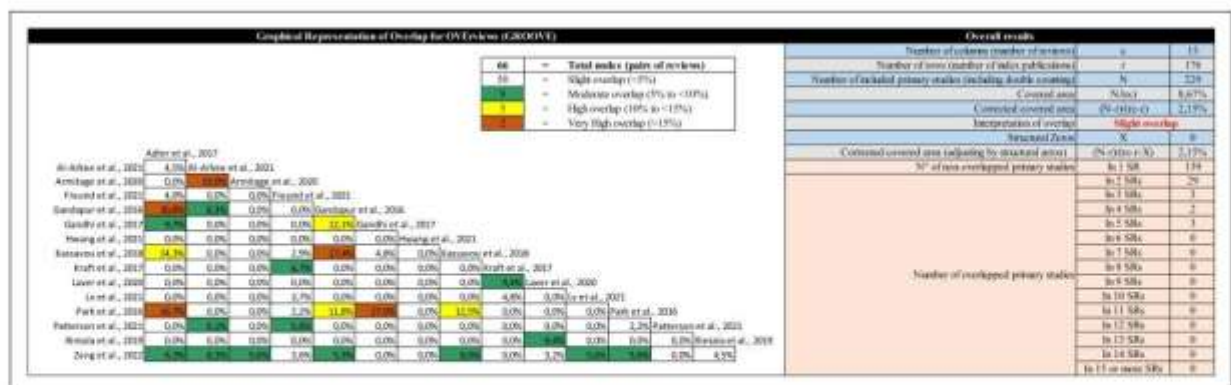


Figure 2. Phase 1: graphical representation of overlap for OVERviews (GROOVE) and overall results.

Table 3. Description of primary studies included in the overview considering the used technology and domain of application of theoretically-informed telehealth interventions

Primary article: country (systematic review source)	Sample size (n): % female	Age (years): mean (SD)	Time after stroke	Experimental group	Control group	Outcomes related to stroke secondary prevention	Main findings
Cellphone and internet for app use, alongside a home blood pressure monitor: remote patient monitoring and mobile health							
Sarfo et al. ⁴⁶ ,	60 (IC: 30; CG: 30); 35% (EG: 40%; CG: 30%)	EG: 54.3 (11.9); CG: 55.9 (13.7)	≤ 1 month	- Phone-based intervention for blood pressure control (home monitoring and reporting blood pressure, daily) + tailored motivational SMS text message based on medication adherence levels - App: NR - Blood pressure monitor: Blue-toothed UA-767Plus - BCT: self-determination theory - Professional: nurse - Length of intervention: 3 months (follow-up: at 6 and 9 months)	SMS text messages on healthy lifestyle behaviors (not related to medication adherence)	- SBP (proportion of individuals with <140 mmHg) - DBP (proportion of individuals with <90 mmHg) - Medication adherence (medication possession ratio)	- SBP and DBP: intragroup change was not reported; no significant change between groups - Medication adherence: significant increase in the EG compared to CG (at 3 months); increase in both groups and no significant change between groups at 9 months
Ghana (Al-Arkee et al. ²⁰ ;							
Freund et al. ⁴⁷ ; Zeng et al. ²¹)							
Cellphone/telephone for call-based delivery alongside a home blood pressure monitor: mobile health							
Mackenzie et al. ⁶⁴ ;	56 (EG: 29; CG: 27); 32.1%	NR	NR	- Medication counselling, provision of home blood pressure monitoring equipment and medication dosette, and telephone calls (monthly intervals for 6 months) to deliver motivational interviewing - Blood pressure monitor: NR - BCT: motivational interviewing, self-efficacy and self-managed care theories - Professional: nurse - Length of intervention: 6 months	Stroke physician specialist assessment, initiation and titration of blood pressure medication, adherence and risk factor counselling at clinic visits and follow-up by family physicians	- SBP (mmHg) - DBP (mmHg) - Medication adherence (%)	Increase in EG and decrease in CG for all measures. No significant change between groups for all measures
Canada (Lv et al. ⁵²)							
Computer and internet for web-site access: mobile health							
Kim J et al. ⁶² ;	36 (EG: 18; CG: 18); 41.7% (EG: 37.5%; CG: 44.4%)	EG: 67.4 (7.3); CG: 63.9 (7.4)	Within 1 year	- Web-based stroke education program on recurrence prevention behaviors (video lectures, automated quizzes, reliable external links to websites; 9 session) - BCT: social cognitive theory	Usual care (prescribed by physician and no further recurrence prevention advice)	- Lipid profile (total cholesterol and triglyceride, mg/dl) - Health diet (amount of fruit and	Lipid profile: triglyceride (decrease in both groups); total cholesterol
Korea (Freund et al. ⁴⁷ ; Kraft et al. ⁵⁰)							

(continued)

Table 3. Continued

Primary article; country (systematic review source)	Sample size (n): % female	Age (years): mean (SD)	Time after stroke	Experimental group	Control group	Outcomes related to stroke secondary prevention	Main findings
				- Professional: doctor and nurse - Length of intervention: 2 months and 1 week (follow-up: at 3 months)		vegetable consumed/week salty food consumed: none, occasionally of very often - Physical activity participation (yes or no; changed positively) - Smoking cessation (yes or no; changed positively) - Safe alcohol consumption (yes or no; changed positively) - Medication adherence (adhere fully, missed occasionally, or changed medication dose; changed positively)	(increase in EG and decrease in CG): no significant change between groups - Medication adherence, smoking cessation and safe alcohol consumption: increase of individuals who change positively in both groups; no significant change between groups - Health diet and physical activity participation: significant increase of individuals who change positively in the EG compared to CG
Computer and internet for web-site access combined with a cellphone/telephone for call-based delivery: mobile health Reeves et al. ⁶⁵ United States (Freund et al. ⁴⁷)	265 (EG-1: 88; EG-2: 90; CG: 87); 49% (EG-1: 46%; EG-2: 55%; CG: 48%)	EG-1: 67.5 (13.0); EG-2: 66.1 (12.7); CG: 65.2 (13.9)	1 month after discharge	- EG-1: Home-based social worker-led case (home visits and follow-up telephone call) - EG-2: Home-based social worker-led case + MISTT website (patient-orientated information on stroke education, prevention, recovery, and community resources management) - BCT: self-management support, community resources, and decision support	Usual care	- Psychosocial stress management (depression symptom: PHQ-9; anxiety: Neuro-QOL) - Recurrent stroke and TIA (frequency)	- Psychosocial stress management: decrease in all groups for both measures - Recurrence rate of stroke and TIA: n = 5 (EG-1); n = 12 (EG-2); n = 7 (CG); no significant difference between

(continued)

Table 3. Continued

Primary article; country (systematic review source)	Sample size (n): % female	Age (years): mean (SD)	Time after stroke	Experimental group	Control group	Outcomes related to stroke secondary prevention	Main findings
Kassavou et al. ²³ ; Park et al. ⁵³ ; Zeng et al. ²¹)							reported; no significant change between groups • DBP: significant decrease in the EG compared to the CG
Wan et al. ⁶⁸ ; China (Lv et al. ⁵² ; Zeng et al. ²¹)	158 (EG: 80; CG: 78); 26.2 (EG: 36.3; CG: 33.3)	NR	NR	- Health belief model comprehensive reminder system on health behaviors and blood pressure (patient calendar handbook; in-person health belief education; telephone health belief education; automated SMS) + health education during hospitalization, a stroke prevention handout, follow-up by doctors at the outpatient department, and telephone follow-up by nurses at 1 week and 1 month after discharge - BCT: goal-setting - Professional: nurse - Length of intervention: 3 months	Usual care (health education during hospitalization, a stroke prevention handout, follow-up by doctors at the outpatient department, and telephone follow-up by nurses at 1 week and 1 month after discharge)	- Physical activity participation (HPLP-II) - Health diet (nutrition and low-salt diet: HPLP-II) - Safe alcohol consumption (limiting alcohol use, HPLP-II) - Medication adherence (HPLP-II) - SBP (mmHg) - DBP (mmHg)	- Physical activity participation, health diet, medication adherence: significant increase in the EG compared to CG - Safe alcohol consumption: increase in both groups; no significant change between groups - SBP and DBP: significant decrease in the EG compared to CG - Medication adherence: significant increase in the EG compared to CG - SBP: significant decrease in the EG compared to CG - DBP: decrease in both groups (at 3 months) and increase in both
Wang et al. ⁶⁸ ; China (Lv et al. ⁵²)	151; (EG: 76; CG: 75); 33.8% (EG: 34.2% CG: 33.3%)	NR	NR	- Comprehensive reminder system based on the health belief model (health belief education, calendar handbook, automated SMS, telephone follow-up interviews) + health education - BCT: goal-setting - Professional: nurse - Length of intervention: 6 months	Usual care (health education during hospitalization, a stroke prevention handout, telephone follow-up by nurses at 1 week and 1 month, and follow-up by doctors at the outpatient department after discharge)	- Medication adherence (HPLP-II) - SBP (mmHg) - DPB (mmHg) - Recurrence stroke (frequency)	- Medication adherence: significant increase in the EG compared to CG - SBP: significant decrease in the EG compared to CG - DBP: decrease in both groups (at 3 months) and increase in both

(continued)

Table 3. Continued

Primary article; country (systematic review source)	Sample size (n): % female	Age (years): mean (SD)	Time after stroke	Experimental group	Control group	Outcomes related to stroke secondary prevention	Main findings
Telephone/cellphone for call-based delivery; mobile health							
Adie et al. ⁵⁶ ; United Kingdom (Kraft et al. ⁵⁰ ; Lv et al. ⁵²)	56 (EG: 29; CG: 27); 50% (EG: 58.6%; CG: 40.7%)	72.5 (8.9); EG: 73.6 (8.0); CG: 71.2 (9.7)	Within 1 month; 16 (8) days	• Telephone-based follow-up (20-min telephone counseling intervention; 7–10 days, 1, 2 and 4 months) ± educational material ± usual care • BCT: social cognitive theory and motivational interviewing • Professional: NR • Length of intervention: 6 months	Usual care (did not include follow-up visits in secondary care; involved instructions for follow-up with their general practitioner)	• SBP (mmHg) • DBP (mmHg) • Lipid profile (total cholesterol; mg/dl) • Physical activity participation (minutes/week) • Smoking cessation (yes or no; changed positively)	• SBP: no change in EG; decreased in the CG • DBP, lipid profile, and smoking cessation: increase in both groups • Physical activity participation: no change in both groups • No significant difference between groups for all measures
Gillham et al. ⁵⁸ ; United Kingdom (Kraft et al. ⁵⁰)	52 (EG: 26; CG: 26); 28.8%	68.3; EG: 67.7 (12.0); CG: 68.9 (13.2)	NR	• Enhanced secondary prevention (information about stroke pathology and individual stroke risk factors, a motivational interviewing about behavior change, and a plan for behavior change ± telephone support and follow-up to discuss progress at two weeks and six weeks) ± conventional care • BCT: motivational interviewing • Professional: NR • Length of intervention: 3 months	Usual care (advice given during routine care; no further secondary prevention advice)	• Psychosocial stress management (HADS: anxiety and depression) • Safe alcohol consumption (units/week) • Smoking cessation (yes or no; changed positively) • Physical activity	• Psychosocial stress management, safe alcohol consumption: increase in both groups; no significant change between groups • Smoking cessation: intragroup change was not reported;

(continued)

Table 3. Continued

Primary article; country (systematic review source)	Sample size (n): % female	Age (years): mean (SD)	Time after stroke	Experimental group	Control group	Outcomes related to stroke secondary prevention	Main findings
Kim H et al. ⁶¹ ; Korea (Kraft et al. ⁵⁰)	61 (EG: 32; CG: 29); 37.7% (EG: 40.6%; CG: 34.5%)	EG: 67.4 (8.5); CG: 66.7 (9.4)	EG: 24 (2– 124) months; CG: 36 (2–188) months	- Lifestyle modification tele-coaching program for secondary stroke prevention (10–20 min/week) ± in-person education - BCT: coaching - Professional: nurse - Length of intervention: 2 months	In-person education	- Safe alcohol consumption (total consumption/month) - Lipid profile (total cholesterol; HDL; triglyceride; LDL; mg/dl) - Physical activity participation (IPAQ) - SBP (mmHg) - DBP (mmHg)	- no significant change between groups - Physical activity participation and health diet: significant increase in the EG compared to the CG - Safe alcohol consumption: increase in EG and no change in CG; no significant change between groups - Lipid profile: total cholesterol and LDL (decrease in both groups), triglyceride and HDL (decrease in EG and increase in CG); no significant change between groups - Physical activity participation: significant increase in the EG compared to the CG - SBP and DBP: significant decrease in the EG compared to CG
Kirkness et al. ⁶²	100 (EG Telephone: 37; EG	EG Telephone: 61.7 (31–85);	Within 4 months	EG Telephone: Living well with stroke 2 brief psychosocial intervention (6 session, average 26 min ± one in-person	Usual care (visits in homes at 8, 21 weeks, and	Psychosocial stress management (depression, HDRS)	Intragroup change was not reported; no significant

(continued)

Table 3. Continued

Primary article; country (systematic review source)	Sample size (n); % female	Age (years): mean (SD)	Time after stroke	Experimental group	Control group	Outcomes related to stroke secondary prevention	Main findings
United States (Laver et al. ⁵¹)	In-person: 35; CG: 28); 50% (EG Telephone: 48.6%; EG In-person: 51.4%; CG: 50%)	EG In-person: 58.5 (23–83); CG: 60.7 (32– 88)		orientation session) • EG In-person: Living well with stroke 2 brief psychosocial intervention (6 session, average 38 min ± one in-person orientation session) • BCT: cognitive behavioral therapy and problem-solving approaches • Professional: nurse • Length of intervention: 2 months (follow-up: at 21 weeks, and at 12 months)	12 months following entry to the study; prescriptions of antidepressants)		change between groups
Hedgegaard et al. ⁵⁹ ; Denmark (Zeng et al. ²¹)	203 (EG: 102; CG: 101); 38.9% (EG: 40.2%; CG: 37.6%)	EG: 64 (56– 73); CG: 68 (61–73)	< 1 month	• A focused medication review followed by dialogue to support adherence and lifestyle changes + a patient interview followed by a list of their own goals and agreed actions + 3 follow-up telephone calls to the participant (1 week, 2 months and 6 months) • BCT: motivational interviewing • Professional: pharmacist • Length of intervention: 6 months (follow-up: 24 months)	Usual care (standard care provided by the managing medical team without any enhancement)	Medication adherence (medication adherence ratio)	Increase in both groups; no significant change between groups
Wan et al. ⁶⁷ ; China (Laver et al. ⁵¹ ; Rintala et al. ⁵⁵ ; Zeng et al. ²¹)	80 (EG: 40; CG: 40); 28.8% (EG: 25.0%; CG: 32.5%)	EG: 59.1 (12.4); CG: 60.2 (12.6)	< 1 month	• Goal-setting telephone follow-up on health behaviors (3 telephone follow-up calls at 1 week and at 1 and 3 months after discharge, each lasting 15–20 min) + usual stroke education • BCT: goal-setting • Professional: nurse • Length of intervention: 3 months (follow-up: at 6 months)	Usual stroke education and appointments with doctors for routine blood pressure measurements and medication adjustment	• Physical activity participation (HPLP-II) • Health diet (nutrition and low-salt diet HPLP-II) • Safe alcohol consumption (unhealthy use of alcohol: HPLP-II) • Medication adherence (HPLP-II)	• Physical activity participation: increase in EG (at 3 and 6 months); increase (at 3 months) and decrease (at 6 months) in CG; no significant change between groups • Health diet: increase in both groups (at 3 and 6 months); no significant change

(continued)

Table 3. Continued

Primary article; country (systematic review source)	Sample size (n): % female	Age (years): mean (SD)	Time after stroke	Experimental group	Control group	Outcomes related to stroke secondary prevention	Main findings
							between groups • Safe alcohol consumption: increase in EG (at 3 and 6 months); increase (at 3 months) and decrease (at 6 months) in CG; no significant change between groups • Medication adherence: significant increase in the EG compared to CG (at 6 months)

Legend: unmarked - information taken from systematic reviews; underlined - information taken from primary studies; BCT - behavior change technique; CG - control group; DBP - diastolic blood pressure; EG - experimental group; EQ-SD - EuroQoL-5 dimension; HDL - high density lipoprotein; HDRS - Hamilton Depression Rating Scale; heiQ - Health Education Impact Questionnaire; IPAQ - International Physical Activity Questionnaire; LDL - low density lipoprotein; MISTT - Michigan Stroke Transitions Trial; MMAS-8 - Morisky Medication Adherence Scale; mmHg - millimeter of mercury; PHQ-9 - Patient Health Questionnaire-9; SBP - systolic blood pressure; HADS - Hospital Anxiety Depression Scale; SMS - short message service.
*Between groups comparisons were not performed. After an intra-groups comparisons, median or logistic regression models were used for assessing potential within group differences.

Table 4. Methodological quality of primary studies included in the overview (phase-2) based on cochrane risk of bias.

Primary studies	Cochrane risk of bias						
	1 Random sequence generation	2 Allocation concealment	3 Blinding of participants and personnel	4 Blinding of outcome assessment	5 Incomplete outcome data	6 Selective reporting	7 Anything else, ideally prespecified
Adie et al. ⁵⁶	Low	Low	High	Unclear	Low	High	Low
Cadilhac et al. ⁵⁷	Low	Low	High	Low	Low	Low	Low
Gillham et al. ⁵⁸	Low	Unclear	High	High	Low	Low	Low
Hedegaard et al. ⁵⁹	Low	Low	High	Low	Low	Low	Low
Kamal et al. ⁶⁰	Low	Low	High	Low	Low	Low	Low
Kim H et al. ⁶¹	Low	Unclear	High	Unclear	Low	Low	Low
Kim J et al. ⁶²	Low	Unclear	High	High	Low	Low	Low
Kirkness et al. ⁶³	Low	Unclear	High	Low	Low	Low	Low
Mackenzie et al. ⁶⁴	Low	Unclear	High	Unclear	Low	Low	Low
Reeves et al. ⁶⁵	Low	High	High	High	Low	Low	High
Sarfo et al. ⁶⁶	Low	Low	High	Low	Low	Low	Low
Wan et al. ⁶⁷	Low	Low	High	Low	Low	Low	Low
Wan et al. ⁶⁸	Low	Low	High	Low	Low	Low	Low
Wang et al. ⁶⁹	Low	Low	High	Low	Low	Low	Low

cessation (n=3),^{56,58,62} safe alcohol consumption (n=5),^{58,61,62,67,68} and emotional self-regulation of psychosocial stress (anxiety and depression) (n=4).^{57,58,63,65} Tertiary outcomes of interest reported included SBP and DBP control (n=7 for both),^{56,60,61,64,66,68,69} total cholesterol levels (n=3),^{56,61,62} triglyceride levels (n=2),^{61,62} LDL levels (n=1)⁶¹ and HDL levels (n=1).⁶¹

Overview of behavior change and self-management theoretically-informed telehealth interventions for stroke secondary prevention

Table 5 depicts GRADE of evidence supporting theoretically-informed telehealth interventions for each meta-analysis conducted by outcome.

Primary outcomes related to cardiovascular events. Data presented permitted pooled analysis from the two studies that reported recurrent stroke outcomes measured as the number of events.^{65,69} Meta-analysis demonstrated a non-significant reduction in recurrent stroke risk (RR: 0.63, 95%CI: 0.33 to 1.19, P: 0%, random-effect) in favor of telehealth interventions (available in Supplementary Files), with very low GRADE certainty of evidence.

Secondary outcomes related to risk-reducing health behaviors

Medication adherence. Data presented permitted pooled analysis from seven studies that reported medication adherence outcomes.^{59,60,64,66–69} The following measures were used in the studies pooled to inform this outcome: Health Promoting Lifestyle Profile II (HPLP II) (medication adherence subcategory),^{67–69} medication possession ratio

score,^{59,66} Morisky Medication Adherence Scale (MMAS),^{60,66} and percentage compliance for one to three medications.⁶⁴ Meta-analysis demonstrated a significant improvement in medication adherence (SMD: 0.38; 95% CI: 0.13 to 0.64; P: 72% random-effect) in favor of telehealth interventions (Figure 3), with low GRADE certainty of evidence. Interventions contributing to this evidence-base used telephone/cellphone for call-based delivery,^{59,67} computer and internet to support sending SMS combined with a cellphone to receive SMS/call,^{60,68,69} cellphone/telephone for call-based delivery alongside a home blood pressure monitor,⁶⁴ cellphone and internet for app use alongside a home blood pressure monitor.⁶⁶ The interventions were informed by motivational interviewing,⁵⁹ health belief model and social cognitive theory,⁶⁰ motivational interviewing, self-efficacy and self-managed care theories,⁶⁴ self-determination theory,⁶⁶ and goal-setting.^{67–69}

Healthy eating. Data presented permitted pooled analysis from all four studies that reported healthy eating outcomes.^{58,62,67,68} Data were pooled from studies employing the following measures: number of servings of fruits and vegetables consumed per week,⁵⁸ amount of fruits and vegetables consumed per week,⁶² and HPLP II (nutrition and low-salt diet subcategories).^{67,68} Meta-analysis demonstrated a significant improvement in healthy eating (SMD: 0.38; 95%CI: 0.15 to 0.60; P: 38%, random-effect) in favor of telehealth interventions (Figure 4), with low GRADE certainty of evidence. Interventions contributing to this evidence-base used telephone/cellphone for call-based delivery,^{58,67} computer and internet for web-site access,⁶² computer and internet to support sending SMS combined with a cellphone to receive SMS/call⁶⁸ and

Table 5. GRADE of evidence supporting telehealth interventions (meta-analyses of primary studies) (phase-2)

Outcome	RCT Studies	Behavior change theories and/or techniques implemented	Technologies used	Participants	Effect estimate [95%CI]	I ²	Quality of evidence (GRADE)	Reasons for down-grade
Primary outcomes Recurrent stroke	Reeves et al. ⁶⁵	Self-management support, community resources, and decision support	Computer and internet to access web-site and cellphone or telephone to receive call	416	RR: 0.63 [0.33 to 1.19]	0%	⊕○○○ Very Low	ROB and imprecision
	Wang et al. ⁶⁸	Goal-setting						
Secondary outcomes Medication adherence	Hedegaard et al. ⁵⁹	Motivational interviewing	Telephone or cellphone to receive call	968	SMD: 0.38 [0.13 to 0.64]	72%	⊕⊕○○ Low	Inconsistency
	Kamal et al. ⁶⁰	Health belief model and social cognitive theory	Computer and internet to support sending SMS and cellphone to receive SMS/call					
	Mackenzie et al. ⁶⁴	Motivational interviewing, self-efficacy and self-managed care theories	Cellphone or telephone to receive call and blood pressure monitor					
	Sarfo et al. ⁶⁶	Self-determination theory	Cellphone and internet to use app and blood pressure monitor					
	Wan et al. ⁶⁷	Goal-setting	Telephone or cellphone to receive call					
	Wan et al. ⁶⁸		Computer and internet to support sending SMS and cellphone to receive SMS/call					
	Wang et al. ⁶⁹							
	Gillham et al. ⁵⁸	Motivational interviewing	Telephone or cellphone to receive call	562	SMD: 0.38 [0.15 to 0.60]	38%	⊕⊕○○ Low	ROB and inconsistency
	Kim J et al. ⁶²	Social cognitive theory	Computer and internet to access web-site					
	Wan et al. ⁶⁷ Wan et al. ⁶⁸	Goal-setting	Computer and internet to support sending SMS and cellphone to receive SMS/call					
Physical activity participation	Gillham et al. ⁵⁸	Motivational interviewing	Telephone or cellphone to receive call	349	SMD: 0.10 [-0.68 to 0.88]	92%	⊕○○○ Very Low	ROB, inconsistency and imprecision
	Kim H et al. ⁶¹	Coaching						
	Wan et al. ⁶⁷ Wan et al. ⁶⁸	Goal-setting	Computer and internet to support sending SMS and cellphone to receive SMS/call					
	Adie et al. ⁵⁶	Social cognitive theory and motivational interviewing	Telephone or cellphone to receive call	92	RR: -0.00 [-0.12 to 0.11]	0%	⊕○○○ Very Low	ROB, inconsistency and imprecision
Smoking cessation	Kim J et al. ⁶²	Social cognitive theory	Computer and internet to access web-site					

(continued)

Table 5. Continued

Outcome	RCT Studies	Behavior change theories and/or techniques implemented	Technologies used	Participants	Effect estimate [95%CI]	I ²	Quality of evidence (GRADE)	Reasons for down-grade
Safe alcohol consumption	Wan et al. ⁶⁷ Wan et al. ⁶⁸	Goal-setting	Computer and internet to support sending SMS and cellphone to receive SMS/call	138	SMD: -0.94 [-2.60 to 0.72]	97%	⊕○○○ Very Low	Inconsistency and imprecision
Psychosocial stress management	Cadilhac et al. ⁵⁷	Social cognitive theory, information-motivation-behavioral theory and operant condition	Computer and internet to support sending SMS combined with a cellphone to receive SMS/call	423	SMD: 0.05 [-0.16 to 0.26]	10%	⊕○○○ Very Low	ROB and imprecision
Tertiary outcomes SBP (mmHg)	Gillham et al. ⁵⁸	Motivational interviewing	Telephone or cellphone to receive call					
	Reeves et al. ⁶⁵	Self-management support, community resources, and decision support	Computer and internet to access web-site and cellphone or telephone to receive call					
	Kim H et al. ⁶¹	Coaching	Telephone or cellphone to receive call	426	MD: -9.19 [-12.89 to -5.49]	0%	⊕⊕⊕○ Moderate	ROB and indirectness
	Mackenzie et al. ⁶⁴	Motivational interviewing, self-efficacy and self-managed care theories	Cellphone or telephone to receive call and blood pressure monitor					
DBP (mmHg)	Wan et al. ⁶⁷ Wang et al. ⁶⁸	Goal-setting	Computer and internet to support sending SMS and cellphone to receive SMS/call					
	Adie et al. ⁵⁶	Social cognitive theory and motivational interviewing	Telephone or cellphone to receive call	331	MD: -6.34 [-15.73 to 3.06]	91%	⊕○○○ Very Low	ROB, inconsistency and indirectness
	Kim H et al. ⁶¹	Coaching	Cellphone or telephone to receive call and blood pressure monitor					
	Mackenzie et al. ⁶⁴	Motivational interviewing, self-efficacy and self-managed care theories	Computer and internet to support sending SMS and cellphone to receive SMS/call					
Total cholesterol (mg/dl)	Wan et al. ⁶⁷	Goal-setting	Computer and internet to support sending SMS and cellphone to receive SMS/call					
	Adie et al. ⁵⁶	Social cognitive theory and motivational interviewing	Telephone or cellphone to receive call	153	MD: 7.42 [-3.83 to 18.66]	0%	⊕○○○ Very Low	ROB and imprecision
	Kim H et al. ⁶¹ Kim J et al. ⁶²	Coaching Social cognitive theory	Computer and internet to access web-site					

(continued)

Table 5. Continued

Outcome	RCT Studies	Behavior change theories and/or techniques implemented	Technologies used	Participants	Effect estimate [95%CI]	I ²	Quality of evidence (GRADE)	Reasons for down-grade
Triglycerides (mg/dl)	Kim H et al. ⁶¹	Coaching	Telephone or cellphone to receive call	97	MD: -6.02	0%	⊕○○○	ROB and imprecision
	Kim J et al. ⁶²	Social cognitive theory	Computer and internet to access web-site		[-31.86 to 19.82]		Very Low	

Legend: 95%CI - 95% confidence interval; DBP - diastolic blood pressure; GRADE - Grading of Recommendations Assessment, Development and Evaluation; MD - mean difference; ROB - Risk of bias; RCT - randomized controlled trial; RR - Risk Ratio; SBP - systolic blood pressure; SMD - standardized mean difference; SMS - short message service.

were informed by motivational interviewing,⁵⁸ social cognitive theory,⁶² and goal-setting.^{67,68}

Physical activity participation. Data presented permitted pooled analysis from four studies that reported outcomes measuring physical activity participation.^{58,61,67,68} Data were pooled from studies that used the following measures: number of 20-min sessions per week,⁵⁸ International Physical Activity Questionnaire (IPAQ),⁶¹ and HPLP II (physical activity subcategory).^{67,68} Meta-analysis demonstrated a nonsignificant increase in physical activity participation (SMD: 0.10; 95%CI: -0.68 to 0.88; P: 92%, random-effect) (available in Supplementary Files), with very low GRADE certainty of evidence.

Smoking cessation. Data presented permitted pooled analysis from two studies that reported smoking cessation measured as the number of individuals who stopped smoking.^{56,62} Meta-analysis demonstrated a nonsignificant increase in smoking cessation rates (RR: -0.00, 95%CI: -0.12 to 0.11, P: 0% random-effect) (available in Supplementary Files), with very low GRADE certainty of evidence.

Safe alcohol consumption. Data presented permitted pooled analysis from two studies that reported outcome measures addressing safe alcohol consumption (HPLP II; unhealthy use of alcohol subcategory).^{67,68} Meta-analysis demonstrated a nonsignificant reduction in alcohol consumption (SMD: -0.94; 95%CI: -2.60 to 0.72; P: 97%, random-effect) (available in Supplementary Files), with very low GRADE certainty of evidence.

Emotional self-regulation of psychosocial stress. Data presented permitted pooled analysis from two studies that reported outcomes addressing emotional self-regulation (anxiety and depression).^{57,58,65} The following measures were reported in studies addressing this outcome: Hospital Anxiety and Depression Scale (HADS)^{57,58} and Patient Health Questionnaire-9 (PHQ-9).⁶⁵ Meta-analysis demonstrated a nonsignificant improvement in emotional self-regulation of psychosocial stress (anxiety and depression) (SMD: 0.05; 95%CI: -0.16 to 0.26; P: 10%, random-effect) in favor of the telehealth intervention (available in Supplementary Files), with very low GRADE certainty of evidence.

Tertiary outcomes related to physiological risk factors

Systolic blood pressure. Data presented permitted pooled analysis from four studies that reported SBP (mmHg) as an outcome measure.^{61,64,68,69} Meta-analysis demonstrated a significant reduction in SBP (MD: -9.19; 95%CI: -5.49 to -12.89; P: 0%, random-effect) in favor of telehealth interventions (Figure 5), with moderate GRADE certainty of evidence. Interventions contributing to this evidence-base used telephone/cellphone for call-based delivery,⁶¹

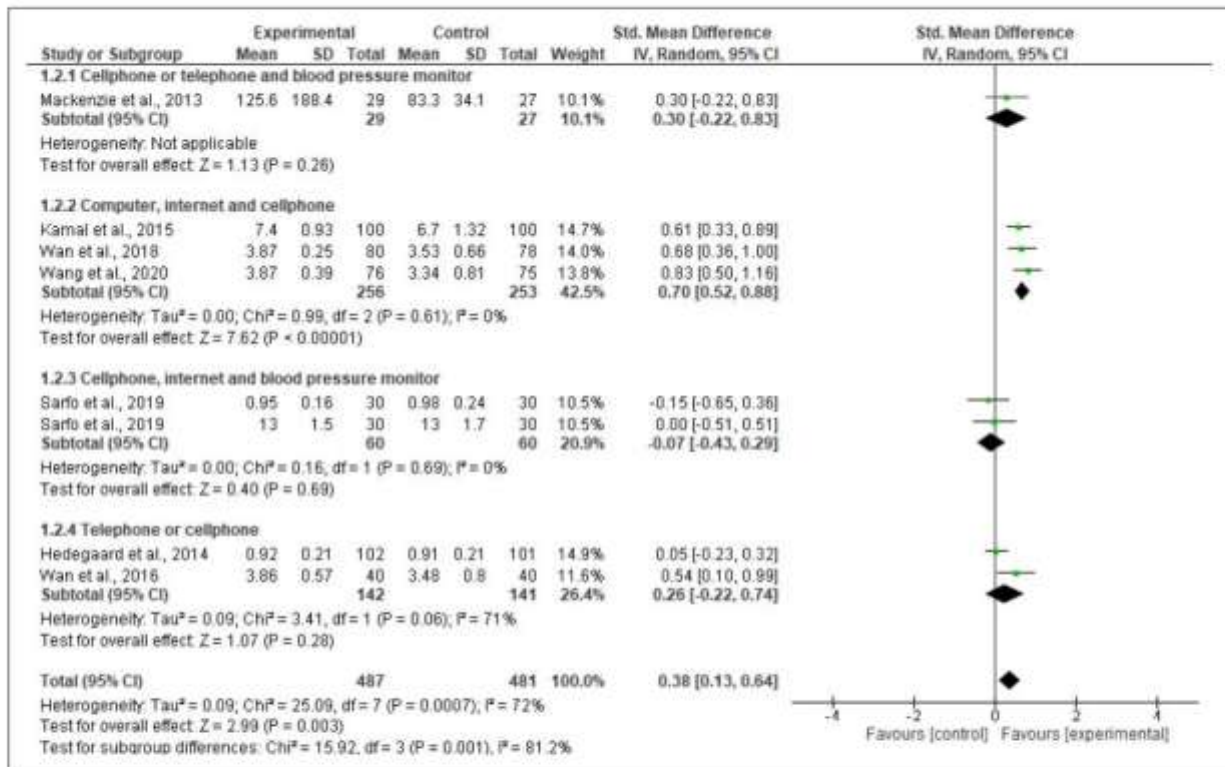


Figure 3. Medication adherence outcome for the comparison of telehealth interventions versus usual care.

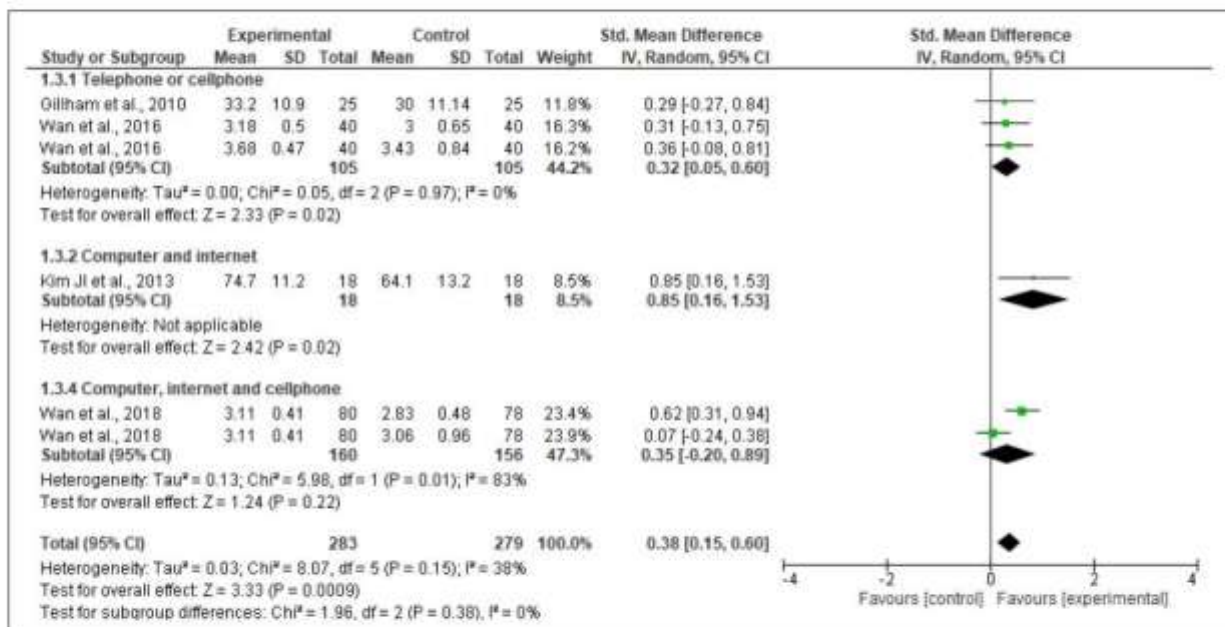


Figure 4. Healthy eating outcome for the comparison of telehealth interventions versus usual care.

cellphone or telephone for call-based delivery alongside a home blood pressure monitor,⁶⁴ computer and internet to support sending SMS combined with a cellphone to

receive SMS/call.^{68,69} The interventions were informed by coaching,⁶¹ motivational interviewing, self-efficacy and self-managed care theories,⁶⁴ and goal-setting.^{68,69}

Diastolic blood pressure. Data presented permitted pooled analysis from four studies that reported DBP (mmHg) as an outcome of interest.^{56,61,64,68} Meta-analysis demonstrated a nonsignificant reduction in DBP (MD: -6.34; 95%CI: 3.06 to -15.73; P : 91%, random-effect) in favor of the telehealth interventions (available in Supplementary Files), with very low GRADE certainty of evidence.

Lipid profiles: total cholesterol and triglyceride control. Data presented permitted pooled analysis from all three studies that reported an outcome of total cholesterol (mg/dl)^{56,61,62} and from two studies that reported an outcome of triglyceride (mg/dl).^{61,62} Meta-analyses demonstrated a nonsignificant increase in total cholesterol levels (MD: 7.42; 95%CI: -3.83 to 18.66; P : 0%, random-effect) (available in Supplementary Files) and a nonsignificant reduction in triglyceride levels (MD: -6.02; 95%CI: -31.86 to 19.82; P : 0%, random-effect) in favor of telehealth interventions (available in Supplementary Files), with very low GRADE certainty of evidence for both outcomes.

Discussion

To the best of our knowledge, this overview is the first to critically appraise and consolidate evidence from SRs on the effectiveness of telehealth interventions designed to affect behavior change and self-management, delivered to individuals for stroke secondary prevention and the first to provide high-level pooled data for theoretically-informed telehealth interventions. The best-evidence synthesis conducted from fifteen published SRs supports telehealth

interventions to affect significant reduction in rates of recurrent angina and recurrent stroke and/or TIA (both with very low GRADE certainty), improvement in medication adherence (low GRADE certainty), physical activity participation (very low GRADE certainty), and achievement of recommended blood pressure targets (low GRADE certainty), reduction in SBP (moderate GRADE certainty) and LDL levels (very low GRADE certainty). Phase-2, which conducted new meta-analyses of data from 14 primary studies which had a theoretical underpinning, in line with best-practice, also demonstrated significant improvements in medication adherence (low GRADE certainty) and SBP reduction (moderate GRADE certainty) and identified new evidence, albeit with low GRADE certainty, for the lifestyle-related outcome of health eating, in favor of telehealth interventions. With the exception of SBP, greater certainty of evidence is required to confirm the utility of telehealth interventions in stroke secondary prevention. These results direct what can now be done and what should be carefully considered regarding theoretically-informed telehealth interventions for stroke secondary prevention. Notably they indicate the need for studies to measure and document cardiovascular events outcomes for secondary prevention and the need for further high quality, well conceptualized trials in this area.

The most interesting result of this overview concerns the lack of evidence for primary outcomes in stroke secondary prevention related to cardiovascular events. Only one published SR performed a meta-analysis addressing the outcome of recurrent cardiovascular events,⁴⁸ with very low GRADE certainty of evidence found. Only two studies were included in this meta-analysis.⁴⁸ Context and populations varied between the two studies included in

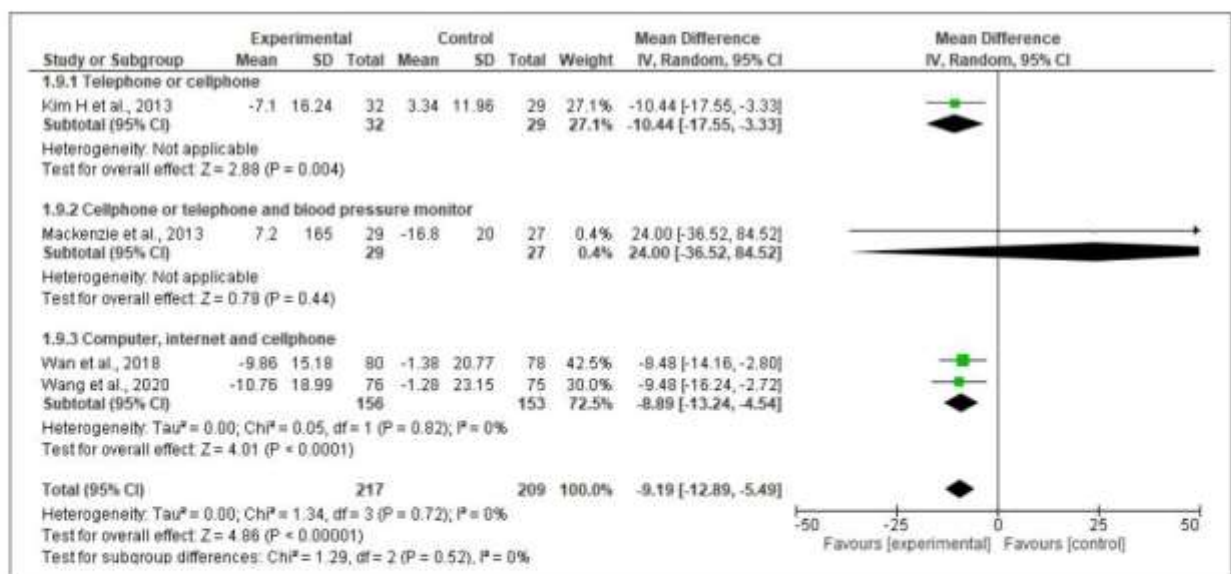


Figure 5. Systolic blood pressure outcome (mmHg) for the comparison of telehealth interventions versus usual care.

this meta-analysis. One was conducted in a hospital setting⁷¹ and one included a mixed population of individuals with cardiovascular disease.⁷² Thus, this meta-analysis does not strengthen the evidence on telehealth interventions for stroke secondary prevention alone. In phase-2, it was possible to perform a new meta-analysis with data from two studies^{65,69} that included only participants post-stroke and that had recurrent stroke as an outcome. Here, a nonsignificant reduction in recurrent stroke, in favor of the telehealth intervention (very low GRADE certainty), was identified, downgraded primarily because of imprecision related to small participant numbers and risk of bias issues. Both studies from which data were drawn had short intervention times (3 and 6 months, respectively),^{65,69} neither included longer-term follow up post intervention and only one study detailed time from stroke at trial entry.⁶⁵ Considering the variability of stroke recurrence rates by time post-stroke,³ it is important that future studies present a longer follow-up time and provide clearer information about the participants time from stroke at trial entry.

Medication is considered a cornerstone of stroke secondary prevention.¹⁰ However, it is well established that up to 40% of individuals post-stroke have poor medication adherence⁷³ and medication persistence.⁷⁴ Across both phases of the present overview, low GRADE certainty of evidence for telehealth interventions targeting improved medication adherence was identified. Methodological concerns in both cases required the evidence to be downgraded. Therefore, future studies that aim to improve medication adherence post-stroke using telehealth interventions should prioritize the methodological quality of the study and ensure adequate sample sizes. Providing detailed intervention descriptions that include the theoretical underpinning and/or techniques may facilitate meta-analyses grouping by behavior change techniques/theory in the future to increase the certainty of evidence supporting theoretically-informed telehealth interventions and direct evidence-based intervention delivery in practice.

Ten potentially modifiable risk factors are collectively associated with 90% of the population attributable risk (PAR) for stroke worldwide.⁷⁵ Hypertension constitutes the largest modifiable risk factor⁷⁵ and this overview of reviews identifies that telehealth interventions post-stroke have the strongest certainty of evidence (moderate GRADE) to reduce SBP by over 9 mmHg. This finding has clinical relevance in stroke secondary prevention as a 10 mmHg reduction in SBP is reported by meta-analysis to significantly reduce the risk of coronary heart disease, stroke and heart failure and is associated with a 13% reduction in all-cause mortality.⁷⁶ Physical inactivity is the second largest PAR for stroke.⁷⁵ Activity participation alongside other lifestyle related PAR for stroke including diet, smoking and unsafe alcohol consumption are also important targets for stroke prevention interventions.⁷⁵

Only one published SR included in this overview provided meta-analyses addressing physical activity participation outcomes, again, with very low GRADE certainty for this finding. When interrogated at primary study level (in phase-2 of this overview), new meta-analyses, albeit with limited study numbers, was permitted for each of these outcomes. Only the outcome of healthy eating provided evidence (low GRADE certainty) in favor of telehealth interventions. Again, high risk of bias in the majority of RCTs and varied effect sizes across studies necessitated a downgrading of the evidence. Once again, high quality, theoretically-informed telehealth interventions post-stroke that address lifestyle related risk factors are required to advance the secondary prevention evidence base in this area.

The gaps highlighted by this overview can help shape future research priorities, and direct future research in this field. There is a need for telehealth trials, with longer follow-up time, that are designed, adequately powered and conducted to address outcomes of stroke recurrence, as well as mortality (all cause and cardiovascular) and other cardiovascular events. Additionally, studies designed to investigate the effectiveness of theoretically-informed (theory based or employing specified behavior change techniques) telehealth interventions with individuals post-stroke are needed to address outcomes related to risk-reducing health behaviors, including the promotion of physical activity, which is the second largest PAR for stroke.⁷⁵ No published meta-analysis or primary study identified in this review addressed the outcome of blood glucose levels. Considering that diabetes mellitus is also one of the ten potentially modifiable risk factors of stroke worldwide⁷⁵ and that the estimated prevalence of diabetes in individuals post-stroke is 28%,⁷⁷ reducing blood glucose levels is a legitimate target for theoretically-informed telehealth interventions post-stroke.

Strengths and limitations

This overview of reviews, adhering to the PRIOR guidelines, critically appraised and consolidated evidence from published SRs of telehealth interventions delivered to address modification of recurrent risk through behavior change and self-management post-stroke. By applying GRADE criteria to published meta-analyses and to new syntheses conducted on primary study level data, the current certainty of evidence associated with telehealth interventions was elucidated to aid in interpretation and application of the findings, where relevant. Furthermore, care was taken at primary study level to include only interventions that were theoretically-informed by behavior change theory and/or techniques, in line with best practice recommendations,⁸ that acknowledge the complexity in implementing behavior change and self-management interventions. This narrowed the critical lens provided by

previous SRs, where only slight overlap in studies existed across reviews. Furthermore, it allows better replication of the interventions in clinical practice by professionals who wish to provide telehealth interventions for stroke secondary prevention.

As phase-2 of this overview utilized primary studies included in the published SRs, it is possible that more recent RCTs may have been excluded. As SRs of RCTs were the sole focus of this overview, the acceptability and uptake of telehealth interventions, alongside their perceived utility were not considered from the perspective of individuals with stroke. Although high levels of satisfaction and acceptance of telehealth interventions for health professional and individuals post-stroke have been reported in the literature,⁷⁸ future studies are required to specifically examine end-users' experiences of telehealth interventions for behavior change and self-management post-stroke and to explore the more effective mechanisms of delivery. Limited data were available for the majority of outcomes of interest in this overview, and no RCTs were identified for a number of outcomes of interest in stroke secondary prevention. Results presented for the majority of outcomes reported need to be interpreted with caution due to the low GRADE certainty of evidence assigned. In addition, limited data provided in study descriptions in many primary studies prevented examination of the findings in relation to the optimal time to deliver interventions of this nature post-stroke, the impact of age of the participants, or the professionals who implemented the telehealth interventions.

Conclusions

Insufficient evidence currently exists by published SRs to support the role of telehealth interventions post-stroke to reduce cardiovascular mortality. Evidence presented does support telehealth interventions to make a meaningful improvement in medication adherence and reduction in SBP, but does not allow replication of the intervention due to notable heterogeneity in the interventions currently pooled in published meta-analyses. Consolidation of evidence on the effectiveness of theoretically-informed telehealth interventions for behavior change and self-management delivered to individuals for stroke secondary prevention provided more granular detail, but only in the telehealth domain of mobile interventions. Here, evidence supports coaching, motivational interviewing, self-efficacy, goal-setting and self-managed care in affecting significant reductions in SBP in comparison to usual care, with moderate GRADE certainty of evidence. Evidence supporting theoretically-informed telehealth interventions to improve medication adherence and health eating currently has too low certainty of evidence to inform practice. High quality RCTs that implement theoretically-informed telehealth interventions addressing both cardiovascular and lifestyle related outcomes and with longer-term follow-up are required.

Data availability statement

The study, as a review of reviews, uses only published data. All included studies are referenced. Important data that validates the results of the present study are presented as supplementary materials, including the search strategy employed and the list of articles that were excluded as they did not meet the eligibility criteria.

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Supplemental material

Supplemental material for this article is available online.

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Supplementary Files

- 1. The preferred reporting guideline for overviews of reviews of healthcare interventions (PRIOR) statement checklist**
- 2. Search strategy**
- 3. Figure. Phase-2: Graphical Representation of Overlap for OVERviews (GROOVE) and Overall results**
- 4. Figure. Citation matrix of included primary studies from the systematic reviews**
- 5. Meta-analyses evident in the included systematic reviews**
- 6. Figure. Meta-analyses**
- 7. List of studies that might appear to meet the inclusion criteria, but were excluded, with the main reason for exclusion**

The preferred reporting guideline for overviews of reviews of healthcare interventions (PRIOR) statement checklist

Section Topic	#	Item	Location reported
TITLE			
Title	1	Identify the report as an overview of reviews.	Page 1
ABSTRACT			
Abstract	2	Provide a comprehensive and accurate summary of the purpose, methods, and results of the overview of reviews.	Page 2
INTRODUCTION			
Rationale	3	Describe the rationale for conducting the overview of reviews in the context of existing knowledge.	Page 3,4
Objectives	4	Provide an explicit statement of the objective(s) or question(s) addressed by the overview of reviews.	Page 4
METHODS			
Eligibility criteria	5a	Specify the inclusion and exclusion criteria for the overview of reviews. If supplemental primary studies were included, this should be stated, with a rationale.	Pages 5,6
	5b	Specify the definition of 'systematic review' as used in the inclusion criteria for the overview of reviews.	Page 6
Information sources	6	Specify all databases, registers, websites, organizations, reference lists, and other sources searched or consulted to identify systematic reviews and supplemental primary studies (if included). Specify the date when each source was last searched or consulted.	Page 5
Search strategy	7	Present the full search strategies for all databases, registers and websites, such that they could be reproduced. Describe any search filters and limits applied.	Supplementary File
Selection process	8a	Describe the methods used to decide whether a systematic review or supplemental primary study (if included) met the inclusion criteria of the overview of reviews.	Pages 6-8
	8b	Describe how overlap in the populations, interventions, comparators, and/or outcomes of systematic reviews was identified and managed during study selection.	Pages 6-8
Data collection process	9a	Describe the methods used to collect data from reports.	Pages 6-8
	9b	If applicable, describe the methods used to identify and manage primary study overlap at the level of the comparison and outcome during data collection. For each outcome, specify the method used to illustrate and/or quantify the degree of primary study overlap across systematic reviews.	Pages 6-8
	9c	If applicable, specify the methods used to manage discrepant data across systematic reviews during data collection.	Page 8
Data items	10	List and define all variables and outcomes for which data were sought. Describe any assumptions made and/or measures taken to identify and clarify missing or unclear information.	Pages 6-8
Risk of bias assessment	11a	Describe the methods used to <u>assess</u> risk of bias or methodological quality of the included systematic reviews.	Page 6
	11b	Describe the methods used to <u>collect</u> data on (from the systematic reviews) and/or <u>assess</u> the risk of bias of the primary studies included in the systematic reviews. Provide a justification for instances where flawed, incomplete, or missing assessments are identified but not re-assessed.	Page 8
	11c	Describe the methods used to <u>assess</u> the risk of bias of supplemental primary studies (if included).	Page 8
Synthesis methods	12a	Describe the methods used to summarize or synthesize results and provide a rationale for the choice(s).	Pages 7,8
	12b	Describe any methods used to explore possible causes of heterogeneity among results.	Pages 7,8

	12c	Describe any sensitivity analyses conducted to assess the robustness of the synthesized results.	NA
Reporting bias assessment	13	Describe the methods used to <i>collect</i> data on (from the systematic reviews) and/or <i>assess</i> the risk of bias due to missing results in a summary or synthesis (arising from reporting biases at the levels of the systematic reviews, primary studies, and supplemental primary studies, if included).	Pages 7,8
Certainty assessment	14	Describe the methods used to <i>collect</i> data on (from the systematic reviews) and/or <i>assess</i> certainty (or confidence) in the body of evidence for an outcome.	Pages 7,8
RESULTS			
Systematic review and supplemental primary study selection	15a	Describe the results of the search and selection process, including the number of records screened, assessed for eligibility, and included in the overview of reviews, ideally with a flow diagram.	Pages 8,9
	15b	Provide a list of studies that might appear to meet the inclusion criteria, but were excluded, with the main reason for exclusion.	Supplementary File
Characteristics of systematic reviews and supplemental primary studies	16	Cite each included systematic review and supplemental primary study (if included) and present its characteristics.	Pages 9-13
Primary study overlap	17	Describe the extent of primary study overlap across the included systematic reviews.	Page 9
Risk of bias in systematic reviews, primary studies, and supplemental primary studies	18a	Present assessments of risk of bias or methodological quality for each included systematic review.	Pages 9,10
	18b	Present assessments (<i>collected</i> from systematic reviews or <i>assessed</i> anew) of the risk of bias of the primary studies included in the systematic reviews.	Page 12
	18c	Present assessments of the risk of bias of supplemental primary studies (if included).	Page 12
Summary or synthesis of results	19a	For all outcomes, summarize the evidence from the systematic reviews and supplemental primary studies (if included). If meta-analyses were done, present for each the summary estimate and its precision and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	Pages 9-13
	19b	If meta-analyses were done, present results of all investigations of possible causes of heterogeneity.	Pages 13-16
	19c	If meta-analyses were done, present results of all sensitivity analyses conducted to assess the robustness of synthesized results.	NA
Reporting biases	20	Present assessments (<i>collected</i> from systematic reviews and/or <i>assessed</i> anew) of the risk of bias due to missing primary studies, analyses, or results in a summary or synthesis (arising from reporting biases at the levels of the systematic reviews, primary studies, and supplemental primary studies, if included) for each summary or synthesis assessed.	Pages 13-16
Certainty of evidence	21	Present assessments (<i>collected</i> or <i>assessed</i> anew) of certainty (or confidence) in the body of evidence for each outcome.	Pages 13-16
DISCUSSION			
Discussion	22a	Summarize the main findings, including any discrepancies in findings across the included systematic reviews and supplemental primary studies (if included).	Page 16,17
	22b	Provide a general interpretation of the results in the context of other evidence.	Pages 16,17
	22c	Discuss any limitations of the evidence from systematic reviews, their primary studies, and supplemental primary studies (if included) included in the overview of reviews. Discuss any limitations of the overview of reviews methods used.	Page 20
	22d	Discuss implications for practice, policy, and future research (both systematic reviews and primary research). Consider the relevance of the findings to the end users of the overview of reviews, e.g., healthcare providers, policymakers, patients, among others.	Pages 16-21
OTHER INFORMATION			
Registration and protocol	23a	Provide registration information for the overview of reviews, including register name and registration number, or state that the overview of reviews was not registered.	Page 4

Search strategy

MEDLINE (OVID)

Stroke

1. cerebrovascular disorders/ or exp basal ganglia cerebrovascular disease/ or exp brain ischemia/ or exp carotid artery diseases/ or exp intracranial arterial diseases/ or exp intracranial arteriovenous malformations/ or exp "intracranial embolism and thrombosis"/ or exp intracranial hemorrhages/ or stroke/ or exp brain infarction/ or vasospasm, intracranial/ or vertebral artery dissection/
2. (stroke or poststroke or post-stroke or cerebrovasc\$ or brain vasc\$ or cerebral vasc\$ or cva\$ or apoplex\$ or SAH or TIA or transient isch?emic attack or vertebral artery dissection).tw.
3. ((brain\$ or cerebr\$ or cerebell\$ or intracran\$ or intracerebral) adj5 (isch?emi\$ or infarct\$ or thrombo\$ or emboli\$ or occlus\$ or disorder\$)).tw.
4. ((brain\$ or cerebr\$ or cerebell\$ or intracerebral or intracranial or subarachnoid) adj5 (haemorrhage\$ or hemorrhage\$ or haematoma\$ or hematoma\$ or bleed\$)).tw.
5. 1 or 2 or 3 or 4

Risk reduction

6. exp Health Education/ or exp Health Promotion/ or exp Health Behavior/ or exp Secondary Prevention/ or exp Counseling/
7. (health education or health promotion or health behavior or secondary prevention or counseling or counsel\$).mp.
8. (health adj5 (educat\$ or program\$ or promotion\$ or behavio?r)).tw.
9. (patient adj5 (educat\$ or program\$)).tw.
10. 6 or 7 or 8 or 9
11. ((secondary or multifactor\$) adj3 (prevention or intervention)).tw.
12. (risk adj3 factor\$ adj5 (reduc\$ or manag\$ or intervent\$)).tw.
13. (lifestyle adj3 (intervent\$ or advice)).tw.
14. (life?style adj3 (intervention\$ or advice or alter\$ or educat\$ or chang\$)).tw.
15. (behavio?r\$ adj3 chang\$).tw.
16. (health?care adj3 advice).tw.
17. non?pharmacologic\$.tw.
18. 11 or 12 or 13 or 14 or 15 or 16 or 17
19. ethanol.mp. or exp Ethanol/

20. (alcohol\$ or ethanol\$ or wine or beer or spirit\$ or ((problem or hazardous or harmful) adj3 drink\$)).tw.

21. 19 or 20

22. exp Tobacco/ or "Tobacco Use Cessation"/ or exp smoking/ or exp smoking cessation/

23. tobacco.mp.

24. (tobacco or smok\$).tw.

25. 22 or 23 or 24

26. diet\$.tw.

27. (healthy adj3 eating).tw.

28. (diet adj3 chang\$).tw.

29. 26 or 27 or 28

30. exercise.mp. or exp Exercise/

31. (physical adj3 activ\$).tw.

32. 30 or 31

33. 10 or 18 or 21 or 25 or 29 or 32

34. 5 and 33

35. limit 34 to humans

Systematic reviews

36. meta-analysis/ or literature review/

37. systematic review.pt.

38. meta?analy\$.tw.

39. ((systematic or quantitative or methodolog\$) adj (overview\$ or review\$)).tw.

40. integrative research review\$.tw.

41. 36 or 37 or 38 or 39 or 40

42. 35 and 41

EMBASE (Platform)

#1 'cerebrovascular disease'/de OR 'basal ganglion hemorrhage'/exp OR 'brain ischemia'/exp OR 'carotid artery disease'/exp OR 'cerebral artery disease'/exp OR 'brain arteriovenous malformation'/exp OR 'brain embolism'/exp OR 'occlusive cerebrovascular disease'/exp OR 'brain hemorrhage'/exp OR 'cerebrovascular accident'/exp OR 'brain infarction'/exp OR 'brain vasospasm'/exp OR 'artery dissection'/exp

#2 stroke:ti,ab,kw OR poststroke:ti,ab,kw OR 'post stroke':ti,ab,kw OR cerebrovsc*:ti,ab,kw OR 'brain vasc*':ti,ab,kw OR 'cerebral vasc*':ti,ab,kw OR

cva*:ti,ab,kw OR apoplex*:ti,ab,kw OR sah:ti,ab,kw OR tia:ti,ab,kw OR 'transient ischaemic attack':ti,ab,kw OR 'transient ischemic attack':ti,ab,kw OR 'vertebral artery dissection':ti,ab,kw

#3 ((brain* OR cerebr* OR cerebell* OR intracran* OR intracerebral) NEAR/5 (ischemi* OR ischaemi* OR infarct* OR thrombo* OR emboli* OR occlus* OR disorder*)):ti,ab,kw

#4 ((brain* OR cerebr* OR cerebell* OR intracerebral OR intracranial OR subarachnoid) NEAR/5 (haemorrhage* OR hemorrhage* OR haematoma* OR hematoma* OR bleed*)):ti,ab,kw

#5 #1 OR #2 OR #3 OR #4

#6 'health education'/exp OR 'health promotion'/exp OR 'health behavior'/exp OR 'secondary prevention'/exp OR 'counseling'/exp

#7 'health education':kw OR 'health promotion':kw OR 'health behavior':kw OR 'health behaviour':kw OR 'secondary prevention':kw OR counseling:kw OR counsel*:kw

#8 ((health NEAR/5 (educat* OR program* OR promotion* OR behavior OR behaviour))):ti,ab,kw

#9 ((patient NEAR/5 (educat* OR program*)):ti,ab,kw

#10 #6 OR #7 OR #8 OR #9

#11 ((secondary OR multifactor*) NEAR/3 (prevention OR intervention)):ti,ab,kw

#12 (risk NEAR/3 factor* NEAR/5 (reduc* OR manag* OR intervent*)):ti,ab,kw

#13 (lifestyle NEAR/3 (intervent* OR advice)):ti,ab,kw

#14 ('life style' NEAR/3 (intervention* OR advice OR alter* OR educat* OR chang*)):ti,ab,kw

#15 (behavior* OR behaviour*) NEAR/3 chang*):ti,ab,kw

#16 (('health care' OR healthcare) NEAR/3 advice):ti,ab,kw

#17 'non pharmacologic':ti,ab,kw OR nonpharmacologic*:ti,ab,kw

#18 #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17

#19 'alcohol'/exp OR 'alcohol'

#20 alcohol*:ti,ab,kw OR ethanol*:ti,ab,kw OR wine:ti,ab,kw OR beer:ti,ab,kw OR spirit*:ti,ab,kw OR (((problem OR hazardous OR harmful) NEAR/3 drink*)):ti,ab,kw

#21 #19 OR #20

#22 'tobacco'/exp OR 'smoking cessation'/exp OR 'smoking'/exp OR 'tobacco use'/exp

#23 tobacco:kw

#24 tobacco:ti,ab,kw OR smok*:ti,ab,kw

- #25 #22 OR #23 OR #24
- #26 diet*:ti,ab,kw
- #27 (healthy NEAR/3 eating):ti,ab,kw
- #28 (diet NEAR/3 chang*):ti,ab,kw
- #29 #26 OR #27 OR #2
- #30 'exercise'/exp OR exercise:kw
- #31 (physical NEAR/3 activ*):ti,ab,kw
- #32 #30 OR #31
- #33 #10 OR #18 OR #21 OR #25 OR #29 OR #32
- #34 #5 AND #33
- #35 #5 AND #33 AND [humans]/lim
- #36 'meta analysis'/exp OR 'literature review'/exp
- #37 'systematic review (topic)'
- #38 'meta analysis'/exp OR 'meta analysis'
- #39 (systematic:ti,ab,kw OR quantitative:ti,ab,kw OR methodolog*:ti,ab,kw) AND (overview*:ti,ab,kw OR review*:ti,ab,kw)
- #40 'integrative research review*':ti,ab,kw
- #41 #36 OR #37 OR #38 OR #39 OR #40
- #42 #35 AND #41

Epistemonikos

Stroke

1. (title:(stroke OR poststroke OR post-stroke OR cerebrovasc* OR "brain vasc*" OR "CVA" OR apoplex* OR "SAH" OR "TIA" OR "transient ischemic attack" OR "transient ischaemic attack" OR "vertebral artery dissection") OR abstract:(stroke OR poststroke OR post-stroke OR cerebrovasc* OR "brain vasc*" OR "CVA" OR apoplex* OR "SAH" OR "TIA" OR "transient ischemic attack" OR "transient ischaemic attack" OR "vertebral artery dissection"))
2. (title:((brain* OR cerebr* OR cerebell* OR intracerebral OR intracranial OR subarachnoid) AND (haemorrhage* OR hemorrhage* OR haematoma* OR hematoma* OR bleed*)) OR abstract:((brain* OR cerebr* OR cerebell* OR intracerebral OR intracranial OR subarachnoid) AND (haemorrhage* OR hemorrhage* OR haematoma* OR hematoma* OR bleed*)))

3. (title:((brain* OR cerebr* OR cerebell* OR intracerebral OR intracranial OR subarachnoid) AND (ischemi* OR ischaemi* OR infarct* OR thrombo* OR emboli* OR occlus* OR disorder)) OR abstract:((brain* OR cerebr* OR cerebell* OR intracerebral OR intracranial OR subarachnoid) AND (ischemi* OR ischaemi* OR infarct* OR thrombo* OR emboli* OR occlus* OR disorder)))

4. 1 OR 2 OR 3 (title:((brain* OR cerebr* OR cerebell* OR intracerebral OR intracranial OR subarachnoid) AND (ischemi* OR ischaemi* OR infarct* OR thrombo* OR emboli* OR occlus* OR disorder)) OR abstract:((brain* OR cerebr* OR cerebell* OR intracerebral OR intracranial OR subarachnoid) AND (ischemi* OR ischaemi* OR infarct* OR thrombo* OR emboli* OR occlus* OR disorder))) OR (title:((brain* OR cerebr* OR cerebell* OR intracerebral OR intracranial OR subarachnoid) AND (ischemi* OR ischaemi* OR infarct* OR thrombo* OR emboli* OR occlus* OR disorder)) OR abstract:((brain* OR cerebr* OR cerebell* OR intracerebral OR intracranial OR subarachnoid) AND (ischemi* OR ischaemi* OR infarct* OR thrombo* OR emboli* OR occlus* OR disorder))) OR (title:(stroke) OR abstract:(stroke)) OR (title:(poststroke) OR abstract:(poststroke)) OR (title:(post-stroke) OR abstract:(post-stroke)) OR (title:(cerebrovasc*) OR abstract:(cerebrovasc*)) OR (title:("brain vasc*") OR abstract:("brain vasc*")) OR (title:(CVA*) OR abstract:(CVA*)) OR (title:(apoplex*) OR abstract:(apoplex*)) OR (title:(SAH) OR abstract:(SAH)) OR (title:(TIA) OR abstract:(TIA)) OR (title:("transient ischaemic attack" OR "transient ischemic attack") OR abstract:("transient ischaemic attack" OR "transient ischemic attack")) OR (title:("vertebral artery dissection") OR abstract:("vertebral artery dissection"))

(title:(stroke OR poststroke OR post-stroke OR cerebrovasc* OR "brain vasc*" OR "CVA" OR apoplex* OR "SAH" OR "TIA" OR "transient ischemic attack" OR "transient ischaemic attack" OR "vertebral artery dissection") OR abstract:(stroke OR poststroke OR post-stroke OR cerebrovasc* OR "brain vasc*" OR "CVA" OR apoplex* OR "SAH" OR "TIA" OR "transient ischemic attack" OR "transient ischaemic attack" OR "vertebral artery dissection")) OR (title:(((brain* OR cerebr* OR cerebell* OR intracerebral OR intracranial OR subarachnoid) AND (haemorrhage* OR hemorrhage* OR haematoma* OR hematoma* OR bleed*))) OR abstract:(((brain* OR cerebr* OR cerebell* OR intracerebral OR intracranial OR subarachnoid) AND (haemorrhage* OR hemorrhage* OR haematoma* OR hematoma* OR bleed*)))) OR (title:(((brain* OR cerebr* OR cerebell* OR intracerebral OR intracranial OR subarachnoid) AND (ischemi* OR

ischaemi* OR infarct* OR thrombo* OR emboli* OR occlus* OR disorder))) OR
 abstract:(((brain* OR cerebr* OR cerebell* OR intracerebral OR intracranial OR
 subarachnoid) AND (ischemi* OR ischaemi* OR infarct* OR thrombo* OR emboli* OR
 occlus* OR disorder))))

Risk

5. (title:(("health education" OR "health promotion" OR "health behavior" OR
 "health behaviour" OR "secondary prevention" OR counseling OR counsel*) OR
 abstract:("health education" OR "health promotion" OR "health behavior" OR "health
 behaviour" OR "secondary prevention" OR counseling OR counsel*))

6. (title:(health AND (educat* OR program* OR promotion* OR behavior OR
 behaviour)) OR abstract:(health AND (educat* OR program* OR promotion* OR
 behavior OR behaviour)))

7. (title:(patient AND (educat* OR program*)) OR abstract:(patient AND (educat*
 OR program*)))

8. 5 OR 6 OR 7 (title:(patient AND (educat* OR program*)) OR
 abstract:(patient AND (educat* OR program*))) OR (title:(health AND (educat* OR
 program* OR promotion* OR behavior OR behaviour)) OR abstract:(health AND
 (educat* OR program* OR promotion* OR behavior OR behaviour))) OR (title:(("health
 education" OR "health promotion" OR "health behavior" OR "health behaviour" OR
 "secondary prevention" OR counseling OR counsel*) OR abstract:("health education"
 OR "health promotion" OR "health behavior" OR "health behaviour" OR "secondary
 prevention" OR counseling OR counsel*))

9. (title:(((secondary OR multifactor*) AND (prevention OR intervention))) OR
 abstract:(((secondary OR multifactor*) AND (prevention OR intervention))))

10. (title:(risk factor* AND (reduc* OR manag* OR intervent*)) OR abstract:(risk
 factor* AND (reduc* OR manag* OR intervent*)))

11. (title:((lifestyle OR life-style) AND (intervent* OR advice OR alter* OR educat*
 OR chang*)) OR abstract:((lifestyle OR life-style) AND (intervent* OR advice OR alter*
 OR educat* OR chang*)))

12. (title:((behavior* OR behaviour*) AND chang*) OR abstract:((behavior* OR
 behaviour*) AND chang*))

13. (title:((health care OR healthcare) AND advice) OR abstract:((health care OR
 healthcare) AND advice))

14. (title:(non-pharmacologic* OR nonpharmacologic*) OR abstract:(non-pharmacologic* OR nonpharmacologic*))
15. 9 OR 10 OR 11 OR 12 OR 13 OR 14 (title:(non-pharmacologic* OR nonpharmacologic*) OR abstract:(non-pharmacologic* OR nonpharmacologic*)) OR (title:((health care OR healthcare) AND advice) OR abstract:((health care OR healthcare) AND advice)) OR (title:((behavior* OR behaviour*) AND chang*) OR abstract:((behavior* OR behaviour*) AND chang*)) OR (title:((lifestyle OR life-style) AND (intervent* OR advice OR alter* OR educat* OR chang*)) OR abstract:((lifestyle OR life-style) AND (intervent* OR advice OR alter* OR educat* OR chang*))) OR (title:(risk factor* AND (reduc* OR manag* OR intervent*)) OR abstract:(risk factor* AND (reduc* OR manag* OR intervent*))) OR (title:(((secondary OR multifactor*) AND (prevention OR intervention))) OR abstract:(((secondary OR multifactor*) AND (prevention OR intervention))))
16. (title:(ethanol OR alcohol) OR abstract:(ethanol OR alcohol))
17. (title:(((alcohol* OR ethanol* OR wine OR beer OR spirit* OR (problem OR hazardous OR harmful)) AND drink*)) OR abstract:(((alcohol* OR ethanol* OR wine OR beer OR spirit* OR (problem OR hazardous OR harmful)) AND drink*)))
18. (title:(tobacco OR smok* OR "tobacco use cessation" OR "smoking cessation") OR abstract:(tobacco OR smok* OR "tobacco use cessation" OR "smoking cessation"))
19. (title:(diet* OR "healthy eating" OR (healthy AND eating) OR (diet AND chang*)) OR abstract:(diet* OR "healthy eating" OR (healthy AND eating) OR (diet AND chang*)))
20. (title:(exercise OR "physical activ*" OR (physical AND activ*)) OR abstract:(exercise OR "physical activ*" OR (physical AND activ*)))
21. 15 OR 16 OR 17 OR 18 OR 19 OR 20 (title:(exercise OR "physical activ*" OR (physical AND activ*)) OR abstract:(exercise OR "physical activ*" OR (physical AND activ*))) OR (title:(diet* OR "healthy eating" OR (healthy AND eating) OR (diet AND chang*)) OR abstract:(diet* OR "healthy eating" OR (healthy AND eating) OR (diet AND chang*))) OR (title:(tobacco OR smok* OR "tobacco use cessation" OR "smoking cessation") OR abstract:(tobacco OR smok* OR "tobacco use cessation" OR "smoking cessation")) OR (title:(((alcohol* OR ethanol* OR wine OR beer OR spirit* OR (problem OR hazardous OR harmful)) AND drink*)) OR abstract:(((alcohol* OR ethanol* OR wine OR beer OR spirit* OR (problem OR hazardous OR harmful)) AND drink*))) OR (title:(ethanol OR alcohol) OR abstract:(ethanol OR alcohol))

33. Risk reduction AND Stroke

(title: (("health education" OR "health promotion" OR "health behavior" OR "health behaviour" OR "secondary prevention" OR counseling OR counsel*)) OR abstract:(("health education" OR "health promotion" OR "health behavior" OR "health behaviour" OR "secondary prevention" OR counseling OR counsel*)) OR (title: ((health AND (educat* OR program* OR promotion* OR behavior OR behaviour))) OR abstract:((health AND (educat* OR program* OR promotion* OR behavior OR behaviour)))) OR (title: ((patient AND (educat* OR program*))) OR abstract:((patient AND (educat* OR program*))) OR (title: (((secondary OR multifactor*) AND (prevention OR intervention))) OR abstract:(((secondary OR multifactor*) AND (prevention OR intervention)))) OR (title: ((risk factor* AND (reduc* OR manag* OR intervent*))) OR abstract:((risk factor* AND (reduc* OR manag* OR intervent*))) OR (title: (((lifestyle OR life-style) AND (intervent* OR advice OR alter* OR educat* OR chang*))) OR abstract:(((lifestyle OR life-style) AND (intervent* OR advice OR alter* OR educat* OR chang*))) OR (title: (((behavior* OR behaviour*) AND chang*)) OR abstract:(((behavior* OR behaviour*) AND chang*)) OR (title: ((health care OR healthcare) AND advice) OR abstract:((health care OR healthcare) AND advice)) OR (title: (non-pharmacologic* OR nonpharmacologic*)) OR abstract:(non-pharmacologic* OR nonpharmacologic*)) OR (title: (ethanol OR alcohol) OR abstract:(ethanol OR alcohol)) OR (title: ((alcohol* OR ethanol* OR wine OR beer OR spirit* OR (problem OR hazardous OR harmful)) AND drink*)) OR abstract:((alcohol* OR ethanol* OR wine OR beer OR spirit* OR (problem OR hazardous OR harmful)) AND drink*)) OR (title: (tobacco OR smok* OR "tobacco use cessation" OR "smoking cessation") OR abstract:(tobacco OR smok* OR "tobacco use cessation" OR "smoking cessation")) OR (title: (diet* OR "healthy eating" OR (healthy AND eating) OR (diet AND chang*)) OR abstract:(diet* OR "healthy eating" OR (healthy AND eating) OR (diet AND chang*))) OR (title: (exercise OR "physical activ*" OR (physical AND activ*)) OR abstract:(exercise OR "physical activ*" OR (physical AND activ*)))

AND

(title:(stroke OR poststroke OR post-stroke OR cerebrovasc* OR "brain vasc*" OR "CVA" OR apoplex* OR "SAH" OR "TIA" OR "transient ischemic attack" OR "transient ischaemic attack" OR "vertebral artery dissection") OR abstract:(stroke OR poststroke OR post-stroke OR cerebrovasc* OR "brain vasc*" OR "CVA" OR apoplex* OR "SAH"

OR "TIA" OR "transient ischemic attack" OR "transient ischaemic attack" OR "vertebral artery dissection")) OR (title:(((brain* OR cerebr* OR cerebell* OR intracerebral OR intracranial OR subarachnoid) AND (haemorrhage* OR hemorrhage* OR haematoma* OR hematoma* OR bleed*))) OR abstract:(((brain* OR cerebr* OR cerebell* OR intracerebral OR intracranial OR subarachnoid) AND (haemorrhage* OR hemorrhage* OR haematoma* OR hematoma* OR bleed*)))) OR (title:(((brain* OR cerebr* OR cerebell* OR intracerebral OR intracranial OR subarachnoid) AND (ischemi* OR ischaemi* OR infarct* OR thrombo* OR emboli* OR occlus* OR disorder))) OR abstract:(((brain* OR cerebr* OR cerebell* OR intracerebral OR intracranial OR subarachnoid) AND (ischemi* OR ischaemi* OR infarct* OR thrombo* OR emboli* OR occlus* OR disorder))))

Stroke

stroke OR poststroke OR post-stroke OR cerebrovasc* OR "brain vasc*" OR "CVA" OR apoplex* OR "SAH" OR "TIA" OR "transient ischemic attack" OR "transient ischaemic attack" OR "vertebral artery dissection" OR ((brain* OR cerebr* OR cerebell* OR intracerebral OR intracranial OR subarachnoid) AND (haemorrhage* OR hemorrhage* OR haematoma* OR hematoma* OR bleed*)) OR ((brain* OR cerebr* OR cerebell* OR intracerebral OR intracranial OR subarachnoid) AND (ischemi* OR ischaemi* OR infarct* OR thrombo* OR emboli* OR occlus* OR disorder))

Risk reduction

((("health education" OR "health promotion" OR "health behavior" OR "health behaviour" OR "secondary prevention" OR counseling OR counsel*)) OR ((health AND (educat* OR program* OR promotion* OR behavior OR behaviour))) OR ((patient AND (educat* OR program*))) OR (((secondary OR multifactor*) AND (prevention OR intervention))) OR ((risk factor* AND (reduc* OR manag* OR intervent*))) OR (((lifestyle OR life-style) AND (intervent* OR advice OR alter* OR educat* OR chang*)) OR (((behavior* OR behaviour*) AND chang*)) OR ((health care OR healthcare) AND advice) OR (non-pharmacologic* OR nonpharmacologic*) OR (ethanol OR alcohol) OR ((alcohol* OR ethanol* OR wine OR beer OR spirit* OR (problem OR hazardous OR harmful)) AND drink*) OR (tobacco OR smok* OR "tobacco use cessation" OR "smoking cessation") OR (diet* OR "healthy eating" OR (healthy AND eating) OR (diet AND chang*)) OR (exercise OR "physical activ*" OR (physical AND activ*))

Combined using AND, limited to Title/Abstract

(title:(((title:(stroke OR poststroke OR post-stroke OR cerebrovasc* OR "brain vasc*" OR "CVA" OR apoplex* OR "SAH" OR "TIA" OR "transient ischemic attack" OR "transient ischaemic attack" OR "vertebral artery dissection" OR ((brain* OR cerebr* OR cerebell* OR intracerebral OR intracranial OR subarachnoid) AND (haemorrhage* OR hemorrhage* OR haematoma* OR hematoma* OR bleed*)) OR ((brain* OR cerebr* OR cerebell* OR intracerebral OR intracranial OR subarachnoid) AND (ischemi* OR ischaemi* OR infarct* OR thrombo* OR emboli* OR occlus* OR disorder)))) OR abstract:(stroke OR poststroke OR post-stroke OR cerebrovasc* OR "brain vasc*" OR "CVA" OR apoplex* OR "SAH" OR "TIA" OR "transient ischemic attack" OR "transient ischaemic attack" OR "vertebral artery dissection" OR ((brain* OR cerebr* OR cerebell* OR intracerebral OR intracranial OR subarachnoid) AND (haemorrhage* OR hemorrhage* OR haematoma* OR hematoma* OR bleed*)) OR ((brain* OR cerebr* OR cerebell* OR intracerebral OR intracranial OR subarachnoid) AND (ischemi* OR ischaemi* OR infarct* OR thrombo* OR emboli* OR occlus* OR disorder)))) AND (title:(((("health education" OR "health promotion" OR "health behavior" OR "health behaviour" OR "secondary prevention" OR counseling OR counsel*)) OR ((health AND (educat* OR program* OR promotion* OR behavior OR behaviour))) OR ((patient AND (educat* OR program*))) OR (((secondary OR multifactor*) AND (prevention OR intervention))) OR ((risk factor* AND (reduc* OR manag* OR intervent*))) OR (((lifestyle OR life-style) AND (intervent* OR advice OR alter* OR educat* OR chang*)) OR (((behavior* OR behaviour*) AND chang*)) OR ((health care OR healthcare) AND advice) OR (non-pharmacologic* OR nonpharmacologic*) OR (ethanol OR alcohol) OR ((alcohol* OR ethanol* OR wine OR beer OR spirit* OR (problem OR hazardous OR harmful) AND drink*)) OR (tobacco OR smok* OR "tobacco use cessation" OR "smoking cessation") OR (diet* OR "healthy eating" OR (healthy AND eating) OR (diet AND chang*)) OR (exercise OR "physical activ*" OR (physical AND activ*)) OR abstract:(((("health education" OR "health promotion" OR "health behavior" OR "health behaviour" OR "secondary prevention" OR counseling OR counsel*)) OR ((health AND (educat* OR program* OR promotion* OR behavior OR behaviour))) OR ((patient AND (educat* OR program*))) OR (((secondary OR multifactor*) AND (prevention OR intervention))) OR ((risk factor* AND (reduc* OR manag* OR intervent*))) OR (((lifestyle OR life-style) AND (intervent* OR advice OR alter* OR educat* OR chang*)) OR (((behavior* OR behaviour*) AND chang*)) OR ((health care OR healthcare) AND advice) OR (non-pharmacologic* OR nonpharmacologic*) OR

(ethanol OR alcohol) OR ((alcohol* OR ethanol* OR wine OR beer OR spirit* OR (problem OR hazardous OR harmful)) AND drink*) OR (tobacco OR smok* OR "tobacco use cessation" OR "smoking cessation") OR (diet* OR "healthy eating" OR (healthy AND eating) OR (diet AND chang*)) OR (exercise OR "physical activ*" OR (physical AND activ*))) OR abstract:((title:(stroke OR poststroke OR post-stroke OR cerebrovasc* OR "brain vasc*" OR "CVA" OR apoplex* OR "SAH" OR "TIA" OR "transient ischemic attack" OR "transient ischaemic attack" OR "vertebral artery dissection" OR ((brain* OR cerebr* OR cerebell* OR intracerebral OR intracranial OR subarachnoid) AND (haemorrhage* OR hemorrhage* OR haematoma* OR hematoma* OR bleed*)) OR ((brain* OR cerebr* OR cerebell* OR intracerebral OR intracranial OR subarachnoid) AND (ischemi* OR ischaemi* OR infarct* OR thrombo* OR emboli* OR occlus* OR disorder))) OR abstract:(stroke OR poststroke OR post-stroke OR cerebrovasc* OR "brain vasc*" OR "CVA" OR apoplex* OR "SAH" OR "TIA" OR "transient ischemic attack" OR "transient ischaemic attack" OR "vertebral artery dissection" OR ((brain* OR cerebr* OR cerebell* OR intracerebral OR intracranial OR subarachnoid) AND (haemorrhage* OR hemorrhage* OR haematoma* OR hematoma* OR bleed*)) OR ((brain* OR cerebr* OR cerebell* OR intracerebral OR intracranial OR subarachnoid) AND (ischemi* OR ischaemi* OR infarct* OR thrombo* OR emboli* OR occlus* OR disorder)))) AND (title:(("health education" OR "health promotion" OR "health behavior" OR "health behaviour" OR "secondary prevention" OR counseling OR counsel*)) OR ((health AND (educat* OR program* OR promotion* OR behavior OR behaviour))) OR ((patient AND (educat* OR program*))) OR (((secondary OR multifactor*) AND (prevention OR intervention))) OR ((risk factor* AND (reduc* OR manag* OR intervent*))) OR (((lifestyle OR life-style) AND (intervent* OR advice OR alter* OR educat* OR chang*))) OR (((behavior* OR behaviour*) AND chang*)) OR ((health care OR healthcare) AND advice) OR (non-pharmacologic* OR nonpharmacologic*) OR (ethanol OR alcohol) OR ((alcohol* OR ethanol* OR wine OR beer OR spirit* OR (problem OR hazardous OR harmful)) AND drink*) OR (tobacco OR smok* OR "tobacco use cessation" OR "smoking cessation") OR (diet* OR "healthy eating" OR (healthy AND eating) OR (diet AND chang*)) OR (exercise OR "physical activ*" OR (physical AND activ*)) OR abstract:(("health education" OR "health promotion" OR "health behavior" OR "health behaviour" OR "secondary prevention" OR counseling OR counsel*)) OR ((health AND (educat* OR program* OR promotion* OR behavior OR behaviour))) OR ((patient AND (educat* OR program*))) OR (((secondary

OR multifactor*) AND (prevention OR intervention))) OR ((risk factor* AND (reduc* OR manag* OR intervent*))) OR (((lifestyle OR life-style) AND (intervent* OR advice OR alter* OR educat* OR chang*))) OR (((behavior* OR behaviour*) AND chang*)) OR ((health care OR healthcare) AND advice) OR (non-pharmacologic* OR nonpharmacologic*) OR (ethanol OR alcohol) OR ((alcohol* OR ethanol* OR wine OR beer OR spirit* OR (problem OR hazardous OR harmful)) AND drink*) OR (tobacco OR smok* OR "tobacco use cessation" OR "smoking cessation") OR (diet* OR "healthy eating" OR (healthy AND eating) OR (diet AND chang*)) OR (exercise OR "physical activ*" OR (physical AND activ*))))))

Limited to systematic reviews

Cochrane Library

1. (MeSH descriptor: [Cerebrovascular Disorders] this term only OR MeSH descriptor: [Basal Ganglia Cerebrovascular Disease] explode all trees OR MeSH descriptor: [Brain Ischemia] explode all trees OR MeSH descriptor: [Carotid Artery Diseases] explode all trees OR MeSH descriptor: [Intracranial Arterial Diseases] explode all trees OR MeSH descriptor: [Intracranial Arteriovenous Malformations] explode all trees OR MeSH descriptor: [Intracranial Embolism and Thrombosis] explode all trees OR MeSH descriptor: [Intracranial Hemorrhages] explode all trees OR MeSH descriptor: [Stroke] this term only OR MeSH descriptor: [Brain Infarction] explode all trees OR MeSH descriptor: [Vasospasm, Intracranial] this term only OR MeSH descriptor: [Vertebral Artery Dissection] this term only)
(#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 = #13)
2. ((stroke OR poststroke OR post-stroke OR cerebrovsc* OR brain vasc* OR cerebral vasc* OR CVA* OR apoplex* OR SAH OR TIA OR transient ischaemic attack OR transient ischemic attack OR vertebral artery dissection)):ti,ab,kw (#14)
3. ((brain* OR cerebr* OR cerebell* OR intracran* OR intracerebral) NEAR/5 (ischemi* OR ischaemi* OR infarct* OR thrombo* OR emboli* OR occlus*)):ti,ab,kw (#15)
4. ((brain* OR cerebr* OR cerebell* OR intracerebral OR intracranial OR subarachnoid) NEAR/5 (haemorrhage* OR hemorrhage* OR haematoma* OR hematoma* OR bleed*)):ti,ab,kw (#16)
5. #13 OR #14 OR #15 OR #16 = #17

6. (MeSH descriptor: [Health Education] explode all trees OR MeSH descriptor: [Health Promotion] explode all trees OR MeSH descriptor: [Health Behavior] explode all trees OR MeSH descriptor: [Secondary Prevention] explode all trees OR MeSH descriptor: [Counseling] explode all trees) (#18 OR #19 OR #20 OR #21 OR #22) = #23
7. ((health education OR health promotion OR health behavior OR health behaviour OR secondary prevention OR counseling OR counsel*)):kw (#24)
8. ((health NEAR/5 (educat* OR program* OR promotion* OR behavior OR behaviour))):ti,ab,kw (#25)
9. ((patient NEAR/5 (educat* OR program*))):ti,ab,kw (#26)
10. #23 OR #24 OR #25 OR #26 = #27
11. (((secondary or multifactor*) NEAR/3 (prevention or intervention))):ti,ab,kw (#28)
12. (((risk NEAR/3 factor* NEAR/5 (reduc* OR manag* OR intervent*)))):ti,ab,kw (#29)
13. ((lifestyle NEAR/3 (intervent* or advice))):ti,ab,kw (#30)
14. (((life style NEAR/3 (intervention* OR advice OR alter* OR educat* OR chang*))):ti,ab,kw (#31)
15. (((behavior* OR behaviour*) NEAR/3 chang*))):ti,ab,kw (#32)
16. (((health care OR healthcare) NEAR/3 advice))):ti,ab,kw (#33)
17. ((non-pharmacologic* OR nonpharmacologic*)):ti,ab,kw (#34)
18. #28 OR #29 OR #30 OR #31 OR #32 OR #33 OR #34 = #35
19. ((ethanol):kw) OR (MeSH descriptor: [Ethanol] explode all trees) (#36 OR #37)
20. (((alcohol* OR ethanol* OR wine OR beer OR spirit* or ((problem or hazardous or harmful) NEAR/3 drink*))):ti,ab,kw (#38)
21. #36 OR #37 OR #38 = #39
22. (MeSH descriptor: [Tobacco] explode all trees OR MeSH descriptor: [Tobacco Use Cessation] explode all trees OR MeSH descriptor: [Smoking] explode all trees OR MeSH descriptor: [Smoking Cessation] explode all trees) (#40 OR #41 OR #42 OR #43) = #44
23. (tobacco):kw
24. (((tobacco OR smok*))):ti,ab,kw
25. (#44 OR #45 OR #46) = #47

26. (diet*):ti,ab,kw #48
27. (((healthy NEAR/3 eating))):ti,ab,kw #49
28. (((diet NEAR/3 chang*))):ti,ab,kw #50
29. #48 OR #49 OR #50 = #51
30. ((exercise):kw) OR (MeSH descriptor: [Exercise] explode all trees) #52
- OR #53
31. (((physical NEAR/3 activ*))):ti,ab,kw
32. #52 OR #53 OR #54 = #55
33. #27 OR #35 OR #39 OR #47 OR #51 OR #55 = #56
34. #17 AND #56 = #57 limit to Cochrane Reviews

Primary studies	Systematic reviews														
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Adie et al., 2010															
Cadilhac et al., 2020															
Gillham et al., 2010															
Hedegaard et al., 2014															
Kamal et al., 2015															
Kim H et al., 2013															
Kim J et al., 2013															
Kirkness et al., 2017															
Mackenzie et al., 2013															
Reeves et al., 2019															
Sarlo et al., 2019															
Wan et al., 2016															
Wan et al., 2018															
Wang et al., 2020															

Figure. Citation matrix of included primary studies from the systematic reviews. Legend: 1 - Adler et al., 2017; 2 - Al-Arkee et al., 2021; 3 - Armitage et al., 2020; 4 - Freund et al., 2021; 5 - Gandapur et al., 2016; 6 - Gandhi et al., 2017; 7 - Hwang et al., 2021; 8 - Kassavou et al., 2018; 9 - Kraft et al., 2017; 10 - Laver et al. 2020; 11 - Lv et al., 2021; 12 - Park et al., 2016; 13 - Patterson et al., 2021; 14 - Rintala et al., 2019; 15 - Zeng et al., 2022

Table. Meta-analyses evident in the included systematic reviews

Systematic review	Outcomes		
	Primary	Secondary	Tertiary

	Mortality (all cause and cardiovascular)	Recurrent stroke and other cardiovascular events	Medication adherence	Physical activity participation	Smoking cessation	Emotional self- regulation of psychosocial stress	Blood pressure	Systolic blood pressure	Diastolic blood pressure	Lipid profile
Al-Arkee et al., 2021			6 studies, MD: 0.90 (95%CI: 0.03 to 1.78), p=0.04, P: 93.32%					Using mean values: 3 studies, MD: -0.74 (95%CI: -1.49 to 2.01)	Using mean values: 2 studies, MD: 0.46 (95%CI: -1.90 to 4.82)	TC: 2 studies, MD: -0.38 (95%CI: -1.14 to 0.38)
								Using mean change values: 3 studies, MD: -3.11 (-7.59 to 1.37)	Using mean change values: 2 studies, MD: -3.13 (95%CI: -6.40 to 0.13)	LDL: 2 studies, MD: -0.46 (95%CI: -0.79 to -0.12), p=0.01, P: 0%
Armitage et al., 2020			9 RCT, OR: 2.12 (95%CI: 1.64 to 2.75), P: 9.8%							
Gandhi et al., 2017	2 studies, OR: 0.19 (95%CI: 0.03 to 1.11), p=0.06	Angina: 3 studies, OR: 0.23 (95%CI: 0.08 to 0.64), p=0.005 Stroke/TIA recurrence: 2 studies, OR: 0.18 (95%CI: 0.08 to 0.41), p<0.0001	9 studies, OR: 4.51 (95%CI: 2.38 to 8.57), p<0.00001, P: 61%	Ability to meet exercise goals: 2 studies, OR: 2.55 (95%CI: 0.93 to 7.01), p=0.07	6 studies, OR: 1.42 (95%CI: 0.57 to 3.51), p=0.45		Ability to meet recommended blood pressure targets: 2 studies, OR: 2.80 (95%CI: 2.04 to 3.86), p<0.001			Ability to meet lipid targets: 2 studies, OR: 1.16 (95%CI: 0.88 to 1.52), p=0.29
Kassavou et al., 2018			17 studies, OR: 1.89 (95%CI: 1.51 to 2.36), p<0.0001, P: 89%							
Kraft et al., 2017								4 studies, MD: -6.14 (95%CI: -10.41 to -1.87), p=0.005, P: 53.12%		
Laver et al. 2020						Depression: 6 studies, SMD: 0.04 (95%CI: -0.19 to 0.11), p=0.58, P: 31%				

Lv et al., 2021								9 studies, MD: -5.49 (95%CI: -7.87 to -3.10), $p<0.001$, I^2 : 23.7%		
Patterson et al., 2021				MVPA minutes/week: 7 studies, MD: 40.35 (95%CI: 1.03 to 79.67), $p=0.04$, I^2 : 51% Steps/day: 3 studies, MD: 2,390 (95%CI: 1,006.9 to 3,791.2), $p=0.0007$, I^2 : 0%						
Zeng et al., 2022			Using scores values: 4 studies, SMD: 0.67 (95%CI: 0.49 to 0.85), $p<0.001$, I^2 : 0% Using ratios values: 6 studies, OR: 2.81 (95%CI: 1.35 to 5.85), $p=0.006$, I^2 : 77%							

Legend: Colors: red – no effect; green - statistically significant effect. 95%CI - 95% confidence interval; LDL - low-density lipoprotein; MD - mean difference; MVPA - moderate-to-vigorous intensity physical activity; OR – odds ratio; RCT - randomized controlled trial; SMD - standardized mean difference; TC - total cholesterol.

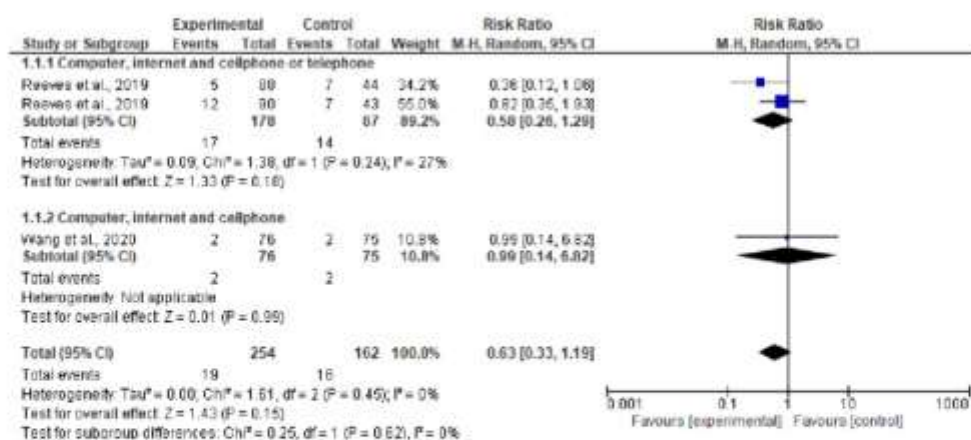


Figure. Recurrent stroke outcome for the comparison of telehealth interventions versus usual care.

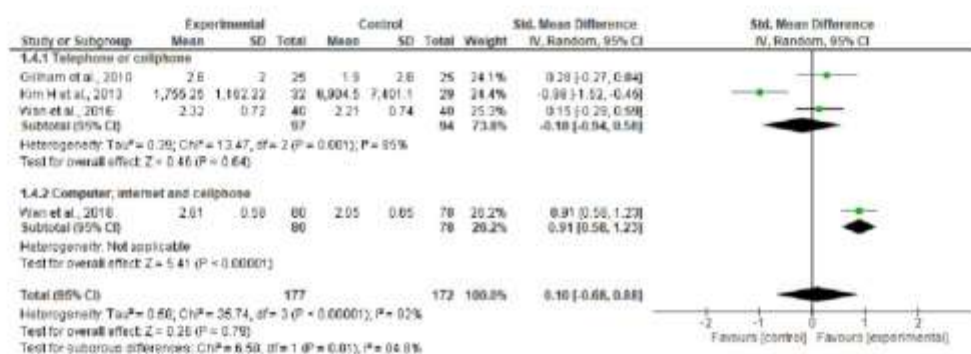


Figure. Physical activity participation outcome for the comparison of telehealth interventions versus usual care.

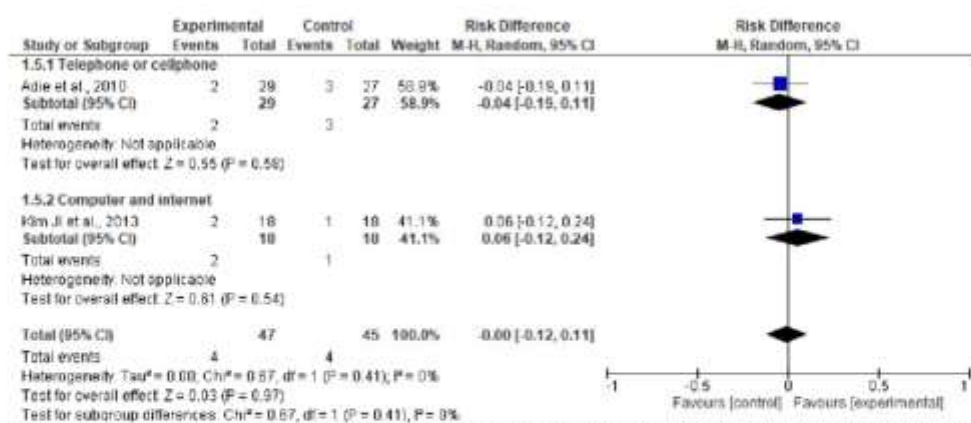


Figure. Smoking cessation outcome for the comparison of telehealth interventions versus usual care.



Figure. Safe alcohol consumption outcome for the comparison of telehealth interventions versus usual care.

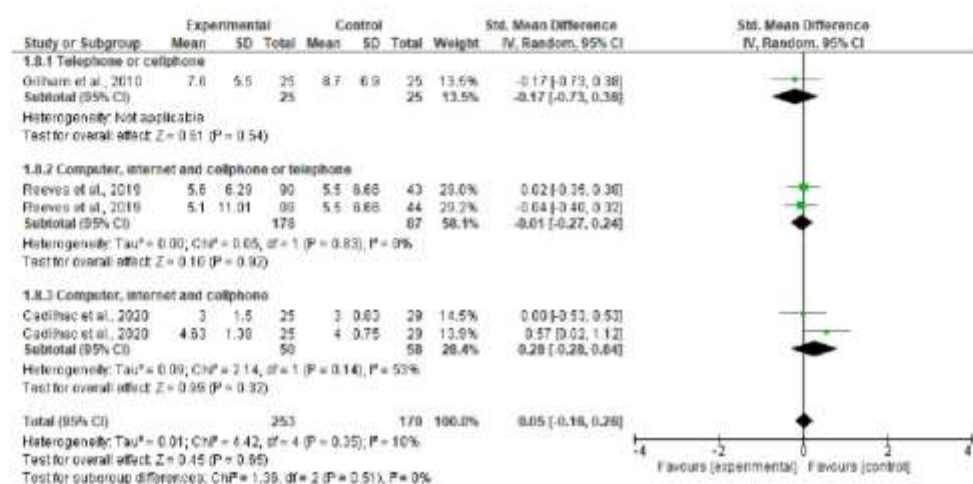


Figure. Emotional self-regulation of psychosocial stress (anxiety and depression) for the comparison of telehealth interventions versus usual care.

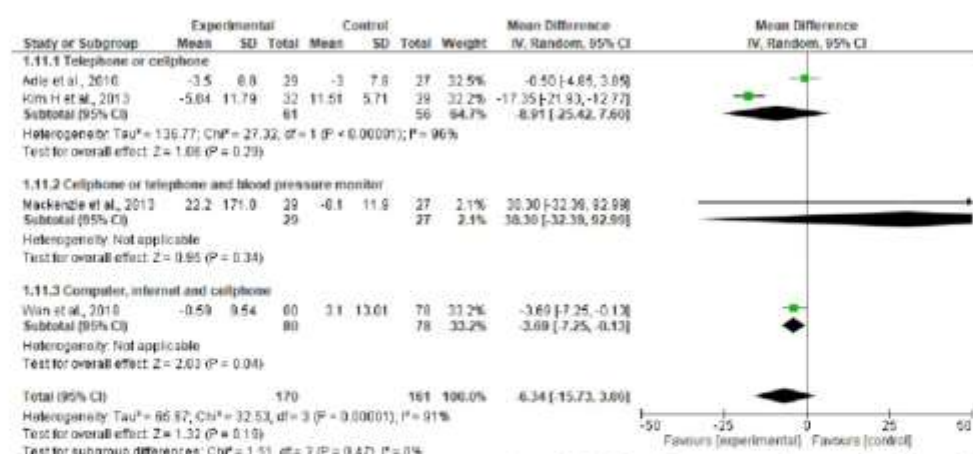


Figure. Diastolic blood pressure outcome (mmHg) for the comparison of telehealth interventions versus usual care.

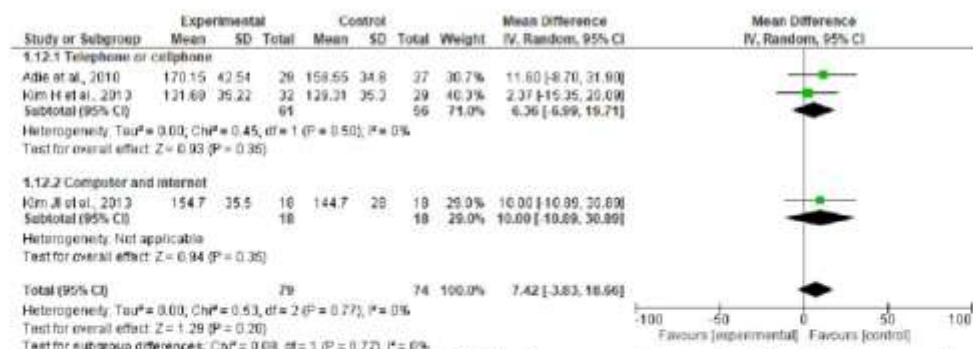


Figure. Total cholesterol outcome (mg/dl) for the comparison of telehealth interventions versus usual care.

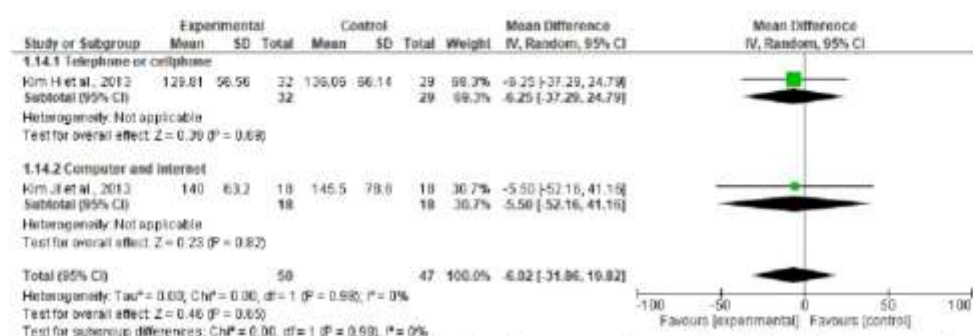


Figure. Triglyceride outcome (mg/dl) for the comparison of telehealth interventions versus usual care.

List of studies that might appear to meet the inclusion criteria, but were excluded, with the main reason for exclusion

Phase-1 (reason for exclusion and citation): 25 records excluded

Not an outcome of interest: n=7

1. Crosbie JH, Lennon S, Basford JR, McDonough SM. Virtual reality in stroke rehabilitation: still more virtual than real. *Disabil Rehabil.* 2007;29(14):1139-46. doi: 10.1080/09638280600960909.
2. Massetti T, Silva TD, Crocetta TB, Guarnieri R, Freitas BL, Lopes PB, et al. The Clinical Utility of Virtual Reality in Neurorehabilitation: A Systematic Review. *J Cent Nerv Syst Dis.* 2018;10:1179573518813541. doi: 10.1177/1179573518813541.
3. Niemeijer M, Sværke KW, Christensen HK. The Effects of Computer Based Cognitive Rehabilitation in Stroke Patients with Working Memory Impairment: A Systematic Review. *J Stroke Cerebrovasc Dis.* 2020;29(12):105265. doi: 10.1016/j.jstrokecerebrovasdis.2020.105265.
4. Qian J, McDonough DJ, Gao Z. The Effectiveness of Virtual Reality Exercise on Individual's Physiological, Psychological and Rehabilitative Outcomes: A Systematic Review. *Int J Environ Res Public Health.* 2020;17(11):4133. doi: 10.3390/ijerph17114133.
5. Staiano AE, Flynn R. Therapeutic Uses of Active Videogames: A Systematic Review. *Games Health J.* 2014;3(6):351-65. doi: 10.1089/g4h.2013.0100.
6. Wiley E, Khattab S, Tang A. Examining the effect of virtual reality therapy on cognition post-stroke: a systematic review and meta-analysis. *Disabil Rehabil Assist Technol.* 2022;17(1):50-60. doi: 10.1080/17483107.2020.1755376.
7. Zhou X, Du M, Zhou L. Use of mobile applications in post-stroke rehabilitation: a systematic review. *Top Stroke Rehabil.* 2018;1-11. doi: 10.1080/10749357.2018.1482446.

Not an intervention targeting risk reduction by changing health behaviors and/or by self-management: n=6

8. Johansson D, Malmgren K, Alt Murphy M. Wearable sensors for clinical applications in epilepsy, Parkinson's disease, and stroke: a mixed-methods systematic review. *J Neurol.* 2018;265(8):1740-1752. doi: 10.1007/s00415-018-8786-y.
9. Appleby E, Gill ST, Hayes LK, Walker TL, Walsh M, Kumar S. Effectiveness of telerehabilitation in the management of adults with stroke: A systematic review. *PLoS One.* 2019;14(11):e0225150. doi: 10.1371/journal.pone.0225150.
10. Johansson T, Wild C. Telerehabilitation in stroke care--a systematic review. *J Telemed Telecare.* 2011;17(1):1-6. doi: 10.1258/jtt.2010.100105.
11. Laver KE, Lange B, George S, Deutsch JE, Saposnik G, Crotty M. Virtual reality for stroke rehabilitation. *Cochrane Database Syst Rev.* 2017;11(11):CD008349. doi: 10.1002/14651858.CD008349.pub4.
12. Shek AC, Biondi A, Ballard D, Wykes T, Simblett SK. Technology-based interventions for mental health support after stroke: A systematic review of their acceptability and feasibility. *Neuropsychol Rehabil.* 2021;31(3):432-452. doi: 10.1080/09602011.2019.1701501.

13. Voinescu A, Sui J, Stanton Fraser D. Virtual Reality in Neurorehabilitation: An Umbrella Review of Meta-Analyses. *J Clin Med*. 2021 Apr 2;10(7):1478. doi: 10.3390/jcm10071478.

Not a RCT with individuals after stroke: n=4

14. Coorey GM, Neubeck L, Mulley J, Redfern J. Effectiveness, acceptability and usefulness of mobile applications for cardiovascular disease self-management: Systematic review with meta-synthesis of quantitative and qualitative data. *Eur J Prev Cardiol*. 2018;25(5):505-521. doi: 10.1177/2047487317750913.
15. Davis AJ, Parker HM, Gallagher R. Gamified applications for secondary prevention in patients with high cardiovascular disease risk: A systematic review of effectiveness and acceptability. *J Clin Nurs*. 2021;30(19-20):3001-3010. doi: 10.1111/jocn.15808.
16. Patel R, Chang T, Greysen SR, Chopra V. Social Media Use in Chronic Disease: A Systematic Review and Novel Taxonomy. *Am J Med*. 2015;128(12):1335-50. doi: 10.1016/j.amjmed.2015.06.015.
17. Sinclair C. Effectiveness and User Acceptance of Online Chronic Disease Management Interventions in Rural and Remote Settings: Systematic Review and Narrative Synthesis. *Clin Med Insights Ther*. 2015;7:43-52. doi: 10.4137/CMT.S18553.

Not a population of interest: n=3

18. Lieber BA, Taylor B, Appelboom G, Prasad K, Bruce S, Yang A, et al. Meta-analysis of telemonitoring to improve HbA1c levels: promise for stroke survivors. *J Clin Neurosci*. 2015;22(5):807-11. doi: 10.1016/j.jocn.2014.11.009.
19. Liu S, Feng W, Chhatbar PY, Liu Y, Ji X, Ovbiagele B. Mobile health as a viable strategy to enhance stroke risk factor control: A systematic review and meta-analysis. *J Neurol Sci*. 2017;378:140-145. doi: 10.1016/j.jns.2017.04.050.
20. Zhu S, Sui Y, Shen Y, Zhu Y, Ali N, Guo C, et al. Effects of Virtual Reality Intervention on Cognition and Motor Function in Older Adults With Mild Cognitive Impairment or Dementia: A Systematic Review and Meta-Analysis. *Front Aging Neurosci*. 2021;13:586999. doi: 10.3389/fnagi.2021.586999.

Not a systematic review: n=3

21. Chau JP, Lo SH. Computer-based interventions for stroke survivors: A systematic review. *JBI Libr Syst Rev*. 2012;10(42 Suppl):1-23. doi: 10.11124/jbisrir-2012-174.
22. Dorstyn DS, Mathias JL, Denson LA. Psychosocial outcomes of telephone-based counseling for adults with an acquired physical disability: A meta-analysis. *Rehabil Psychol*. 2011;56(1):1-14. doi: 10.1037/a0022249.
23. Piran P, Thomas J, Kunnakkat S, Pandey A, Gilles N, Weingast S, et al. Medical Mobile Applications for Stroke Survivors and Caregivers. *J Stroke Cerebrovasc Dis*. 2019;28(11):104318. doi: 10.1016/j.jstrokecerebrovasdis.2019.104318.

Not a telehealth intervention: n=2

24. Lynch EA, Jones TM, Simpson DB, Fini NA, Kuys SS, Borschmann K, et al. Activity monitors for increasing physical activity in adult stroke survivors. *Cochrane Database Syst Rev*. 2018;7(7):CD012543. doi: 10.1002/14651858.CD012543.pub2.
25. McDermott MS, While AE. Maximizing the healthcare environment: a systematic review exploring the potential of computer technology to promote self-

management of chronic illness in healthcare settings. *Patient Educ Couns*. 2013;92(1):13-22. doi: 10.1016/j.pec.2013.02.014.

Phase-2 (reason for exclusion and citation): 16 records excluded

Not a theoretically informed telehealth interventions: n=11

1. Grau-Pellicer M, Lalanza JF, Jovell-Fernández E, Capdevila L. Impact of mHealth technology on adherence to healthy PA after stroke: a randomized study. *Top Stroke Rehabil*. 2020;27(5):354-368. doi: 10.1080/10749357.2019.1691816.
2. Hanley J, Fairbrother P, Krishan A, McCloughan L, Padfield P, Paterson M, et al. Mixed methods feasibility study for a trial of blood pressure telemonitoring for people who have had stroke/transient ischaemic attack (TIA). *Trials*. 2015;16:117. doi: 10.1186/s13063-015-0628-y.
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Did not present separate data for the population of individuals after stroke or transient ischemic attack: n=1

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CAPÍTULO 3

ESTUDO 2

CAPÍTULO 3 – ESTUDO 2

O artigo do Estudo 2, intitulado “*Telehealth intervention involving the HEARTS Technical Package and the additional use of an activity monitor to increase physical activity level post-stroke: Protocol for a feasibility randomized controlled trial*”, foi publicado em 2025 no periódico PLoS One.

STUDY PROTOCOL

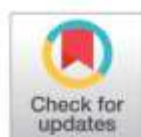
Telehealth intervention involving the HEARTS Technical Package and the additional use of an activity monitor to increase physical activity level post-stroke: Protocol for a feasibility randomized controlled trial

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Data availability statement: No datasets were generated or analysed during the current study. All relevant data from this study will be made available upon study completion.

Abstract

Background

Low physical activity level is a common risk factor for recurrent stroke. Feasibility studies show behavior change interventions can increase physical activity participation, but face barriers (e.g., home visits or internet access). Low-cost telehealth approaches, like telephone calls, may overcome these challenges. Another low-cost strategy involves motivational tools supporting "Behavioral Regulation," such as physical activity monitors. However, evidence is insufficient to support their use in increasing physical activity levels post-stroke. A systematic review suggests integrating these devices into multifaceted behavior change interventions (e.g., the 5As brief intervention outlined in the HEARTS Technical Package) may enhance their effectiveness. Combined with physical activity monitors and telephone follow-up, this approach has proven feasible for individuals post-stroke. These findings underscore the need to explore combining the 5As brief intervention with physical activity monitors to assess potential added benefits. This feasibility randomized controlled trial (RCT) study will investigate whether the telehealth intervention (by telephone call) combining the 5As brief intervention, as outlined in the HEARTS Technical Package, and physical activity monitoring, compared to a control group receiving only the 5As brief intervention, is feasible and supports a fully powered RCT.

Methods

A feasibility RCT study, with blinded assessment, will assign 24 individuals post-stroke (diagnosed ≥ 6 months), aged ≥ 18 years, inactive, able to walk 10 meters independently, and medically approved for physical activity, to experimental ($n = 12$) or control group

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($n = 12$). Both groups will undergo the 5As brief intervention (Ask, Advise, Assess, and Assist delivered face-to-face, and Arrange via telephone call follow-up), for 12 weeks, with the experimental group also using a physical activity monitor. Outcomes include feasibility of recruitment, intervention, measurement, and blinding the outcome assessor, cost and clinical outcomes.

Discussion

The intervention aligns with stroke secondary prevention recommendations and utilizes low-cost telehealth approaches. This study will contribute to defining future RCT phases.

Trial registration

ClinicalTrials.gov [NCT06068036](https://clinicaltrials.gov/ct2/show/study/NCT06068036).

Introduction

Recurrent strokes, although largely preventable, contribute significantly to the high global stroke burden [1,2]. They can be prevented using evidence-based strategies emphasizing life-style modifications to manage modifiable risk factors [1,3]. A low level of physical activity is a key modifiable risk factor for recurrent stroke [4–9]. Physical inactivity is commonly observed in individuals post-stroke [4–9] and is associated with an increased risk of stroke recurrence, mortality, and other cardiovascular conditions (e.g., heart attack) [8,9]. Additionally, physical inactivity is associated with depressive symptoms, poor sleep quality, and a reduced quality of life [10]. Therefore, addressing this modifiable risk factor - low physical activity levels - is crucial by encouraging participation in physical activity among individuals post-stroke.

Encouraging physical activity participation post-stroke is complex and requires personalized interventions focused on lifestyle behavior change [4]. Such interventions must include educational strategies, be theoretically-informed, and be tailored to individual needs [9,11,12]. It is also crucial to consider factors such as personal preferences, environment context, available resources [9,11,12], barriers (e.g., cost and lack of information on how to exercise), and facilitators (e.g., beliefs about health improvement and reducing the risk of recurrent stroke) [13]. Intervention planning should also be guided by established guidelines on the frequency, intensity, and duration of physical activity post-stroke [4]. Recent feasibility studies promoting physical activity participation with individuals post-stroke have shown that interventions meeting these criteria, delivered both in person [14,15] and via telehealth [16], are feasible and can increase participation. However, challenges such as the need for home visits [14,15] or internet access [16] limit their clinical applicability. Implementing low-cost telehealth interventions, such as telephone calls, could help address these barriers and enhance access to support.

Another low-cost approach to encouraging physical activity participation among individuals post-stroke involves the use of physical activity monitors [17,18]. These devices are considered motivational tools for promoting physical activity engagement [19–22], aligning with “Behavioral regulation”, a construct within the Theoretical Domains Framework (TDF) of behavior change, which supports self-monitoring by tracking steps [23]. The use of physical activity monitors is also highlighted in key guidelines for promoting physical activity post-stroke [4]. However, a systematic review investigating the impact of these devices on increasing physical activity levels in individuals post-stroke concluded that the evidence remains insufficient to support their use in clinical practice [17]. Notably, the evidence in the systematic review primarily stemmed from studies conducted in hospital settings (three of

the four included studies) [17]. Sedentary lifestyle, a significant influence on physical activity levels post-stroke [6], is challenging to modify within the constraints of hospital settings. The review's authors reported very little and limited confidence in the estimated effects of the analyzed outcomes [17]. Moreover, the authors hypothesized that integrating physical activity monitors into a multifaceted behavior change intervention might prove more effective in increasing physical activity levels post-stroke in future studies [17].

One such multifaceted behavior change intervention is the 5As brief intervention (Ask, Advise, Assess, Assist, and Arrange), outlined in the HEARTS Technical Package [24]. Developed by organizations such as the World Health Organization (WHO) and the World Stroke Organization (WSO), the HEARTS Technical Package is an established and recommended approach for improving cardiovascular health [24]. It comprises six modules: H – “Healthy lifestyle,” E – “Evidence,” A – “Access,” R – “Risk,” T – “Team,” and S – “Systems for monitoring” [24]. The H – “Healthy lifestyle” module outlines the 5As brief intervention for promoting physical activity [24]. This intervention involves planning, practical counseling, and social support [24], addressing seven theoretical domain of behavior change: “Knowledge,” “Intentions,” “Beliefs about capabilities,” “Goals,” “Social influences,” “Environmental context and resources,” and “Reinforcement” [23]. The 5As brief intervention has been implemented with individuals post-stroke [25–27] and in other populations (e.g., diabetics, hypertensives and obese individuals) [28–30] involving the encouragement of the adoption of healthy lifestyle behaviors. Additionally, studies on cardiovascular risk management [31,32] found the HEARTS Technical Package [24] feasible for implementation by communities, patients, providers, decision-makers, and funders. However, current evidence has yet to integrate this multifaceted behavior change intervention with the use of physical activity monitors to demonstrate the additional effect of this technology on increasing physical activity levels in individuals post-stroke.

Recently, Liljehult et al. [27] demonstrated that the 5As brief intervention, combined with the use of physical activity monitors and follow-up via telephone, is feasible for implementation with individuals post-stroke. However, in this study [27], the control group received usual care, making it impossible to determine the additional effect of incorporating physical activity monitors into the multifaceted behavior change intervention. Therefore, the aims of this feasibility randomized controlled trial (RCT) study are 1. to investigate whether the telehealth intervention (by telephone call) combining the 5As brief intervention, as outlined in the HEARTS Technical Package [24], with the use of a physical activity monitor, compared to a control group receiving only the 5As brief intervention (by telephone call), is feasible to be implemented and 2. to estimate the parameters for conducting a fully powered RCT.

Materials and methods

Design

This phase 1 feasibility RCT study [33,34], with concealed allocation and blinded assessments, that will adhere to the CONSORT extension for pilot or feasibility trials [34] will be carried out in Belo Horizonte (Minas Gerais, Brazil). This study was prospectively registered with ClinicalTrials.gov (NCT06068036) and received approval from the institutional ethics review board (Comitê de Ética em Pesquisa, Universidade Federal de Minas Gerais, CAAE: 66980723.2.0000.5149, number: 5.980.632, April 3, 2023). Fig 1 shows the schedule of enrolment, interventions, and assessments. Fig 2 shows the study conduction flowchart. Community-dwelling individuals post-stroke will be recruited and randomly assigned to experimental group or control group (Fig 3). Participant recruitment began in October 2023, and is expected to be completed in October 2024.

TIMEPOINT	STUDY PERIOD				
	Enrolment	Allocation	Post allocation		Close-out
	-4 ₁	0	t ₁	T ₁₂ (after the 12-week intervention)	T ₁₆ (4 weeks post-intervention)
ENROLMENT:					
Eligibility screen	X				
Informed consent	X				
Allocation		X			
INTERVENTIONS:					
[Experimental Group]			←————→		
[Control Group]			←————→		
ASSESSMENTS:					
[Sociodemographic data]	X				
[Feasibility outcomes]	X	X	X	X	X
[Clinical outcomes]	X			X	X

Fig 1. Schedule of enrolment, interventions, and assessments.

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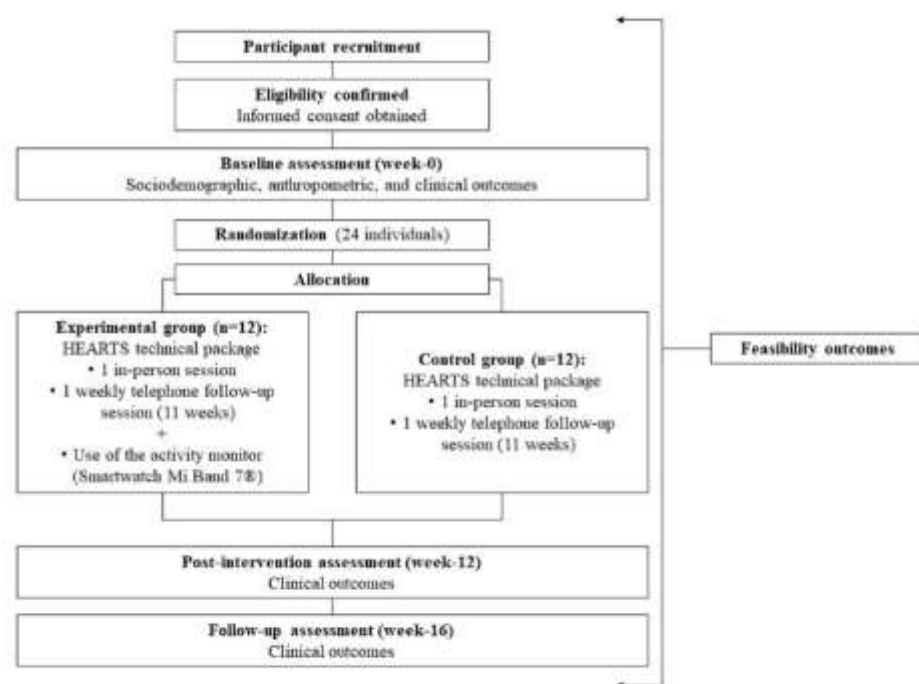


Fig 2. Study conduct flowchart.

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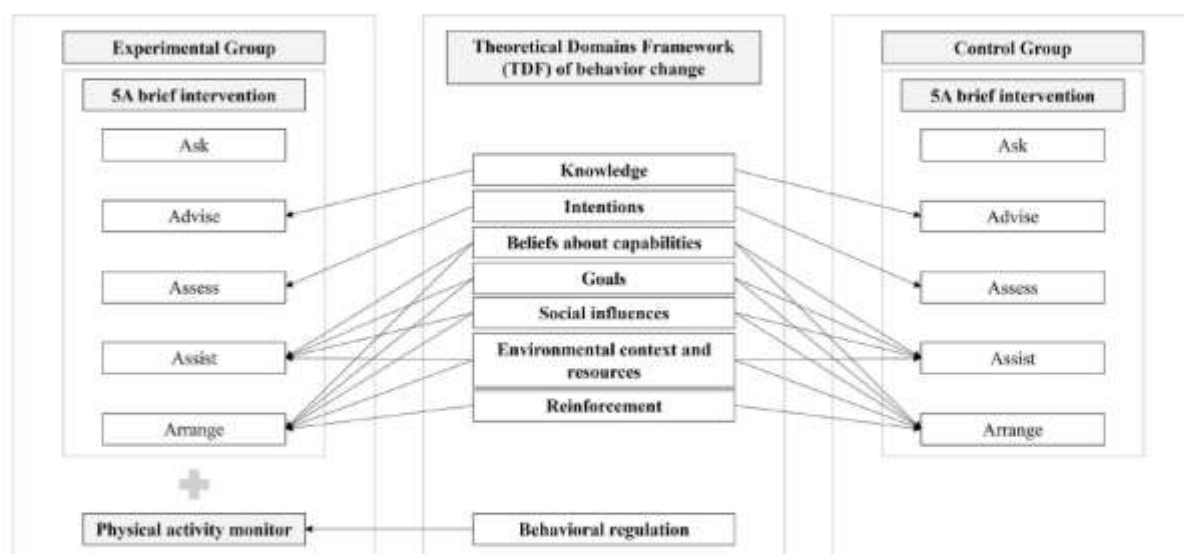


Fig 3. Mapping of the telehealth intervention proposed in the present study considering the Theoretical Domains Framework (TDF) of behavior change proposed by Atkins et al. [23].

<https://doi.org/10.1371/journal.pone.0320026.g003>

Participants

A non-probabilistic sample will be recruited from the community. Recruitment strategies will include [35]:

1. Circulation of physical leaflets: these leaflets will be distributed in strategic locations in the city (e.g., universities, hospitals, health centers, outpatient clinics, rehabilitation clinics, and churches);
2. Referral by other researchers and health professionals: researchers and health professionals in the city will be contacted via conversations, email, social media, and phone calls, will be informed of the study, and will be invited to publicize the study or provide contact details of individuals post-stroke who could participate in the study. Physical and/or digital leaflets will be provided to these researchers/professionals.
3. Targeted campaign in support groups: support groups for individuals post-stroke in the city will be identified, contacted, and invited to publicize the study or provide contact details of individuals post-stroke who could participate in the study. Physical and/or digital leaflets will be provided.
4. Online advertising: attempts will be made to publicize the study on websites (e.g., university website); a specific social media to publicize the study will be created; and social media of organizations and institutions (e.g., other universities) will be identified and invited to publicize the study.

Individuals will be included according to the following criteria: present with a medical diagnosis of stroke and in the chronic phase (≥ 6 months); be aged ≥ 18 years; be classified as "Inactive" according to Adjusted Activity Score (AAS) from the Human Activity Profile (HAP) [36]; be able to walk 10 meters independently with or without a walking device (considering that walking is a preferred physical activity pointed by individuals post-stroke [37,38]

and is a potential way to participate in physical activity [4]; and provide medical approval to participate in physical activity [39]. Individuals will be excluded according to the following criteria: present with a positive screening test for possible cognitive impairment determined by the education-adjusted cut-off scores (in points) of the Mini-Mental State Examination (illiterate: 13 points; elementary and middle school: 18 points; and high-school: 26 points) [40]; and have pain or other disorders (e.g., vestibular disorders, severe arthritis or any other diagnosed disease of the nervous system) precluding their participation [39].

Randomization

A blinded trained researcher, not involved in the study, will generate the computer-randomization sequence prior to study commencement and will store the sequential numbers in opaque sealed envelopes. Individuals will be randomly allocated (1:1) to experimental or control group (Figs 2 and 3) by another blinded trained researcher. After confirmation of eligibility, the envelopes containing the random allocation sequence will be revealed by the physiotherapist researcher responsible for implementing the intervention.

Intervention

Both groups will receive the telehealth intervention based on the 5As brief intervention (Ask, Advise, Assess, Assist, Arrange) to promote physical activity participation presented in the HEARTS Technical [24] (Fig 3). This established and recommended behavior change theoretically-informed telehealth intervention aligns with TDF constructs for behavior change (Fig 3) [23]. The first A (Ask) involves asking the participants about their physical activity participation in the last week [24]. The second A (Advise) involves advising the participant (in a clear, simple and personalized way) about participation in physical activity [24]. The researcher will inform the participants about recommended time for participation in physical activity per week, and advantages related to this health behavior [24], which aligns with the TDF construct for behavior change "Knowledge" [23]. The third A (Assess) involves assessing the participant's readiness to initiate behavior change to become physically active and whether the individual believes they will be successful in increasing physical activity levels [24]. This part aligns with the TDF construct for behavior change "Intentions", which refers to a conscious decision to perform a behavior [23], such as becoming physically active. The fourth A (Assist) involves helping the participant devise a plan that increases the chances of successfully increasing participation in physical activity, and providing practical counselling [24]. In this section, the researcher will help the participants to identify parts of their daily life where they could start to increase their activity levels, to identify activities that they would enjoy doing, and to identify possible challenges and suggest how to overcome them [24]. Therefore, these aspects are aligned with the TDF construct for behavior change "Beliefs about capabilities", where the participants will be able to modify their self-confidence and perceived competence to become physically active [23]. In addition, the cooperation between the participants and the researcher to develop the plan aligns with the TDF construct for behavior change "Goals", where they will set goals to increase their participation in physical activity [23]. This part also aligns with the TDF construct for behavior change "Social influences", where the researcher will provide social support [23]. Finally, the activities involved in this step also align with the TDF construct for behavior change "Environmental context and resources", where factors related to the participants' environment will be considered to encourage their participation in physical activity [23]. The fifth A (Arrange) involves following up with the participant, which can be by telephone, to discuss successes (and congratulate them) and difficulties (discuss ways to face challenges and encourage

renewed commitment to the plan) [24]. Therefore, this part aligns with the TDF construct for behavior change "Reinforcement" [23], since these activities have the objective to increase the chance that the individual will continue to want to become physically active. As this last step involves revising the plan and the social support provided by the researcher, the other four TDF constructs for behavior change ("Beliefs about capabilities", "Goals", "Social influences", "Environmental context and resources") [23] mentioned before are also aligned to this part.

Participants will undertake a 12-week intervention. A researcher will be responsible for implementing the intervention. She has experience in conducting research with individuals post-stroke in-person and remotely, including conducting activities that aimed to encourage the adoption of healthy lifestyle behaviors in the context of stroke secondary prevention. In addition, she has completed training focused on the implementation of the proposed intervention. In week one, participants will complete the first four steps of the 5As brief intervention (Ask, Advise, Assess, Assist), following the script provided in the HEARTS Technical Package [24] in-person, in a university setting, with the physiotherapist researcher mentioned above. They will receive the diary of regular participation in physical activity, will be guided on how to fill it out, and will schedule the best times to receive the weekly telephone call [23]. Also following the script provided in the HEARTS Technical Package [24], the fifth A (Arrange) will be carried out for the subsequent 11 weeks, where participants in their home setting will be followed up remotely, by the same physiotherapist and by telephone call [24], once a week. If the participant does not answer the telephone call on the previously defined day and time, two attempts at new calls on different days will be made.

Experimental group

Participants will undergo the telehealth intervention involving the 5As brief intervention (Ask, Advise, Assess, Assist), following the script provided in the HEARTS Technical Package [24], and the use of an activity monitor (Smartwatch Mi Band 7®) (Fig 3). The use of this physical activity monitor fits into the TDF construct for behavior change "Behavioral regulation", where the participants can objectively observe their physical activity practice (self-monitor) and influence their decision about this behavior [23]. Participants will receive their physical activity monitor, will be advised on how to use it, and will be instructed to return it at the end of the intervention (week-12). Physical activity monitors from the same brand have been used in other clinical trials [41–44]. The Smartwatch Mi Band 7® model was obtained for this study and the cost was approximately 50\$ (R\$235) each.

Control group

Participants will perform the telehealth intervention involving the 5As brief intervention (Ask, Advise, Assess, Assist), following the script provided in the HEARTS Technical Package [24] (Fig 3). These participants will not receive the physical activity monitor.

Procedures

All subjects will be informed about the study procedures and will provide written consent. The feasibility outcomes will be identified considering the different phases of conducting the study (Figs 1 and 2). A trained researcher, blinded to the group allocation, will collect the sociodemographic, anthropometric, and clinical outcomes, in a university laboratory setting. Two independent examiners, blinded to the group allocation, will enter the data into a statistical software package, verify any missing or apparently wrong values. Original paper forms will be kept in a secure place. Electronic files will be available only to the research team. Analysis

will be carried-out by a researcher, blinded to the group allocation. All individuals will receive an identification code to ensure anonymity.

Outcome of interest

Feasibility of recruitment. Feasibility of recruitment will be determined by the ratio between the total number of eligible individuals (EI) and the total number of screened individuals (SI) (measure = EI/SI), and by the ratio between the total number of eligible individuals (EI) and the total number of recruited individuals (RI) (measure = EI/RI) [15,35,45–47]. In addition, the time expenditure for recruitment of study participants will also be identified [48]. A measure of EI/SI $\geq 10\%$ will be considered as a success criterion [45].

Feasibility of intervention. Feasibility of intervention will be determined by examining retention, follow-up of individuals, attendance, safety, satisfaction with treatment and perceived effectiveness.

Retention will be determined by the ratio between the total number of individuals who completed the proposed intervention program and the total number of individuals who started the proposed intervention program. The reasons for individuals dropping out of the intervention program will be recorded [35,45–47,49–51]. A measure of $\geq 90\%$ retention will be considered as a success criterion [45].

Follow-up of individuals will be determined by the ratio between the total number of individuals who remained in the same group to which they were initially allocated until follow-up and the total number of individuals who were allocated [47,51].

Attendance will be determined by the ratio between the total number of sessions performed and the total number of sessions offered. The number and reasons for absence for sessions will be recorded [15,35,45,47]. A measure of $\geq 85\%$ completion of in home proposed 11 sessions will be considered as a success criterion [45].

Safety will be determined by the number and reasons of adverse events (e.g., pain, falls, hospitalization, and death) identified during the period of intervention and follow-up of the individual [15,45,47,49,50].

Satisfaction with treatment will be assessed by the following situation: "Please listen to the sentence I am about to say and select the answer that is closest to your opinion. There is no right or wrong answer, we are interested in your opinion. "Overall, I am satisfied with the type of treatment I received"; totally agree, partially agree, agree, neither agree nor disagree, disagree, partially disagree, totally disagree". The response provided will be registered by the examiner. A measure of $\geq 90\%$ of participants reporting "totally agree, partially agree, or agree" will be considered as a success criterion [45].

Perceived effectiveness will be determined by the following question: "Comparing how it was before you carried out the intervention and now, do you think that your ability to perform routine physical activity is: much worse, moderately worse, a little worse, the same, a little better, moderately better, or much better?". The response provided will be registered by the examiner.

Feasibility of measurement. Feasibility of measurement will be determined by the percentage of clinical outcomes measured (ratio between the number of clinical outcomes measured and the number of clinical outcomes proposed to be measured), and the percentage of participants who filled-out the diary (ratio between the number of individuals who filled-out the diary and the number of individuals who started the proposed intervention program) [15]. The diary will be considered completed if participants provide information regarding physical activity practice for at least 75% (8 weeks) of the 11 weeks of intervention proposed to be carried out remotely [52]. The time taken to obtain the outcome measures will be recorded.

In addition, the number and reasons of adverse events (e.g., pain, falls, hospitalization, and death) identified during the assessments will be registered.

Feasibility of blinding the outcome assessor. The feasibility of blinding the outcome assessor will be determined by the number of participants and percentage of treatment allocations correctly guessed by the blinded assessor [53].

Cost. Costs for staff training (e.g., materials and transportation), recruitment (e.g., related to telephone call and printing of folders), screening, examination of the inclusion and exclusion criteria and investigation of the outcomes (e.g., transportation for both participants and staff, printing of evaluations, and material costs), as well as the execution of the intervention (e.g., related to telephone call) will be registered [54].

Clinical outcomes. Clinical outcomes will be evaluated to estimate the parameters for conducting a fully powered RCT including: physical activity levels and the number of individuals post-stroke who met the threshold to be considered physically active, systolic blood pressure (SBP) and diastolic blood pressure (DBP), cardiorespiratory fitness, self-efficacy for physical activity and health-related quality of life.

Physical activity levels and the number of individuals post-stroke who became more physically active will be measured with the HAP [36]. The questionnaire has 94 items hierarchically graded according to metabolic equivalent [36]. AAS, one of the HAP measures, provides a best estimate of the respondent's average level of energy expended [36]. Higher scores indicate better outcomes [36]. Another measure of the HAP is the "Activity Rating", which provides an overall rating of the respondent's activity level into "Inactive", "Moderately active" and "Active" [36]. The mean difference between groups and the standard deviation for the AAS outcome will be used to estimate the required sample size to conduct a future fully powered RCT.

SBP and DBP will be assessed by a trained researcher using Tycos® aneroid sphygmomanometer (WelchAllyn Inc., NY, USA, Model DS44) and stethoscope (Litmann Classic II SE 3M®, USA) and following these steps: the participants will be seated at rest in a chair, with legs uncrossed, for 5–10 minutes prior to the evaluation commencing; the sphygmomanometer will be positioned on the non-hemiplegic arm of the participant, and their arm will be supported at the level of the heart [55,56]. These measures will be operationalized in millimeters of mercury (mmHg).

Cardiorespiratory fitness will be measured by HAP [36,57]. One of the HAP measures is "Lifestyle Energy Consumption" (LEC), operationalized in $\text{ml.kg}^{-1}.\text{min}^{-1}$. [36]. The HAP is a valid instrument to estimate the cardiorespiratory fitness of individuals post-stroke [57].

Self-efficacy for physical activity will be measured by the Self-efficacy for Physical Activity Scale, and will be operationalized as the total score [15,58]. The scale has 10 items and has two response options: "yes" is computed as 1 and "no" is computed as 0 [58]. The total score is defined by the sum of the scores for each item [58]. Therefore, the minimum total score is 0 and the maximum total score is 10 [58]. Higher scores indicate better outcomes [58]. The Self-efficacy for Physical Activity Scale presents adequate validity, internal consistency, and reliability [58].

Health-related quality of life will be measured by the Stroke-Specific Quality of Life Scale (SSQOL), and will be operationalized as the total score [59]. The instrument has 49 items distributed across 12 domains [59]. The instrument has three different sets of responses and the items are rated on a 5-point Likert scale. The total score is defined by the sum of the scores for each item [59]. Therefore, the minimum total score is 49 and the maximum total score is 245 [59]. Higher scores indicate better outcome [59]. SSQOL presents adequate measurements properties when applied in individuals post-stroke [59].

Sample size calculation

As a feasibility study, no formal sample size calculation is conducted [60]. Following the recommendation proposed by Julious [61] for feasibility studies with parallel groups, the present feasibility RCT study will present a sample size of 24 individuals, with 12 individuals in each group.

Statistical analyses

All analyses will be performed using SPSS version 21.0 (SPSS Inc., Chicago, IL, USA). Descriptive statistics will be calculated for all outcomes. The mean difference between groups and the standard deviation for the AAS outcome obtained from the HAP [35] will be identified. No studies investigating the minimal detectable change (MDC) (or related measures) for this outcome in individuals post-stroke were identified to date. However, Davidson et al. [62], in a systematic review, calculated the MDC at 90% confidence for the AAS obtained by the HAP in individuals with chronic conditions (e.g., chronic pain and arthritis) and reported a value of 6.8. A change greater than 6.8 for the AAS is expected in the present study. The effect sizes for this outcome will be calculated to determine the magnitude of within-groups and between-groups comparisons. The level of significance will be set at 5%.

Ethics

This phase 1 feasibility RCT study [34] was prospectively registered with ClinicalTrials.gov (NCT06068036) and received approval from the institutional ethics review board (Comit  de  tica em Pesquisa, Universidade Federal de Minas Gerais, CAAE: 66980723.2.0000.5149, number: 5.980.632, April 3, 2023). Participants will provide signed, informed consent form. Researchers will take appropriate measures to ensure privacy, confidentiality, and data protection. This protocol will not generate primary data. However, data collected during the conduct of the trial will be made available in an open data repository.

Discussion

To the best of our knowledge, this will be the first study to investigate whether the telehealth intervention (provided by telephone call) utilizing the 5As brief intervention, as outlined in the HEARTS Technical Package [24], alongside provision of an activity monitor, compared to a control group receiving only the 5As brief intervention (by telephone call), is feasible to be implemented. The results of the present study will also inform a fully powered RCT.

Insufficient evidence to recommend the use of physical activity monitors to increase physical activity levels post-stroke is based primarily on studies conducted in the hospital setting [17]. Considering that changing physical activity levels involves modifying sedentary lifestyle behaviors [6], the use of physical activity monitors in the real-world individual post-stroke setting has the potential to result in an additional change in physical activity levels post-stroke. The need for further studies investigating the additional effect of physical activity monitors integrated with multifaceted behavior change interventions to increase the physical activity level in individuals post-stroke has been highlighted in the literature [17]. The 5As brief intervention, a multifaceted behavior change approach, combined with the use of physical activity monitors and follow-up via telephone call, has been shown to be feasible for implementation with individuals post-stroke [27]. Based on this, the present study compared this intervention with a control group receiving only the 5As brief intervention, also delivered via telephone call.

Studies aiming to increase physical activity participation post-stroke using theoretically-informed behavior change interventions have included individuals in the acute phase [14], the

subacute phase [15] or from the acute to the chronic phase [16]. In the present study, individuals post-stroke in the chronic phase will be included. The interventions offered in these previous studies have limited clinical applicability, as they require home visits [14,15] or internet access [16]. In contrast, the intervention in the present study will be delivered via telehealth, using low-cost technologies (e.g., telephone call). This approach is expected to overcome these barriers, enhancing the clinical applicability of the intervention.

Finally, the presented intervention - the 5As brief intervention outlined in the HEARTS Technical Package [24], combined with the use of a physical activity monitor - is characterized as a multifaceted theoretically-informed behavior change intervention, as it comprises several constructs from the TDF for behavior change [23] (Fig 3), meeting the stroke secondary prevention recommendations [8,9]. Moreover, the additional use of the physical activity monitor introduces a theoretical domain ("Behavioral regulation") not addressed in the 5As brief intervention, supporting the rationale for its potential to produce an additional effect in increasing physical activity levels. To evaluate this, and in line with recommendations for conducting a RCT, it is necessary to first conduct this phase 1 feasibility RCT study [34].

A limitation of the present study is that the results will not be able to be generalized for individuals post-stroke who are not able to walk independently. Therefore, future studies aiming to promote participation in physical activity using the proposed intervention should address this topic. Furthermore, although the sample size of the present study can be considered as small, it should be taken into account that it was determined considering recommendations from the literature for feasibility studies [60,61]. Related to this last point, it should be noted that the main objective of the present study is not to investigate the effectiveness of the proposed interventions, since the feasibility study does not have this objective [63]. The preliminary analysis of clinical outcomes will focus on effect sizes as signs of improvement (or not) that justify planning to conduct a definitive fully powered RCT.

Supporting information

S1 File. Complete protocol approved by the ethics committee (in English).
(PDF)

S2 File. Complete protocol approved by the ethics committee (in Portuguese).
(PDF)

S3 File. SPIRIT checklist.
(DOC)

Author contributions

Conceptualization: Paula da Cruz Peniche, Olive Lennon, Jordana de Paula Magalhães, Jéssica Melo dos Santos, Janaine Cunha Polese, Christina Danielli Coelho de Moraes Faria.

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CAPÍTULO 4

ESTUDO 3

CAPÍTULO 4 – ESTUDO 3

O artigo do Estudo 3, intitulado “*Telehealth intervention involving the HEARTS Technical Package and the additional use of an activity monitor to increase physical activity level post-stroke: a feasibility randomized controlled trial*”, será submetido ao periódico *Clinical Rehabilitation*.

Telehealth intervention involving the HEARTS Technical Package and the additional use of an activity monitor to increase physical activity level post-stroke: a feasibility randomized controlled trial

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**Telehealth intervention involving the HEARTS Technical Package and the
additional use of an activity monitor to increase physical activity level post-stroke:
a feasibility randomized controlled trial**

Abstract

Objective: 1. To assess the feasibility of implementing the 5As brief intervention from the HEARTS Technical Package with a physical activity monitor versus the 5As brief intervention alone to increase physical activity levels post-stroke. 2. To explore changes in physical activity levels in both study arms, focusing on effect sizes to inform the design of a fully powered randomized controlled trial (RCT).

Design: Phase 1 feasibility RCT, with concealed allocation and blinded assessments.

Setting: University laboratory (Belo Horizonte, Minas Gerais, Brazil).

Participants: 24 individuals post-stroke.

Interventions: Both groups received the 5As brief intervention, from the HEARTS Technical Package. The experimental group (EG) also used a physical activity monitor (Smartwatch Mi Band 7®).

Outcome measures: Feasibility indicators (e.g. recruitment, retention, and cost) and clinical variables (e.g. physical activity level).

Results: Trial feasibility was supported regarding recruitment, intervention delivery, and measurement. Challenges included participant attrition. Main costs were related to transportation for in-person assessments. Physical activity levels clinically increased in both groups, with a large within-group effect in the EG (Cohen's $d = 1.01$) versus a moderate effect in the control group (Cohen's $d = 0.76$).

Conclusion: Both interventions were feasible and led to clinical changes in physical activity levels post-stroke, with greater effects in the EG. These findings should inform a

future, larger RCT addressing retention, follow-up, and formally evaluating the added potential of the physical activity monitor.

Key-words: Stroke, physical activity, activity monitor, telehealth, feasibility study

Clinical Messages

- A low-cost, theoretically informed telehealth intervention (5As brief intervention, from the HEARTS Technical Package) with or without a physical activity monitor is feasible post-stroke.
- Adding a monitor showed a larger within-group effect compared to a moderate effect without monitor use.
- A larger randomized controlled trial is needed to explore effectiveness.

Introduction

Physical inactivity post-stroke is a major risk factor for recurrent stroke events.^{1, 2} Therefore, stroke secondary prevention guidelines emphasize the importance of encouraging individuals post-stroke to become more physically active.^{1, 2} Engaging in physical activity after a stroke is further associated with reduced mortality risk,³ improved functional recovery,⁴ better health-related quality of life⁵ and reduced depressive symptoms,^{6, 7} while also helping to moderate other known risk factors, such as high blood pressure and elevated cholesterol.⁸ However, a considerable proportion of individuals post-stroke, at least 30% in countries such as the United States, Sweden, and Brazil, remain physically inactive after the event.⁹⁻¹¹

Theoretically informed interventions and educational strategies are recommended to promote behavior change among individuals post-stroke and encourage the adoption of healthy lifestyle behaviors, such as becoming physically active.¹² Furthermore, to be successful, such interventions must be tailored to the specific context, abilities, needs, and personally relevant goals of individuals post-stroke and their families.¹² Feasibility studies offering theory-based, educational, and individually tailored interventions for individuals post-stroke have shown promising results in increasing physical activity levels.^{13, 14} Preston et al.¹³ delivered a home-based self-management program to increase physical activity in individuals in the acute phase post-stroke who could walk without a walking aid. The intervention included five 60-minute sessions over three months.¹³ Caetano et al.¹⁴ implemented a similar program, based on Preston et al.¹³'s intervention, targeting individuals in the subacute phase post-stroke. This intervention consisted of six 60-minute sessions over three months.¹³ Neither study^{13, 14} included individuals in the chronic phase post-stroke, who also present with low physical activity levels.¹⁰ Moreover,

both interventions required a professional to visit the patient's home to deliver the sessions,^{13, 14} which may limit the clinical applicability of these theoretically informed and educational strategies for promoting physical activity post-stroke.

Telehealth, which involves the use of electronic communication and information technologies to deliver healthcare services remotely,¹⁵ is a resource that can help improve the clinical implementation of interventions aimed at increasing physical activity levels among individuals post-stroke. English et al.¹⁶, in a feasibility study also reporting feasibility data, delivered a telehealth intervention to individuals post-stroke that included encouragement to increase physical activity levels. They demonstrated promising improvements in physical activity among participants.¹⁶ However, the intervention was delivered using videoconferencing software, which required access to compatible devices and a stable internet connection,¹⁶ factors that may limit the clinical implementation of the intervention all over the world. A low-cost technological solution for broader implementation is telephone calls, which have already shown a robust evidence base, according to an overview of systematic reviews, when used with individuals post-stroke to support the adoption of healthy lifestyle behaviors.¹⁷ Moreover, telehealth intervention delivered via telephone calls is more accessible in lower-income countries, as it is less expensive and requires fewer technological resources, such as internet access.

Low-cost physical activity monitors, such as smartwatches (e.g., Smartwatch Mi Band 7®), are more affordable than devices like the Garmin Forerunner 920XT, BodyMedia SenseWear MF, and Garmin Vivoactive,¹⁸ and have previously been used successfully to increase physical activity levels among individuals post-stroke.¹⁹⁻²¹ The use of such technology is also endorsed in key documents guiding post-stroke physical activity practices.¹⁹⁻²¹ However, a systematic review continues to report inconclusive evidence regarding the effect of this tool, with authors suggesting that future studies

should combine the use of physical activity monitors with multifaceted behavior change interventions to better understand the potential of this technology to enhance physical activity after stroke.²²

One example of a multifaceted behavior change intervention is the 5As brief intervention (Ask, Advise, Assess, Assist, and Arrange), outlined in the HEARTS Technical Package,¹⁹ an established and recommended approach for improving cardiovascular health developed by organizations such as the World Health Organization (WHO) and the World Stroke Organization (WSO). Liljehult et al.^{23, 24} recently showed that implementing the 5As brief intervention alongside physical activity monitors and follow-ups via telephone calls is feasible for individuals post-stroke during acute phase. However, since the control group (CG) in this study^{23, 24} received only usual care, it was not possible to isolate the specific effect of the physical activity monitors within the broader behavior change intervention.

Therefore, this feasibility randomized controlled trial (RCT) aims to:

- (1) Investigate the feasibility of implementing a multifaceted, theoretically informed telehealth intervention, delivered via telephone call, that combines the 5As brief intervention, as outlined in the HEARTS Technical Package,¹⁹ with the additional use of a physical activity monitor, compared to a CG receiving only the 5As brief intervention via telephone call, among individuals in the chronic phase post-stroke, with the goal of increasing physical activity levels.
- (2) Explore changes in physical activity levels in both study arms, with particular attention to effect sizes, to inform the design of a fully powered RCT.

Methods

Design

This was a phase 1 feasibility RCT study,^{25, 26} with concealed allocation and blinded assessments, reported in accordance with the CONSORT extension for pilot or feasibility trials.²⁵ The study was carried out in [*blinded information*], received approval from the institutional ethics review board ([*blinded information*]), was prospectively registered on ClinicalTrials.gov ([*blinded information*]), and had its protocol previously published.²⁷ In the published protocol,²⁷ within- and between-group analyses of physical activity levels had been planned. However, feasibility studies are designed to support the development of a future definitive RCT and are not intended to investigate intervention effectiveness or efficacy.^{25, 28} Consequently, feasibility studies do not include formal sample size calculations²⁹, and are not recommended to conduct exploratory analyses or formal hypothesis testing for effectiveness or efficacy, as they are underpowered to do so.^{25, 28} Therefore, within- and between-group comparisons were not conducted in the present study. Participant recruitment began in October 2023 and finished in October 2024.

A trained, blinded researcher not involved in the study generated the computer-based randomization sequence prior to study commencement and stored the sequential numbers in opaque, sealed envelopes. Once the participant's eligibility has been confirmed, the physiotherapist researcher responsible for implementing the intervention opened the corresponding envelope. Participants were randomly assigned to receive either: (1) a multifaceted, theoretically informed telehealth intervention, delivered via telephone call, combining the 5As brief intervention as outlined in the HEARTS Technical Package¹⁹ with the additional use of a physical activity monitor (experimental group, EG) or (2) the 5As brief intervention alone, as outlined in the HEARTS Technical

Package¹⁹ (CG). A trained, blinded researcher collected written informed consent and outcome measures at baseline (week-0), post-intervention (week-12), and follow-up (week-16). All assessments were conducted in a university laboratory.²⁷ In addition to sociodemographic data, the Six-Minute Walk Test (6MWT)³⁰⁻³² and the 10-Meter Walk Test (10mWT)^{32, 33} were performed to characterize participants. Both tests have adequate measurement properties for evaluating individuals post-stroke.³¹⁻³³

Participants

A non-probabilistic sample was recruited from the community.²⁷ Recruitment strategies included distributing physical leaflets in strategic city locations (e.g., universities and hospitals); contacting and inviting researchers, health professionals, and local stroke support groups to either publicize the study or provide contact information of individuals post-stroke; promoting the study through websites and institutional social media; and creating a dedicated study social media page.^{27, 34}

Participants were eligible if they had a medical diagnosis of stroke in the chronic phase (≥ 6 months), were aged ≥ 18 years, were classified as “Inactive” according to the Adjusted Activity Score (AAS) from the Human Activity Profile (HAP) (Souza et al., 2006),³⁵ were able to walk 10 meters independently with or without a walking device, and had received medical approval to participate in physical activity.²⁷ Individuals were excluded if they screened positive for possible cognitive impairment based on education-adjusted cut-off scores of the Mini-Mental State Examination,³⁶ or if they had pain or other conditions (e.g., any other diagnosed disease of the nervous system) that could affect their ability to perform the tests.²⁷

Intervention

Both groups (EG and CG) received the multifaceted, theoretically informed telehealth intervention based on the 5As brief intervention to promote physical activity participation as outlined in the HEARTS Technical.¹⁹ The first A (Ask) consists of inquiring about the participant's physical activity over the past week. The second A (Advise) provides clear, simple, and personalized guidance about engaging in physical activity, including the recommended weekly duration and its health benefits. The third A (Assess) evaluates the participant's readiness to change and their confidence in becoming more physically active. The fourth A (Assist) supports the participant in developing a personalized action plan. The researcher helps identify enjoyable activities, opportunities to increase activity in daily life, and potential barriers, discussing strategies to overcome them. The fifth A (Arrange) involves follow-up via telephone call to reinforce progress, celebrate successes, address challenges, revise the plan if needed, and strengthen social support and motivation.^{19,27} More details of the intervention can be accessed in the protocol previously published.²⁷

Participants underwent a 12-week intervention. In the first week, they completed the initial four steps of the 5As brief intervention (Ask, Advise, Assess, Assist) in person, at a university setting, following the script provided in the HEARTS Technical Package.¹⁹ During this session, they received a physical activity diary, were instructed on how to complete it, and scheduled the most convenient times to receive weekly telephone calls. In the diary, participants were asked to record the days they engaged in physical activity, the duration of each activity, and their perceived exertion on a scale from 0 to 10 (with higher scores indicating greater fatigue). In accordance with the HEARTS Technical Package,¹⁹ the fifth step (Arrange) was implemented over the following 11 weeks. During this period, participants were remotely followed up at home through weekly telephone calls. If a participant did not answer the call at the scheduled time, two additional attempts

were made on different days. A trained research physiotherapist was responsible for delivering the intervention.²⁷

Experimental group

In addition to the previously described intervention,^{19,27} participants in the EG received a physical activity monitor (Smartwatch Mi Band 7®), were instructed on how to use it (including how to charge the battery and the importance of wearing it as much as possible, especially during physical activity sessions), and were asked to return the device at the end of the intervention period (week-12).²⁷ The physical activity diary for these participants also included recording the number of steps taken, as provided by the physical activity monitor. During the telephone sessions, participants were asked about and encouraged to use the physical activity monitor.

Control group

Participants received only the previously described intervention.^{19,27}

Outcomes of interest

Feasibility of recruitment

Feasibility of recruitment was assessed using the following measures: (1) the ratio of eligible individuals to the total number of screened individuals; (2) the ratio of eligible individuals to recruited individuals; and (3) the total time required to complete participant recruitment.^{14, 27, 34, 37-40} A recruitment rate of $\geq 10\%$ for the first measure was considered the threshold for success.^{27, 37}

Feasibility of the intervention

Feasibility of the intervention was assessed through the following indicators: retention, participant follow-up, attendance, safety, satisfaction with the intervention, and perceived effectiveness.²⁷

Retention was defined as the ratio between the number of participants who completed the intervention and the number who started it.²⁷ Reasons for participant dropout were documented.^{27, 34, 37, 38, 41-43} A retention rate of $\geq 90\%$ was considered the criterion for success.^{27, 37}

Follow-up of individuals at two post-intervention time points was assessed by calculating the proportion of individuals who remained in the group to which they were initially allocated through to the follow-up (week-12 e week-16), relative to the total number of individuals originally allocated.^{27, 40, 43}

Attendance was calculated as the ratio of the number of sessions completed to the total number of sessions offered.^{14, 27, 34, 37, 40} The number of missed sessions and the reasons for absence were documented.^{14, 27, 34, 37, 40} Completion of at least 85% of the 11 proposed home-based sessions was considered a criterion for success.^{27, 37}

Safety was assessed based on the number and causes of adverse events (e.g., pain, falls, hospitalizations, and deaths) reported during the intervention and follow-up periods.^{14, 27, 37, 40-42}

Satisfaction with the treatment was assessed using the statement: "Overall, I am satisfied with the type of treatment I received", with the following response options: "totally agree", "partially agree", "agree", "neither agree nor disagree", "disagree", "partially disagree", and "totally disagree".²⁴ A success criterion was defined as $\geq 90\%$ of participants selecting "totally agree", "partially agree", or "agree".^{27, 37} For situations in which participants responded "disagree", "partially disagree", or "totally disagree", the reasons for their responses were identified.

Perceived effectiveness was assessed with the following question: “Comparing how you were before you carried out the intervention and now, do you think that your ability to perform routine physical activity is: much worse, moderately worse, a little worse, the same, a little better, moderately better, or much better?”.²⁷

Feasibility of measurement

Feasibility of measurement was assessed based on two main indicators: (1) the percentage of clinical outcomes measured, calculated as the ratio between the number of clinical outcomes actually measured and the number initially proposed; and (2) the percentage of participants who completed the activity diary, calculated as the ratio between the number of individuals who filled out the diary and those who started the proposed intervention program.^{14, 27} A diary was considered complete if the participant provided information on physical activity for at least 75% (8 weeks) of the 11-week remotely delivered intervention.^{27, 44} The time required to collect outcome measures was recorded.²⁷ Additionally, the number and reasons for any adverse events (e.g., pain, falls, and hospitalization) identified during the assessments were documented.²⁷

Feasibility of blinding the outcome assessor

Blinding feasibility was assessed by calculating the number and percentage of group allocations correctly identified by the blinded outcome assessor.^{27, 45}

Cost

The costs related to conducting the study, including expenses such as team training, participant recruitment, assessments, and delivery of the intervention, were recorded.^{27, 46}

Clinical outcomes

Seven clinical outcomes were assessed: (1) physical activity levels; (2) the number of individuals post-stroke meeting the threshold for being physically active; (3) systolic blood pressure (SBP); (4) diastolic blood pressure (DBP); (5) cardiorespiratory fitness; (6) self-efficacy for physical activity; and (7) health-related quality of life.²⁷ The number of individuals post-stroke who met the threshold to be considered physically active could be assessed exclusively at the post-intervention time points (week-12 and week-16). Therefore, six outcomes were assessed at baseline (week-0), and all seven were assessed at the post-intervention follow-ups (week-12 and week-16).

Physical activity levels and the number of individuals post-stroke who became more physically active were measured using the Human Activity Profile (HAP).^{27, 35} The Adjusted Activity Score (AAS) was used to assess physical activity levels.^{27, 35} Another HAP measure, the Activity Rating, categorizes individuals as "Inactive", "Moderately active", or "Active".³⁵ The number of individuals post-stroke who became more physically active was also identified.^{27, 35} The instrument presents adequate measurement properties for use with individuals post-stroke.⁴⁷ As previously planned, the mean difference between groups and the standard deviation (SD) for the AAS outcome were proposed as parameters to estimate the sample size required for a future fully powered RCT.²⁷

SBP and DBP were assessed using a Tycos® aneroid sphygmomanometer (Welch Allyn Inc., NY, USA, Model DS44) and a stethoscope (Littmann Classic II SE 3M®, USA).²⁷ Blood pressure values were recorded in millimeters of mercury (mmHg).²⁷

Cardiorespiratory fitness was assessed using the HAP.^{27, 35, 48} One of its measures, Lifestyle Energy Consumption (LEC), was expressed in $\text{ml.kg}^{-1}.\text{min}^{-1}$.^{27, 48} The instrument is valid for estimating cardiorespiratory fitness in individuals post-stroke.⁴⁸

Self-efficacy for physical activity was measured using the Self-Efficacy for Physical Activity Scale, operationalized as the total score.^{14, 27, 49} The instrument demonstrates adequate validity, internal consistency, and reliability.⁴⁹

Health-related quality of life was assessed using the Stroke-Specific Quality of Life Scale (SSQOL), also operationalized as a total score.^{27, 50} The instrument presents adequate measurement properties for use with individuals post-stroke.⁵⁰

Sample size calculation

As this was a feasibility study, no formal sample size calculation was conducted.²⁹ Following the recommendation proposed by Julious⁵¹ for feasibility studies with parallel groups, the study included a sample size of 24 individuals, with 12 individuals in each group.²⁷

Statistical analyses

Statistical analyses were conducted by an independent examiner based on intention-to-treat principle. For participants who dropped out, the last observation carried forward (LOCF) method was applied to account for missing assessments.^{52, 53} Descriptive statistics were calculated for all outcomes. To date, no studies have established the minimal detectable change (MDC) or related metrics for the AAS outcome obtained from the HAP³⁵ in individuals post-stroke.²⁷ In a systematic review, Davidson et al.⁵⁴ estimated the MDC at 90% confidence for the AAS outcome in individuals with chronic conditions (e.g., chronic pain and arthritis), reporting a value of 6.8, which was used here as an

approximate reference. Changes exceeding this value were expected, particularly in the EG receiving the additional physical activity monitor. Effect sizes were calculated using Cohen's *d*, interpreted as small ($d=0.20$), medium ($d=0.50$), and large ($d=0.80$).⁵² The significance level was set at 5%, and all analyses were performed using SPSS version 21.0 (SPSS Inc., Chicago, IL, USA).

Results

Participants

Table 1 presents the sociodemographic and clinical characteristics of the 24 participants included in the study.

Table 1. Descriptive characteristics of participants

Variables	EG (n=12)	CG (n=12)
Age, y, mean (SD); [min-max]	68.92 (9.21); [55-86]	61.17 (8.63); [49-77]
Sex, n men (%)	7 (58.3%)	7 (58.3%)
Educational level, n (%)		
Illiterate and/or incomplete primary education	5 (41.7%)	5 (41.7%)
Primary education	4 (33.3%)	3 (25.0%)
Secondary education	3 (25.0%)	3 (25.0%)
Higher education	0 (0.0%)	1 (8.3%)
Cases of recurrent stroke, n (%)	5 (41.7%)	1 (8.3%)
Paretic side, n (%)		
Right	6 (50.0%)	6 (50.0%)
Left	5 (41.7%)	5 (41.7%)
Bilateral or not applicable	1 (8.3%)	1 (8.3%)
Time after stroke, months, mean (SD); [min-max]	35.25 (24.89); [7-85]	32.8 (37.85); [10-140]
Walking assistive device users, n (%)	6 (50.0%)	4 (33.3%)
Comfortable gait speed, m/s, mean (SD); [min-max]	0.62 (0.35); [0.06-1.01]	0.70 (0.32); [0.19-1.33]
Distance in the 6MWT, m, mean (SD); [min-max]	283.33 (174.04); [19-481]	308.58 (131.25); [77-508]

Legend: 6MWT - Six-Minute Walk Test; CG - control group; DBP - diastolic blood pressure; EG - experimental group; SBP - systolic blood pressure

Feasibility of recruitment

A total of 3,639 individuals post-stroke were approached and 66 were assessed to confirm their eligibility (Figure 1). Of these, 42 individuals were excluded, mainly because they were not physically inactive (69.0%), resulting in 24 individuals post-stroke (12 in each group) included in the present study. Recruitment feasibility measures were as follows: (1) the ratio of eligible individuals (n=24) to the total number of individuals assessed for eligibility (n=66) of 36.4%, which exceeds the predefined success threshold of 10%; (2) the ratio of eligible individuals (n=24) to the total number of individuals initially approached (n=3,639) of 0.66%; and (3) a recruitment period of eight months (from October 2023 to May 2024).

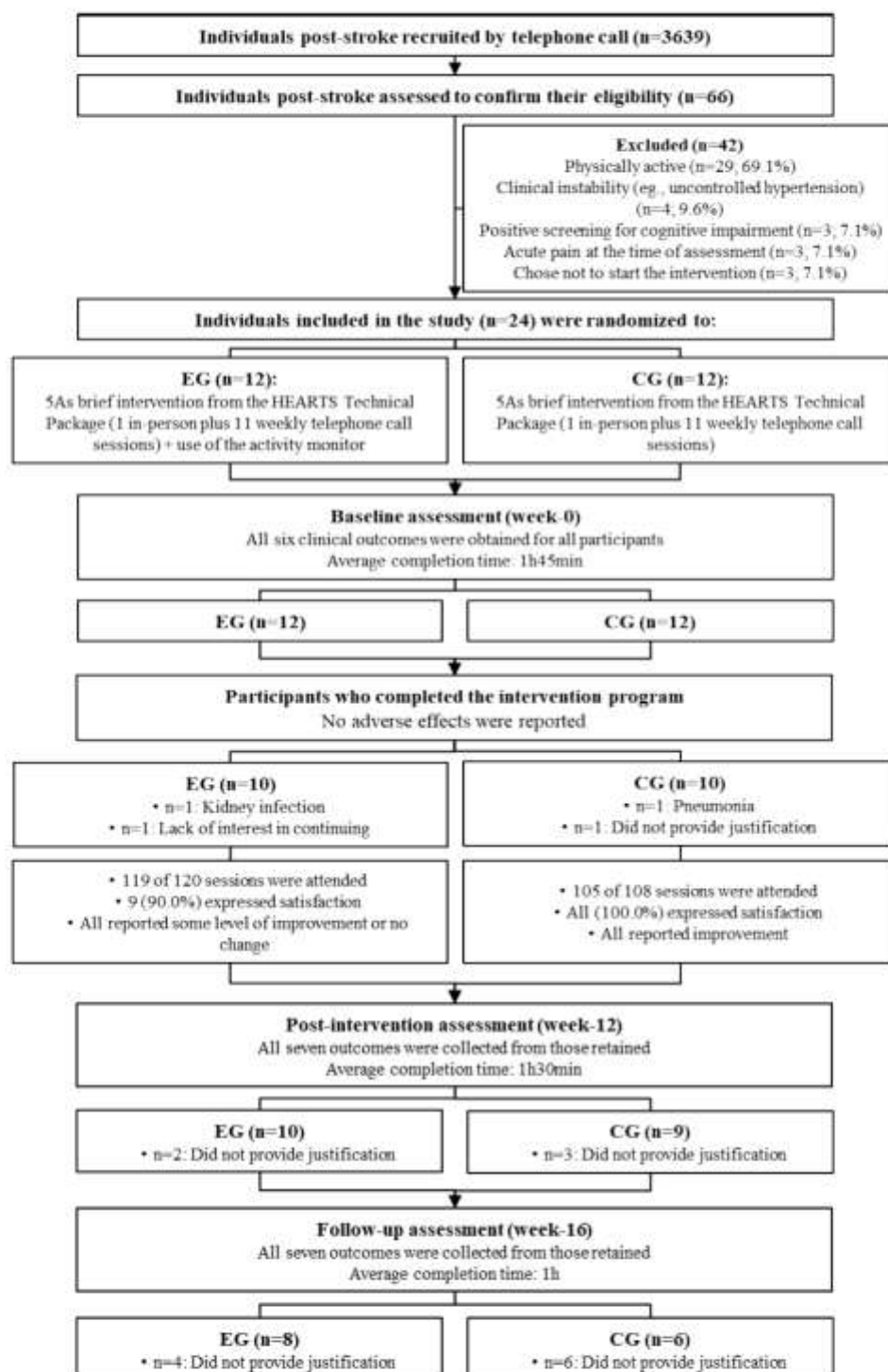


Figure 1. Feasibility outcomes of study conduct. **Legend:** CG - control group; EG - experimental group.

Feasibility of intervention

Retention

Of the 12 participants randomized to the EG, one discontinued participation due to a comorbid condition (kidney infection), and another withdrew citing a lack of interest in continuing. Of the 12 participants randomized to the CG, one discontinued participation due to pneumonia, and another withdrew without providing a justification. Therefore, 10 participants per group completed the intervention, yielding a retention rate of 83.3%, below the predefined success threshold of $\geq 90\%$.

Follow-up of individuals at two post-intervention time points

In the EG, 10 participants (83.3%) completed the post-intervention assessment (week-12), and 8 (66.7%) completed the follow-up assessment (week-16). Missed assessments (2 at week-12 and 4 at week-16) occurred without specific justification. Overall, 66.7% of EG participants (n=8) completed all follow-up phases of the study.

In the CG, 9 participants (75.0%) completed the post-intervention assessment (week-12), and 6 (50.0%) completed the follow-up assessment (week-16). Missed assessments (3 at week-12 and 6 at week-16) occurred without specific justification. Overall, 50.0% of CG participants (n=6) completed all follow-up phases of the study.

Attendance

Twelve sessions (1 in-person and 11 by telephone call) were offered to each of the 24 participants included in the study (12 in each group), totaling 144 sessions per group.

The 12 EG participants completed 132 sessions, resulting in an attendance rate of 91.7%. Among the 10 participants who completed the program, 119 of 120 sessions were

attended, resulting in an attendance rate of 99.2%, with one missed due to travel, as reported by the participant. The 12 CG participants completed 130 sessions, resulting in an attendance rate of 90.3%. Among the 9 participants who completed the program, 105 of 108 sessions were attended, resulting in an attendance rate of 97.2%. Participants did not provide a reason for the three missed sessions (one per participant).

As the first session was in-person and mandatory, absences were recorded only for telephone sessions. Among those who completed the intervention program ($n=10$ in the EG and $n=9$ in the CG), attendance rates for the 11 telephone call-based sessions were 99.1% for the EG (109 of 110 sessions) and 97.0% for the CG (96 of 99 sessions), both above the $\geq 85\%$ success threshold.

Safety

No adverse effects were reported. One participant in the CG reported an episode of falling during the study, unrelated to the intervention.

Satisfaction with the treatment

Among the 10 participants in the EG who completed the post-intervention assessment (week-12), 9 participants (90.0%) expressed satisfaction, meeting the success criterion. Of these, 8 (80.0%) reported being totally satisfied ("totally agree") and 1 (10.0%) reported being satisfied ("agree"), while one participant (10.0%) reported being not satisfied ("totally disagree"). The participant who reported being dissatisfied with the treatment received stated that he would have preferred the follow-up by the professional to be conducted in-person and that he would have liked to have a professional accompanying him during physical activity sessions.

Among the nine participants in the CG who completed the post-intervention assessment (week-12), all (100.0%) expressed satisfaction, also meeting the success criterion: seven (77.8%) reported being totally satisfied (“totally agree”) and two (22.2%) reported being satisfied (“partially agree”).

Perceived effectiveness

Among the 10 participants in the EG who completed the post-intervention assessment (week-12), all reported some level of improvement or no change: three (30.0%) reported being “much better”, two (20.0%) “moderately better”, four (40.0%) “a little better”, and one (10.0%) “the same”.

In the CG, all nine participants who completed the post-intervention assessment (week-12) reported improvement: five (55.6%) “much better”, one (11.1%) “moderately better”, and three (33.3%) “a little better”.

Feasibility of measurement

At baseline, all six outcomes were obtained for all participants. At week-12, all seven outcomes were collected from those retained (EG=10; CG=9). At week-16, all seven outcomes were obtained from the remaining participants (EG=8; CG=6).

In the EG, eight participants (66.7%) returned the physical activity diary at post-intervention (week-12), reporting data for an average of 8.8 (± 3.4) of the 11 remotely delivered weeks. Among them, six (75.0%) completed at least 8 weeks (75.0%) of remote sessions. In the CG, four participants (33.3%) returned the diary, with an average of 9.5 (± 1.7) weeks reported, and three (75.0%) also completed at least 8 weeks.

The average time required to complete the baseline assessments was one hour and 45 minutes; for the post-intervention assessment (week-12), one hour and 30 minutes; and for the follow-up assessment (week-16), one hour.

No serious adverse events were identified during the participants' assessments.

Feasibility of blinding the outcome assessor

The blinded outcome assessor correctly guessed the group allocation for 62.5% (n=15) of the 24 participants randomized: 7 (46.7%) in the EG and 8 (53.3%) in the CG.

Cost

The main study costs are summarized in Table 2. The primary expenses included transportation for both the research team and the individuals post-stroke, totaling approximately USD 675.00 (around R\$ 3,507.50), and the purchase of physical activity monitors, which amounted to about USD 543.00 (around R\$ 2,820.00). The overall cost was approximately USD 1,273.00 (around R\$ 6,697.10).

Table 2. Costs related to the conduct of the study

Item	Calculation	Unit cost (R\$)	Total cost (R\$)
Pre-intervention: training of the research project team			
Bus fare (in-person training)	2 bus fares/day for 5 evaluators (1 physiotherapist and 5 undergraduate physiotherapy students) x 5 days=50	5.75	287.50
Phone plan (participant recruitment calls)	1	20.00	20.00
Pre-intervention: baseline evaluation			
Bus fare (research project team)	2 bus fares/day for 2 evaluators x 22 days (66 individuals post-stroke evaluated, ~3/day)=44	5.75	253.00
Bus fare (participants)	2 bus fares/day for 66 individuals post-stroke=132	5.75	759,00
Printing of evaluation forms	10 pages x 66 individuals post-stroke assessed=660	0.20	132.00
Intervention			
Bus fare (physiotherapist-led in-person session; week-1)	2 bus fares/day to deliver the intervention to 24 participants=48	5.75	276.00

Bus fare (participants; in-person session during week-1)	2 bus fares/day to deliver the intervention to 24 participants=48	5.75	276.00
Phone plan (calls for conducting remote sessions)	8	20.00	160.00
Physical activity monitor	12	235.00	2,820.00
Post-intervention (week-12)			
Printing of evaluation forms	6 pages x 24 participants=144	0.20	28.80
Bus fare (research project team)	2 bus fares/day for 2 people x 24 days=96	5.75	552.00
Bus fare (participants)	2 bus fares/day for 24 participants=48	5.75	276.00
Post-intervention (week-16)			
Printing of evaluation forms	6 pages x 24 participants=144	0.2	28.80
Bus fare (research project team)	2 bus fares/day for 2 people x 24 days=96	5.75	552.00
Bus fare (participants)	2 bus fares/day for 24 participants=48	5.75	276.00
Total cost			6,697.10

Clinical outcomes

Means and SD across three assessment time points (week-0, week-12, and week-16), as well as within- and between-group differences for the physical activity level clinical outcome, are presented in Table 3. Physical activity levels increased in both study arms following the intervention, with a large within-group effect size in the EG (week-12 minus week-0: Cohen's $d = 1.01$; week-16 minus week-0: Cohen's $d = 1.07$), while the CG showed a medium within-group effect size (week-12 minus week-0: Cohen's $d = 0.76$; week-16 minus week-0: Cohen's $d = 0.63$). The descriptive data of the other clinical outcomes (number of individuals post-stroke meeting the threshold for being physically active, SBP, DBP, cardiorespiratory fitness, self-efficacy for physical activity, and health-related quality of life) at the three assessment time points (week-0, week-12 and week-16) are presented in Table 4.

Table 3. Means (SD) across three assessment time points and within- and between-group differences for physical activity level

	Groups						Difference within groups				Difference between groups	
Clinical outcome	Week-0		Week-12		Week-16		Week-12 minus week-0		Week-16 minus week-0		Week-12 minus week-0	Week-16 minus week-0
	EG (n=12)	CG (n=12)	EG (n=12)	CG (n=12)	EG (n=12)	CG (n=12)	EG (n=12)	CG (n=12)	EG (n=12)	CG (n=12)	EG-CG	EG-CG
Physical activity levels (total score)	41.67 (9.45)	36.42 (10.47)	53.75 (18.36)	48.25 (18.09)	53.92 (17.74)	46.58 (15.69)	12.08±12.01 ^a	11.83±15.51 ^b	12.25±11.46 ^c	10.17±15.99 ^d	0.25 (-11.49 to 11.99)	2.08 (-9.70 to 13.86)

Legend: ^a - Cohen's d = 1.01; ^b - Cohen's d = 0.76; ^c - Cohen's d = 1.07; ^d - Cohen's d = 0.63; CG - control group; EG - experimental group; SD - standard deviation

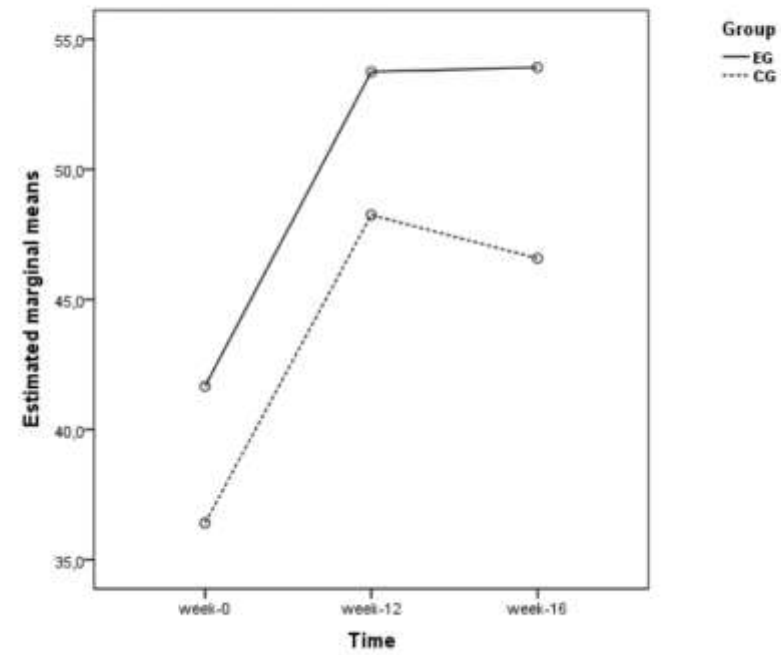


Figure 2. Estimated marginal means of physical activity level at week-0, week-12, and week-16. **Legend:** CG - control group; EG - experimental group.

Table 4. Means (SD) of all clinical outcomes, except physical activity level, for the EG and CG over time

Clinical outcomes	Week-0		Week-12		Week-16	
	EG (n=12)	CG (n=12)	EG (n=12)	CG (n=12)	EG (n=12)	CG (n=12)
Number of individuals who met the threshold to be considered physically active (n)	NA	NA	7	6	8	5
SBP (mmHg)	121.67 (16.42)	121.67 (14.03)	118.33 (14.67)	123.33 (13.03)	120.83 (16.76)	120.83 (11.65)
DBP (mmHg)	75.00 (9.05)	79.17 (10.84)	74.17 (9.00)	82.5 (9.65)	73.33 (8.88)	82.5 (8.66)
Cardiorespiratory fitness (ml.kg ⁻¹ .min ⁻¹)	13.25 (3.33)	11.83 (3.16)	17.25 (5.82)	15.58 (5.32)	17.25 (5.64)	15.08 (4.83)
Self-efficacy for physical activity (total score)	3.25 (1.82)	2.58 (2.27)	5.08 (2.94)	4.75 (2.73)	4.58 (2.75)	4.25 (2.93)
Health-related quality of life (total score)	172.17 (35.77)	150.25 (19.89)	162.92 (34.56)	150.58 (24.70)	165.33 (35.67)	152.67 (32.72)

Legend: CG - control group; DBP - diastolic blood pressure; EG - experimental group; NA - not applicable; SBP - systolic blood pressure

Discussion

This study aimed to investigate the feasibility of implementing a multifaceted, theoretically informed telehealth intervention delivered via telephone calls,¹⁹ and to examine whether adding a physical activity monitor to provide objective feedback²⁷ is important to include. This design enabled planning for a future larger-scale RCT to identify the effect of the additional use of a physical activity monitor on increasing physical activity levels among individuals post-stroke.²⁷ Positive results were observed for recruitment feasibility and intervention feasibility, although there were low retention rates and losses at post-intervention assessments (week-12 and week-16). Measurement feasibility also showed positive results, despite the low number of participants who returned their diaries at the end of the intervention. Most costs were related to transportation for both research staff and participants for the in-person assessments, as well as the purchase of physical activity monitors. Physical activity levels increased in both study arms, with large within-group effect sizes in the EG and medium effect sizes in the CG. These findings suggest that the addition of the physical activity monitor may enhance intervention outcomes. Although this feasibility study was not powered to detect within- or between-group differences, the results provide promising preliminary evidence and support the need for a fully powered RCT to formally evaluate intervention effectiveness.

The present study did not meet the criterion of retaining 90% of participants to achieve success in the retention rate.²⁷ An overall retention rate of 83.3% was observed across both groups. However, attrition rates of $\geq 20\%$ are generally considered problematic and pose serious threats to validity,^{55, 56} which was not the case in the present study. The reasons for participants not completing the intervention were as follows: one

discontinued participation due to a comorbid condition (kidney infection), another withdrew citing a lack of interest in continuing, one discontinued participation due to pneumonia, and another withdrew without providing a justification. Other health conditions have previously been identified as reasons for participant loss in clinical trial studies involving individuals post-stroke.^{13, 14, 16, 34} This is a non-modifiable factor inherent to the study design. On the other hand, the lack of interest in continuing, also previously reported in another study with individuals post-stroke,³⁴ may be related to low interest and motivation to engage in physical activity: a barrier frequently reported by individuals post-stroke when adopting this behavior.⁵⁷⁻⁵⁹ In this regard, it is important that future studies involving individuals post-stroke clearly identify the reasons for participant dropout in order to address this barrier.

The present study experienced participant losses at the post-intervention assessments (week-12 and week-16), which limited the ability to fully identify the outcomes of interest and, consequently, to determine the impact of the interventions. In these cases, participants declined to complete the assessments without providing a specific justification. Nevertheless, attendance rates during the intervention sessions were high (>90%). Since assessments were conducted in person, transportation costs, distance from participants' homes, and the time required to travel may have hindered their return to the university to complete them. Similar transportation-related barriers have been reported in other studies involving individuals post-stroke as obstacles to research participation.^{34, 60} Conducting assessments via telehealth could be a viable alternative to improve feasibility. However, a recent systematic review investigating the measurement properties and clinical utility of tools used in telerehabilitation for individuals with neurological conditions (including post-stroke) found no instruments specifically designed to assess physical activity after stroke remotely.⁶¹ Future research should

therefore examine the measurement properties of tools such as the PAH³⁵ for remotely assessing physical activity levels post-stroke, to support the implementation of effective intervention programs like the one proposed in this study.

An additional effect of using a physical activity monitor on increasing physical activity levels post-stroke was expected, based on the inclusion of the “Behavioral Regulation” domain of behavior change theory⁶² in the intervention.²⁷ This domain refers to strategies aimed at managing or changing objectively observed or measured actions,⁶² such as self-monitoring by tracking steps.²⁷ In the EG, eight of the twelve participants returned the physical activity diary at post-intervention (week-12), reporting data for an average of 8.8 (± 3.4) of the 11 remotely delivered weeks. In this context, in addition to the two dropouts in this group, two participants did not return the diary, which prevents determining whether they used it to record their step counts, consequently compromising the evaluation of the real impact of the additional use of the activity monitor. Caetano et al.¹⁴, who also proposed the use of a diary to monitor physical activity in individuals post-stroke, reported a lower adherence rate (28%), suggesting that this lower rate may be associated with the low educational level of the study population, which, as in the present study, consisted of Brazilian participants. An alternative approach to self-monitoring steps could involve low-cost technologies, such as social media messaging groups. This would allow continuous recording, self-monitoring, and reinforcement of results among participants.

The EG demonstrated a greater effect (large effect size) on the improvement of the clinical outcome of physical activity level post-intervention compared to the CG (moderate effect size). While the CG did not receive the activity monitor and thus lacked an objective, observable measure like step count, the intervention delivered to both groups included techniques related to “Action planning”, a construct within both the “Behavioral

regulation” and “Goals” domains.^{27, 62} According to Michie et al.⁶³, action planning involves prompting detailed planning of behavior performance, including elements such as context, frequency, duration, or intensity. Therefore, although the CG did not benefit from real-time feedback through step tracking, it was still exposed to strategies that may influence physical activity behavior. Recent findings by Gilchrist et al.⁶⁴ showed that behavior change technique (BCT) groupings with higher positive effects in physical activity interventions included “goals and planning” (particularly action planning), “feedback and monitoring”, “social support”, and “repetition and substitution”. The 5As brief intervention, as outlined in the HEARTS Technical Package,¹⁹ proposed in the present study incorporated several of these techniques,²⁷ which may help explain the positive outcomes observed in both groups.

Both groups showed improvements over time, with post-intervention changes exceeding the MDC at 90% confidence for the AAS outcome (6.8 points),⁵⁴ and the EG demonstrated larger gains in effect size than the CG, as expected.²⁷ In this context, the tested intervention²⁷, a free, theoretically informed, multimodal behavior change program delivered via telephone, appears to be a promising, low-cost, and widely accessible strategy to increase physical activity post-stroke. Although the physical activity monitor represented one of the main expenses for conducting this study, it remains a relatively low-cost technology compared with other options¹⁸. In addition, it has been reported that approximately 25% of physiotherapists already use physical activity monitors in daily rehabilitation care for individuals post-stroke, and that 79% of those who do not currently use them would like to do so in the future.⁶⁵ However, to formally recommend its use among individuals post-stroke as an additional strategy to increase physical activity levels, a RCT is required to investigate this added effect. To this end, future phases of this research should also address the barriers identified in the present study.

Among the main limitations of the present study, the high attrition rates observed in post-intervention assessments, particularly at the 4-week follow-up (week-16), stand out. Implementing remote assessments could help minimize missing data, enhance participant engagement, and reduce logistical barriers such as travel, thereby improving retention rates during longer follow-up periods in a future RCT. Additionally, the intervention addressed multiple theoretical domains of behavior change simultaneously,²⁷ which makes it challenging to determine which components were most effective in driving change. Strategies such as dismantling studies or factorial designs could be employed to isolate and assess the impact of each theoretical component on the observed outcomes.

Conclusion

This feasibility RCT demonstrated that the 5As brief intervention, as outlined in the HEARTS Technical Package,¹⁹ with or without the additional use of a physical activity monitor, delivered as a multifaceted, theoretically informed telehealth intervention via telephone calls, is feasible and results in clinical changes in physical activity levels post-stroke, with a greater effect observed in EG. However, careful consideration is needed in the design of a powered RCT to address the challenges related to participant retention and follow-up, in order to determine the added potential of using a physical activity monitor to increase physical activity levels post-stroke.

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CAPÍTULO 5

ESTUDO 4

CAPÍTULO 5 – ESTUDO 4

O artigo do Estudo 4, intitulado “*A scoping review of patient and public involvement in empirical stroke research*”, foi publicado em 2024 no periódico *International Journal of Stroke*.



Review



A scoping review of patient and public involvement in empirical stroke research

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Abstract

Background: Impactful, evidence-based solutions in surveillance, prevention, acute care, and rehabilitation for stroke survivors are required to address the high global burden of stroke. Patient and public involvement (PPI), where patients, their families, and the public are actively involved as research partners, enhances the relevance, credibility, and impact of stroke-related research.

Aims: This scoping review, adhering to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) Scoping Review guidelines, aims to identify and summarize how PPI is currently implemented and reported in empirical stroke research using a participatory approach.

Summary of review: A comprehensive search strategy was developed and implemented across Medline, CINAHL, EMBASE, PsynchrINFO, and Cochrane electronic databases, supplemented by gray literature searches. Empirical stroke research articles in the English language, published from 2014 up to 2023, and documenting PPI activity were included. Of the 18,143 original articles identified, 2824 full-text manuscripts matching from this time window were screened. Only 2% (n = 72) of these directly reported embedded PPI activity in empirical research. The majority were qualitative in design (60%) and conducted in high-income countries (96%). Only one included study originated from a developing country, where the burden of stroke is highest. Most studies (94%) provided some information about the activities carried out with their PPI partners, mainly centered on the study design (57%) and management (64%), with only 4% of studies integrating PPI across all research cycle phases from funding application to dissemination. When studies were examined for compliance with the Guidance for Reporting Involvement of Patients and the Public (GRIPP) short-form checklist, only 11% of included studies were 100% compliant. Twenty-one studies (29%) reported barriers and facilitators to including PPI in stroke research. Organization, authentic partnership, and experienced PPI representatives were common facilitators and identified barriers reflected concerns around adequate funding, time required, and diversity in perspectives. A positive reporting bias for PPI impact was observed, summarized as keeping the patient perspective central to the research process, improved care of study participants, validation of study findings, and improved communication/lay-summaries of complex research concepts.

Conclusions: PPI is underutilized and inconsistently reported in current empirical stroke research. PPI must become more widely adopted, notably in low- and middle-income countries. Consensus-driven standards for inclusion of PPI by funding organizations and publishers are required to support its widespread adoption.

Keywords

Patient and public involvement, patient engagement, patient participation, stakeholder involvement, stroke, review

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Introduction

Evidence-based solutions and active involvement of all invested parties is recommended in optimal stroke care.¹ Patient and public involvement (PPI) and/or engagement, often defined as research conducted “with” or “by” members of the public rather than “on,” “about,” or “for” them,^{2–4} actively engages patients, their families, and the public as co-researchers to make the research more relevant, credible, and impactful.^{2,5–9} While often confused with qualitative research or used interchangeably with co-design and participatory action research (where power is also redistributed between citizens and researchers), PPI partners are not study participants.¹⁰

Emergent PPI issues in research include inconsistent reporting, poor conceptualization, and limited information on context, processes, and impact provided.^{11–13} It has been contended that measuring PPI impact may not be possible and risks missing the intrinsic value of PPI in and of itself.^{14,15} However, existing evidence supports PPI as positively impacting research design and delivery and as being clinically impactful at the level of the individual in health-care research. Scoping reviews in pre-clinical research, cancer, dementia, orthopedic, and occupational therapy populations identify limited formal evaluation of PPI and mostly anecdotal evidence supporting improved research relevance, research design, and research ethics.^{16–21} Standards for reporting PPI in research, for example, the Guidance for Reporting Involvement of Patients and the Public (GRIPP), and checklists have been developed to improve the quality of reported PPI and ensure consistency across the international literature.^{8,22}

Stroke research has grown exponentially.²³ For example, the number of studies indexed under stroke in PubMed in 2020 was five times greater than that in 2010.²⁴ It is unknown whether adoption of PPI in stroke research has kept pace with this growth. Therefore, this scoping review aims to identify PPI uptake in empirical stroke research, summarize the available literature on how PPI is currently being implemented and reported, and identify any gaps. This scoping review actively involves a stroke survivor as a research partner, allowing their say in how this research is undertaken and providing unique insights.²⁵

Methods

Design

As the extent and nature of the phenomenon under review remains largely unknown, a scoping review was conducted.²⁶ Its purpose was to clarify the concept of PPI in the stroke literature; identify and map key characteristics or factors related to this concept and identify and analyze gaps in this emergent topic.²⁷ This review followed published scoping review guidelines,^{28–30} adhering to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis

(PRISMA) extended guidelines and checklist for scoping reviews.^{29,31} The protocol was co-produced with a PPI partner and pre-published.³²

Identifying the research question

The overarching review question simply asks: What PPI activities are conducted and reported in stroke research? Included articles were interrogated with the following questions:

- What types of stroke research utilize PPI?
- How is PPI in stroke research reported?
- What is the profile of PPI participants involved in stroke research, including representation of stroke-related disabilities?
- Where in the research cycle is PPI being used?
- What barriers and facilitators to PPI in stroke research are documented?
- What impact from PPI activities is documented?

Population, concept, and context (PCC) of the scoping review

The PCC structure helped define the review,²⁸ as per the published protocol:³²

- Population: individuals with lived experience of stroke, including stroke survivors, carers, and family members.
- Concept: PPI as described.^{2,3}
- Context: empirical stroke research.¹

Search strategy and inclusion/exclusion criteria

A comprehensive PCC search strategy was developed with a library liaison officer. Electronic databases, searched to January 2023, included PubMed, CINAHL, EMBASE, and PsycINFO. Gray literature databases (Leanus, OpenGrey,

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and relevant stroke organizational websites) were searched for additional relevant research. A sample search strategy is provided (Supplemental file 1).

Inclusion criteria comprised:

- Studies published from 2014 onwards. This criterion was imposed based on the volume of papers returned during searches from database inception and the clear cutoff timepoint provided by the first PPI in research guideline publication;
- Empirical stroke research including qualitative, quantitative, and mixed methods and, where directly referenced in the empirical studies, associated published consultation/PPI processes;
- English language publications;
- Studies documenting PPI activity/initiatives fitting the principles of PPI in research,^{2,3} irrespective of terminology.

Exclusion criteria:

- Studies that did not explicitly involve PPI partners;
- Studies reporting mixed populations or conditions other than stroke;
- Publications that did produce original empirical data (e.g., editorials, commentary pieces) and conference abstracts;
- Studies mistakenly reporting PPI activity: where the people with lived experience of stroke were study participants, not co-researchers.

Screening process

Identified studies were collated (duplicates removed) in Covidence review software and screened independently by title and abstract by two reviewers, drawn from a bank of reviewers (OL, PCP, RG, AR, LMC, POB, DM, CF, CDF). A conservative approach was taken whereby if the study met the empirical stroke research criterion, but PPI was not mentioned in the abstract, it progressed to full-text review. Full-text screening was independently conducted by two reviewers. A publication date cutoff from 2014 onwards was imposed at this stage. Conflicts arising between reviewers were resolved through wider group discussions (OL, PCP, CF, CDF).

Extracting and charting the data

A data extraction pro forma was developed for charting and extracting data,²⁸ aligned to the research questions. Study design was considered across the continuum from descriptive to exploratory to explanatory research as defined by Portney (2020).³³ PPI activity was staged according to the research cycle framework³ and reporting of PPI activity checked against GRIPP2 short-form

checklist¹¹ mandatory items. Two researchers (PCP and CF) independently extracted data items to ensure consistency. Per scoping review guidelines, study quality was not formally assessed.²⁸

Data synthesis

Extracted data were tabulated under predefined headings, providing a summary of the primary studies. Adherence to reporting guidelines was collated in tabular format. Narrative and graphical syntheses were next conducted, identifying the type and geographical representation of stroke research using PPI; the profile of PPI participants; where in the research cycle PPI was included;³ and barriers and facilitators to PPI and its impact in stroke research.¹¹

Results

Figure 1 details article retrieval, screening, and inclusion stages. From $n=18,143$, unique studies identified across the databases from inception to January 2023, $n=3874$, were eligible for full review ($n=2824$ from 2014 onward). Only 2% ($n=72$) of publications from 2014 onwards met the inclusion criteria.^{34–105} The included studies reporting PPI activity originated from high-income countries: United Kingdom^{35,37,38,40,41,46–48,52,55–58,60,62,65,68,71,72,78–80,83,84,86,87,89,91–96,100–103} ($n=37$, 52%), Ireland^{90,64,75–77} ($n=5$, 8%), United States^{36,39,51,59,104} ($n=5$, 8%), Australia^{44,74,90,99} ($n=4$, 6%), Canada^{67,70,81} ($n=3$, 4%), Germany^{43,63,85} ($n=3$, 4%), Sweden^{53,61,66} ($n=3$, 4%), Norway^{42,97} ($n=2$, 3%), Belgium⁴⁹ ($n=1$, 1%), Cyprus⁴⁵ ($n=1$, 1%), Netherlands⁸⁸ ($n=1$, 1%), Portugal⁹⁸ ($n=1$, 1%), and New Zealand⁵⁴ ($n=1$, 1%), higher-middle-income countries like China^{69,73,105} ($n=1$, 1%) and Malaysia³⁴ ($n=3$, 4%), and one lower-middle-income country Bangladesh⁸² ($n=1$, 1%; Figure 2).

A detailed table summarizing all included studies is available (Supplementary file 2), with a narrative summary addressing the review question provided below.

Types of stroke research utilizing PPI

Descriptive research was most represented (qualitative $n=43$; survey $n=10$). Exploratory research designs identified included cohort ($n=4$), methodological ($n=12$), and correlational/predictive ($n=1$) studies. Explanatory research, identified in six studies, described pragmatic clinical ($n=4$), randomized control ($n=1$), and quasi-experimental ($n=1$) trials. Three studies synthesized existing data.

PPI reporting in stroke research

Only 13% ($n=9$) of manuscripts included a definition of their PPI concept. A greater percentage (67%; $n=48$) detailed the PPI activities undertaken. The included studies'

Figure 1. PRISMA flow chart depicting search results and study selection.

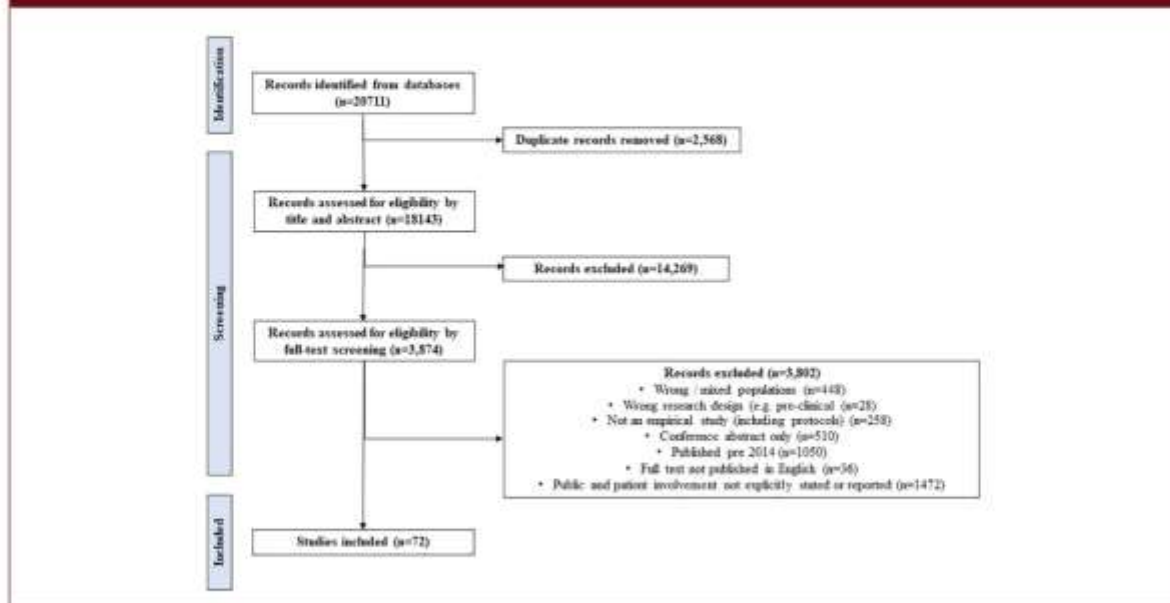
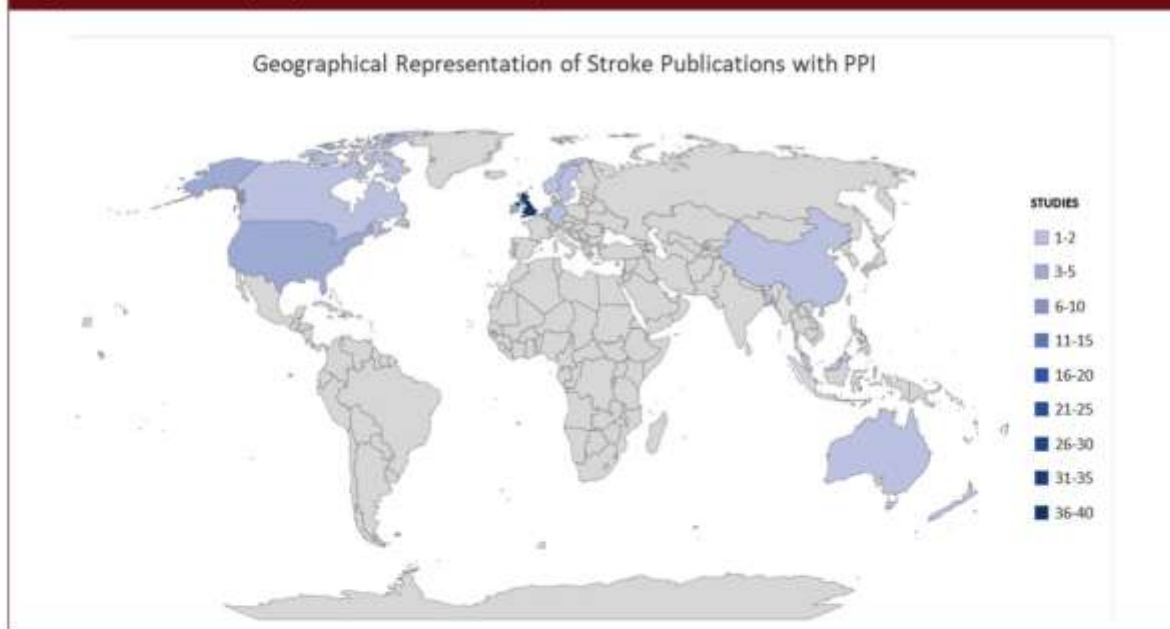
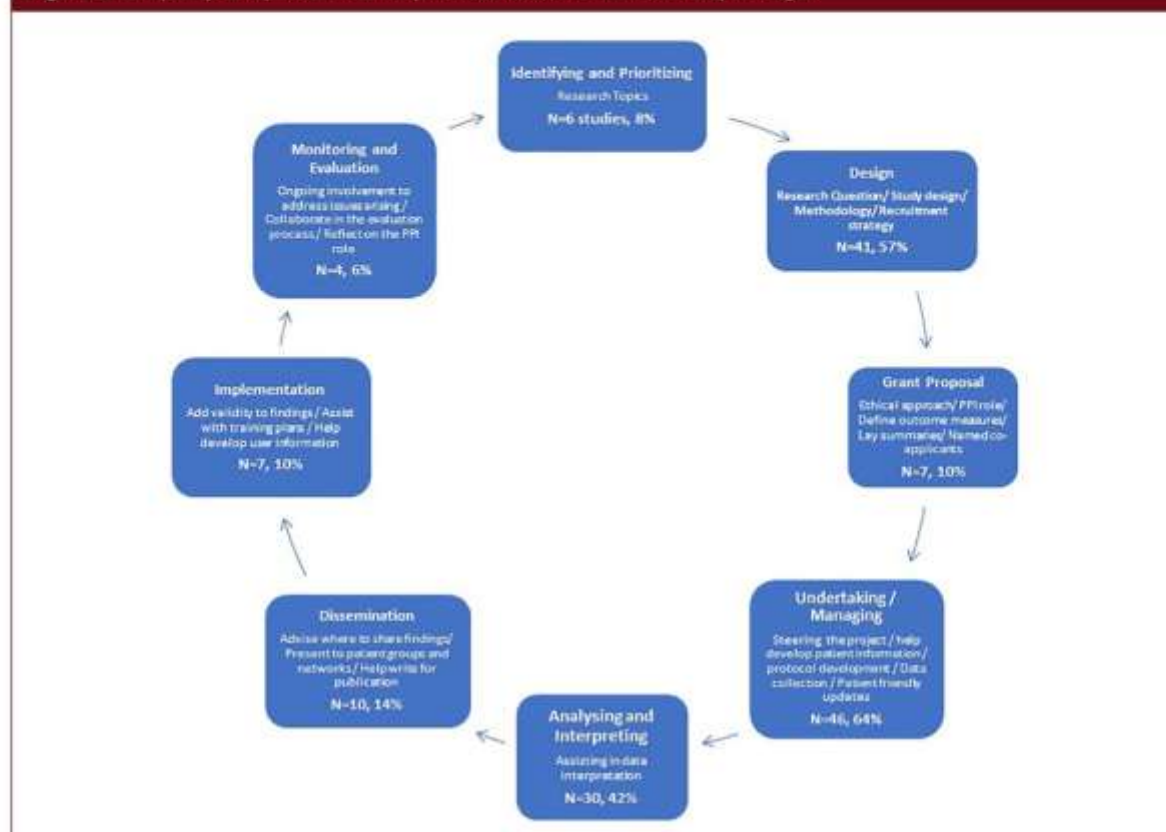


Figure 2. Global heatmap of publications with PPI in empirical stroke research.



compliance with the GRIPP2¹¹ short-form checklist items for reporting PPI are detailed (Supplementary file 3). Five studies (7%) failed to report any items.^{44,57,58,70,72} One study (1%) cited the GRIPP2 checklist, eight studies (11%)

demonstrated 100% compliance with all checklist items (mandating both positive and negative discussion and reflection items), and 25 studies (35%) partially reported all five checklist items. Across all studies, the aims (n=65,

Figure 3. Frequency of reported PPI in empirical stroke across the research cycle stages.

90%) and methods ($n=65$, 90%) checklist items were most consistently reported. Notably, many studies (57%) failed to critically reflect on their PPI activities.

Profile of PPI participants involved in stroke research

All studies provided information whereby PPI representation could be identified; 64% ($n=46$) reported information about the profile of their PPI partners, primarily sex and/or age, with one study providing ethnicity. Where the number of PPI partners across the studies was reported, $n=285$ were people with stroke (ages ranging from 32 to 91 years and time from stroke between 2 and 12 years); $n=44$ were family members/carers; and $n=46$ studies referenced public representatives/stroke support organizations. Stroke-related disability, where reported, reflected the research topic: $n=15$ (21%) reported aphasia; $n=3$ (4%) visual impairment; $n=3$ (4%) cognitive difficulties; $n=1$ (1%) mood issues; $n=1$ (1%) motor weakness unspecified; and $n=1$ (1%) upper-limb weakness. No study profiled wheelchair-use or mobility issues.

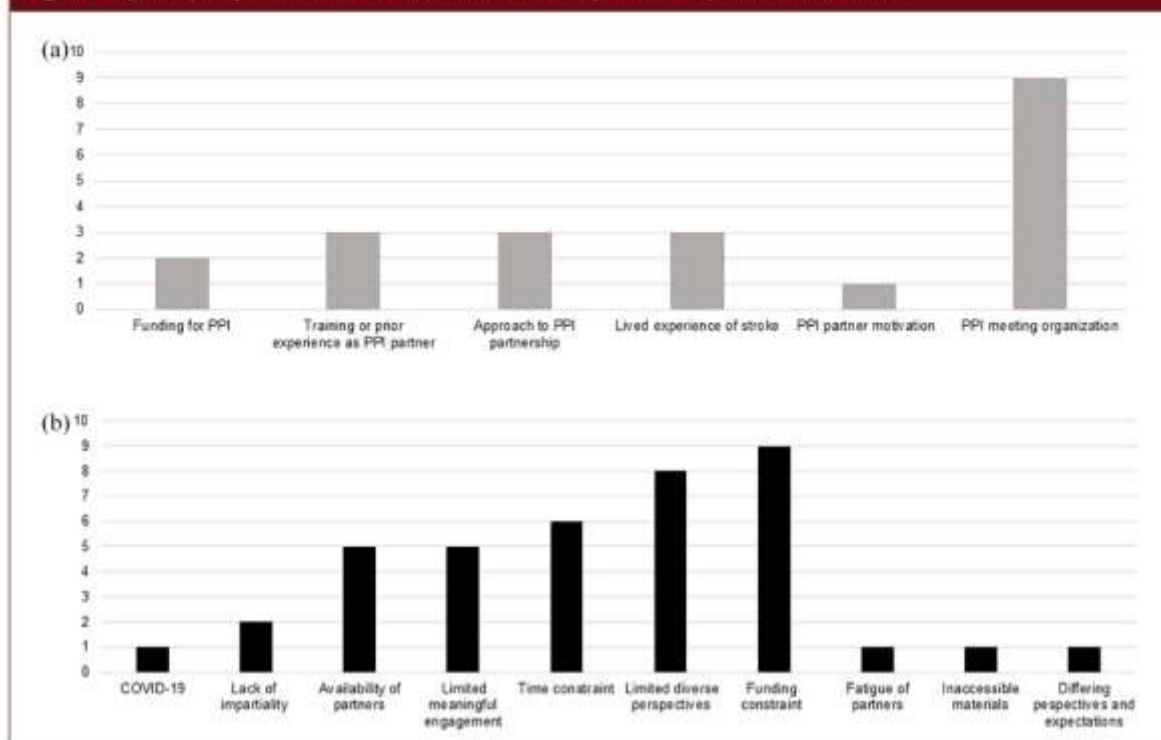
PPI across the research cycle

Sixty-eight studies (94%) provided information about their PPI activities, summarized in Figure 3 under the published National Institute for Health and Care Research (NIHR) PPI research phases. Three studies (4%) integrated PPI across all research phases.^{37,98,104} The majority included PPI in undertaking/managing research ($n=46$, 64%) and study design ($n=41$, 57%). Five studies (7%) reported PPI contributions in the acknowledgment section or named a PPI co-author without elaboration,^{44,57,58,70,72} meaning activities/contributions to research cycle stages could not be identified.

Documented barriers and facilitators to PPI in stroke research

Only 29% of studies ($n=21$) reported facilitators and/or barriers to PPI integration in their research. The most frequently reported facilitator was well-organized PPI meetings, alongside aspects including trained/experienced PPI partners and authentic partnership (Figure 4(a)). Barriers to PPI in stroke research primarily reflected funding, limited PPI diversity, and time constraints (Figure 4(b)).

Figure 4. (a) Frequency of facilitators and (b) barriers to PPI reported in empirical stroke research.



Documented impacts of PPI activities

Of the studies ($n=40$, 56%) reporting impact (Supplementary file 2), only positive items were documented including that the insights provided by PPI representatives improved the care of study participants, helped validate findings, kept patient perspectives central to the research process, and improved communication/lay-summaries of complex concepts.

Discussion

This scoping review, conducted with its primary aim to clarify the concept of PPI in empirical stroke research,²⁷ identifies poor uptake and reporting of PPI in stroke despite PPI being a well-supported research concept for over 20 years.^{3,106–112} Only 2% of articles reviewed reported PPI activity. The need for wider education in stroke research about PPI and facilitation of PPI activities in future stroke research is evident, alongside gaps identified in current PPI practices. PPI, where reported in stroke research, was feasible to embed in descriptive, exploratory, explanatory, and synthesis methods.

The United Kingdom dominates published PPI-embedded stroke research, as identified in previous scoping reviews addressing PPI.^{17,18,113} Results likely reflect the

countries where policy-driven initiatives have promoted PPI in healthcare.^{3,107–111} All studies included in this review, with one exception, were conducted in developed countries. Results further emphasize the need for widespread support of PPI around the world, particularly in middle- and low-income countries, where 90% of all stroke-related deaths and the stroke burden (e.g. higher disability-adjusted life years)¹¹⁴ are concentrated.

Clinical trials alongside implementation science address efficacy and effectiveness of interventions. These make a substantial contribution to evidence-based care³³ and are most likely to benefit from PPI.¹¹⁵ Only six clinical trials in stroke (8%) were included in this review, signaling a lack of PPI contribution to current high-level stroke research. Furthermore, four of these failed to sufficiently detail their PPI activities (see Supplemental Table 2). PPI in clinical trials can include research priority setting, study design (including selection of outcomes), as well as dissemination and implementation of trial findings.^{116–118} Evidence identifies PPI inclusion can improve recruitment and retention and increase the uptake of research findings by better meeting healthcare consumers' needs.^{116,119} Person-centered care, characterized by a strong partnership between patient and clinician, is already strongly endorsed,⁷¹ but partnership is also needed in the scientific evidence that underpins

care to be truly responsive to the needs and priorities of people with stroke.

Inconsistency was evident in how PPI was reported across studies. Often, quality of the engagement could not be determined (e.g. articles which included a PPI co-author or recognized PPI contribution in acknowledgements only), an approach that has been labeled as “virtue signaling” in the literature.¹¹⁸ This is important to address in future stroke research to eliminate current ambiguity on what constitutes PPI and its impact.¹²⁰ Standardized reporting guidelines reduce time and reporting biases and increase manuscript quality and readers’ comprehension.¹²¹ We recommend PPI checklist items be adopted in stroke research reporting to ensure transparency and consistency across the international literature^{8,22} as inconsistencies were evident in this review’s findings. Indeed, authors of this review could not exclude studies by abstract, as PPI seldom appeared in this section.

Facilitators and barriers to PPI, with important considerations for future stroke research, were identified in $n=21$ studies in this scoping review. Organization, particularly with respect to PPI meetings, was the most-cited facilitator to successful PPI-implementation, although capacity-building for PPI partners and adequate resourcing of PPI activities were deemed important. In contrast, funding constraints, time required, and limited representation from marginalized groups were commonly identified barriers. We observed a positive reporting bias for PPI in stroke research.¹²² One of two previously identified pitfalls, summarized as the tale of two towers, was identified: (1) The Tower of Babel, where medical jargon/paradigms propagate impressions of academic elitism (identified in this review as inaccessible PPI materials), and (2) The Ivory Tower (not identified), where critical inputs from outside academia that challenge views are unwelcome.¹²²

Some limitations in this scoping review require consideration. We restricted our search to English language publications from 2014 onwards. It is possible we may have missed studies including PPI. We excluded articles that only described PPI methodologies and study protocols detailing PPI activity as they did not meet the criterion of empirical research. Where research cited a twinned article addressing its PPI methods, we did include this research. Many conference abstracts addressing PPI activities were eliminated. We justified these choices as consumers of research (clinicians, service funders/providers) usually seek empirical evidence, alongside patient preferences, to guide practice.^{123–125}

In keeping with GRIPP2 reporting items, we briefly reflect on PPI in this scoping review. Our PPI partner and co-author provided insights that helped refine the published protocol and shape the review questions. The review findings, considered from the perspective of someone with lived experience of stroke and experience as an active PPI panel member, helped expand our discussion points. Our

collaboration was facilitated by having a PPI partner with prior research experience and well-established working relations. PPI activities, conducted in personal time, required balancing work and family commitments.

Conclusion and future research recommendations

There is poor uptake of PPI in published stroke research currently, notably in low- and middle-income countries. Where included, articles reporting PPI lack consistency in what they report and how they report it. To improve the quantity and quality of PPI-embedded empirical stroke research, several key recommendations are made:

- Senior stroke researchers must lead by example, welcoming PPI as a necessary cultural change in research conduct.
- Experiential knowledge of PPI partners should be considered in all research cycle phases to improve relevance, quality, and validity of stroke research and to ensure opportunity for equitable partnership and contribution as authors.
- Investment in training for researchers and PPI partners is required to build working relations, establish clear roles and responsibilities, and ensure transparency in communication and documentation.
- Financial remuneration that reflects PPI partners’ time is required.
- Ethical engagement with diverse stroke communities is needed to ensure adequate representation in PPI partners.
- PPI should be integral to ongoing global efforts to build stroke research capacity in low- and middle-income countries.
- PPI should become a standard item for journal submission, including a reporting checklist (e.g. GRIPP2) for quality and consistency, and PPI should be referenced in the abstract/keywords.

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Supplemental material

Supplemental material for this article is available online.

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Supplementary file 1: Example of search strategy

Population: #3 = #1 AND #2	#1: patient* OR survivor* OR adult* OR famil* OR carer* OR caregiver* OR parent* OR stepfamil* OR step-famil* OR young-adult* OR consumer
	#2: stroke OR Poststroke OR "post-stroke" OR "Cerebrovascular disease" OR "Cerebrovascular disorder" OR CVD OR CVA OR "brain infarction" OR "Intracranial arterial diseases" OR TIA OR "transient ischemic attack"
Concept: #4	#4: "patient and public involvement" OR "patient involvement" OR "patient partnership" OR "patient collaboration" OR "patient engagement" OR "patient advocacy" OR "patient participation" OR "consumer participation" OR "consumer involvement" OR "consumer engagement" OR "stakeholder participation" OR "stakeholder engagement" OR "patient driven" OR "survivor participation" OR PPI OR PPIE OR "client participation" OR "experience based" OR "experience-based" OR experiential OR Consultation OR consultancy
Context: #7 = #5 AND #6	#5: stroke OR Poststroke OR "post-stroke" OR "Cerebrovascular disease" OR "Cerebrovascular disorder" OR CVD OR CVA OR "brain infarction" OR "Intracranial arterial diseases" OR TIA OR "transient ischemic attack"
	#6: research OR review OR investigate OR study OR project OR evaluation
Final Search	#3 AND #4 AND #7

Supplemental file 2: **Table 2.** Description of included studies.

Citation; country	Study Objective	Research type	Public and Patient Involvement		
			1. PPI Concept reported (yes / no) 2. Approach	PPI partners: 1. Population 2. Profile	PPI valuation, benefits, and/or impact
Ainuddin et al. 2021 ³⁴ Malaysia	Synthesize evidence for rehabilitation in falls and risk of falls after stroke in Southeast Asia.	Synthesis of research (scoping review) and descriptive (qualitative)	1. No 2. Consultation by focus group	1. Patients (n=6) Family/caregivers (n=7) Public representative/support organization (n=7 healthcare professionals) 2. Public representative/support organization: 5 physiotherapists, 1 occupational therapist, and 1 speech therapist; 1–5 years of professional experience.	• Scoping review was inadequate alone to gain a realistic view of practices in Southeast Asia. Stakeholder consultation provided added value.
Allen et al. 2019 ³⁵ United Kingdom	Examine the utility of simulation and machine learning to enhance SSNAP clinical audit outputs.	Exploratory (methodological)	1. No 2. Meetings (3 times during the course of the project)	1. Patients or caregivers (n=5) 2. NR	NR
Andrews et al. 2018 ³⁶ United States of America	Detail a novel approach to address the challenges of blending clinical care and research in a pragmatic clinical trial.	Descriptive (qualitative)	1. No 2. NR	1. Patients (n=2) Family/caregivers (n=2) 2. NR	• Ensured consistency with Belmont principles and regulatory requirements in testing complex interventions. • Kept the patient perspective central throughout the process for the team and the institutional review board. • Helped ensure that patients received better care during the study; patients and their caregivers saw that healthcare systems continue to learn how to improve post-stroke care; and patients and caregivers' choices were respected.

Aries et al. 2021 ³⁷ United Kingdom	Describe the role of PPI in a mixed-methods feasibility study (MoTaStim-Foot).	Descriptive (qualitative)	1. Yes 2. A series of interactive workshops and regular meetings	1. Patients (n=9)* Family/caregivers (n=9)* Public representative/support organization (n=5) *Numbers summed across workshops A and B 2. Patients: 3-12 years post-stroke Public representative/support organization: 3 experienced clinicians and 2 academic members	• Authors identified standards for PPI that worked well /could be improved including implementation of appropriate support and learning, good communication, enabling PPI advisors to influence governance of the research and evaluating the impact of PPI. • PPI contributions were deemed essential to inform the funding application and important for study management and overall research process. • No specific negative effects with such intensive PPI levels.
Barnfield et al. 2017 ³⁸ United Kingdom	Report the process of public involvement in the cocreation, improvement and dissemination of lay summaries in the COGFAST study.	Descriptive (qualitative and process evaluation)	1. Yes 2. Focus group	1. Patient (n=2) Family/caregivers (n=3) 2. Patient: 1 female Family/caregivers: 1 female	• Feasible and successful to prioritize and adapt lay summaries to communicate the findings of complex scientific research. • An evident strength was jargon identification missed by the academic team due to familiarity. • Insights likely to have resulted in more accessible resources for members of the public. • The authors endorsed the use of existing general guidelines on the production of lay summaries in conjunction with input from members of the public.
Bharmal et al. 2016 ³⁹ United States of America	Describe the CPPR approach to increasing stroke awareness and elicit community perspectives serving minority	Descriptive (qualitative)	1. No 2. Meetings at least weekly by phone or in person	1. Public representative/support organization (n=16; 3 community partners, 1 staff, 2 students, 10 community members)	• The majority of the members of the planning committee and Community Action Panel agreed knowledge about Los Angeles Stroke Intervention and Research Program increased and the symposium was valuable to their work.

	communities about stroke prevention and research participation.			2. NR	
Black et al. 2019 ⁴⁰ United Kingdom	Examine the organization of centralized acute stroke at different times of day/week in services, and explore temporal consistency variations.	Descriptive (qualitative)	1. No 2. NR	1. Patient (n=2) 2. NR	NR
Blatchford et al. 2022 ⁴¹ United Kingdom	Understand the potential role of self-management programs such as My Life After Stroke.	Descriptive (survey and qualitative)	1. No 2. Consultation meetings	1. Patients (n=NR) Family/caregivers (n=NR) Public representative/support organization (n=NR) 2. Patients or family/caregivers: survivor and carer support groups in the community Public representative/support organization: lay membership of the Programme Steering Committee and Intervention Development Group, a lay representative coapplicant, active engagement with The Stroke Association.	NR
Bogstrand et al. 2022 ⁴² Norway	Investigate multidisciplinary health professionals' experiences of long-term services for patients with mild to moderate poststroke cognitive impairment	Descriptive (qualitative)	1. No 2. Discussion	1. Patients (n=NR) Family/caregivers (n=NR) Public representative/support organization (n=NR) 2. Patients or family/caregivers: from a stroke organization	NR

	in a North Norwegian context.				
Busetto et al. 2022 ⁴³ Germany	Identify the patient pathways in acute stroke, including interactions from the perspective of stroke patients.	Descriptive (qualitative)	1. No 2. Discussion	1. Patients (n=NR) 2. Patients: Patient Council of the Department of Neurology 2. NR	NR
Cadilhac et al. 2016 ⁴⁴ Australia	Assess the effects of cognitive, language, or global impairments on participation in a stroke self-management program.	Exploratory (cohort)	1. No 2. NR	1. Advisory committee chair came from the National Stroke Foundation 2. NR.	NR
Charalambo us et al. 2022 ⁴⁵ Cyprus	Analyze and compare the views of and barriers and facilitators to PPI for people with aphasia and stroke survivors without aphasia.	Descriptive (qualitative)	1. Yes 2. Meetings	1. Patients (n=1) 2. Patients: 32-year-old female, with mild-moderate anomic aphasia; 5 years post stroke; master's degree in Research Methodologies and Stroke Ambassador of the Cyprus Stroke Association; the community social worker under the auspices of the European program "Solidary Network in Action" for the Municipality of Nicosia (Cyprus).	• The PPI partner helped the study team formulate the research questions and actively contributed to the study's methodology. • She reported a positive PPI experience during the study as co-researcher and felt well-supported. • She was a key player in the consensus meeting for the emergence of the four themes.
Clarke et al. 2021 ⁴⁶ United Kingdom	Report the process evaluation of the Collaborative Rehabilitation in Acute Stroke (CREATE) Study.	Descriptive (qualitative)	1. No 2. NR	1. Patient (n=NR) Family/caregivers (n=NR) 2. NR	• Provided important insights about participants' involvement that would not have been known otherwise

Donetto et al. 2021 ⁴⁷ United Kingdom	Discuss the liminality lens in understanding and interpreting behaviors and interactions between co-design participants for space and place in the stroke unit.	Descriptive (qualitative)	1. No 2. Participatory approach using interviews, events, and co-design groups	1. Patients (n=14) Family/caregivers (n=9) Public representative/support organization (n=21) Numbers summed across EBCD cycles 2. NR	• Visible changes to the environment were implemented as product of collective action including family members • Codesign and partnership continued beyond the celebration event.
Eltringham et al. 2019 ⁴⁸ United Kingdom	Explore and include the experiences of people with swallowing difficulties following stroke and informal caregivers in understanding delivery of care.	Descriptive (qualitative)	1. Yes 2. Participatory methods approach	1. Public representative/support organization (n=3) 2. NR	• Enriched the themes identified by the researcher, allowed validity checking of the conclusions from a stroke survivors perspective and highlighted findings that were relevant to people affected by stroke. • Identified the frequency of feeling words used by the participants describing their reactions to the stroke event and how they felt about the medical interventions and care processes. • Empathized with findings detailing lack of communication to patients about the importance of adequate nutrition and hydration and they perceived a lack of standardization in procedures and communication about the risk of pneumonia and transitioning from short term to long term nutrition. • Future improvements: sometimes members brought up things from their own experiences, which had not always been raised by the interview participants; and learning outcome for the future would be to include more time for building research skills and discussion

Espinoza et al. 2016 ⁴⁹ Belgium	1. Describe the practices and experiences with development and implementation of the Prehospital Stroke Study (PreSSUB) of in-ambulance telestroke; 2. Report PreSSUB-I pilot study results.	Exploratory (methodological)	1. No 2. Interview	1. Patients (n=NR) Public representative/support organization (n=NR) 2. NR	NR
Franklin et al. 2017 ⁵⁰ Ireland	Identify the top 10 research priorities for long-term aphasia.	Descriptive (survey and qualitative)	1. Yes 2. Survey and consensus meetings	1. Patients (n=31)* Family/caregivers (n=10)* Public representative/support organization (n=27) *Numbers summed across survey and consensus 2. Patients: 4 mild, 11 moderate, and 6 severe aphasia; among the other 10 patients, at least one individual with Wernicke-type aphasia, ages ranged from 48-91 years. Public representative/support organization: 27 speech and language therapists (hospital and community therapists)	• Top 10 research priorities relating to aphasia were identified by key stakeholders. • Demonstrated that people with aphasia are fully able to participate in research priority setting. • Using this methodology, rather than just “be researched”, people with aphasia were able to add their own knowledge, experience and perspective to “what should be researched”. The authors believe this is an important first step to ensuring that future aphasia research reflects what is important to those affected
Gesell et al. 2020 ⁵¹ United States of America	Describe stakeholders’ contributions to the design, conduct, and dissemination of findings from a multicenter pragmatic clinical trial.	Descriptive (qualitative)	1. No 2. Focus groups and group discussions	1. Patients (n=NR) Family/caregivers (n=NR) Public representative/support organization (n=NR) 2. Patients: female, African American, and rural North Carolinians.	• Engagement resulted in important changes to aspects of post-acute stroke care represented by stakeholder’s perspectives. • The diverse leadership team provided perspectives that were often different and sometimes even opposing, deemed to have resulted in better problem solving and products.

				Family/caregivers: represented varied income and educational levels and rural/urban areas. Public representative/support organization: hospitals, health systems, and training institutions: all relevant members of hospital based stroke teams (rural/urban areas), quality/performance improvement coordinators, case managers/social workers, nurse managers, patient education directors and senior hospital administrators. Community-based services: networks were aging service providers, caregiver support services providers and pharmacists (rural/urban areas). Advocacy organization, and policymakers: influential leaders involved in high level advising to support dissemination and sustainability (examples: National advocacy organization and Regional networks of health and human service providers	• Multiple study points where stakeholders drove engagement activities that clearly strengthened the study. • Inclusion of stakeholders in the design and implementation of future studies and programs recommended.
Golding-Day et al. 2022⁵² United Kingdom	Develop an online questionnaire and conduct a national survey to collate the views of orthotists, physiotherapists, and occupational therapists, on current practice and their perceptions of factors determining the delivery of orthotic interventions to stroke patients in the United Kingdom.	Exploratory (methodological) and descriptive (survey)	1. No 2. NR	1. Public representative/support organization (n=NR) 2. Public representative/support organization: a team of stroke clinicians including an orthotist, physiotherapist and occupational therapists, and stroke clinical academic researchers, and members of the Nottingham Stroke Research Partnership Group.	• The public representative (an orthotist and two occupational therapists) and stroke partnership group influenced the research team by their clinical and lived experiences of orthotic interventions.

Gustavsson et al. 2020 ⁵³ Sweden	To explore healthcare professionals' use / potential use of ICT to enable person-centred stroke rehabilitation.	Descriptive (qualitative)	1. No 2. NR	1. Public representative/support organization (n=1) 2. NR	NR
Hale et al. 2014 ⁵⁴ New Zealand	Adaptation of the Bridges stroke self-management program for people with stroke in New Zealand, and exploration of its acceptability to patients, extended family (whānau), health professionals, and support services.	Descriptive (qualitative)	1. No 2. Consultation and focus group	1. Patients (n=60)* Family/caregivers (n=NR) Public representative/support organization (n=17)* *reported in study for one phase only 2. Patients: age 50-80 years Family/caregivers: NR Public representative/support organization: managers and field officers of local branches and the central office of the Stroke Foundation of New Zealand in six towns and cities, physiotherapists and occupational therapists working in neurorehabilitation and the Stroke Foundation of New Zealand in three cities and towns	NR
Hazelton et al., 2022 ⁵⁵ United Kingdom	Assess the effectiveness of interventions addressing perceptual disorders after stroke on measures of performance in activities of daily living when compared to no	Synthesis of research (systematic review)	1. No 2. "Top and tail" approach	1. Patients (n=5) Public representative/support organization (n=4) 2. Patients: people with lived experience of stroke Public representative/support organization: expert clinical knowledge	- Following a detailed discussion with the stakeholder group, the authors refined and clarified the scope of the definition to include disorders affecting six areas. - In discussion with the stakeholder group, the authors decided how to address more complex, stroke-related disorders.

	intervention or control				
Hepworth et al. 2019 ⁵⁶ United Kingdom	Develop a patient reported vision-related quality of life outcome measure after stroke.	Exploratory (methodological)	1. No 2. Consultation, nominal group session and Delphi approach	1. Patients (n=177)* Public representative/support organization (n=64)* *summed across study phases 2. Patients: stroke survivors with visual impairment Public representative/support organization: eye specialists involved in stroke care (orthoptists, ophthalmologist, and occupational therapist)	NR
Hepworth et al. 2021 ⁵⁷ United Kingdom	Explore the reported symptoms of post-stroke visual impairment using epidemiology data.	Exploratory (cohort)	1. No 2. NR	1. NR (PPI coauthor named only) 2. NR	NR
Heron et al. 2017 ⁵⁸ United Kingdom	Assess the feasibility of a novel adapted home-based cardiac rehabilitation program.	Explanatory (pragmatic clinical trial)	1. No 2. NR	1. NR (PPI coauthor named only) 2. NR	NR
Hinckley et al. 2014 ⁵⁹ United States of America	Incorporate the views of people with aphasia on current research needs.	Descriptive (qualitative)	1. Yes 2. Nominal group technique	1. Patients (n=25 Suncoast Aphasia Support Group Members) 2. Patients: between year and 16 years post onset, with a range of types of severities of aphasia.	• Topics of importance to researchers that were not of particular importance to those living with impairment were identified underscoring the need for joint research priority areas. • Better consideration for dissemination of best practices and aphasia research results in an accessible manner for individuals with aphasia. • Productive process that enabled meaningful contribution to the

					discussion, review and edit of results.
Howard et al. 2021 ⁶⁰ United Kingdom	Determine factors predicting adaptation to visual impairment after stroke from an early stage.	Exploratory (cohort)	1. No 2. Consultation and regular involvement	1. Patients (n=NR) Public representative/support organization (at least 5) 2. Patients: Stroke survivors with visual impairment Public representative/support: members of VISable organization	NR
Hu et al. 2022 ⁶¹ Sweden	Develop a digital tool, Rehabkompassen® and conduct preliminary evaluation of the usability and feasibility of the developed instrument for both stroke patients and health care professionals in an out-patient clinical setting.	Exploratory (methodological) an descriptive (qualitative)	1. No 2. Iterative and participatory design process	1. Patients (n=NR) Public representative/support organization (n=NR) 2. Patients: NR Public representative/support organization: multi-professional medical staff with expertise in stroke rehabilitation, experts in biomedical engineering and human interaction.	- Based on the feedback from both patients and physicians, the instrument developed allowed rapid capture of a patient's unmet rehabilitation needs in clinical practice. - Both patients and medical staff involved in the development and evaluation of the instrument provided extra strength to the study.
Johnson et al. 2022 ⁶² United Kingdom	Develop an evidence-based, theory-driven, structured self-management programme for stroke survivors to address their unmet psychosocial and	Descriptive (qualitative)	1. No 2. Consultation workshops	1. Patients* Family/caregivers* Public representative/support organization (n=12) *n=4-8 in total 2. Patients: NR Family/caregivers: NR	Consultation highlighted priority areas for the self-management programme.

	information needs about stroke and stroke management.			Public representative/support organization: healthcare professionals (2 physiotherapists, 2 nurses, 1 occupational therapist, 1 speech and language therapist, 1 support worker and 2 consultants), Stroke Association manager, Stroke Association group leader and the Early Supported Discharge Stroke manager.	
Kampling et al. 2020 ⁶³ Germany	Describe the processes for development of practice guidelines to support decision-making by a multidisciplinary team in stroke rehabilitation in individual cases.	Descriptive (survey and qualitative)	1. No 2. Workshop and focus group	1. Patients (n=5)* Summed across phases where reported; NR for focus group study. Public representative/support organization (n=18) 2. Patients: patients who had a stroke with mild to moderate cognitive impairment. Public representative/support organization: experts with expertise in psychology, neurorehabilitation and rehabilitation, and/or neurosciences (3 clinical psychologists, 3 psychologists specialized in psychological (and occupational) research, 3 physicians, and 1 therapist for occupational, speech and physical therapy specialized in stroke care, respectively as well as a nurse representative, and an expert on rehabilitation) and the head psychologist of the German Statutory Pension.	NR
Kearns et al. 2019 ⁶⁴ Ireland	1. Co-develop a feedback questionnaire for people with aphasia who undertake ICT-delivered aphasia rehabilitation.	Exploratory (methodological) and descriptive (qualitative)	1. Yes 2. Collaborative co-design process through workshops	1. Patients (n=6) 2. Patients: 5 males, ages ranged from 43 to 76 years (60.7±11.3 years), 1.9–11.4 years post-stroke (5.8±3.8 years), presenting with mild to severe aphasia.	•Co-design, grounded on collaboration between those with a lived experience of aphasia and an SLT facilitator with expertise in ICT-delivered aphasia rehabilitation, resulted in a final product that reflects this collaboration. •Co-design provided opportunities for social interaction with other people

	2. Describe the collaborative co-design process. 3. Explore the experiences of the co-designers in the collaborative design process.				with aphasia and allowed co-designers to reflect on their own abilities. •The design process, including the interactions, was engaging and contributions were valued. •The development of a feedback questionnaire was time and labor intensive but was an appropriate and feasible approach that was valued by all involved. •The process was inclusive, co-designers reported feeling comfortable about contributing in the workshops, reflected in individual exit interviews. •People with aphasia can, and should, be included in all stages of aphasia research processes.
King et al. 2020⁶⁵ United Kingdom	Project future incidence, prevalence and cost of stroke among people aged 45 and over in the United Kingdom.	Exploratory /Observational (correlational /predictive)	1. No 2. Consultation through Delphi approach	1. Patients (n=NR) Public representative/support organization (n=2) 2. Public representative/support organization: members of Stroke Association	NR
Kjörk et al. 2022⁶⁶ Sweden	Develop a digital previsit tool and explore potential end user's perceptions prior to testing it in a clinical setting, using a participatory approach with stroke as a case example.	Exploratory (methodological)	1. No 2. Participatory co-design approach	1. Patients (n=1) 2. NR	•The participatory approach, using service design principles, led to the creation of a tool based on user needs.
Kwok et al., 2023⁶⁷	Explore patient and therapist	Descriptive (qualitative)	1. No	1. Patients (n=3)	•This research significantly benefitted from the addition of three patient

Canada	perspectives of outcome measures used post-stroke.		2. NR	2. Patients: experience of a severe stroke, ranging from two to ten years prior to the start of the research, with a variety of stroke consequences, including motor weakness and aphasia.	partners, who ensured the work reflected the patient experience.
Kyle et al. 2020 ⁶⁸ United Kingdom	Examine stroke care managers and health professionals' barriers and enablers to minimizing treatment burden and maximizing patient capacity.	Descriptive (qualitative)	1. No 2. Interviews	1. Patients Family/caregivers Public representative/support organization n=4 in total 2. NR	NR
Lam et al. 2022 ⁶⁹ China	Understand stroke survivors' expectations and perceptions of a home-based virtual clinic, and (ii) survivors' perceived facilitators of and barriers to receiving care at this virtual clinic.	Descriptive (qualitative)	1. No 2. NR	1. Patients (n=2) 2. NR	NR
Langstaff et al. 2014 ⁷⁰ Canada	To examine hospital length of stay and readmission rates following improved access to timely intensive home-based stroke rehabilitation.	Explanatory (quasi-experimental)	1. No 2. NR	1. NR specifically 2. Members of the Regional Stroke Steering Committee and partners of the Stroke Network of Southeastern Ontario.	NR
Lawrence et al. 2019 ⁷¹	Generate an evidence-based	Exploratory (methodological)	1. No	1. Public representative/support organization (n=NR)	Consultation enabled Delphi participants to consider the relevance and

United Kingdom	definition of non-pharmacological/no n-surgical stroke secondary prevention.		2. A structured, iterative process through Delphi approach	2. NR	meaningfulness of agreed key elements and draft definitions from stakeholders' perspectives.
Lievesley et al. 2022 ⁷² United Kingdom	Describe the methods and outputs of a multidisciplinary research team who developed an oral health intervention.	Descriptive (qualitative)	1. No 2. NR	1. NR (PPI coauthor named only) 2. NR	NR
Luo et al. 2015 ⁷³ China	Develop a PROM for patients with stroke that captures the patient's viewpoint.	Exploratory (methodological)	1. No 2. In-depth open-ended interviews	1. Patients (n=20)* Public representative/support organization (n=3) *Summed across study phases 2. Patients**: 8 female, 3 with age ≤ 45 years, 7 with ages between 45-65 years, and 5 with ages ≥ 65 , with varying educational levels **Profile absent for one study phase	Identifying the items of the Stroke-PROM by including face-to-face interviews with patients strengthened the content validity of the preliminary scale.
Lynch et al. 2021 ⁷⁴ Australia	Describe the process incorporating consumers and health professionals to systematically prioritize guideline recommendations for implementation.	Descriptive (survey)	1. No 2. Consultation through workshops and surveys	1. Patients (n=5) Family/caregivers (n=1) Public representative/support organization (n=104) Unspecified consumers (n=18) 2. Patients: NR Family/caregivers: NR Public representative/support organization: 81% female, median age 36 Consumers: 80% female, median age 51	- Feasible to implement an inclusive process, including patients and caregivers to systematically prioritize guideline recommendations for implementation. - Helps reveal a collective vision, overcome barriers and facilitate collective action towards successful implementation.
Manning et al. 2021 ⁷⁵ Ireland	Address under-representation of the perspectives of working aged adults with post-stroke	Descriptive (qualitative)	1. No 2. NR	1. Patients (n=4) 2. Patients: 3 females, working age living with post-stroke aphasia for 3-30 years	Improved the validity and transferability of the findings, with relevance for adults with post-stroke aphasia in other countries, and other patient groups with communication

	aphasia in social participation and living well with aphasia.				impairment from other etiologies.
Manning et al. 2022a ⁷⁶ Ireland	Explore the perspectives of adults with post-stroke aphasia on what has or would help them to live well.	Descriptive (qualitative)	1. No 2. Participatory research approach	1. Patients (n=4) 2. Patients: 3 females, working age living with post-stroke aphasia for 3–30 years	• Accessible, inclusive interviews were designed to facilitate meaningful participation of adults with post-stroke aphasia, including those with severe aphasia, and to obtain rich, relevant information.
Manning et al. 2022b ⁷⁷ Ireland	Explore the ways in which people emotionally integrate and regulate negative psychological responses to aphasia.	Descriptive (qualitative)	1. No 2. Participatory learning and action tools	1. Patients (n=4) 2. Patients: Individuals with post-stroke aphasia	NR
Marshall et al. 2020 ⁷⁸ United Kingdom	Trial of EVA Park (delivery platform) hosting a remote support group intervention.	Explanatory (pragmatic clinical trial)	1. No 2. NR	1. Patients (n=4) Family/caregivers (n=1) Public representative/support organization (n=3) 2. Patients: with aphasia	NR
McCormick et al. 2022 ⁷⁹ United Kingdom	Report the development of the See, Imagine, Move: Upper Limb Action Therapy (SIMULATE) iPadTM- based application and the results of an early feasibility study.	Explanatory (pragmatic clinical trial)	1. No 2. Steering group meetings	1. Patients (n=NR)* Family/caregivers (n=NR)* Public representative/support organization (n=2) *public and patient involvement and engagement (PPIE) representatives (n=3) 2. Public representative/support organization: a Stroke Association UK Coordinator, and an occupational therapist	• The findings suggest highly usable technology-dependent therapy can be designed and developed with people living with stroke, for people living with stroke.

McKevitt et al. 2015 ⁸⁰ United Kingdom	Investigate stroke survivors' research awareness, use of research evidence in their medical care and willingness to be involved in research processes.	Descriptive (survey)	1. No 2. Discussions	1. Patients (n=24) 2. Patients: members of an existing stroke patient research group	•An appropriate strategy was used to design and test the questionnaire by working with members of the target population.
Mir et al. 2018 ⁸¹ Canada	Synthesize the evidence supporting PFO closure plus antiplatelet therapy, antiplatelet therapy alone and anticoagulation alone on patients aged <60 years with cryptogenic stroke and PFO.	Synthesis of research (systematic review)	1. No 2. NR	1. Patients (n=3) Public representative/support organization (n=NR) 2. Patients: had experienced a cryptogenic stroke (two of whom had undergone PFO closure) Public representative/support organization: BMJ Rapid Recommendation panel	The patients stressed the importance of several outcomes and uniquely highlighted the importance of detailed information about the device or procedure-related adverse events.
Mondal et al. 2022 ⁸² Bangladesh	Gather evidence on the current prevalence and risk factors of stroke among Bangladeshi population using a survey instrument informed by people with stroke.	Descriptive (survey)	1. No 2. Discussion	1. Patients (n=NR) Family/caregivers (n= NR) 2. NR	NR
Morris et al. 2016 ⁸³ United Kingdom	Explore how community stroke staff understand their role and respond to the psychological needs of stroke patients and carers.	Descriptive (qualitative and survey)	1. No 2. Focus group	1. Public representative/support organization (n=22) 2. Public representative/support organization: psychologists, 3 Stroke Association co-ordinators and two volunteers, 23 females, average age 40.0 or average age 46.8 or average age 45.7	•Participant consultation to frame questions ensured that lack of familiarity with particular technical terms and techniques was not an impediment and that the language used was appropriate for the population. •However, this did entail the avoidance of some common terms and reference

				years; average length of service 8.2 or 3.2 years or 8.4 years; 4 of the staff were in management roles, the remainder had roles described as “stroke co-ordinators”, “peer support co-ordinators”, “communications support coordinators”. 7 members of the groups had current membership of professional bodies. 14 had qualifications in health and social care ranging from professional nursing and social work qualifications to certificates in specific therapies. 3 held management qualifications.	to specific intervention and assessment procedures.
Morris et al. 2022 ⁸⁴ United Kingdom	Describe initial development of We Walk, a multistage project to develop and pilot a theory-based, person-centred, dyadic behaviour change intervention to promote PA through outdoor walking in community-dwelling people with stroke.	Descriptive (qualitative)	1. No 2. NR	1. Patients (n=4) Family/caregivers (n=NR) Public representative/support organization (n=NR) 2. Patients: males with stroke Family/caregivers: patients’ female companions Public representative/support organization: members of two Scottish Chest Heart and Stroke Scotland support groups and local exercise groups.	•PPI helped inform final intervention refinement prior to piloting.
Nave et al. 2019 ⁸⁵ Germany	Determine the efficacy of aerobic treadmill based, physical fitness training on maximal walking speed and activities of daily living compared to relaxation.	Explanatory (randomized controlled trial)	1. No 2. NR	1. Patient (n=1) 2. NR	NR

Patchick et al. 2015 ⁸⁶ United Kingdom	Inform the development of a PROM for cognition by exploring stroke-survivor perspectives on the important, measurable impacts of persisting post-stroke cognitive problems.	Descriptive (qualitative)	1. No 2. Consultation	1. Patients (n=NR) 2. Patients: who had experience cognitive problems	• Communication aids were developed because of PPI input and guidance made qualitative interviews with cognitively impaired stroke survivors less challenging and possible. • PPI influenced the decision to interview stroke survivors independently of their carers as service users felt that a more open and honest dialogue would be achieved one-to-one. • The interview schedule was refined through pilot testing with cognitively impaired service users as part of the PPI process. This had the added benefit of providing training for researchers.
Porat et al. 2019 ⁸⁷ United Kingdom	Identify stakeholders' priorities and information needs in long-term stroke care. Codesign and evaluate an intervention integrated with the electronic health record system.	Descriptive (qualitative)	1. No 2. Active feedback using focus groups, face-to-face interviews and usability evaluations	1. Patients or family/caregivers (n=19) Public representative/support organization (n=30) 2. Patients: 4 female, average age of 65.5±11.4 years, ranging between 49–81; all had hypertension, 2 had heart problems, 1 was suffering from depression, 4 had mobility issues and 4 had minor cognitive deficiencies (attention and memory)) Public representative/support organization: 16 health and social care professionals, 6 commissioners and policymakers, and 8 general practitioners. General practitioners (4 men, 4 female, average of 10.3 years of experience in providing care to stroke survivors).	Engaging stakeholders throughout the design and evaluation process ensured that the intervention (features and functions) was in line with the needs reported by stroke survivors.
Prick et al., 2022 ⁸⁸	Develop a patient decision aid with integrated outcome	Exploratory (methodological)	1. No	1. Patients (n=1) Public representative/support organization (n=NR)	NR

Netherlands	information for hospitalized patients with stroke.		2. Co-creation sessions	2. Patients: NR Public representative/support organization: neurologists, rehabilitation specialists, geriatricians, a stroke nurse, an occupational therapist and a speech therapist	
Rai et al. 2021 ⁸⁹ United Kingdom	Optimization of a digital intervention for stroke patients a person-based approach with PPI.	Descriptive (qualitative)	1. Yes 2. NR	1. Patients (n=2) Public representative/support organization (n=2; Different Strokes Southampton and the Oxford Aphasia Group) 2. Public representative/support organization: a senior representative of Speakeasy (a charity supporting people with aphasia)	• Essential contributions to the design of the intervention and research decisions from an early stage. • Drove a person-based approach that will hopefully inform wider discussions regarding the development of complex health interventions to make them attractive, engaging, useable and most importantly beneficial, for the widest range of people.
Ramage et al. 2022 ⁹⁰ Australia	1. Provide practical guidance for researchers to co-produce interventions ready for clinical trial 2. Describe, as an exemplar, the development of the intervention package.	Descriptive (qualitative)	1. NR 2. Co-production	1. Patients (n=1) Public representative/support organization (n=4) 2. Patients: NR 2. Public representative/support organization: clinicians with research training and experience	• Early involvement of knowledge users within the co-production team was deemed critical in guiding the development of a more broadly acceptable intervention. • The authors felt the key elements, adaptations, or refinements resulting from knowledge user input played a crucial role in the success of the intervention. • The authors felt the process was a worthy investment of resources.
Rowe et al. 2017 ⁹¹ United Kingdom	Survey orthoptists' practice internationally in care provision for poststroke visual impairment.	Descriptive (survey)	1. No 2. Consultation	1. Public representative/support organization (n=NR; identified through non-specified stroke user forums in the United Kingdom) 2. NR	NR

Rowe et al. 2022 ⁹² United Kingdom	Co-develop a stroke-vision care pathway for stroke survivors with visual impairment.	Descriptive (qualitative)	1. No 2. NR	1. Patients (n=3) Public representative/support organization (n=5) 2. Public representative/support organization: 3 research and clinically active orthoptists, 1 neuro-ophthalmologist, 1 orthoptic professional society representative	NR
Sadler et al. 2016 ⁹³ United Kingdom	Development and preliminary evaluation of a novel intervention to promote resilience after stroke.	Descriptive (qualitative) and explanatory (pragmatic clinical trial)	1. No 2. Consultation and group discussion	1. Patients (n=NR) Public representative/support organization (n=NR) 2. Public representative/support organization: service user representatives from the King's College London Stroke Research Patients and Family Group	•Engaging service users in co-designing appropriate interventions improved their relevance and impact for longer-term outcomes in stroke and other populations.
Sadler et al. 2017 ⁹⁴ United Kingdom	Develop a process to engage stakeholders in the use of clinical and research data to co-produce solutions to improve long-term care for stroke survivors with multimorbidity.	Descriptive (qualitative)	1. No 2. Group meetings, focus groups, nominal group techniques and interviews	1. Patients Family/caregivers Public representative/support organization Total n=37 2. NR	•The stakeholder engagement study adds to the co-production literature in terms of reflecting on the benefits and methodological challenges of undertaking research informed by a co-production approach to improve health care, which has received little attention. •The process developed potential solutions and pragmatically prioritized those solutions in collaboration with users and providers of stroke services. Further work is required to evaluate the impact and implementation of co-produced data-driven interventions for long-term stroke survivors.
Shiggins et al., 2022 ⁹⁵ United Kingdom	Produce a Patient Research Experience Survey that would be accessible to people with aphasia.	Descriptive (qualitative)	1. Yes 2. Co-production	1. Patients (n=NR) Family/caregivers (n=NR) Public representative/support organization (n=NR)	•The project provides an example of how the research feedback mechanism can be made more accessible and inclusive, while working collaboratively with a range of stakeholders.

				2. Patients: people with aphasia with varying presentations and severities of aphasia (mild-severe) Family/caregivers: NR Public representative/support organization: academics, a clinician, and a representative from the NIHR	
Smith et al. 2018⁹⁶ United Kingdom	Investigate the experiences and ongoing needs of community-dwelling stroke survivors with upper limb dysfunction and that of their caregivers.	Descriptive (qualitative)	1. No 2. NR	1. Patients (n=NR) Family/caregivers (n=NR) 2. NR	NR
Solbakken et al., 2022⁹⁷ Norway	Describe the pragmatic priority setting process used to identify a prioritized top 10 list of research needs around communication and collaboration in transitional care for patients with acute stroke (TracStroke).	Descriptive (qualitative)	1. No 2. NR	1. Public representative/support organization (n=NR) 2. Public representative/support organization: health personnel and organizations for persons with stroke	NR
Sousa et al. 2019⁹⁸ Portugal	Collate national data on access to and delivery rates for acute stroke unit care, intravenous thrombolysis and endovascular treatment throughout Europe.	Descriptive (survey)	1. No 2. NR	1. Public representative/support organization (n=NR) 2. Public representative/support organization: Representative from SAFE patient organization	NR

Thayabaranathan et al. 2022 ⁹⁹ Australia	Describe the processes involved in co-designing a contextually appropriate yoga-based MBI for survivors of stroke and its formative evaluation.	Descriptive (qualitative)	1. No 2. NR	1. Patients (n=3) Family/caregivers (n=1) Public representative/support organization (n=NR) 2. Patients: NR Family/caregivers: NR Public representative/support organization: a clinical neuropsychologist, epidemiologist, statistician, exercise physiologist, occupational therapists, physiotherapists, yoga experts, basic scientists, and a neuroscientist	•The advisory committee helped ensure the manual-based program would be practical, achievable, and inclusive for participants of varying abilities.
Turner et al. 2019 ¹⁰⁰ United Kingdom	Explore patient and healthcare providers' experiences of: (i) residual problems post-TIA/minor stroke; (ii) the impact of TIA/minor stroke on patients' lives; (iii) current follow-up care and sources of support.	Descriptive (qualitative)	1. No 2. Consultation and discussion	1. Patients (n=NR) 2. NR	NR
Wairagkar et al. 2017 ¹⁰¹ United Kingdom	Develop a high dosage, combined language and motor rehabilitation tool for individuals with acquired brain injury; pilot with three stroke survivors.	Exploratory (methodological)	1. No 2. Consultation	1. Patients (n=2) Family/caregivers (n=1) 2. Patients: both suffered the stroke 11 months prior, suffered from aphasia and upper-limb weakness	•Patient members of the research team indicated satisfaction from a service user's perspective with the multimodal approach to rehabilitation techniques and enhanced usability for individuals with acquired brain injury. •Suggestions from service users were included in the games developed. •Involvement of service users in the design process, helped increase motivational aspects of the therapy and usability.

Webster et al. 2021 ¹⁰² United Kingdom	Investigate people with aphasia's perception of their current reading ability and activities and their feelings about reading.	Exploratory (methodological)	1. No 2. Consultation	1. Patients (n=10) 2. Patients: with chronic aphasia, with a mean time post-onset of 88.8 ± 36.12 months (range 27–143 months, 6 female, mean age of 67.7 ± 11.88 years (range 45–83). There was diversity in terms of years of education, previous occupation, type and severity of aphasia, and reading difficulties.	NR
Wilson et al. 2016 ¹⁰³ United Kingdom	Understand how service factors contribute to delays to specialist assessment following action to seek help from a healthcare professional.	Descriptive (qualitative)	1. No 2. NR	1. Steering group members with patient/carer experience from public representative/support organization (n=NR) 2. NR	•The process helped ensure the emergent understanding of issues associated with delays reflected patients' and general practitioners' perspectives rather than those of team members.
Xian et al. 2015 ¹⁰⁴ United States of America	Evaluate the association between warfarin treatment and longitudinal outcomes after ischemic stroke in the atrial fibrillation population.	Exploratory (cohort)	1. No 2. A series of focus groups and a qualitative survey	1. Patients (n=NR) Family/caregivers (n=NR) Public representative/support organization (n=NR) 2. Public representative/support organization: stakeholders representing the varied interests of patients, caregivers, physicians, nurses, healthcare systems, policy makers, governmental agencies, and professional societies.	•Patient co-investigators made high value contributions to both the design and the implementation of the study, retaining the rigors of the scientific work. •One of the strengths of the study is the integration of home time, which was a patient centered measure of longitudinal functional outcomes prioritized by stroke survivors and stakeholders.
Zhu et al. 2019 ¹⁰⁵ China	Development and psychometric evaluation of a scale for patients with stroke, at different stages of their rehabilitation..	Exploratory (methodological)	1. NR 2. Interviews, consultation using the Delphi approach	1. Patients (n=8) 2. Patients: 3 females; mean age of 64.38 ± 16.80 years; mean time since stroke of 15.00 ± 19.89 months; 7 ischemic stroke and 1 both ischemic and hemorrhagic	NR

Supplementary file 3. Adherence to GRIPP2 short form item across included studies.

Item	Aim	Methods	Study results	Discussion and conclusions	Reflections/critical perspective
Study	Were the aims of PPI in the study reported?	Were the methods used for PPI in the study described?	Were the results of PPI in the study, including both positive and negative outcomes reported?	Was the extent to which PPI influenced the study (both positive (+) and negative (-) effects) described?	Did the authors critically reflect on the things that went well (+) and those that did not in PPI (-)?
Ainuddin et al. 2021 ³³	Yes	Yes	Yes	Yes (+)	No
Allen et al. 2019 ³⁴	Yes	Yes	No	No	No
Andrews et al. 2018 ³⁵	Yes	Yes	Yes	Yes (+)	Yes (+ and -)
Aries et al. 2021 ³⁶	Yes	Yes	Yes	Yes (+ and -)	Yes (+ and -)
Barnfield et al. 2017 ³⁷	Yes	Yes	Yes	Yes (+ and -)	Yes (+ and -)
Bharmal et al. 2016 ³⁸	Yes	Yes	Yes	Yes (+)	Yes (+ and -)
Black et al. 2019 ³⁹	Yes	Yes	No	No	No
Blatchford et al. 2022 ⁴⁰	Yes	Yes	No	No	No
Bogstrand et al. 2022 ⁴¹	Yes	Yes	Yes	No	No
Busetto et al. 2022 ⁴²	Yes	Yes	Yes	No	No
Cadilhac et al. 2016 ⁴³	No	No	No	No	No
Charalambous et al. 2022 ⁴⁴	Yes	Yes	Yes	Yes (+)	Yes (+ and -)
Clarke et al. 2021 ⁴⁵	Yes	Yes	Yes	Yes (+)	No
Donetto et al. 2021 ⁴⁶	Yes	Yes	Yes	Yes (+)	Yes (+ and -)
Eltringham et al. 2019 ⁴⁷	Yes	Yes	Yes	Yes (+ and -)	Yes (+ and -)

Espinoza et al. 2016 ⁴⁸	Yes	Yes	No	No	No
Franklin et al. 2017 ⁴⁹	Yes	Yes	Yes	Yes (+ and -)	Yes (+ and -)
Gesell et al. 2020 ⁵⁰	Yes	Yes	Yes	Yes (+ and -)	Yes (+ and -)
Golding-Day et al. 2022 ⁵¹	Yes	No	Yes	Yes (+)	No
Gustavsson et al. 2020 ⁵²	Yes	No	No	No	No
Hale et al., 2014 ⁵³	Yes	Yes	Yes	Yes (+)	Yes (+ and -)
Hazelton et al. 2022 ⁵⁴	Yes	Yes	Yes	Yes (+)	No
Hepworth et al. 2019 ⁵⁵	Yes	Yes	Yes	Yes (+)	Yes (+)
Hepworth et al. 2021 ⁵⁶	No	No	No	No	No
Heron et al. 2017 ⁵⁷	No	No	No	No	No
Hinckley et al. 2014 ⁵⁸	Yes	Yes	Yes	Yes (+ and -)	Yes (+ and -)
Howard et al. 2021 ⁵⁹	Yes	Yes	No	No	No
Hu et al. 2022 ⁶⁰	Yes	Yes	Yes	Yes (+)	No
Johnson et al. 2022 ⁶¹	Yes	Yes	Yes	Yes (+)	No
Kampling et al. 2020 ⁶²	Yes	Yes	Yes	Yes (+)	Yes (+ and -)
Kearns et al. 2019 ⁶³	Yes	Yes	Yes	Yes (+ and -)	Yes (+ and -)
King et al. 2020 ⁶⁴	Yes	Yes	Yes	No	No
Kjörk et al. 2022 ⁶⁵	Yes	Yes	Yes	Yes (+)	Yes (+ and -)
Kwok et al., 2022 ⁶⁶	Yes	Yes	Yes	Yes (+)	Yes (+ and -)
Kyle et al. 2020 ⁶⁷	Yes	Yes	No	No	No
Lam et al. 2022 ⁶⁸	Yes	Yes	Yes	No	No
Langstaff et al. 2014 ⁶⁹	No	No	No	No	No

Lawrence et al. 2019 ⁷⁰	Yes	Yes	Yes	Yes (+)	No
Lievesley et al. 2022 ⁷¹	No	No	No	No	No
Luo et al. 2015 ⁷²	Yes	Yes	Yes	Yes (+)	Yes (+)
Lynch et al. 2021 ⁷³	Yes	Yes	Yes	Yes (+)	Yes (+)
Manning et al. 2020 ⁷⁴	Yes	Yes	Yes	Yes (+)	Yes (+)
Manning et al. 2022a ⁷⁵	Yes	Yes	Yes	Yes (+)	Yes (+)
Manning et al. 2022b ⁷⁶	Yes	Yes	Yes	No	No
Marshall et al. 2020 ⁷⁷	Yes	Yes	No	No	No
McCormick et al. 2022 ⁷⁸	Yes	Yes	Yes	No	Yes (+)
McKevitt et al. 2015 ⁷⁹	Yes	Yes	Yes	Yes (+)	Yes (+)
Mir et al. 2018 ⁸⁰	Yes	Yes	Yes	Yes (+)	No
Mondal et al., 2022 ⁸¹	Yes	Yes	Yes	No	No
Morris et al. 2016 ⁸²	Yes	Yes	Yes	Yes (+ and -)	Yes (+)
Morris et al. 2022 ⁸³	Yes	Yes	Yes	No	No
Nave et al. 2019 ⁸⁴	No	Yes	No	No	No
Patchick et al. 2015 ⁸⁵	Yes	Yes	Yes	Yes (+)	Yes (+)
Porat et al. 2019 ⁸⁶	Yes	Yes	Yes	Yes (+)	No
Prick et al., 2022 ⁸⁷	Yes	Yes	Yes	No	No
Rai et al. 2021 ⁸⁸	Yes	Yes	Yes	Yes (+)	Yes (+ and -)
Ramage et al. 2022 ⁸⁹	Yes	Yes	Yes	Yes (+ and -)	Yes (+ and -)
Rowe et al. 2017 ⁹⁰	Yes	Yes	No	No	No
Rowe et al. 2022 ⁹¹	Yes	Yes	Yes	No	No

Sadler et al. 2016 ⁹²	Yes	Yes	Yes	Yes (+)	Yes (+)
Sadler et al. 2017 ⁹³	Yes	Yes	Yes	Yes (+ and -)	Yes (+)
Shiggins et al., 2022 ⁹⁴	Yes	Yes	Yes	Yes (+ and -)	Yes (+ and -)
Smith et al. 2018 ⁹⁵	No	Yes	No	No	No
Solbakken et al., 2022 ⁹⁶	Yes	Yes	Yes	No	No
Sousa et al. 2019 ⁹⁷	Yes	Yes	No	No	No
Thayabaranathan et al. 2022 ⁹⁸	Yes	Yes	Yes	Yes (+)	Yes (+)
Turner et al. 2019 ⁹⁹	Yes	Yes	No	No	No
Wairagkar et al. 2017 ¹⁰⁰	Yes	Yes	Yes	Yes (+)	Yes (+)
Webster et al. 2021 ¹⁰¹	Yes	Yes	Yes	No	No
Wilson et al., 2016 ¹⁰²	Yes	Yes	Yes	Yes (+)	No
Xian et al. 2015 ¹⁰³	Yes	Yes	Yes	Yes (+)	Yes (+)
Zhu M et al., 2019 ¹⁰⁴	Yes	Yes	Yes	No	Yes (+ and -)

CAPÍTULO 6

ESTUDO 5

CAPÍTULO 6 – ESTUDO 5

O artigo do Estudo 5, intitulado *“Prioritizing components for a healthy lifestyle intervention post-stroke: A cross-country Patient and Public Involvement-based descriptive analysis”*, está submetido ao periódico *American Journal of Health Promotion*.

Title: Prioritizing components for a healthy lifestyle intervention post-stroke: a cross-country Patient and Public Involvement-based descriptive analysis

Running heading: Post-stroke lifestyle intervention: a cross-country PPI-based analysis

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Statements and Declarations

Ethical approval and informed consent statements: This study was approved by the Ethics Committee (Comitê de Ética em Pesquisa, Universidade Federal de Minas Gerais, CAAE: 7083023.0.0000.5149, number: 6.683.329, March 4, 2024). All individuals provided written informed consent before inclusion in the study.

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Data availability statement: The datasets generated and/or analyzed during the current study are not publicly available due to confidentiality agreements and ethical restrictions but are available from the corresponding author on reasonable request.

American Journal of Health Promotion

Prioritizing components for a healthy lifestyle intervention post-stroke: a cross-country Patient and Public Involvement-based descriptive analysis

Journal:	<i>American Journal of Health Promotion</i>
Manuscript ID:	Draft
Manuscript Type:	Quantitative Research
Keywords:	Stroke, Healthy Lifestyle, Secondary Prevention, Patient and Public Involvement, Cross-country comparison, Brazil, Ireland
Abstract:	Purpose: To identify similarities and differences in how individuals post-stroke in Patient and Public Involvement (PPI) panels in Ireland (high-income) and Brazil (middle-income) prioritize components for a healthy lifestyle intervention. Design: Descriptive, cross-sectional study. Setting: Participants rated core components across six behaviors (healthy diet, medication adherence, mood management, physical activity participation, safe alcohol consumption, and smoking cessation) as "definitely important," "maybe important," or "not important". Sample: Each country's PPI panel was composed of five individuals post-stroke. Measures: Frequencies of responses were calculated per behavior. A cross-country similarity was defined when a majority (>50%) from both panels rated a component the same ("definitely important" or "not important"); otherwise, perspectives were considered different. Analysis: Descriptive statistics. Results: Most components were rated "definitely important" by >50% in both panels, except for healthy diet. No component was largely deemed "not important". Differences emerged: only the majority of the Irish PPI panel rated "Have medications review with pharmacist/general practitioner" as "definitely important"; only the Brazilian panel rated all diet, physical activity, and smoking cessation components as "definitely important". Only in Ireland most PPI members rated 18-50% of the components across all behaviors as "maybe important". Conclusion: Shared priorities suggest common core elements for post-stroke lifestyle interventions, while differences emphasize the importance of cultural adaptation when implementing interventions across income settings.

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Prioritizing components for a healthy lifestyle intervention post-stroke: a cross-country Patient and Public Involvement-based descriptive analysis

Abstract

Purpose: To identify similarities and differences in how individuals post-stroke in Patient and Public Involvement (PPI) panels in Ireland (high-income) and Brazil (middle-income) prioritize components for a healthy lifestyle intervention.

Design: Descriptive, cross-sectional study.

Setting: Participants rated core components across six behaviors (healthy diet, medication adherence, mood management, physical activity participation, safe alcohol consumption, and smoking cessation) as “definitely important,” “maybe important,” or “not important”.

Sample: Each country’s PPI panel was composed of five individuals post-stroke.

Measures: Frequencies of responses were calculated per behavior. A cross-country similarity was defined when a majority (>50%) from both panels rated a component the same (“definitely important” or “not important”); otherwise, perspectives were considered different.

Analysis: Descriptive statistics.

Results: Most components were rated “definitely important” by >50% in both panels, except for healthy diet. No component was largely deemed “not important”. Differences emerged: only the majority of the Irish PPI panel rated “Have medications review with pharmacist/general practitioner” as “definitely important”; only the Brazilian panel rated all diet, physical activity, and smoking cessation components as “definitely important”. Only in Ireland most PPI members rated 18-50% of the components across all behaviors as “maybe important”.

Conclusion: Shared priorities suggest common core elements for post-stroke lifestyle interventions, while differences emphasize the importance of cultural adaptation when implementing interventions across income settings.

Keywords: Stroke, Healthy Lifestyle, Secondary Prevention, Patient and Public Involvement, Cross-country comparison, Brazil, Ireland

Indexing keywords: Stroke, Healthy Lifestyle, Secondary Prevention, Patient Participation, Cross-Cultural Comparison, Brazil, Ireland

1. Introduction

Stroke has a high global burden¹, being the third leading cause of death worldwide in 2020 and 2021, in both high-income countries (e.g., Ireland) and Latin American countries (e.g., Brazil)². Stroke is also the neurological condition that results in the most disability-adjusted life years (DALYs)³. Furthermore, projections suggest an increase in the global burden of stroke⁴. Recurrent stroke significantly contributes to the high stroke global burden⁵, with an incidence of around 20-30%⁵⁻⁷. Additionally, recurrent lead to greater disability than single episodes⁶. Considering that about 45-80% of recurrent strokes can be prevented⁸⁻¹⁰, stroke secondary prevention has been considered one of the pragmatic solutions to reduce the global burden of stroke¹.

Stroke secondary prevention reduces the risk of stroke recurrence and other major vascular events, as well as improving health and well-being of individuals post-stroke in their daily lives^{5,11}. Core elements of stroke secondary prevention interventions involve adherence to preventive medication and adoption of healthy lifestyle behaviors, which are aimed at controlling modifiable risk factors (e.g., hypertension and depression) related to the cause of first stroke and stroke recurrence^{5,9,12-14}. These interventions should be contextualized and person-centered, addressing the needs and priorities of individuals post-stroke and their families^{11,12}. Despite the adoption of healthy lifestyle behaviors being the core element of stroke secondary prevention^{5,12}, clinical guideline documents, mainly from low- and middle-income countries, have not included this recommendation¹⁵.

Recently, meta-analyses of randomized controlled trials (RCTs), developed through overviews of systematic reviews, demonstrated the effect of behavior change interventions in improving stroke secondary prevention outcomes^{12,16-18}. Face-to-face

behavior change interventions were effective in improving medication adherence, physical activity participation, smoking cessation, and modulating low mood post-stroke¹⁶. Telehealth behavior change interventions were effective in improving medication adherence, promoting healthy eating, and reducing systolic blood pressure (SBP)¹⁸. Both overviews of systematic reviews^{16, 18} highlight the need for future studies investigating the effect of theory-informed behavior change interventions on recurrent stroke, cardiovascular mortality and lifestyle-related behaviors. Furthermore, these studies^{16, 18} have shown that most evidence on behavior change interventions for stroke secondary prevention comes from high-income countries.

In high-income countries, there is scientific evidence supporting lifestyle-based stroke secondary prevention^{16, 18-22}. Studies from Ireland, where the Patient and Public Involvement (PPI) panel in this study is based, have explored predictors of adherence to healthy lifestyle behaviors post-stroke²³, and examined the barriers to adopting healthy lifestyles post-stroke²⁴. Additional studies provided evidence of increasing research in this area through published pilot and feasibility studies^{25, 26} and research protocols²⁷. These studies highlight ongoing efforts in this area, as well as significant financial support for research²⁸⁻³¹. Additionally, joint United Kingdom (UK) and Ireland stroke guidelines emphasize the importance of healthy lifestyle behaviors for stroke secondary prevention, including recommended parameters for physical activity (e.g., frequency and intensity)³², along with a plain language summary for individuals post-stroke³³. In contrast, middle-income countries like Brazil, which face a greater stroke burden³⁴, lack scientific evidence on the topic^{16, 18} and face barriers such as lack of specific research funding³⁵. While Brazilian clinical guidelines highlight the importance of the adoption of healthy lifestyle behaviors post-stroke³⁶⁻³⁹, they lack specific intervention guidance. Due to this

gap, Brazil relies on evidence from high-income countries like Ireland to promote healthy lifestyle behaviors post-stroke.

Behavior change, key to stroke secondary prevention interventions, is strongly influenced by factors such as social and environmental conditions⁴⁰. This study builds on the design of a fit-for-purpose stroke secondary prevention intervention in Ireland⁴¹, a country with a Social Progress Index (SPI) of 55.76, ranking 9th globally, based on dimensions such as health, security, and education⁴². The PPI input into the codesign workshops was also conducted in Brazil, which has a public health system (*Sistema Único de Saúde*, SUS) primarily serving low-income individuals⁴³ and with a SPI score of 72.35, ranking 55th globally, indicating a lower social state compared to Ireland⁴². Therefore, understanding the similarities and differences in perspectives of individuals with lived experience of stroke on components to be included in an intervention aimed at promoting the adoption of healthy lifestyle behaviors in these two distinct cultural and social contexts (Ireland and Brazil) is crucial. These insights will inform stroke secondary prevention actions, particularly in middle-income countries, where evidence on the topic is more limited^{16, 18}.

The objective of this study is to identify similarities and differences in how individuals post-stroke in Patient and Public Involvement (PPI) panels from a high-income country (Ireland) and a middle-income country (Brazil) prioritize components to be included in an intervention aimed at promoting the adoption of healthy lifestyle behaviors during co-design workshops.

2. Methods

2.1 Study design

This is a cross-sectional and descriptive study, approved by the Ethics Committee of the [blinded information]. The study was developed and reported according to Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines ⁴⁴. All individuals provided written informed consent before inclusion in the study.

2.2 Patient and Public Involvement (PPI) participants

A PPI panel of five individuals post-stroke was formed in each country (Ireland ⁴¹ and Brazil) to support wider research programs in stroke care and secondary prevention and to contribute to co-design workshops. The PPI panels in both countries were matched for age and sex, were in the chronic phase of stroke, and were able to walk independently: 1 female member, aged 51-65 years; 2 male members, aged 51-65 years; and 2 female members, aged 36-50 years.

PPI in research refers to the establishment of an active partnership between patients and/or members of the public (e.g., families, carers, and organizations who represent patients and users) and researchers ⁴⁵. In this approach, patients and the public are considered co-researchers and contribute to making the research more relevant and impactful ⁴⁵⁻⁵¹. PPI panel size is not formally defined. Studies that included PPI approach in stroke research have varied in the number of PPI patient representatives (individuals post-stroke), with many studies including around five individuals with lived experience of stroke ⁵².

2.3 Procedures

In-person workshops were conducted with PPI panels in Ireland and Brazil as part of a cross-country co-design initiative to build a theory-informed and fit for purpose stroke secondary prevention intervention ⁴¹. Two researchers (PP and CF) were present at both workshops. Previous workshops, conducted using the Stanford 5D framework situated in empathize, define and ideate phases ⁵³, resulted in the identification of 67 intervention components ⁴¹, organized under six categories: 5 components were identified as priority to encourage the adoption of a healthy diet, 17 components for medication adherence, 27 components for mood management, 10 components for physical activity participation, 4 components for safe alcohol consumption and 4 components for smoking cessation ⁴¹ (Supplementary Materials). During the PPI workshops, panel members were asked to prioritize these components for inclusion in the intervention. They rated each component using three options: “definitely important” (marked with green), “maybe important” (marked with orange), and “not important” (marked with red).

2.4 Statistical analysis

The frequency of component rating (“definitely important”, “maybe important” and “not important”) under each lifestyle behavior theme (healthy diet, medication adherence, mood management, physical activity participation, safe alcohol consumption and smoking cessation) was determined. A cross-country similar perspective was defined when the majority (>50%) of PPI panel members from both countries simultaneously rated the components as either “definitely important” or “not important”. Otherwise, a different perspective was considered between the two countries. Descriptive statistics were used.

3. Results

3.1 Cross-country similarities

Over half of the components proposed for five healthy lifestyle behaviors were simultaneously rated as “definitely important” by the majority (>50%) of PPI panel members from both countries: 65% of the components for medication adherence, 59% for mood management, 50% for physical activity participation, 50% for safe alcohol consumption, and 75% for smoking cessation. For the healthy diet behavior, only 40% of the components were simultaneously rated as “definitely important” by the majority of both panels. Figure 1 depicts these components. No component was simultaneously rated as “not important” by the majority of PPI panel members (Figure 2).

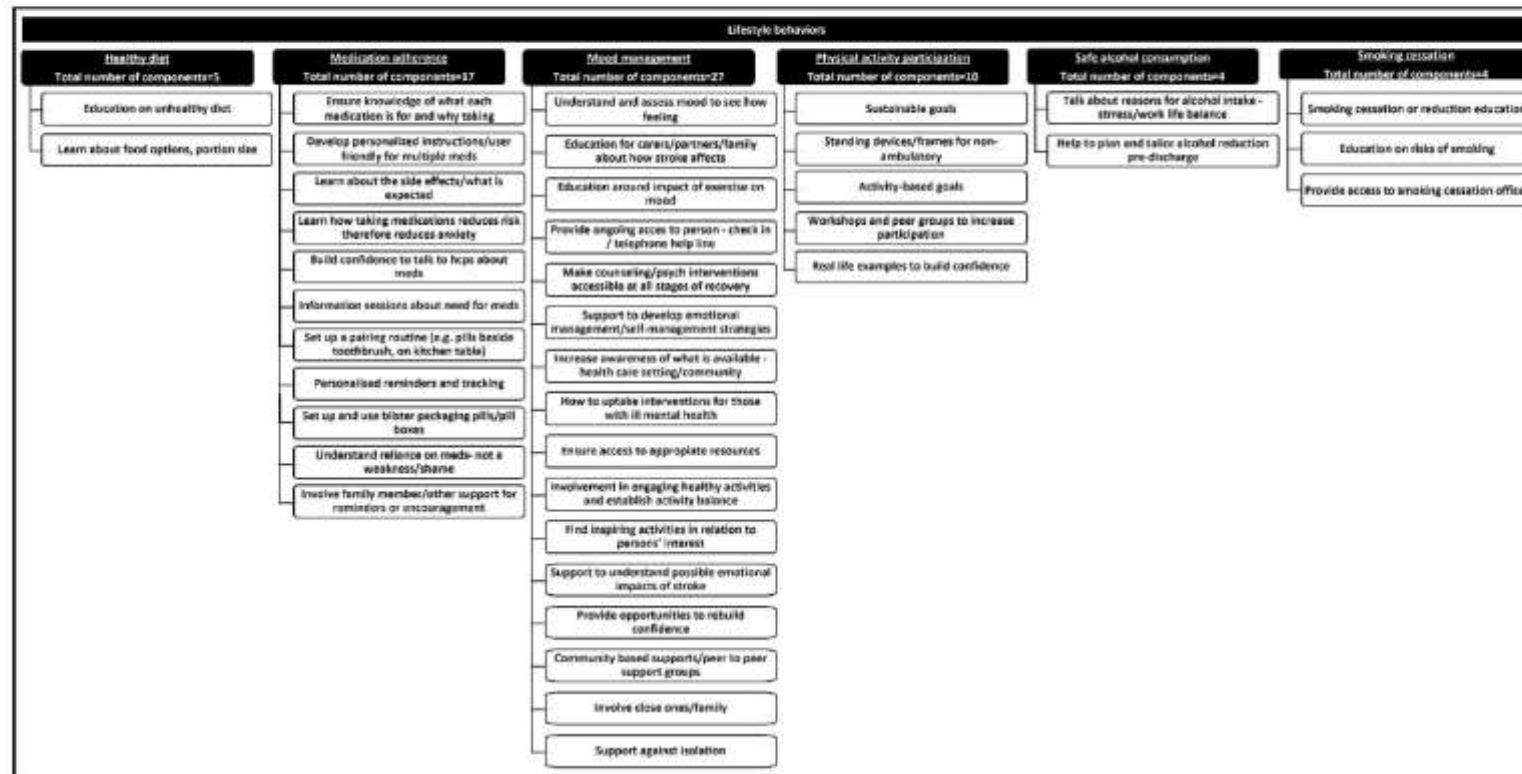


Figure 1. Components of a stroke secondary prevention intervention simultaneously rated as “definitely important” by the majority of PPI panel members in both Ireland and Brazil. Legend: PPI - Patient and Public Involvement.

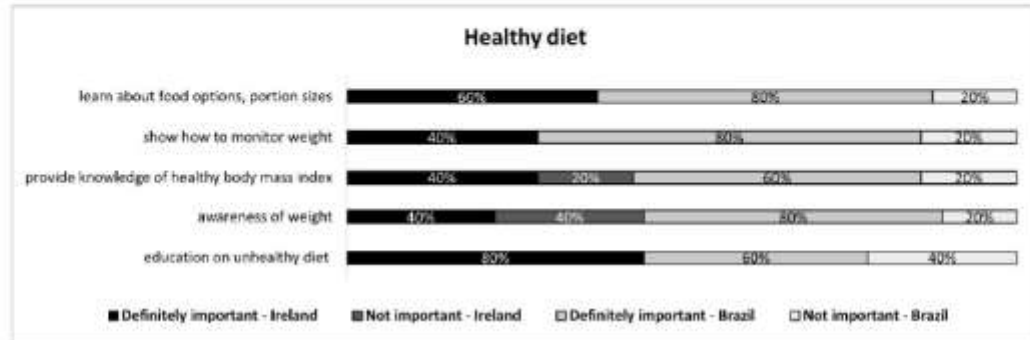


Figure 2a. Healthy diet components rated as “definitely important” or “not important” by country.

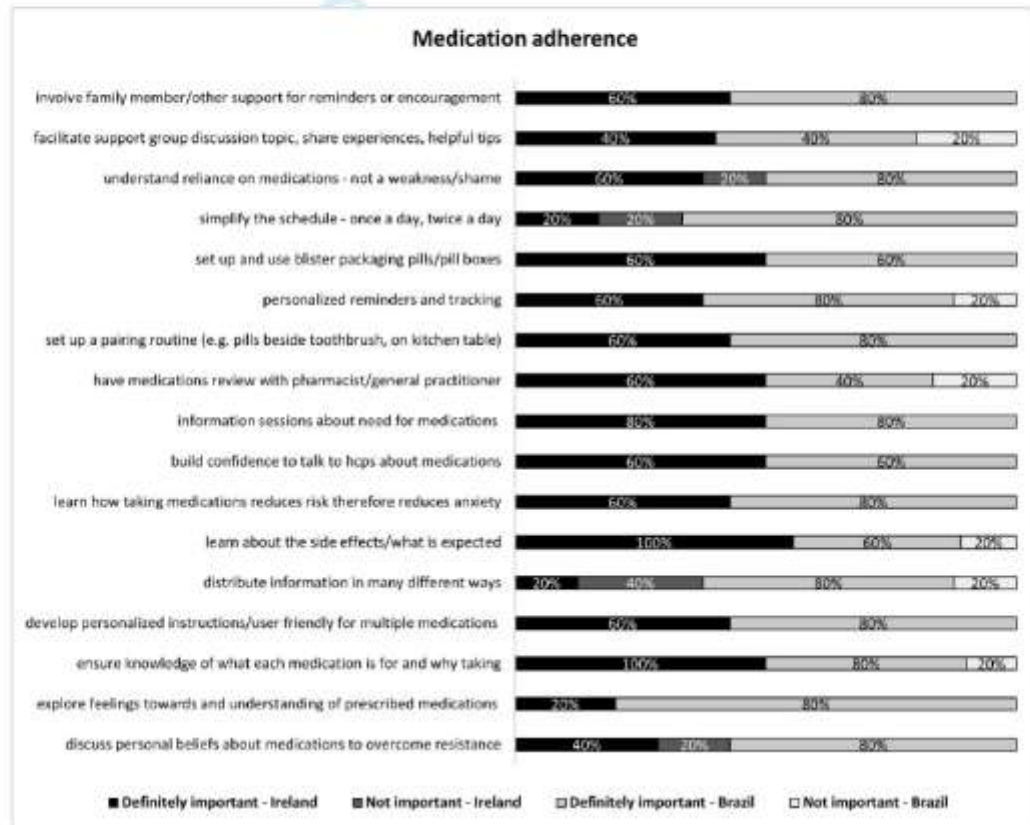


Figure 2b. Medication adherence components rated as “definitely important” or “not important” by country.



Figure 2c. Mood management components rated as “definitely important” or “not important” by country.

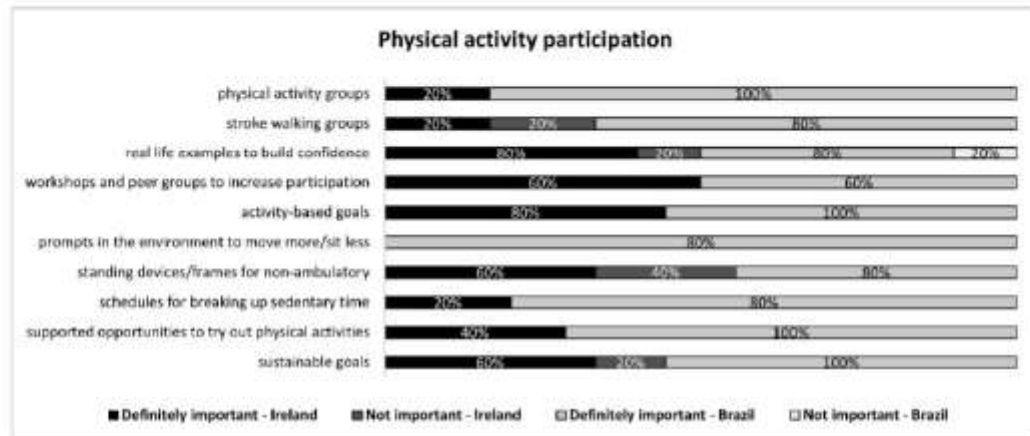


Figure 2d. Physical activity participation components rated as “definitely important” or “not important” by country.

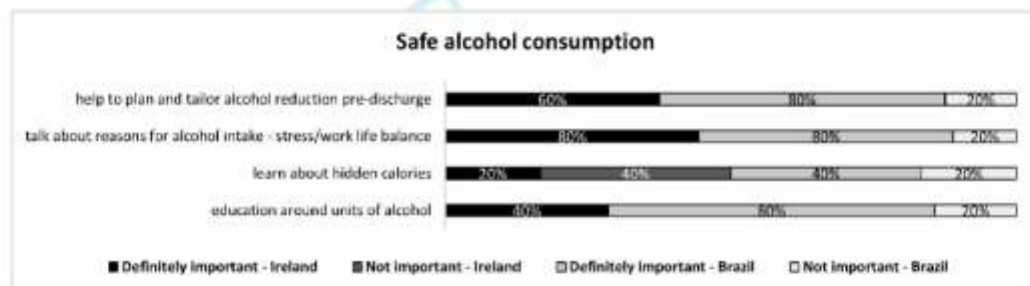


Figure 2e. Safe alcohol consumption components rated as “definitely important” or “not important” by country.

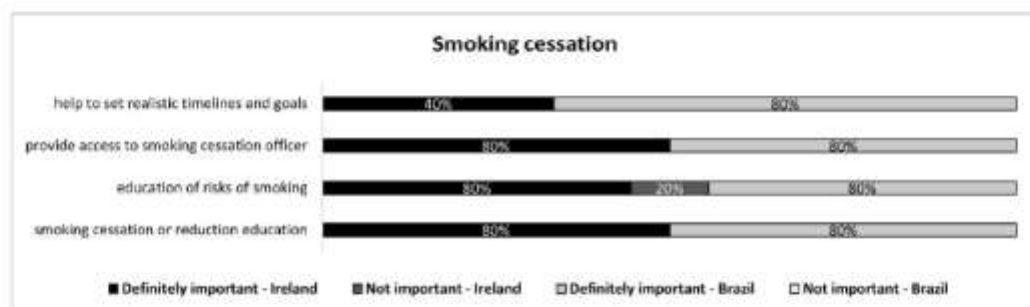


Figure 2f. Smoking cessation components rated as “definitely important” or “not important” by country.

3.2 Cross-country differences

Table 1 presents a breakdown of the intervention components that did not simultaneously receive a majority rating of “definitely important” in both countries. One medication adherence component related to medication review with a general practitioner (GP) or pharmacist was rated as “definitely important” by the majority of the Irish PPI panel, but this was not replicated by the Brazilian panel, which rated four different medication adherence components as “definitely important”. For the other healthy lifestyle behaviors, the majority of the Brazilian PPI panel members rated several components as “definitely important” that were not reflected in the Irish PPI panel: three under healthy diet, ten under mood management, five under physical activity participation, one under safe alcohol consumption, and one under smoking cessation.

Table 1. Components of a stroke secondary prevention intervention under development rated as “definitely important” by the majority of PPI panel members from only one country.

Lifestyle behaviors	Components rated as “definitely important” only by the majority of Irish PPI panel members	Components rated as “definitely important” only by the majority of Brazilian PPI panel members
Healthy diet	No component	- “Awareness of weight” - “Provide knowledge of healthy body mass index” - “Show how to monitor weight”
Medication adherence	- “Have medications review with pharmacist/general practitioner”	- “Discuss personal beliefs about medications to overcome resistance” - “Explore feelings towards and understanding of prescribed medications” - “Distribute information in many different ways” - “Simplify the schedule - once a day, twice a day”
Mood management	No component	- “Build rapport to allow those in need to open up, time” - “Increase awareness of role of mood in health” - “Discuss/support resistance to medications for mental health” - “Provide alternative options for mental health”

		- "Support resistance to looking at difficult thoughts or feelings" - "Opportunities to engage with appropriate psych support" - "Provide options for group therapy/one to one" - "Enable opportunity for art and creative therapy" - "Stress reduction support in immediate aftermath or key times" - "Help to build support structures"
Physical activity participation	No component	- "Supported opportunities to try out physical activities" - "Schedules for breaking up sedentary time" - "Stroke walking groups" - "Physical activity groups" - "Prompts in the environment to move more/sit less"
Safe alcohol consumption	No component	- "Education around units of alcohol"
Smoking cessation	No component	- "Help to set realistic timelines and goals"

Legend: PPI - Patient and Public Involvement.

Figure 2 presents a breakdown of component ratings for the response options “definitely important” and “not important” provided by PPI panel members from each country across the six lifestyle behaviors. All components of three lifestyle behaviors (healthy diet (Figure 2a), physical activity participation (Figure 2d), and smoking cessation (Figure 2f)) were rated as “definitely important” by the majority of Brazilian PPI panel members. In contrast, none of the lifestyle behaviors had all their components rated as “definitely important” by the majority of Irish PPI panel members.

Additionally, the majority of Brazilian PPI panel members rated most components of the other three lifestyle behaviors (medication adherence, mood management, and safe alcohol consumption) as “definitely important”. The following components, specific to each lifestyle behavior, were rated differently: two components for medication adherence (“facilitate support group discussion topic, share experiences, helpful tips” and “have medications review with pharmacist/general practitioner”) (Figure 2b), one component for mood management (“mindfulness and meditation/skills development and practice”) (Figure 2c), and one component for safe alcohol consumption (“learn about hidden calories”) (Figure 2e).

In Ireland, it was the only case where the majority of PPI panel members rated some components of every lifestyle behavior as “maybe important”. These included: 20% of the components for healthy diet (Figure 2a), 18% for medication adherence (Figure 2b), 33% for mood management (Figure 2c), 50% for physical activity participation (Figure 2d), 25% for safe alcohol consumption (Figure 2e), and 25% for smoking cessation (Figure 2f).

[Insert Figure 2 here:]

Figure 2a, Figure 2b, Figure 2c, Figure 2d, Figure 2e, and Figure 2f

4. Discussion

To date, no study has investigated cross-country similarities and differences in how individuals post-stroke prioritize components to be included in an intervention under development aimed at promoting the adoption of healthy lifestyle behaviors, based on PPI input from two distinct cultural and social contexts: a high-income country (Ireland) and a middle-income country (Brazil). There was strong overall agreement between Brazil and Ireland in prioritizing components as “definitely important”. The only exception was healthy diet, for which 40% of the related components received the same rating from both PPI panels. Both groups also agreed that none of the components was unimportant. Regarding differences, one medication adherence component was rated as “definitely important” only by the majority of Irish PPI panel members, while Brazilian PPI panel members uniquely prioritized components across all lifestyle behaviors. Only in Ireland the majority rated some components as “maybe important” for every lifestyle behavior. While some similarities were identified, differences in priorities were more pronounced. This finding highlights the need for caution when applying evidence from high-income countries (e.g., Ireland) to low- and middle-income countries (e.g., Brazil), particularly when the goal is to promote healthy lifestyle adoption post-stroke.

Low levels of physical activity have been associated with an increased burden of stroke-related DALYs³⁴. Accordingly, participation in physical activity is recognized as a protective factor in reducing stroke⁵⁴ risk and all-cause mortality⁵⁵, and as a key strategy for improving life post-stroke⁵⁶. Under the physical activity category, the majority of the Brazilian PPI panel members considered all components proposed (n=10) as “definitely important”. In contrast, the Irish PPI panel members classified five components as “definitely important” and five as “maybe important”. This finding aligns

with studies that have investigated barriers to physical activity participation post-stroke in both contexts. In Ireland, the most frequently reported barrier was “physical difficulties”⁵⁷. In Brazil, in addition to “fatigue”, the most reported barriers were the availability of and distance to exercise facilities⁵⁸. Further emphasizing this difference, the component “prompts in the environment to move more/sit less” was considered “definitely important” by 80% of the Brazilian PPI panel members but was not classified as such by any of the Irish panel members. The clinical guideline for stroke developed for use in the UK and Ireland states that, in addition to promoting physical activity post-stroke, it is also necessary to encourage the reduction of sedentary behavior³². Therefore, the absence of this priority among the Irish PPI panel may be explained by the fact that encouraging the reduction of sedentary behavior post-stroke is likely already a reality in that context. Given the complexity of encouraging physical activity participation⁵⁹ and the differences between countries in prioritizing components related to physical activity participation, locally tailored strategies should be considered.

One discrepancy between countries in the medication adherence components of a co-designed stroke secondary prevention intervention that warrants further discussion is that the only component rated as “definitely important” exclusively by the majority of Irish PPI panel members was “have medications review with pharmacist/general practitioner”. In Ireland, both private and public healthcare services are available⁶⁰. While public health services are available for all, not all are free of charge, some services do require a fee⁶⁰. Additionally, nearly half of the Irish population (47%) have health insurance, based on 2023 figures⁶⁰. In Brazil, on the other hand, the public healthcare system - known as the Unified Healthcare System (*Sistema Único de Saúde, SUS*) - covers all types of healthcare for all residents and visitors, including undocumented individuals, with no application process required to access services^{61, 62}. The public

healthcare system also provides free medication for chronic diseases such as hypertension and diabetes through the Brazil's Popular Pharmacy Program ⁶¹. Additionally, it is estimated that approximately 20% of the Brazilian population has private medical/hospital insurance ⁶². It is possible that Brazilian individuals post-stroke have easier access to pharmacists/general practitioners through the public health system compared to those in Ireland. As a result, they may not perceive the component "have medications review with pharmacist/general practitioner" as a barrier to medication adherence and therefore did not consider it as "definitely important". In Ireland, post-stroke care policies, including those focused on secondary prevention, should consider improving access to pharmacists/general practitioners to support medication adherence. Additionally, interventions developed for low- and middle-income countries should reflect the other priorities identified by Brazilian individuals post-stroke to improve medication adherence (Table 1).

Differences in dietary habits exist between Ireland and Brazil ^{63, 64}. For example, in 2019, 33% of Irish adults consumed at least five portions of fruits and/or vegetables per day ⁶⁴, whereas in Brazil, this percentage was 21% for the same period ⁶³. Additionally, Lennon et al. ²³ showed that 54% of individuals post-stroke from Ireland included in the study consumed ≥ 5 portions of fruit and vegetables/day. Studies describing the fruit and vegetable consumption profile of individuals post-stroke in Brazil are needed, but it has been observed that only about 20% of Brazilian adults meet the recommended consumption of fruits and vegetables (≥ 5 portions/day) ⁶⁵. This may help, at least in part, to explain the differing ratings of healthy diet components to be included in the intervention under development. Healthy diet was the only lifestyle behavior in which a minority of the components (n=2; 40%) were considered "definitely important" by the majority of members from both PPI panels. However, all components were

considered “definitely important” by the majority of the Brazilian PPI panel members. Therefore, there is a clear need for interventions that encourage adequate consumption of fruits and vegetables in actions aimed at stroke secondary prevention in both contexts: high- and middle-income countries. It should be noted that the components most frequently rated as “definitely important” by the Brazilian PPI panel members were related to health knowledge (e.g., learning about food options and portion sizes). A resource for Brazilian primary care health professionals offers dietary guidance for individuals with cardiovascular risk factors⁶⁶. It promotes health and strengthen food and nutrition security by detailing healthy choices and portion sizes⁶⁶. Therefore, dietary interventions designed to Brazilian individuals post-stroke should consider using this resource⁶⁶.

The findings should be interpreted in light of the specific context in which they were generated: a high-income country (Ireland) and a middle-income country (Brazil). The results reflect the activities of PPI panels involved in the co-design of a stroke secondary prevention intervention⁴¹. Each panel consisted of five individuals post-stroke and is not intended to be broadly representative of all stroke survivors. PPI activity in stroke research is still rarely reported in the literature⁵², and, as in this study, often excludes wheelchair users, who may be harder to recruit for research panels. However, individuals with aphasia were included, and the workshop materials were adapted to accommodate their needs. Additionally, all PPI members were in the chronic phase of stroke recovery and able to walk independently. Future research should strive to include more diverse individuals, including those with different levels of disability and those in the acute or subacute phases of recovery. Lastly, the components of stroke secondary prevention presented to the panels were developed in workshops with clinicians, researchers, and representatives from support organizations. It is essential that future

studies also explore the personal perspectives of individuals post-stroke to complement and expand upon the current findings.

5. Conclusions

There were both cross-country similarities and differences in the perspectives of individuals post-stroke regarding the components to be included in a stroke secondary prevention intervention, considering two distinct cultural and social contexts: a high-income country (Ireland) and a middle-income country (Brazil). The cross-country similarities highlight core components that should be considered in both contexts to encourage the adoption of healthy lifestyle behaviors post-stroke. The cross-country differences underscore the need to consider local culture and context in stroke secondary prevention. Therefore, it is important for low- and middle-income countries, such as Brazil, to exercise caution when fully adopting intervention plans developed in high-income countries, such as Ireland, that aim to encourage the adoption of healthy lifestyle behaviors post-stroke.

So What?

What is already known on this topic?

Current literature shows lifestyle interventions are effective in stroke secondary prevention, but most evidence comes from high-income countries. Patient-centered and culturally adapted interventions are needed to be effective.

What does this article add?

This study directly compares the priorities of individuals post-stroke from a high-income country (Ireland) and a middle-income country (Brazil). It identifies core components that

are important in both contexts and, most crucially, highlights the differences that show the need to adapt interventions to the local context.

What are the implications for health promotion practice or research?

For practitioners, results suggest a one-size-fits-all approach is insufficient. While essential elements can be shared, interventions must be tailored to local context. For researchers, this study reinforces the importance of including diverse individuals post-stroke through PPI to ensure future interventions are relevant and impactful across socioeconomic settings.

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For Peer Review

CAPÍTULO 7

ESTUDO 6

CAPÍTULO 7 – ESTUDO 6

O artigo do Estudo 6, intitulado “*Brazilian adaptation of the “iHELP Stroke: Improving Health and Lifestyle Programme” and feasibility study*”, será submetido ao periódico *International Journal of Stroke*.

Article title: Brazilian adaptation of the “iHELP Stroke: Improving Health and Lifestyle Programme” and feasibility study

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Data availability statement: The datasets generated and/or analyzed during the current study are not publicly available due to confidentiality agreements and ethical restrictions but are available from the corresponding author on reasonable request.

Keywords: Stroke, Healthy Lifestyle, Secondary Prevention, Feasibility Studies, Brazil, Ireland

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Brazilian adaptation of the “iHELP Stroke: Improving Health and Lifestyle Programme” and feasibility study

Abstract

Background: Recurrent stroke contributes to the high global burden of this disease. Low- and middle-income countries (LMICs) (e.g., Brazil) are disproportionately affected by stroke and have limited access to secondary prevention. A theoretically-informed intervention (“iHELP Stroke: Improving Health and Lifestyle Programme”) for risk reduction after stroke was recently co-designed with experts and people with lived experience of stroke in a high-income country (Ireland). Before implementation in Brazil, adaptations were required due to cultural, social, and economic differences.

Aims: To describe the adaptation of the “iHELP Stroke” to the Brazilian context and assess the feasibility of the intervention with Brazilians who have experienced stroke.

Methods: A mixed-methods study was conducted following ADAPT guidance. Phase I included two stakeholder panels (15 experts and 10 stroke survivors) to adapt the intervention for adequate reach, effectiveness, cost-effectiveness, adoption, implementation, and sustainability. Phase II involved a feasibility study with 10 Brazilian individuals post-stroke to evaluate recruitment, retention, adherence, acceptability, perceived effectiveness, and clinical outcomes. Descriptive statistics were applied.

Results: Phase I identified 11 contextual themes, leading to adaptations including translation of materials into Brazilian Portuguese, renaming as “iVIDAVC: *intervenção para melhorar a saúde e o estilo de vida pós-AVC*”, and provision of an additional educational session. Phase II showed high retention (80%) and attendance (88.9%), strong acceptability and satisfaction, and half completely achieving primary goals. Needed refinements included extended session times for invited professionals, one participant finding the eight-week duration too short, and a group session conducted with only a single participant.

Conclusions: The “iVIDAVC” program was successfully adapted for the Brazilian context and demonstrated feasibility. Future studies should test the full 14-week program, ensure repeated participation of invited professionals, include at least four participants per group and refine outcome assessment for comprehensive evaluation.

Keywords: Stroke, Healthy Lifestyle, Secondary Prevention, Feasibility Studies, Brazil, Ireland

Introduction

Recurrent strokes account for nearly 30% of all stroke events.¹ Stroke survivors face an estimated risk of recurrence of about 25% within 5 years and 40% within 10 years of the initial episode.² Stroke recurrence is associated with worse clinical outcomes,³ higher healthcare costs,³ increased mortality,⁴⁻⁶ and represents the leading cause of hospital readmission within the first year post-stroke.⁷ Projections indicate that stroke, including recurrent events, will remain a major global health challenge, disproportionately affecting low- and middle-income countries (LMICs).⁸ Middle-income countries such as Brazil are expected to face the greatest burden,⁸ underscoring the need for targeted secondary prevention efforts in these settings.⁸⁻¹²

Stroke secondary prevention aims to reduce recurrence risk while supporting long-term health and daily well-being.^{12, 13} Theory-based interventions and individually tailored educational strategies are recommended to promote self-management of modifiable risk factors.¹²⁻¹⁵ Risk factors to be addressed include poor medication adherence, cardiovascular conditions (e.g., diabetes, hypertension, and hypercholesterolemia), psychosocial issues (e.g., anxiety, depression, and stress), and unhealthy lifestyle behaviors (e.g., smoking, physical inactivity, poor diet, harmful alcohol use).¹²⁻¹⁵ Effective prevention should combine regular monitoring, medication support, and behavior change strategies.^{10, 12} Nonetheless, many individuals post-stroke continue to demonstrate poor adherence and unhealthy behaviors,¹⁶⁻¹⁹ underscoring the need for targeted efforts.

The tendency of individuals post-stroke to maintain unhealthy lifestyles¹⁶⁻¹⁹ may be linked to healthcare professionals' limited access to clear, evidence-based guidance on behavior change interventions. A recent scoping review found substantial gaps in stroke guidelines for secondary prevention, particularly a lack of emphasis on modifiable risk factors.²⁰ Among 27 documents analyzed, 13 originated from Europe, 8 from the Americas, and only one from Brazil.²⁰ The single Brazilian document identified provided general recommendations without practical guidance.²¹ Two recent overviews of systematic reviews, one on face-to-face²² and another on telehealth interventions,²³ reported a scarcity of theoretically-informed behavior change strategies in clinical trials, especially from LMICs like Brazil, again underscoring the need for interventions that meet stroke secondary prevention recommendations.¹²⁻¹⁵

In Ireland, a high-income country, a secondary prevention intervention to support healthy lifestyle participation after stroke was developed through a co-design process grounded in evidence and theory.²⁴ Following the Design Thinking framework²⁵ and Medical Research Council (MRC) guidance,²⁶ researchers, clinicians, advocacy organizations, and people with lived stroke experience contributed to the development of the “iHELP Stroke: Improving Health and Lifestyle Programme”. The program includes an initial individualized session followed by group sessions over 6-12 weeks, covering six components: stroke prevention education, activity-based goal setting, physical activity practice, emotional self-regulation, healthy behavior skills training, and peer support.²⁴ In addition to being evidence-informed and theoretically grounded, the intervention incorporates personalized risk recognition and goal setting,²⁴ meeting key stroke secondary prevention recommendations.^{12, 13, 15} Given the scarcity of suitable interventions in LMICs,^{22, 23} the “iHELP Stroke” has strong potential for use in countries such as Brazil.

However, directly applying the “iHELP Stroke” to the Brazilian context poses challenges. Behavior change, essential for stroke secondary prevention, is shaped by social and environmental factors.²⁷ Ireland, a high-income country, ranks 9th on the Social Progress Index (SPI score: 88.1), while Brazil, a middle-income country, ranks 55th (SPI score: 72.4), indicating lower overall social progress.²⁸ Healthcare systems also differ: in Ireland, public services may involve fees and nearly half of the population has private insurance,²⁹ whereas in Brazil, the Unified Healthcare System (*Sistema Único de Saúde*, SUS) provides free universal coverage, with only around 20% of the population holding private insurance.^{30, 31} Finally, Brazil has a vast territorial area, being the fifth largest country in the world, with socioeconomic differences across its regions.^{32, 33} This factor affects the provision of healthcare services.³² These differences suggest that individuals post-stroke in each country may have distinct needs that require adaptation to both the content and delivery of stroke secondary prevention interventions. This study therefore describes the adaptation of the Irish intervention “iHELP Stroke” for the Brazilian context (phase I) and investigates the feasibility of implementing the adapted version with Brazilian individuals post-stroke (phase II).

Methods

This was a mixed-methods study including qualitative (Phase I) and quantitative (Phase II) methodologies.³⁴ The study was conducted in *[blinded information]* and received approval from the institutional ethics review board (*[blinded information]*). It was prospectively registered on ClinicalTrials.gov (*[blinded information]*). In both phases, participants provided written informed consent. The study followed the ADAPT guidance for adapting and transferring interventions to new contexts.³⁵ Figure 1 maps the phases of this study against the ADAPT guidance³⁵ framework.

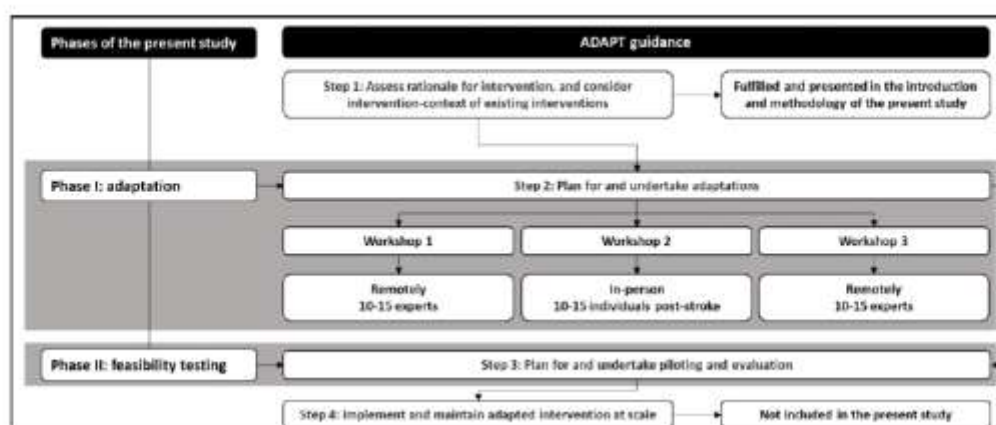


Figure 1. Mapping of the study phases against the steps of the ADAPT guidance³⁵.

The ADAPT guidance³⁵ is presented in four sequential steps, which are detailed below in reference to the current study.

In Step 1,³⁵ the rationale and contextual relevance of an intervention were assessed, noting that LMICs such as Brazil face a disproportionately high burden of stroke,^{8, 10, 11} including recurrent events, while having limited access to secondary prevention strategies.^{20, 22, 23} In Ireland, in collaboration with Brazilian researchers, a series of studies^{20, 22-24, 36, 37} supported the development of a novel intervention tailored to secondary prevention needs.²⁴ This research was one of four projects within the doctoral programme Improving Pathways for Acute Stroke And Rehabilitation (iPASTAR), funded by the Irish Health Research Board.^{38, 39} Because the intervention aligned with stroke secondary prevention recommendations and was theory-funded,²⁴ it was considered a promising candidate for adaptation to the Brazilian context. Continuous collaboration between Irish and Brazilian research teams, including a nine-month exchange of the first author (PCP) at the Irish university, enabled an in-depth understanding of the intervention. At the same time, socioeconomic and cultural

differences between Ireland and Brazil²⁸ were examined, and their influence on the delivery of the intervention was further elucidated. To explore these contextual differences, a complementary study (currently under submission) compared the perspectives of individuals post-stroke participating in Patient and Public Involvement (PPI) panels in Ireland and Brazil, showing shared priorities for lifestyle interventions but also highlighting the need for cultural adaptation when transferring interventions across contexts. Based on these findings, and with the endorsement and collaboration of the primary developers of the original Irish intervention “iHELP Stroke” (OL and PH), the intervention was considered appropriate for adaptation to the Brazilian context, thus concluding Step 1 of the ADAPT guidance.³⁵

Step 2, which consists of planning and undertaking adaptations,³⁵ was addressed in this study during Phase I, described below. Step 3, which involves planning and undertaking piloting and evaluation,³⁵ was addressed in Phase II. Step 4 of the ADAPT guidance,³⁵ which addresses the implementation and maintenance of the adapted intervention at scale,³⁵ was outside the scope of the study.

Phase I: adaptation of the “iHELP Stroke” to the Brazilian context

Following Step 2 of the ADAPT guidance,³⁵ two panels were established, one with experts and another with individuals post-stroke, to ensure the inclusion of a diverse group of stakeholders. The expert panel included researchers on stroke secondary prevention, healthcare professionals from different disciplines (e.g., occupational therapists, physicians, and physiotherapists) with experience in stroke care, and representatives of stroke associations. Recruitment strategies involved identifying Brazilian authors of key publications (e.g., national guidelines), clinical professionals engaged in stroke-related organizations identified through the websites of these organizations, and representatives of stroke associations. Potential participants were contacted by email. The individuals post-stroke who comprised the second panel were recruited from a longitudinal extension project involving people with stroke.⁴⁰ Eligibility criteria were: age ≥ 20 years, medical diagnosis of stroke (any stage), and ability to walk independently with or without a walking device. These criteria were verified by telephone call. Across both panels, the aim was to include 10-15 participants.⁴¹

Three workshops were conducted as part of the adaptation process (Figure 1): the first was held online with experts, the second in person with stroke survivors, and the third online with experts. Prior to the first workshop, experts received background

material outlining the research project and providing detailed information on the “iHELP Stroke”, including its components (individual and group sessions) and implementation procedures (session content, facilitator, delivery setting, frequency and timing, customization, required materials, and the group session schedule covering the six predefined components). In summary, “iHELP Stroke” comprises one individual session (approximately one hour) and 6-12 weekly group sessions (each lasting about two hours). The intervention includes interactive experiential learning activities facilitated by a coordinator, with the option of guest speakers. Coordinators may be health professionals, health promoters, or advocates, while guest speakers may include nurses, pharmacists, physiotherapists, nutritionists, psychologists, or mindfulness specialists. In the individual session, participants, together with the intervention coordinator, are encouraged to define at least three lifestyle improvement goals, ranked by priority, with the first considered the most important and necessary to achieve. The six core components of the group sessions are stroke prevention education, activity-based goal setting, physical activity practice, emotional self-regulation, healthy behavior skills training, and peer support. Each session is delivered weekly.²⁴

The first workshop, held online with experts, aimed to identify and address barriers and facilitators to the delivery of “iHELP Stroke” in Brazil, with the goal of supporting adequate reach, effectiveness, cost-effectiveness, adoption, implementation, and sustainability.³⁵ Material sent in advance of the workshop was reviewed and each component of the intervention was discussed. Participants were asked to identify potential barriers and facilitators for implementing the intervention in Brazil, as well as possible solutions for each barrier and strategies to enhance the facilitators. They were divided into three online breakout rooms, and discussions were recorded using digital tools (online PowerPoint), by the coordinators responsible for each group.

Following a similar approach, the second workshop was conducted in-person with individuals with experience of stroke, addressing similar content to the first workshop. These participants were not given any reading material beforehand. However, a detailed presentation of the intervention was prepared, using accessible language and illustrations. Participants were divided into three groups, and discussions were recorded on flipcharts and post-its by the group coordinators.

Prior to the third workshop, participants received a document summarizing the grouped barriers and facilitators, along with the proposed solutions and enhancing strategies to adapt the intervention. This allowed time for reflection during the workshop

with experts. In this workshop, experts were asked to assess whether any new observations emerged, in order to evaluate data saturation. The absence of new insights confirmed that the existing data sample was sufficient to guide the necessary adaptations to the intervention. In addition, because the intervention's name had been initially proposed in English, the group discussed an appropriate title for use in Brazil, considering that Portuguese is the country's primary language.

Throughout this entire process, PCP, LAAL, JMSF, and CDCMF analyzed and synthesized the findings to guide the adaptation. Based on the findings, PCP and CDCMF outlined the required and feasible adaptations. The adapted version was presented to PH to ensure that the core active components of the intervention were preserved.³⁵ Identified adaptations were systematically mapped to the Framework for Reporting Adaptations and Modifications to Evidence-Based Interventions (FRAME) to guide the documentation and classification process, ensuring transparency and consistency in reporting the modifications made for the Brazilian context.⁴²

Phase II: feasibility of implementing the adapted version with Brazilian individuals post-stroke

Following Step 3 of the ADAPT guidance,³⁵ the feasibility of implementing the adapted intervention was investigated. This was completed as a phase I feasibility, single-group, pre-post intervention study, reported in accordance with the CONSORT extension for pilot or feasibility trials.⁴³

Recruitment of individuals post-stroke followed the same strategy as in Phase I. Eligibility criteria were: medical diagnosis of stroke (any stage), age ≥ 20 years, ability to walk independently with or without a walking device. Exclusion criteria included a positive cognitive screening test (Brazilian telephone version of the Mini Mental State Examination (Braztel-MMSE)⁴⁴ or expressive aphasia. These criteria were verified by telephone call.

As a feasibility study, no primary outcome was selected, nor was a power calculation performed.⁴⁵ A sample size of at least 10 participants, as used in other single-group feasibility studies,^{46, 47} was determined for the present study. Considering that the intervention is intended for groups of individuals post-stroke, groups of at least three participants were formed until a minimum of 10 participants had been enrolled in the study. Thus, a first group was formed, followed by a second and then a third. The same intervention was delivered to all three groups.

The intervention, as adapted for the Brazilian context and tested in this study, is presented in the Results section of Phase I. The original intervention proposed the delivery of 6-12 group sessions;²⁴ for feasibility testing, six group sessions were planned.

PCP was the researcher responsible for conducting the intervention. She is a physiotherapist with experience in research involving individuals post-stroke, including in the context of stroke secondary prevention, and actively participated both in the development phase of the intervention in Ireland²⁴ and in its adaptation to the Brazilian context. Considering that PCP is a physiotherapist, it was planned to invite nutritionists, pharmacists, and psychologists as guest professionals. A trained assessor, who was not involved in delivering the intervention, was responsible for collecting the study's outcomes of interest, which included recruitment feasibility, intervention feasibility, and clinical outcomes.

Recruitment feasibility was evaluated using the following measures: (1) the ratio of eligible participants to those recruited, and (2) the ratio of eligible participants to those who completed the baseline assessment.⁴⁸⁻⁵⁰

Intervention feasibility was assessed through several measures:

- Retention was defined as the ratio between participants who completed the intervention and those who started it, with reasons for dropout documented.⁴⁸⁻⁵⁰
- Attendance was calculated as the ratio of sessions attended to the total number of sessions offered. Missed sessions and reasons for non-attendance were recorded.⁴⁸⁻⁵⁰
- Safety was monitored based on the number and causes of adverse events, such as pain, falls, hospitalizations, and deaths reported during the intervention.⁴⁸⁻⁵⁰
- Adherence to planned session components was assessed by comparing the delivered content to the planned protocol, and reasons for deviations were noted.
- Acceptability of the intervention was assessed using participant feedback via five-point Likert scales ("totally agree", "partially agree", "neither agree nor disagree", "partially disagree", and "totally disagree") on the following items: 1. Overall satisfaction with the activities conducted by the health professional during the intervention; 2. Helpfulness of the educational materials in supporting the adoption of a healthy lifestyle; 3. Satisfaction with the overall time required for the intervention (total number of weekly sessions); 4. Satisfaction with the length of the intervention sessions (1 hour for the educational, 1 hour for the individual

session; 2 hours for group sessions); 5. Overall satisfaction with the intervention. These scales were informed by prior studies.^{48, 51}

- Perceived effectiveness was assessed using participant feedback to the following statements: 1. "Compared to before participating in the intervention, how would you rate your overall health now?"; 2. "Compared to before participating in the intervention, how would you rate your lifestyle now?". The answer options were: "much better", "somewhat better", "about the same", "somewhat worse", "much worse". These statements were informed by prior studies.^{48, 51}
- Costs associated with the study were also recorded, including expenses for team training, participant recruitment, assessments, and intervention delivery.⁴⁸

Clinical outcomes included the number and proportion of participants who reached their pre-defined main secondary prevention goal, measured using Goal Attainment Scaling (GAS).^{52, 53} For each participant, initial (baseline) T-scores, final (achieved) T-scores, and the change between the two were calculated.^{52, 53} Participants were categorized based on the final T-score: a score <50 indicated the goal was not achieved, while a score ≥ 50 indicated the goal was achieved.^{52, 53} Using this classification, the number and proportion of participants who met the pre-defined main goal were determined.

Patient and Public Involvement (PPI)

A patient and public involvement (PPI) representative (female, 45 years old, who had experienced two strokes) contributed to the planning of this study. She was introduced to the intervention content and the proposed materials. She provided positive feedback on the materials used and suggested increasing the font size on the slides for the sessions. The PPI representative also assisted in recruiting potential participants by promoting the project among her contacts. She considered the individual session form very comprehensive and suggested including information on whether participants had genetic predispositions to conditions such as stroke, as well as their family history of stroke. She highlighted the importance of informing participants about available smoking cessation support groups at primary care units of the Brazilian public health system (SUS) and support from Alcoholics Anonymous Group for managing harmful alcohol consumption. Suggestions that could not be implemented were related to modifying the predetermined time allocated for each component of the group sessions.

Statistical analysis

In Phase I, qualitative data analysis employed a combined inductive-deductive approach to guide the adaptation of the intervention, from data preparation to an analytical synthesis of findings.^{54, 55} The process was structured into stages to ensure rigor and systematic handling. After each workshop, the primary researcher (PCP) compiled all material (PowerPoint slides and post-it notes) into a single Excel spreadsheet. In the final workshop, participants were asked to report any new observations to assess data saturation, ensuring that the process captured the full range of perspectives and that no important issues were overlooked. The coding process included familiarization with the data, data cleaning (initial coding), and analytical classification (focused coding). To enhance reflexivity and consistency, two researchers (PCP and CDCMF) coded independently, holding regular discussions to mitigate bias and deepen interpretation. Disagreements were resolved through consultation with a third examiner (LAAL), strengthening the validity of the findings. The project team reviewed all contributions and decided which adaptations to implement, considering feasibility, anticipated impact, and alignment with the intervention's objectives. These adaptations were then mapped to FRAME categories,⁴² ensuring a rigorous and transparent analysis of modifications.

In Phase II, descriptive statistics were used. Analyses were conducted with SPSS version 21.0 (SPSS Inc., Chicago, IL, USA).

Results

Phase I: adaptation of the “iHELP Stroke” to the Brazilian context

Fifteen experts were invited to and attended the first online workshop. The sample included 5 physiotherapists, 2 nurses, 2 occupational therapists, 1 nutritionist, 1 pharmacist, 1 physician, 1 psychologist, and 2 representatives of stroke associations. Fourteen attended the third online workshop (the occupational therapist did not participate due to medical reasons). In addition, 25 individuals post-stroke were initially contacted, 16 confirmed their interest in participating, and 10 attended the in-person workshop.

As shown in Figure 2, a total of 250 entries were extracted from the three workshops and included in the analysis. In the final workshop with experts, no substantially new observations were raised, suggesting that data saturation had been achieved. Through the coding process, 11 main contextual themes justified the

adaptations made. Table 1 presents these themes along with their respective explanations and adaptations. Finally, Figure 3 depicts the adaptations made, mapped to the FRAME domains.⁴² It was confirmed with the Irish researcher responsible for developing the intervention (PH) that all core active components were preserved.

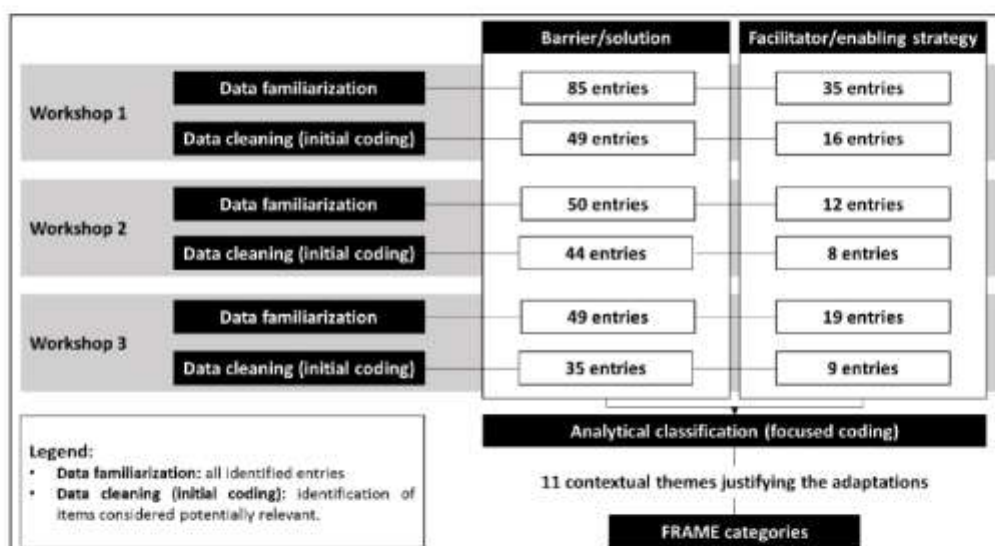


Figure 2. Qualitative data analysis.

Table 1. Analytical classification and adaptations implemented in the intervention.

Context	Explanation	Adaptation
Limited spatial accessibility	Mobility barriers in public spaces in Brazil (irregular flooring, lack of ramps, poor signage, insufficient lighting, limited adapted facilities)	Conduct the intervention in accessible locations; if not possible, identify and minimize spatial barriers at the intervention sites
Limited access to healthcare services	Individuals post-stroke face barriers in accessing complementary care (e.g., physiotherapy, psychology, and nutrition)	Establish prior partnerships with community professionals and projects (e.g., universities) for referrals and continuity of care
Language barriers (English)	Healthcare professionals in Brazil may have difficulties accessing scientific evidence published in English	Provide all intervention-related materials in Brazilian Portuguese, including name of the intervention and assessment instruments
Low educational level of individuals post-stroke	Most individuals post-stroke in Brazil have only primary education, impacting understanding of treatment, medication adherence, and lifestyle changes	- Conduct a preliminary educational session on stroke, risk factors, and healthy lifestyle behaviors - Clarify misconceptions - Use clear, accessible language - Reinforce content with visuals, printed materials, and telehealth tools - Apply strategies to check understanding (e.g., quizzes and peer explanations)
Routine presence of caregivers	In Brazil, caregivers often accompany individuals post-stroke, and their absence can hinder healthcare access	Identify the main caregiver (including education level, relationship, and availability). Involve them in sessions and goal-setting when appropriate, respecting participant preferences - Assess income and its impact on lifestyle
Socioeconomic challenges (low income)	Many individuals have low income and difficulties affording transport and healthy food	- Check transport conditions and inform about transportation passes - Consider conducting the sessions in nearby locations (e.g., primary care units) - Provide education on affordable dietary choices (seasonal fruits and food reuse)

Use of laboratory exams	Laboratory results are commonly used in Brazil for monitoring chronic conditions and can support lifestyle management	Incorporate results (cholesterol and blood glucose measures) in goal-setting and educational sessions
Dietary assessment tools	The Mediterranean Diet Score does not reflect typical Brazilian dietary behaviors	Use instruments developed in Brazil to assess dietary adherence (<i>Formulário de Marcadores de Consumo Alimentar (versão 3.0)</i> and/or <i>Escala de qualidade da dieta (ESQUADA)</i>); base education on the Brazilian cardioprotective diet manual
Food insecurity	Millions of Brazilians still experience severe food insecurity	Apply the Brazilian food insecurity risk screening tool to identify at-risk families
Low adherence to physical activity	Limited participation in physical activity among Brazilian individuals post-stroke	Use the Brazilian physical activity guide; home-based exercises must consider public programs
Emotional factors assessment	In addition to the planned instruments, other tools commonly used in clinical practice with individuals post-stroke in Brazil were recommended	Use the Patient Health Questionnaire-9 (PHQ-9) and the Geriatric Depression Scale (Brazilian Portuguese versions)

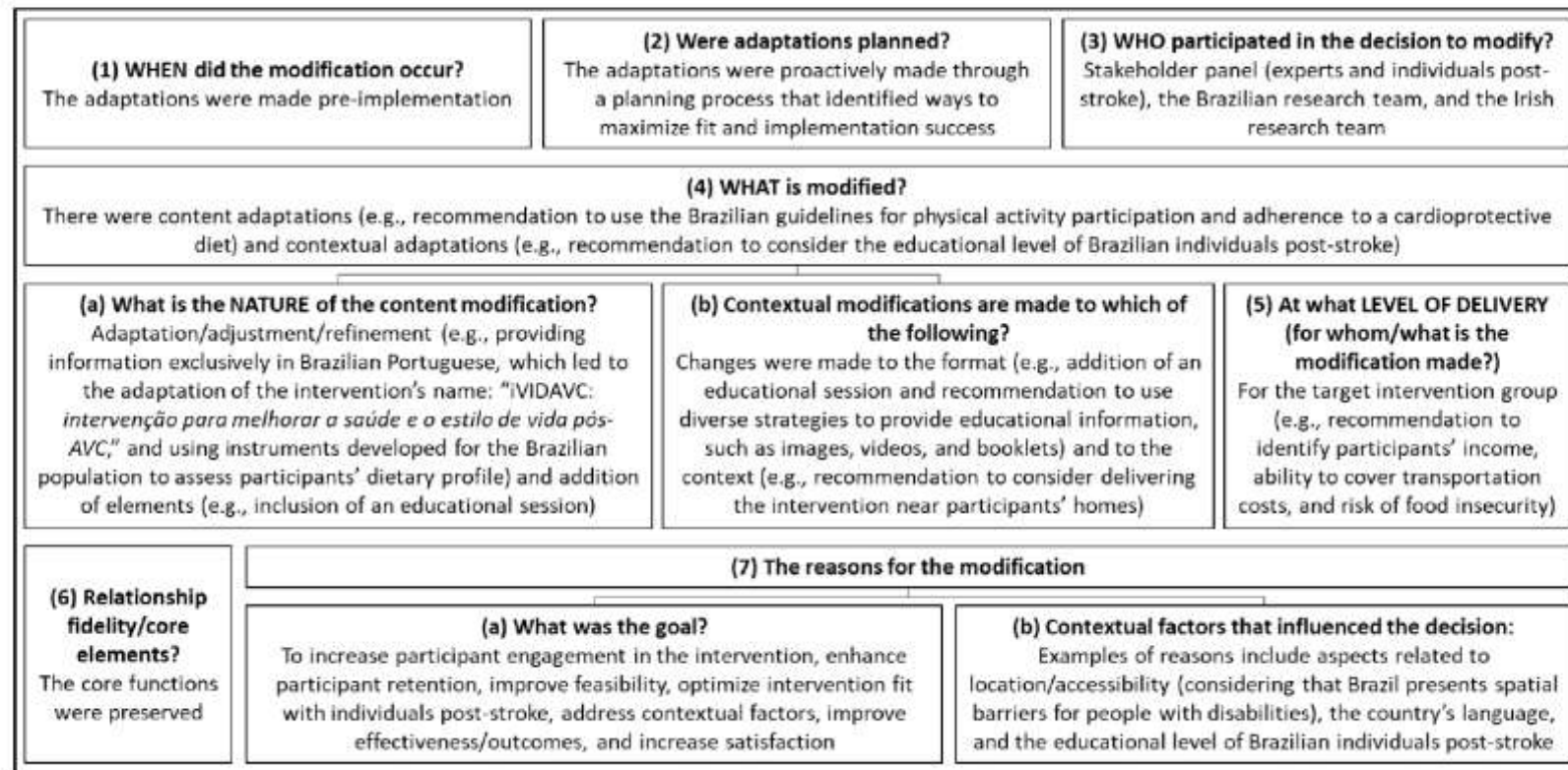


Figure 3. Mapping adaptations to the Framework for Reporting Adaptations and Modifications-Expanded (FRAME).

In summary, the adaptation process of the “iHELP Stroke” resulted in the definition of a new name adapted to the local Brazilian language (“iVIDAVC: *intervenção para melhorar a saúde e o estilo de vida pós-AVC*”), the use of assessment tools and all materials in Brazilian Portuguese, the addition of a new educational session justified by the low educational level of the population, and content adaptations aligned with Brazilian clinical guidelines related to promoting healthy lifestyle behaviors. Considering the inclusion of the new session, the intervention tested in the present study comprised: one educational session (approximately one hour), one individual session (approximately one hour), and six group sessions (approximately two hours each). Sessions were held weekly, resulting in a total duration of eight weeks (Supplementary Material).

Phase II: feasibility of implementing the adapted version with Brazilian individuals post-stroke

The recruitment of individuals post-stroke who participated in this phase is presented in Figure 4. The metrics used to assess recruitment feasibility were: 13.7% (ratio of eligible participants to those recruited; 10/73), and 55.6% (ratio of eligible participants to those who completed the baseline assessment; 10/18). A total of ten individuals post-stroke were included in the study, with a mean age of 59.7 (± 12.3) years, the majority being female (70%). None of the participants used walking aids or had caregivers. In addition, only one participant reported food insecurity risk, indicating that vegetables had run out because the money was gone. Additional descriptive data are provided in Table 2.

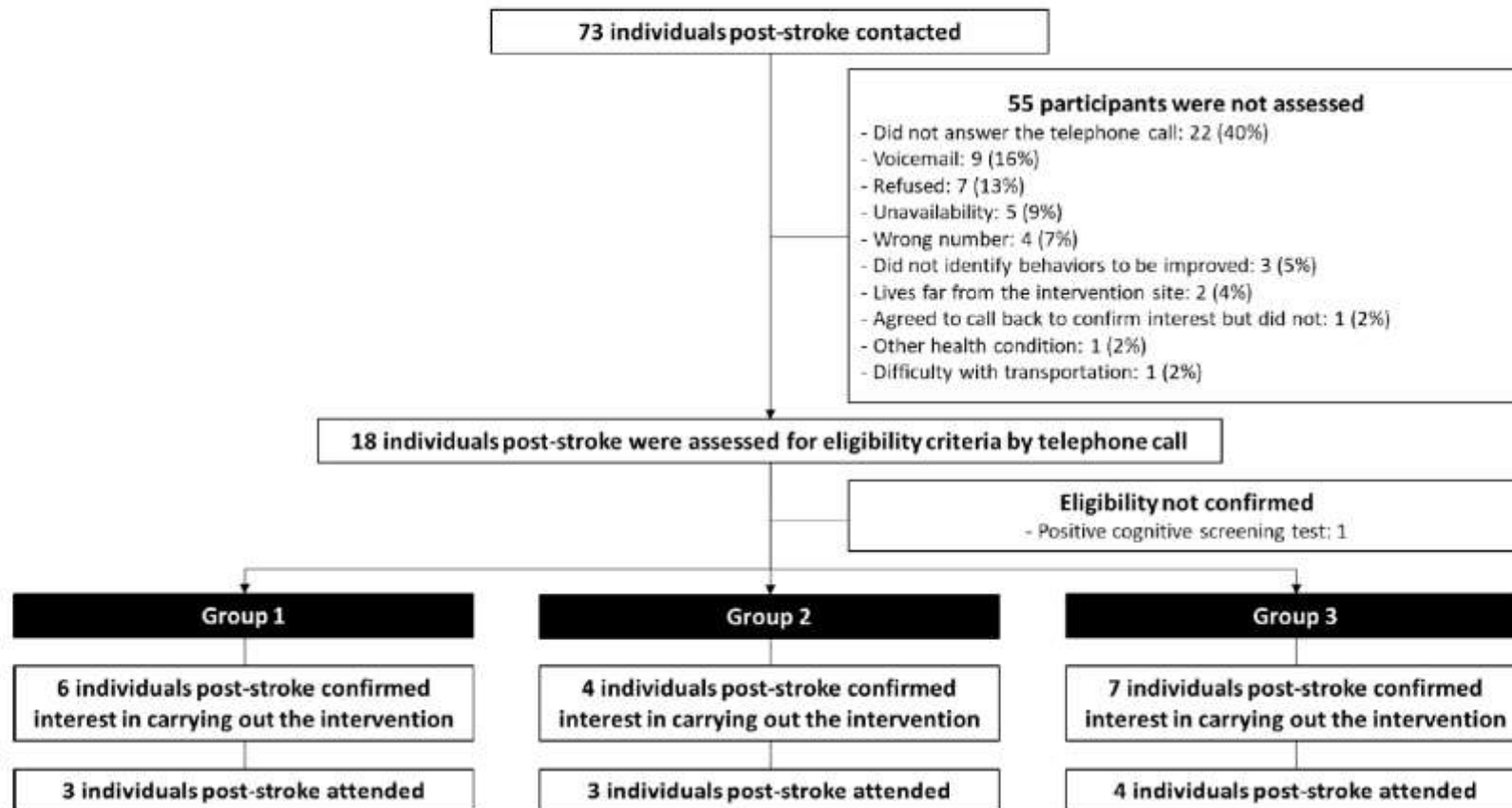


Figure 4. Recruitment flowchart and formation of participant groups that took part in the “iVIDAVC: *intervenção para melhorar a saúde e o estilo de vida pós-AVC*”

Table 2. Descriptive characteristics of participants.

Variables	n=10
Age, y, mean (SD); [min-max]	59.7 (12.3); [34-71]
Sex, n woman (%)	7 (70%)
Educational level, n (%)	
Illiterate and incomplete primary education	2 (20%)
Primary education	3 (30%)
Secondary education	3 (30%)
Higher education	2 (20%)
Marital status	
Married	6 (60%)
Divorced	1 (10%)
Single	2 (20%)
Widowed	1 (10%)
Living with, n (%)	
Partner/family	9 (90%)
Alone	1 (10%)
Employment status, n (%)	
Employed	3 (30%)
Unemployed	1 (10%)
Retired	6 (60%)
Monthly income, R\$, mean (SD); [min-max]	2,207.20 (1,666.00); [0-5,000.00]
Medical diagnosis of, n (%)	
Hypercholesterolemia, n yes (%)	7 (70%)
Hypertension, n yes (%)	7 (70%)
Diabetes, n yes (%)	4 (40%)
Time after stroke, months, mean (SD); [min-max]	25.6 (24.0); [1-65]
Type of stroke, n ischemic (%)	9 (90%)
Hemiparesis, n (%)	
Right	2 (20%)
Left	5 (50%)
Not applicable	3 (30%)
Cases of recurrent stroke, n (%)	2 (20%)
Paretic side, n (%)	
Right	2 (20%)
Left	5 (50%)
Bilateral or not applicable	3 (30%)

In total, 10 participants started the intervention, which was delivered in two groups of three participants each and one group of four participants. Two participants discontinued participation in the sixth week: one due to lack of interest and the other due to a health condition (dental problem). A retention rate of 80% was identified.

A total of eight sessions were planned to be delivered in-person to each of the 10 participants. All planned sessions were conducted. Of the 80 planned sessions, 71 were attended, resulting in an adherence rate of 88.9%. Considering only the retained participants (n=8), of the 64 planned sessions, 56 were attended, yielding a retention rate

of 87.5%. Participants were absent eight times: medical appointments ($n=3$), caregiving responsibilities for another family member at home (e.g., grandfather or daughter) ($n=3$), accompanying a family member to a medical appointment ($n=1$), and feeling unwell due to high blood pressure ($n=1$). One session was delivered with only one participant as the other two participants were absent due to medical appointments.

For safety outcomes of interest, only one adverse event was identified. Prior to the “physical activity practice” component of a group session, a participant felt unwell. Her blood pressure was taken (170/90 mmHg). She reported not having had time for lunch that day, having eaten only a savory pastry. The participant was provided with a snack (fruit and biscuits), and her blood pressure was continuously monitored, decreasing to 140/80 mmHg. She was advised to maintain regular meals and to seek medical support. This event was not related to the intervention itself.

Of all eight sessions offered to each of the three groups, totaling 24 sessions, only three were not conducted as originally planned. One group session was interrupted 30 minutes before completion, with the “physical activity practice” component not performed, as one participant had to leave early for a medical appointment and another presented with elevated blood pressure (170/90 mmHg) and reported feeling unwell. The other two situations also occurred during group sessions, in which the “physical activity practice” component was not performed due to the extension of the “healthy behavior skills training” component, which had originally been planned for 25 minutes. The components in which the nutritionist and the psychologist were invited to participate lasted approximately one hour, each occurring in one group session.

Regarding intervention acceptability, of the participants retained until the end of the program, all ($n=8$; 100%) “totally agreed” they were satisfied with the activities conducted by the health professional during the intervention, that the educational materials were helpful in supporting the adoption of a healthy lifestyle, that they were satisfied with the duration of the intervention sessions (1 hour for the educational and individual session; 2 hours for group sessions), and that overall, they were completely satisfied with the intervention they participated in. Finally, five participants (62.5%) “totally agreed” that they were satisfied with the overall duration of the intervention (total number of weekly sessions), two (25%) “partially agreed”, and one (12.5%) “partially disagreed”. The participant who reported “partially disagree” indicated that the intervention could have lasted longer, without specifying a duration, and noted that eight weeks was too short.

Regarding perceived intervention effectiveness, among the eight participants retained until the end of the program, four (50%) reported feeling “much better” when rating their lifestyle now compared to before participating in the intervention, and four (50%) reported “somewhat better”. In addition, four participants (50%) reported feeling “much better” when rating their overall health compared to before the intervention, two (25%) reported “somewhat better”, and two (25%) reported “about the same”.

Table 3 summarizes the costs, with the main expenses being printing materials and transportation.

Table 4 presents the primary goal defined for each participant and the results of the GAS scale. The main goals of the 10 participants involved adherence to regular physical activity (n=6), healthy eating (n=1), and emotional management (n=1). Regarding the clinical outcome of achievement of the main goal defined by the participants, the initial (baseline) T-score was 31.3 (± 3.5), the final (achieved) T-score was 48.8 (± 16.6), and the degree of achievement of the previously established main goal was 17.5 (± 12.8). According to the categorization of participants based on the final (achieved) T-scores, 4 (50%) achieved the final goal and 4 (50%) did not. For the four participants who did not achieve their main goal, the primary target involved engaging in regular physical activity. The following contexts were identified: the second participant reported that her work demanded much of her time, and her income required her to take extra shifts to increase earnings, leaving her with no time available for physical activity (Participant 03); one participant experienced emotional instability after running out of prescribed medication for the management of depressive and anxiety symptoms, which made it impossible for her to engage in regular physical activity (Participant 04); one participant had a medical diagnosis of neuropathic pain that prevented long-duration walking and was advised to seek physiotherapy support (Participant 08); the main goal was to practice physical activity for at least one hour on at least three days per week; however, the participant was able to exercise only twice per week (Participant 10).

Table 3. Costs related to the conduct of the study.

Item	Calculation	Unit cost (R\$)	Total cost (R\$)
Pre-intervention			
Bus fare (in-person training)	2 bus fares/day for 5 persons (1 physiotherapist and 4 undergraduate physiotherapy students) x 3 days=30	5.75	172.50
Phone plan (participant recruitment calls and baseline evaluation)	1	20.00	20.00
Intervention (week-0 to week-12)			
Bus fare (physiotherapist-led in-person sessions, 8 weeks, 3 groups)	2 bus fares/day to deliver the intervention=48	5.75	276.00
Bus fare (10 participants, in-person session, 8 weeks)	2 bus fares/day=160	5.75	920.00
Snack (fruits, coffee, and cookies)	8 weeks x 3 groups=24	20.00	480.00
Printing of materials	2 color pages/week x 8 weeks x 10 participants=160	6.00	960.00
Post-intervention (week-8)			
Printing of evaluation forms	4 pages x 10 participants=40	0.50	20.00
Bus fare (research project evaluator)	2 bus fares/day x 3 days=6	5.75	34.50
Total cost (BRL, R\$)			2,883.00
Total cost (USD, \$)			532.00

Table 4. Main goal defined for each participant and the results of the Goal Attainment Scaling (GAS).

Participant code	Risk factor	Goal	Importance ^a	Probability ^b	Baseline ^c	T-score baseline ^e	Achieved ^d	T-score achieved ^d	Variance	T-score change ^e
01	Physical inactivity	Engage in physical	2	3	-1	40	1	60	Pilates was practiced	20

		activity (e.g., Pilates once per week for 1 hour; walking for 40 minutes at least three times per week), with weekly monitoring of time spent on activities. The goal was to establish regular physical activity within six weeks, which was relevant for improving health, breathing, and cholesterol levels.							twice a week, a treadmill was purchased, and daily walks were planned on non-Pilates days. During this period, walking was performed for 40 minutes twice a week.	
02	Unhealthy eating	Gradually reduce the consumption	2	2	-2	30	1	60	A weight loss of 2 kg was	30

		of soda and cookies (the baseline intake was three units of each per week), replacing them with healthier options (e.g., fruits), while monitoring daily consumption. The goal was complete elimination within six weeks, which was relevant for disease prevention, weight management, and overall health maintenance.							achieved, cookie consumption was reduced to half a package per week, and soda was consumed only on special occasions (one glass). Cookies and soda were replaced with fruits, smoothies, and natural juices.	
03	Physical inactivity	Walking three times	2	2	-2	30	-2	30	Did not start physical	0

		per week for one hour, with weekly monitoring of frequency and duration of physical activity, gradually increasing both time and frequency. The goal was to achieve this target within six weeks, aiming to promote physical, mental, and emotional well-being.							activity due to work routine.	
04	Physical inactivity	Engaging in physical activity (e.g., walking) at least three times per week for	2	2	-2	30	-1	40	Walking was performed twice per week for one hour. She	10

		approximately one hour, with weekly evaluation of duration and frequency. The goal was to achieve this target within six weeks, which was relevant for improving lifestyle, mind, and body.							experienced emotional instability after running out of prescribed medication for depressive and anxiety symptoms, preventing engagement in regular physical activity.	
05	Physical inactivity	Engaging in physical activity (e.g., 30 minutes of HIIT plus 30 minutes of walking), five times per week, with gradual increases in weekly duration. The	3	2	-2	30	2	70	Physical activity was performed five days per week, 30 to 40 minutes per session, three times per week, with walking up	40

		goal was to achieve this target within six weeks, which was relevant for improving self-esteem, mood, health, and stress reduction.							to 6 km on Sundays.	
06	Physical inactivity	Engaging in physical activity (walking three times per week and stair climbing for 10 minutes, three times per week), with weekly evaluation of exercise duration and frequency. The goal was to achieve this target	1	2	-2	Participation in the intervention was not continued.				

		within six weeks, which was relevant for improving health, quality of life, and overall energy levels.				
07	Related to psychosocial aspects (symptoms of stress and anxiety)	Visiting at least one friend per week (a pleasurable activity that was missed, aimed at managing stress and anxiety). The goal was to achieve this target within six weeks, which was relevant for improving lifestyle, mind, body, and spirit.	2	3	-2	Participation in the intervention was not continued.

08	Physical inactivity	Engaging in physical activity (40 minutes of walking and 20 minutes in the outdoor gym – “ <i>Academia a céu aberto</i> ”, an initiative funded by the Brazilian Ministry of Health) every day of the week, with weekly evaluation of duration and frequency. The goal was to achieve this target within six weeks, which was relevant for improving health and well-being.	3	2	-2	30	-1	40	Walking was performed three times per week for 30 minutes, and outdoor gym sessions were conducted twice per week for 20 minutes. Neuropathic pain in the right thigh was reported, which caused caution during activities.	10

09	Physical inactivity	Engaging in physical activity for 40 minutes per day (20 minutes of walking and 20 minutes at the gym) every day of the week, with weekly monitoring of duration and type of activity. The goal was to achieve this target within six weeks, which was relevant for improving health and longevity.	3	2	-2	30	0	50	Physical activity was performed four times per week, with longer sessions consisting of 30 minutes of walking and 30 minutes at the gym.	20
10	Physical inactivity	Engaging in physical activity (walking) for one hour, at	2	3	-2	30	-1	40	Walking was not adopted, but Pilates was well-	10

		least three times per week, with monitoring of duration and number of days per week the activity was performed. The goal was to achieve this target within six weeks, which was relevant for improving health, mental well-being, and promoting weight loss.							received, and sessions were attended twice per week.	

Legend: ^a - Important=1, Very important=2, Extremely important=3; ^b - doubtful=-1, possible=2, probable=3; ^c - Some function=-1; No function=-2; ^d - A lot more achieved=2, A little more achieved=1, Achieved as expected=0, Partially achieved=-1, Unchanged=baseline score, Worse=-2

Discussion

This study presented the successful adaptation of the “iHELP Stroke” to the Brazilian context (Phase I), resulting in the intervention “iVIDAVC”. The adaptation process identified key factors that could influence the implementation of the “iHELP Stroke” in Brazil (Table 1). These factors guided the modifications that were made, ensuring the intervention was suitable for people who had experienced stroke in Brazil while maintaining fidelity to its original active components. In the feasibility phase (Phase II), high retention and adherence rates were observed. In addition, no adverse events related to the intervention were reported, and participants expressed high levels of acceptability and satisfaction, along with positive perceptions of improvements in both lifestyle and health. On the other hand, some aspects require refinement in future studies building on this work, such as sessions involving other health professionals exceeding the planned duration and one group session being conducted with only a single participant.

To date, no studies have been identified that adapted interventions to new contexts specifically aimed at promoting healthy lifestyle behaviors for stroke secondary prevention. A recently published scoping review sought to understand current approaches to adapting complex health interventions for people with long-term conditions.⁵⁶ However, none of the included studies targeted stroke secondary prevention.⁵⁶ One study included in the scoping review⁵⁶ explored the perceptions of diverse stakeholders in an urban Ghanaian community regarding challenges to optimal hypertension management in the context of primary stroke prevention, as well as facilitators and barriers to implementing an evidence-based educational tool developed in the United States.⁵⁷ This study was conducted prior to the publication of the ADAPT Guidance,³⁵ nonetheless, the authors involved a stakeholder panel but did not assess the feasibility of implementing the adapted intervention in the new context.⁵⁷

Another study described in the scoping review⁵⁶ detailed the cultural adaptation and development of an intervention and training program for the treatment and prevention of comorbid heavy drinking and depression, for use in Latin America (Colombia, Mexico, and Peru), originally developed in United Kingdom.⁵⁸ The authors employed a pre-existing adaptation framework that included information gathering, preliminary adaptation, adaptation testing, and refinement, which provided clarity on the adaptation process.⁵⁸ They emphasized a lack of evidence regarding Latin American communities’ experiences with culturally adapted health interventions in different contexts.⁵⁸ The

present study contributes to filling this gap by documenting the adaptation of an intervention in a Latin American middle-income country. The hitherto absence of adaptive studies specifically focused on stroke secondary prevention⁵⁶ further underscores the need for research in this area, following best practice recommendations for conducting and reporting adaptation processes.

A systematic review conducted by Escoffery et al.⁵⁹ examined the reasons and common types of adaptations made to evidence-based public health interventions in community settings, the steps described to guide these adaptations, and the outcomes assessed in evaluation studies. The main reason for exclusion of studies in that review was the lack of description of the adaptation process or methods.⁵⁹ Moreover, fewer than half of the included reports explicitly named an adaptation framework to guide the process.⁵⁹ The present study followed both the ADAPT Guidance³⁵ to inform and conduct the adaptation, and the FRAME⁴² to report the adaptations made. Given the limited research exploring how adaptation occurs in practice (who is involved, what types of modifications are made, and which mechanisms are employed),⁵⁹ the use of these frameworks^{35,42} in this study provides a clearer understanding of how the adaptation was conducted.

Despite the positive indicators of feasibility, such as high retention and adherence, absence of adverse events, high acceptability and satisfaction, and positive perceptions of lifestyle and health improvements, future stages of the study should address several considerations. Sessions involving multiple health professionals (“healthy behavior skills training” component) extended beyond the planned time, one participant reported that eight weeks were insufficient, and one group session was held with only one participant, which limited an important peer support component. Therefore, a future pilot study (Phase I of a randomized controlled trial (RCT))⁶⁰ should implement the originally format (1 individual session and 6–12 group sessions, now including an additional educational session), with a total duration of 14 weeks,²⁴ allowing for repeated involvement of health professionals and ensuring that the planned content can be delivered without compromise. Furthermore, to avoid compromising the delivery of group sessions and the “peer support” component,²⁴ it is recommended that groups of at least four participants be formed. In the present study, groups of three participants, in which two were absent, hindered the conduct of the group session.

Although participation in physical activity was the most frequently chosen primary goal, this does not diminish the importance of individuals post-stroke

simultaneously adopting multiple healthy lifestyle behaviors for stroke secondary prevention, as well as managing additional modifiable risk factors, including psychosocial risks.^{12, 15} Participation in physical activity was prioritized because it was perceived as the most challenging goal by the participants, requiring greater support. Encouraging physical activity after stroke is complex and depends on managing multiple factors.⁶¹⁻⁶³ For instance, one participant experienced emotional instability after running out of prescribed medication for depression and anxiety, which hindered regular physical activity. Although emotional management was not her primary goal, it directly affected adherence, highlighting the need to consider psychosocial factors alongside participants' main goals. Another participant reported that her low income requires her to work extra hours to supplement her earnings, leaving little time for physical activity. This socioeconomic aspect of the country must be carefully considered when promoting physical activity after stroke in Brazil.

Another participant, whose primary goal was regular physical activity, was classified as not having achieved her target (at least one hour of exercise on three days per week), as she was only able to exercise twice weekly. Although the present study did not aim to evaluate the impact of the intervention, but rather to test its feasibility, the fact that she did not meet the exact target still represents a meaningful behavioral change that warrants careful interpretation. This raises questions about the definition of outcomes in this study. Escoffery et al.⁵⁹ noted that, beyond behavioral outcomes, other outcomes such as knowledge, self-efficacy, attitudes, and skills are often assessed in evaluations of adapted evidence-based public health interventions. Future stages of the study should therefore incorporate these additional outcomes to better capture the impact of the intervention.

While this study successfully described the adaptation of a stroke secondary prevention intervention and its feasibility for implementation in the Brazilian context, the results should be interpreted cautiously and in light of several limitations. While conducted in Brazil, the generalizability of findings to other LMICs may be limited due to cultural, economic, and structural differences. Although the intervention was tailored to the Brazilian context, other countries may face different challenges in post-stroke intervention implementation. Future research could include feasibility testing in other cultural settings to evaluate the effectiveness and adaptability of the intervention across populations. A future pilot trial is now required to test the feasibility of implementing the program with a greater number of sessions (9-14 sessions), with repeated engagement of

health professionals, and ensuring groups include at least four participants in a group to avoid compromising the delivery of group sessions due to absenteeism. Future studies could test a broader range of relevant behavior change outcomes, including knowledge, self-efficacy, attitudes, and skills, using validated measurement tools beyond those reported in this study, which focused on goal attainment. Finally, the study did not include a longitudinal follow-up, limiting our understanding of the sustainability of behavior changes identified over time.

Conclusion

This study reports the adaptation to the Brazilian context of a theoretically-informed behavior change intervention for stroke secondary prevention, originally developed in a high-income country (Ireland) (“iHELP Stroke”), resulting in “iVIDAVC”. Findings from the feasibility phase indicated that the adapted intervention was well received, with high retention, adherence, and satisfaction rates among participants, as well as positive perceptions of improvements in lifestyle and health. However, adjustments are still needed, including testing the program with the provision of a greater number of sessions, ensuring invited health professionals participate on more than one occasion, and including at least four individuals post-stroke in each group session to prevent disruption where multiple participants are absent. In addition, outcome assessment should be refined to allow a more comprehensive understanding of the intervention’s impact. This study provides a strong foundation for future research on the implementation of stroke secondary prevention interventions and underscores the importance of adapting and evaluating models that address the social, cultural, and individual complexities of the target populations.

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Supplementary Material

Article title: Brazilian adaptation of the “iHELP Stroke: Improving Health and Lifestyle Programme” and feasibility study

Content and components of the adapted version of the “iHELP Stroke”

- **One Educational Session**

The coordinator provides knowledge about stroke, including what stroke and recurrent stroke are, their signs and symptoms, and lifestyle-related risk factors. The session explains and clarifies lifestyle-related risk factors that contribute to stroke recurrence and highlights the importance of adopting healthy lifestyle behaviors. In addition, the coordinator addresses beliefs that may negatively impact adherence to prescribed medications and the adoption of healthy behaviors, such as the idea that medications are harmful if taken long-term or that lifestyle changes are unnecessary to prevent another stroke.

- **One Individual Session**

The session begins with the identification of the participant's current self-reported health status after stroke; the recognition and awareness of lifestyle-related risk factors, including goal setting for behavior change; and the identification of the individual's preferences and ability to participate in the intervention program. The facilitator builds rapport, checks readiness, identifies risk factors, sets individual goals, and confirms commitment. During this process, the facilitator collects demographic data (such as sex, age, marital status, living arrangement, primary caregiver, employment status, educational level, and monthly income), information on the use of mobility aids (e.g., wheelchairs or walking aids), and the participant's preference regarding caregiver involvement, which may occur at any point during the intervention, for example, during goal-setting to support behavior change and the adoption of healthy lifestyle behaviors. Monthly income is assessed to determine whether it facilitates access to public transportation and food, along with the risk of food insecurity. The facilitator also reviews laboratory test results brought by participants, particularly those related to recurrent stroke, such as lipid levels and diabetes-related outcomes, and collects stroke-related information (time since stroke onset and treatment received), pre-stroke functional status, self-rated health (categorized as “less good,” “good,” or “very good,” and rated

from 0 to 100), comorbidities (including prior stroke, diabetes, heart disease, arrhythmia, and hypertension), and lifestyle-related behaviors, such as medication adherence, smoking, alcohol consumption, diet, physical activity participation, and emotional factors or mood. After all information is collected and analyzed, the coordinator works with the participant to set three behavior-change goals to encourage the adoption of a healthy lifestyle. The coordinator supports the participant in defining these goals, which are structured using the SMART Goals method. Throughout this initial individual session, particularly during the identification of risk factors and goal setting (such as concerns about long-term medication use or doubts about the need for lifestyle changes to prevent another stroke).

- **Six to Twelve Group Sessions**

Each group session consists of six components: education, focusing on essential information about stroke and healthy lifestyles; goal setting, which includes reviewing and adjusting previously established goals; participation in physical activity, with demonstrations and supervised practice; emotional self-regulation, involving demonstrations and practice of coping and mood-management strategies; skills training, carried out through interactive skill acquisition using a “see and do” cycle; and peer learning, promoted through supportive interactions among participants. A total of 6 to 12 group sessions are planned to be delivered. Below, the content of the minimum six sessions is presented. If additional sessions are conducted, they should be tailored to participants’ needs and cover the six components described above. Similar session scripts to those already presented may also be followed.

GROUP SESSION - WEEK 1		
Component (time required)	Suggested content ("iHELP Stroke")	Intervention content delivered in Brazil ("iVIDAVC")
Education (20 min)	Introduction to stroke, types of stroke, impact, risk factors	• Reinforce and check knowledge about what stroke is, signs and symptoms, and risk factors • Clarify any doubts related to this content • Note: this content is intended to be covered in the educational session
Goal setting (20 min)	SMART goals - short and long term, assistance with goal setting	• Review goals established in the initial individual session (printed information) • Discussion: What needs to be done in the short term (during the next week) to meet the main goal? What long-term goals are proposed? Does any previously defined goal need to be modified?
Physical activity participation (30 min)	Individual exercise stations - monitoring exertion	• Educational component: concepts of physical activity and intensity • Demonstration: walking in the corridor with encouragement to increase speed while identifying intensity
Peer learning (15 min)	Sharing experiences and reflections	• Explore experiences related to achieving goals during the previous week
Emotional self-regulation (10 min)	Support for self-assessment; demonstration and practice	• Educational component related to support for self-assessment: anxiety screening • Demonstration and practice: meditation (audio link used: https://hotsite.sextante.com.br/atencaoplena/4Track.mp3)
Skills training (25 min)	"Ask the Expert" sessions (e.g., physiotherapist, nutritionist, pharmacist)	• Suggestion 1: Invite a pharmacist. Topics may include beliefs that negatively affect medication adherence (preference for herbal teas instead of medications, self-medication, importance of taking medications at correct times) and laboratory test results (indicating hyperlipidemia and diabetes). • Suggestion 2: Practical exercise to identify situations that trigger smoking; record these situations; identify strategies to address them.

GROUP SESSION - WEEK 2		
Component (time required)	Suggested content ("iHELP Stroke")	Planning of what was carried out in Brazil ("iVIDAVC")
Goal setting (20 min)	Support for weekly self-review, modification, and redefinition	- Review goals established in the initial individual session (printed information) - Discussion: Identify whether any short-term goals have been achieved. If not, why? Review and adjust as needed. If they have been achieved, what contributed to this success?
Physical activity participation (30 min)	Individual exercise stations - monitoring exertion	- Educational component: addressing the concepts of heart rate and training range - Demonstration: exercise stations (stepping up and down, hallway walking, portable cycle ergometer (identifying preference for upper or lower limbs), and sit-to-stand), combined with participants' identification of exercise intensity
Education (20 min)	Discussion about modifiable risk factors - behaviors that can be changed	- Suggestion 1: smoking cessation. Content to be addressed includes the risks associated with smoking and the support programs available in the city for smoking cessation. Knowledge check: each participant identifies one risk associated with smoking. - Suggestion 2: safe alcohol consumption. Content to be addressed includes the risks associated with harmful alcohol use and the support programs available in the city to reduce alcohol consumption. Knowledge check: each participant identifies one risk associated with harmful alcohol use.
Peer learning (15 min)	Problem solving	Identify at least one barrier to achieving goals and discuss strategies to overcome it
Skills training (10 min)	Learn-practice-homework	- Skill to be trained: learning to use outdoor gym equipment (Brazilian Physical Activity Program: "Academia a céu aberto"; videos recorded by the coordinator) - Encourage participants to visit and practice physical activity at the outdoor gym
Emotional self-regulation (25 min)	Self-assessment support Example demonstration by an invited professional (ideally, optional)	- Educational component related to support for self-assessment: mood-change screening - Demonstration and practice: deep abdominal breathing

GROUP SESSION - WEEK 3		
Component (time required)	Suggested content ("iHELP Stroke")	Planning of what was carried out in Brazil ("iVIDAVC")
Emotional self-regulation (10 min)	Self-assessment support Example demonstration by an invited professional (ideally, optional)	- Educational component related to support for self-assessment: screening for depressive symptoms - Demonstration and practice: Emotion diary. Complete the emotion diary considering the past week. Reflections: Which feelings were most frequent? Are there any factors that need to be managed?
Education (20 min)	Physical activity and FITT (Frequency, Intensity, Time, and Type of exercise) recommendations	- Educational component: explain FITT (frequency, intensity, time, type) - Knowledge check: participants explain each FITT component
Goal setting (20 min)	Support for weekly self-review, modification, and redefinition Identify strategies for success	- Review goals established in the initial individual session (printed information) - Discussion: Identify at least one success in achieving the established goals and review what is necessary
Peer learning (15 min)	Group discussions	- Suggestion 1: Which physical activities are most enjoyable for you? What motivates you to engage in physical activity? - Suggestion 2: Have you ever tried to quit smoking? What helped you quit or reduce the number of cigarettes you smoke per day? What do you think made the quitting process difficult? - Suggestion 3: Do you consume alcohol in excess? In which situations? Can you identify any reason related to excessive alcohol consumption?
Physical activity participation (30 min)	Individual exercise stations - monitoring exertion	Demonstration: exercise stations (stair climbing, corridor walking, portable cycle ergometer (identifying preference for upper or lower limbs), and sit-to-stand), combined with participants' identification of exercise intensity
Skills training (25 min)	See and do - healthy diet	- Introductory education: minimally processed, processed, and ultra-processed foods - Skill to be trained: preparing a healthy snack. Activity: using pictures of foods, ask participants which items should be prioritized when preparing a healthy snack (examples: fruit salad and healthy sandwich). Address the seasonality of fruit availability in Brazil and encourage participants to prepare a snack at home. Provide fruit salad to the participants.

GROUP SESSION - WEEK 4		
Component (time required)	Suggested content ("iHELP Stroke")	Planning of what was carried out in Brazil ("iVIDAVC")
Skills training (25 min)	"Ask the Expert" sessions (e.g., physiotherapist, nutritionist, pharmacist)	- Suggestion 1: Invite a nutritionist. Topics that can be encouraged during the discussion include beliefs that may negatively affect adherence to healthy eating (such as excessive use of animal fat or colored salts on salads) and food reuse. - Suggestion 2: practical exercise to identify situations that trigger the urge to consume alcohol, record these situations, and identify strategies to address them.
Emotional self-regulation (10 min)	Self-assessment support Example demonstration by an invited professional (ideally, optional)	- Educational component related to support for self-assessment: stress screening - Demonstration and practice: meditation (audio link used: https://hotsite.sextante.com.br/atencao plena/8Track.mp3)
Peer learning (15 min)	Combination of social and peer elements	Propose group discussions based on the following prompts: identify whether participants find it valuable to invite a companion to attend the next session; and ask them which community resources support the adoption of healthy behaviors, such as public places for physical activity or educational talks at local health centers
Physical activity participation (30 min)	Individual exercise stations - monitoring exertion	Demonstration: exercise stations (stair climbing, corridor walking, plantar flexion, and sit-to-stand), combined with participants' identification of exercise intensity
Education (20 min)	Mediterranean diet, dietary approaches, common pitfalls	- Educational component: cardioprotective eating, including guidance on building a healthy plate - Knowledge check: which foods are included in a healthy lunch
Goal setting (20 min)	Support for weekly self-review, modification, and redefinition	- Review goals established in the initial individual session (printed information) - Discussion: how goal achievement is progressing and identify which goals need to be reviewed and modified

GROUP SESSION - WEEK 5		
Component (time required)	Suggested content ("iHELP Stroke")	Planning of what was carried out in Brazil ("iVIDAVC")
Education (20 min)	Psychoeducation, exploring mood and management strategies	• Educational component: psychoeducation (supporting participants in coping with the consequences of stroke, including managing emotional aspects and recovering functionality; exploring participants' perceptions regarding psychological follow-up). • Knowledge check: ask participants how they recognize the need to seek help for managing emotional aspects.
Physical activity participation (30 min)	Individual exercise stations - monitoring exertion	• Demonstration: exercise stations (stair climbing, hallway walking, plantar flexion, and sit-to-stand), combined with participants' identification of exercise intensity
Emotional self-regulation (10 min)	Self-assessment support Example demonstration by an invited professional (ideally, optional)	• Educational component: explore experiences practicing meditation and deep breathing at home • Demonstration and practice: deep abdominal breathing
Goal setting (20 min)	Support for weekly self-review, modification, and redefinition	• Review goals established in the initial individual session (printed information) • Discussion: how goal achievement is progressing and identify which goals need to be reviewed and modified
Peer learning (15 min)	Family, friends, and caregiver involvement	• Presence of a companion • Propose group discussions based on the following prompts: How do you believe this relationship impacts the adoption of a healthy lifestyle? How can mutual collaboration support you in adopting healthy lifestyle behaviors?
Skills training (25 min)	"Ask the Expert" sessions (e.g., physiotherapist, nutritionist, pharmacist)	• Suggestion 1: Invite a psychologist. Topics that can be encouraged during the discussion include how managing emotional aspects can positively influence smoking cessation or safe alcohol consumption • Suggestion 2: explore practical tips to improve medication adherence

GROUP SESSION - WEEK 6		
Component (time required)	Suggested content ("iHELP Stroke")	Planning of what was carried out in Brazil ("iVIDAVC")
Emotional self-regulation (10 min)	Self-assessment support Example demonstration by an invited professional (ideally, optional)	- Educational component related to self-assessment support: identifying the emotional factors experienced during the past week - Demonstration and practice: completing the emotion diary considering the past week. Reflections: Which feelings were most frequent? Are there any factors that need to be managed?
Skills training (25 min)	Learn-practice-homework-feedback	- Suggestion 1: practical tips for quitting smoking - Suggestion 2: practical tips for reducing alcohol consumption
Physical activity participation (30 min)	Individual exercise stations - monitoring exertion	Demonstration: outdoor walk with encouragement to increase speed while identifying intensity
Peer learning (15 min)	Providing information about available additional support	Propose group discussions based on the following prompts: Ask participants what additional support they have sought to become healthier (for example, services at local health centers). List the main resources mentioned and provide information about additional support options available.
Goal setting (20 min)	Support for self-assessment, future goal-setting, and maintenance of changes	- Review goals established in the initial individual session (printed information) - Discuss: Which goals have been achieved? For those that have not been achieved, what is needed to complete them? Which new goals are identified as necessary for adopting a healthy lifestyle?
Education (20 min)	Importance of medication adherence; correcting and clarifying beliefs	- Educational component: medication adherence, including the importance of taking prescribed medications (at the correct time) and explaining why prescribed medications should not be missed, as well as information about medications available through the "<i>Farmácia Popular</i>" Program (Brazilian Popular Pharmacy Program). Propose group discussions based on the following prompts: Do you take all your prescribed medications? If yes, why? If not, why not? - Knowledge check: ask participants about their perception of how important they consider taking their prescribed medications

CONSIDERAÇÕES FINAIS

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O tema central desta tese envolve a adoção de comportamentos de estilo de vida saudável na prevenção secundária do acidente vascular cerebral (AVC), alinhando-se à linha de pesquisa “Estudos em Reabilitação Neurológica no Adulto” do Programa de Pós-Graduação em Ciências da Reabilitação (PPGCR) da UFMG. A proposta pedagógica do PPGCR da UFMG fundamenta-se na Classificação Internacional de Funcionalidade, Incapacidade e Saúde (CIF) da Organização Mundial da Saúde (OMS, 2001), que contempla Fatores Contextuais relacionados ao ambiente, ao histórico e ao estilo de vida. Embora os Fatores Pessoais, como o estilo de vida, não estejam classificados pela CIF, eles integram seu modelo e influenciam a funcionalidade, a incapacidade e a saúde. Nesta tese, o estilo de vida de indivíduos pós-AVC foi abordado tanto como fator pessoal quanto como uma atividade de cuidado em saúde.

Para ampliar a compreensão da temática, além da introdução (Capítulo 1), foram desenvolvidos seis estudos originais. A *overview* de revisões sistemáticas (Estudo 1; Capítulo 2) (Peniche *et al.*, 2025a) mostrou que intervenções de telessaúde reduzem a recorrência de eventos cardiovasculares e AVC, melhoram a adesão à medicação, alimentação saudável, prática de atividade física e o controle da pressão arterial e do colesterol, com redução da PAS. O nível de certeza das evidências variou de muito baixo a moderado, sendo este último apenas para a PAS. Os achados indicam a necessidade de estudos mais robustos e apontam a escassez de intervenções teoricamente informadas via telessaúde em países de baixa e média renda, como o Brasil, inclusive para incentivar a participação em atividade física pós-AVC.

O Estudo 2 (Capítulo 3) (Peniche *et al.*, 2025b) apresentou o protocolo de um estudo de viabilidade de uma intervenção teoricamente informada, combinando a intervenção breve dos 5As do Pacote Técnico HEARTS ao uso de monitor de atividade física por telessaúde para aumentar o nível de atividade física pós-AVC no GE, enquanto o GC não utilizou o monitor. O Estudo 3 (Capítulo 4) apresentou a condução desse estudo, mostrando que as intervenções foram viáveis e geraram mudanças clinicamente relevantes nos níveis de atividade física. Como o GE teve maior tamanho de efeito que o GC, as próximas etapas devem ajustar questões como baixa retenção e perdas de seguimento para avaliar o efeito adicional do monitor no aumento do nível de atividade física pós-AVC.

Fundamentada na necessidade de uma intervenção que contemplasse o gerenciamento dos fatores de risco relacionados ao estilo de vida, bem como, dos fatores de risco cardiovasculares e psicossociais para a recorrência do AVC em países de baixa e média renda, como o Brasil, a intervenção irlandesa “*iHELP Stroke*” (Hall *et al.*, 2025) foi considerada com

potencial de aplicação no contexto brasileiro por alinhar-se às diretrizes de prevenção secundária do AVC e às recomendações para intervenções complexas. Diante das diferenças socioeconômicas e culturais entre os países, a adaptação prévia da intervenção mostrou-se necessária. Para acompanhar o movimento de pesquisa em saúde em parceria (NIHR, 2024), planejou-se envolver indivíduos pós-AVC como representantes do EPP na adaptação da intervenção. Contudo, a escassez de estudos com EPP, especialmente em pesquisas sobre AVC, motivou a realização de uma revisão de escopo (Peniche *et al.*, 2024) (Estudo 4, Capítulo 5) para identificar como a abordagem de EPP vem sendo implementada e relatada em pesquisas empíricas sobre AVC. A revisão de escopo confirmou a escassez de pesquisas sobre AVC, principalmente no contexto da prevenção secundária, em países de baixa e média renda que incluam a abordagem de EPP e recomendou ampliar o uso dessa iniciativa nesses contextos. Além disso, considerando a importância de contextualizar a prevenção secundária de acordo com as necessidades e prioridades de indivíduos pós-AVC (Lawrence *et al.*, 2019), desenvolveu-se o quinto estudo desta tese (Capítulo 6). Neste estudo, foi identificada a concordância entre indivíduos pós-AVC irlandeses e brasileiros ao classificar a maioria dos componentes a serem incluídos em intervenções destinadas a incentivar a adoção de comportamentos de estilo de vida saudável pós-AVC como “definitivamente importantes”, o que reforça o potencial da “*iHELP Stroke*” (Hall *et al.*, 2025) para aplicação em indivíduos pós-AVC brasileiros. No entanto, divergências também foram identificadas, evidenciando a necessidade de cautela ao transferir intervenções de países de alta renda, como a Irlanda, para contextos de baixa e média renda, como o Brasil.

Complementando o estudo anterior, o sexto estudo, apresentado no Capítulo 7, descreveu o processo de adaptação da intervenção irlandesa “*iHELP Stroke*” (Hall *et al.*, 2025) para o contexto brasileiro, que incluiu a abordagem de EPP contando com uma representante pós-AVC como co-pesquisadora, resultando na versão denominada “*iVIDAVC*”. A fase de viabilidade demonstrou alta aceitação, adesão e satisfação entre os participantes, com relatos de melhorias em saúde e estilo de vida. Ajustes, entretanto, foram recomendados para estudos futuros, como: aplicar o programa completo de 14 semanas, envolver os profissionais de saúde convidados em múltiplas sessões, incluir pelo menos quatro participantes por grupo e aprimorar os métodos de avaliação dos desfechos clínicos de interesse. Além disso, considerando a utilidade clínica da tele saúde no cuidado de indivíduos pós-AVC, é importante que futuros estudos avaliem a viabilidade de implementar a intervenção de forma remota. Este estudo fornece uma base para pesquisas futuras sobre a implementação de intervenções de prevenção secundária do AVC e ressalta a importância de investigar mais profundamente os modelos de

adaptação e avaliação que abordam as complexidades sociais, culturais e individuais das populações-alvo.

Conclui-se que este conjunto de seis estudos permitiu explorar aspectos relevantes sobre a adoção de comportamentos de estilo de vida saudável na prevenção secundária do AVC, incluindo: síntese de evidências sobre intervenções de prevenção secundária no contexto da telessaúde, oferecendo direcionamento aos profissionais de saúde; apresentação de uma intervenção teoricamente informada viável de ser implementada por telessaúde para aumentar o nível de atividade física pós-AVC; direcionamento quanto à recomendação de incluir a abordagem de EPP em pesquisas sobre AVC em países de baixa e média renda, como o Brasil; reforço da necessidade de cautela ao transferir intervenções de países de alta renda para contextos de média renda; e apresentação de uma intervenção adaptada ao contexto brasileiro voltada ao incentivo de comportamentos de estilo de vida saudável pós-AVC, viável de ser implementada localmente. Todos os estudos apontaram lacunas e barreiras, fornecendo também direcionamentos para futuras pesquisas.

Por fim, destaco a contribuição do doutorado para a minha formação. O doutorado-sanduíche na Irlanda possibilitou a minha participação em *workshops* de escrita científica e de EPP na pesquisa, meu engajamento na condução de projetos com indivíduos pós-AVC, a participação em reuniões científicas, bem como o desenvolvimento, escrita e publicação de artigos com diferentes metodologias, além de apresentações e palestras em eventos científicos. Nas demais fases do doutorado, desenvolvi habilidades em coordenação e coordenação de equipes de graduação e pós-graduação, aprimorei minha escrita acadêmica e comunicação em inglês, adquiri competências para conduzir diversos tipos de pesquisa (qualitativa, ensaios clínicos, estudos de viabilidade, descritivos e revisões), passei a dominar diferentes análises estatísticas, orientei e coorientei trabalhos acadêmicos, tive formação docente em ensino de graduação e pós-graduação, e atuei como revisora de artigos científicos.

A presente tese confirma o atendimento aos objetivos do PPGCR da UFMG, ao proporcionar: 1. formação pessoal, técnica e científica adequada para o exercício das atividades profissionais de ensino e pesquisa; 2. aprofundamento do conhecimento acadêmico e profissional na área de reabilitação, com ênfase no cuidado à saúde de indivíduos pós-AVC através do incentivo à adoção de comportamentos de estilo de vida saudável; 3. desenvolvimento das competências necessárias para conduzir pesquisas originais e independentes na área de reabilitação; e 4. capacidade de propor e conduzir, de maneira autônoma, estudos originais na área de reabilitação.

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ANEXOS

ANEXO A

Consultar Atividades em Curso e Cursadas

[Informação para simples consulta]

Aluno 2021704224 PAULA DA CRUZ PENICHE

Curso 3581 CIÊNCIAS DA REABILITAÇÃO/D

Relação de Atividades no Histórico

Período	Turma	Nome Atividade	Tipo Mat	Freq	Nota	Conc	Sit Final	Créd	Integr ?
2021/2	DCR GER000	DISPENSA DE CREDITO					4	15	Sim
2021/2	DIP CRE801	METODOLOGIA DA PESQUISA CIENTÍFICA I					4	4	Sim
2021/2	DIP CRE817	INICIAÇÃO À DOCÊNCIA I		S	100	A	A	2	Sim
2021/2	DIP EST814	PRINCÍPIOS DE BIOESTATÍSTICA					4	4	Sim
2022/1	DIP CRE802	METODOLOGIA DA PESQUISA CIENTÍFICA II		S	94	A	A	04	Sim
2022/1	DIP CRE803	SYSTEMATIC REVIEWS AND META-ANALYSES		S	93	A	A	04	Sim
2022/1	DIP CRE818	INICIAÇÃO À DOCÊNCIA II		S	100	A	A	2	Sim
2022/2	DIP CRE808	MODELOS DE FUNÇÃO E DISFUNÇÃO HUMANA		S	97	A	A	04	Sim
2022/2	DIP CRE815	ATUALIZAÇÃO EM REABILITAÇÃO NEUROLÓGICA		S	100	A	A	04	Sim
2023/1	DIP CRE807	SEMINÁRIOS DE DOUTORADO		S	98	A	A	02	Sim
2023/2	ETF GER000	ELABORACAO DE TRABALHO FINAL						0	Sim
2024/1	EQP CRE005	EXAME DE QUALIFICAÇÃO					A	0	Sim
2024/1	ETF GER000	ELABORACAO DE TRABALHO FINAL						0	Sim
2024/2	ETF GER000	ELABORACAO DE TRABALHO FINAL						0	Sim
2025/1	ETF GER000	ELABORACAO DE TRABALHO FINAL						0	Sim
2025/2	ETF GER000	ELABORACAO DE TRABALHO FINAL						0	Sim

ANEXO B

UNIVERSIDADE FEDERAL DE
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**PARECER CONSUBSTANCIADO DO CEP****DADOS DO PROJETO DE PESQUISA**

Título da Pesquisa: EFEITO DE UM PROGRAMA DE INTERVENÇÃO POR TELERREABILITAÇÃO NA PROMOÇÃO DE ATIVIDADE FÍSICA SUFICIENTE EM INDIVÍDUOS PÓS-ACIDENTE VASCULAR ENCEFÁLICO: UM ENSAIO CLÍNICO ALEATORIZADO

Pesquisador: Christina Danielli Coelho de Moraes Faria

Área Temática:

Versão: 2

CAAE: 66980723.2.0000.5149

Instituição Proponente: PRO REITORIA DE PESQUISA

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 5.980.632

Apresentação do Projeto:

Trata-se de um ensaio clínico aleatorizado, com avaliador cegado e com alocação oculta. O projeto será submetido ao Comitê de Ética em Pesquisa da Universidade Federal de Minas Gerais (COEP/UFMG). A folha de rosto encontra-se em anexo (ANEXO 1). Todas as anuências necessárias para o desenvolvimento do estudo foram obtidas (ANEXO 2). Além disso, esse projeto foi aprovado pela câmara do Departamento de Fisioterapia da UFMG (ANEXO 3). Este estudo será registrado no www.ClinicalTrials.gov e realizado conforme as recomendações do Consolidated Standards of Reporting Trials (CONSORT) (Schulz et al., 2010). O recrutamento dos indivíduos e a coleta de dados serão iniciados após a aprovação do Comitê de Ética em Pesquisa da Universidade Federal de Minas Gerais. Todos os indivíduos serão orientados sobre os procedimentos que serão realizados

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Continuação do Parecer: 5.980.632

e apenas serão incluídos após concordarem com a participação voluntária e assinarem o Termo de Consentimento Livre e Esclarecido (TCLE)

Objetivo da Pesquisa:

Objetivo primário: Investigar o efeito de um programa de intervenção por telerreabilitação envolvendo o pacote técnico HEARTS e a prática de atividade física

auto-monitorada na promoção de atividade física suficiente em indivíduos pós-AVE;

Objetivo secundário: Investigar o efeito de um programa de intervenção por telerreabilitação envolvendo o pacote técnico HEARTS e a prática de atividade física auto-monitorada na redução da pressão arterial sistólica e diastólica, aumento do nível de atividade física, melhora da autoeficácia e da qualidade de vida relacionada à saúde de indivíduos pós-AVE.

Avaliação dos Riscos e Benefícios:

Riscos:

Os riscos associados com os testes e com o programa de intervenção são mínimos e similares aos que você está exposto no seu dia a dia. Durante as sessões de treinamento em domicílio você pode vir a sentir-se cansado. Em casos de cansaço extremo, períodos de repouso podem ser realizados. Qualquer tipo de desconforto vivenciado durante os testes ou treinamento deve ser revelado para que os pesquisadores tomem as devidas providências com o objetivo de minimizá-lo.

Benefícios:

Você e futuros pacientes poderão se beneficiar com os resultados desse estudo, principalmente porque o objetivo principal do mesmo é determinar a melhor abordagem para promoção de atividade física em indivíduos pós-AVE, que contribuirá para uma melhor saúde e funcionalidade desses indivíduos. Se após a conclusão do estudo for observado maior benefício alcançado em um grupo em relação aos demais, a intervenção de maior benefício será ofertada para os participantes do grupo controle.

Comentários e Considerações sobre a Pesquisa:

Pesquisa relevante para a área de Fisioterapia com previsão de término em 30/09/2025. As solicitações do COEP foram atendidas: 1) Foi detalhado o TCLE e exigidos atestados médicos para a prática de atividade física (como critério de inclusão); 2) Foi incluído maior detalhamento sobre os procedimentos que impliquem na realização de exames físicos e de esforço e apresentados os

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formulários para estes exames; 3) Foi especificado como será realizado o monitoramento da prática de atividade física, caso o indivíduo seja alocado no grupo intervenção.

Considerações sobre os Termos de apresentação obrigatória:

Apresentou todos os documentos incluindo uma nova carta de anuência do NUEROLAB onde o primeiro contato para coleta de dados possa ser realizado.

Recomendações:

Recomenda-se a aprovação do projeto de pesquisa.

Conclusões ou Pendências e Lista de Inadequações:

Somos favoráveis à aprovação do projeto "EFEITO DE UM PROGRAMA DE INTERVENÇÃO POR TELLERREABILITAÇÃO NA PROMOÇÃO DE ATIVIDADE FÍSICA SUFICIENTE EM INDIVÍDUOS PÓS-ACIDENTE VASCULAR ENCEFÁLICO: UM ENSAIO CLÍNICO ALEATORIZADO" da pesquisadora responsável Profa. Dra. Christina Danielli Coelho de Moraes Faria.

Considerações Finais a critério do CEP:

Tendo em vista a legislação vigente (Resolução CNS 466/12), o CEP-UFMG recomenda aos Pesquisadores: comunicar toda e qualquer alteração do projeto e do termo de consentimento via emenda na Plataforma Brasil, informar imediatamente qualquer evento adverso ocorrido durante o desenvolvimento da pesquisa (via documental encaminhada em papel), apresentar na forma de notificação relatórios parciais do andamento do mesmo a cada 06 (seis) meses e ao término da pesquisa encaminhar a este Comitê um sumário dos resultados do projeto (relatório final).

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_2063312.pdf	24/03/2023 09:53:27		Aceito
Outros	PARECER_CAMARA_DEPARTAMENTAL.pdf	24/03/2023 09:51:57	Christina Danielli Coelho de Moraes Faria	Aceito
Outros	FICHA_DE_REAVALIACAO.pdf	24/03/2023 09:50:58	Christina Danielli Coelho de Moraes Faria	Aceito
Outros	FICHA_DE_AVALIACAO.pdf	24/03/2023 09:50:34	Christina Danielli Coelho de Moraes Faria	Aceito
Outros	CARTA_RESPOSTA.pdf	24/03/2023 09:48:16	Christina Danielli Coelho de Moraes	Aceito

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Continuação do Parecer: 5.980.632

Outros	CARTA_RESPOSTA.pdf	24/03/2023 09:48:16	Faria	Aceito
Outros	ANUENCIA_LABORATORIO_NEUROL AB.pdf	24/03/2023 09:47:13	Christina Danielli Coelho de Moraes Faria	Aceito
Projeto Detalhado / Brochura Investigador	PROJETO_DE_PESQUISA.pdf	24/03/2023 09:43:43	Christina Danielli Coelho de Moraes Faria	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE.pdf	24/03/2023 09:43:02	Christina Danielli Coelho de Moraes Faria	Aceito
Orçamento	ORCAMENTO.pdf	24/03/2023 09:42:54	Christina Danielli Coelho de Moraes Faria	Aceito
Cronograma	CRONOGRAMA.pdf	24/03/2023 09:42:35	Christina Danielli Coelho de Moraes Faria	Aceito
Folha de Rosto	FOLHA_DE_ROSTO.pdf	27/01/2023 13:51:13	Christina Danielli Coelho de Moraes Faria	Aceito

Situação do Parecer:

Aprovado

Necessita Apreciação da CONEP:

Não

BELO HORIZONTE, 03 de Abril de 2023

**Assinado por:
Corinne Davis Rodrigues
(Coordenador(a))**

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ANEXO C

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PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: Adaptação ao contexto brasileiro de uma intervenção para prevenção secundária do Acidente Vascular Cerebral direcionada à adoção de estilo de vida saudável

Pesquisador: Christina Danielli Coelho de Moraes Faria

Área Temática:

Versão: 1

CAAE: 77083023.0.0000.5149

Instituição Proponente: PRO REITORIA DE PESQUISA

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 6.683.329

Apresentação do Projeto:

O acidente vascular cerebral (AVC) apresenta elevada carga globalmente, que é ainda maior nos países de baixa e média renda. O AVC recorrente é um fator que contribui para que o AVC apresente elevada carga global. Por isso, a prevenção secundária do AVC tem sido apontada como uma das soluções pragmáticas para reduzir a carga global do AVC. A prevenção secundária do AVC visa a redução do risco de recorrência do AVC utilizando de diversas estratégias, dentre elas, a adoção de estilo de vida saudável. Na Irlanda, uma intervenção para reduzir o risco de recorrência do AVC direcionada à adoção de estilo de vida saudável está sendo desenvolvida, atendendo às recomendações das diretrizes de prevenção secundária do AVC e considerando metodologias recomendadas para o desenvolvimento e avaliação de intervenções para mudança de comportamento. No Brasil, não tem sido identificada, até o momento, uma intervenção para prevenção secundária do AVC direcionada à adoção de estilo de vida saudável. Considerando isso, a intervenção que está sendo desenvolvida na Irlanda poderia ser considerada potencial de ser utilizada no Brasil. Porém, os países apresentam características socioculturais e econômicas distintas que

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justificam a necessidade de adaptar a intervenção antes de utilizá-la com indivíduos pós-AVC brasileiros. No momento, o desenvolvimento da intervenção, na Irlanda, encontra-se na última etapa: testagem da intervenção. Portanto, o objetivo do presente projeto de pesquisa é adaptar uma intervenção para prevenção secundária do AVC direcionada à adoção de estilo de vida saudável que está sendo desenvolvida em país de alta renda (Irlanda) ao contexto brasileiro. O projeto será submetido ao Comitê de Ética em Pesquisa da Universidade Federal de Minas Gerais (COEP/UFMG). O presente projeto de pesquisa apresenta três etapas: 1. Comparação da priorização de componentes a serem incluídos em uma intervenção para prevenção secundária do AVC direcionada à adoção de estilo de vida saudável definida por indivíduos pós-AVC de um país de alta renda (Irlanda) e de um país de média renda (Brasil); 2. Adaptação de uma intervenção para prevenção secundária do AVC direcionada à adoção de estilo de vida saudável que está sendo desenvolvida em país de alta renda (Irlanda) ao contexto brasileiro; 3. Investigação da viabilidade da intervenção para prevenção secundária do AVC direcionada à adoção de estilo de vida saudável adaptada para o contexto brasileiro. Todos os indivíduos serão orientados sobre os procedimentos que serão realizados e apenas serão incluídos após concordarem com a participação voluntária e assinarem o Termo de Consentimento Livre e Esclarecido. Este projeto incorporará métodos mistos (metodologias qualitativas e quantitativas). A metodologia qualitativa será utilizada nas Etapas 1 e 2, e a metodologia quantitativa será utilizada nas Etapas 1 e 3. As Etapas 2 e 3 serão baseadas nas orientações propostas no ADAPT guidance, para adaptar e transferir intervenções para novos contextos, e nas orientações propostas no Medical Research Council, para guiar o desenvolvimento e avaliação de intervenções complexas. Nas etapas em que forem incluídos indivíduos pós-AVC, os seguintes critérios serão considerados: apresentar diagnóstico clínico de AVC na fase crônica (mais que seis de meses de evolução do AVC), ter idade entre 20 e 80 anos, e apresentar gravidade do AVC de leve a moderada. Serão excluídos indivíduos que apresentarem teste de rastreio positivo para possíveis alterações cognitivas. Nas etapas

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em que forem incluídos experts, para garantir uma ampla representação, pesquisadores que realizam estudos sobre prevenção secundária do AVC, profissionais de diferentes áreas da saúde (por exemplo, fisioterapeutas, médicos e terapeutas ocupacionais) que apresentam experiência em atender indivíduos pós-AVC, e representantes de organizações ou associações para indivíduos pós-AVC serão convidados para participar. Na Etapa 1 do presente projeto de pesquisa, 5 indivíduos pós-AVC brasileiros pareados quanto ao sexo, idade e nível de escolaridade aos indivíduos pós-AVC irlandeses serão incluídos. Na Etapa 2, 10-15 indivíduos pós-AVC e 10-15 experts serão incluídos. Etapa 3, um tamanho amostral de pelo menos 10 indivíduos será utilizado nesta etapa. Portanto, 45 indivíduos serão incluídos no presente projeto de pesquisa. Considerando que o projeto incorporará métodos mistos (metodologias qualitativas e quantitativas), análises qualitativas e quantitativas serão utilizadas no presente estudo. Além das análises específicas apontadas em cada etapa para as análises qualitativas, os dados sociodemográficos e clínicos e os desfechos referentes à viabilidade da intervenção serão apresentados utilizando estatística descritiva de acordo com as características das variáveis. As análises quantitativas serão realizadas com o programa estatístico SPSS 29.0.

Objetivo da Pesquisa:

Objetivo Primário:

Adaptar uma intervenção para prevenção secundária do AVC direcionada à adoção de estilo de vida saudável que está sendo desenvolvida em país de alta renda (Irlanda) ao contexto brasileiro.

Objetivo Secundário:

Etapa 1: comparar a priorização de componentes a serem incluídos em uma intervenção para prevenção secundária do AVC direcionada à adoção de estilo de vida saudável definida por indivíduos pós-AVC de um país de alta renda (Irlanda) e de um país de média renda (Brasil). Etapa 2: adaptar uma intervenção para prevenção secundária do AVC direcionada à adoção de estilo de vida saudável que está sendo desenvolvida em país de alta renda (Irlanda) ao contexto brasileiro. Etapa 3: investigar a viabilidade da intervenção para

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prevenção secundária do AVC direcionada à adoção de
estilo de vida saudável adaptada para o contexto brasileiro

Avaliação dos Riscos e Benefícios:

Riscos:

Para indivíduos pós-AVC: Os procedimentos adotados durante os workshops não apresentam riscos específicos além daqueles

presentes no seu dia a dia. Além disso, você participará do estudo apenas se concordar. Durante os workshops, caso você sinta qualquer

desconforto durante os momentos interativas com os demais participantes, informe ao pesquisador responsável para que ele tome as devidas

providências com o objetivo de minimizá-lo.

Para experts: Os procedimentos e testes adotados nessas diferentes etapas não apresentam riscos específicos além

daqueles presentes no seu dia a dia. Além disso, você participará do estudo apenas se concordar. Durante as reuniões presenciais, caso você sinta qualquer desconforto durante os momentos interativas com os demais participantes, informe ao pesquisador responsável para que ele tome as devidas providências com o objetivo de minimizá-lo.

Benefícios:

Para indivíduos pós-AVC: Vocês contribuirão ativamente no processo de adaptação de uma intervenção para o contexto brasileiro. Indivíduos pós-AVC também poderão se beneficiar com os resultados desta pesquisa, principalmente porque o seu objetivo primário é adaptar, ao contexto brasileiro, uma intervenção para prevenção secundária do AVC direcionada à adoção de estilo de vida saudável. Considerando a inexistência de

uma intervenção específica para prevenção secundária do AVC direcionada à adoção de estilo de vida saudável, no Brasil, os resultados do

presente projeto permitirão identificar uma intervenção que poderá ser utilizada por vocês, experts (profissional da área da saúde e/ou pesquisador)

com indivíduos pós-AVC para reduzir o risco de recorrência do AVC.

Para experts: Você e futuros pacientes poderão se beneficiar com os resultados desta pesquisa, principalmente porque o seu objetivo primário é

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Continuação do Parecer: 6.683.329

adaptar, ao contexto brasileiro, uma intervenção para prevenção secundária do AVC direcionada à adoção de estilo de vida saudável. Considerando a inexistência de uma intervenção para esse objetivo, específica para indivíduos pós-AVC, no Brasil, os resultados do presente projeto permitirão identificar uma intervenção que poderá ser utilizada por profissionais da área da saúde do país com vocês, que já tiveram AVC, para reduzir o risco de recorrência do AVC. Além disso, a adaptação da intervenção será baseada nas suas percepções apresentadas nas reuniões interativas, indicando, portanto, que a intervenção final será contextualizada às suas preferências e necessidades apresentadas.

Comentários e Considerações sobre a Pesquisa:

O Tema é de extrema importância e relevância para saúde pública do Brasil.

Considerações sobre os Termos de apresentação obrigatória:

O Projeto apresenta todos os documentos obrigatórios.

Conclusões ou Pendências e Lista de Inadequações:

O Projeto não apresenta pendências ou inadequações.

Considerações Finais a critério do CEP:

Tendo em vista a legislação vigente (Resolução CNS 466/12), o CEP-UFMG recomenda aos Pesquisadores: comunicar toda e qualquer alteração do projeto e do termo de consentimento via emenda na Plataforma Brasil, informar imediatamente qualquer evento adverso ocorrido durante o desenvolvimento da pesquisa (via documental encaminhada em papel), apresentar na forma de notificação relatórios parciais do andamento do mesmo a cada 06 (seis) meses e ao término da pesquisa encaminhar a este Comitê um sumário dos resultados do projeto (relatório final).

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_2263219.pdf	12/01/2024 15:14:00		Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE.pdf	12/01/2024 15:13:47	Christina Danielli Coelho de Moraes Faria	Aceito
Informações	PB_INFORMAÇÕES_BÁSICAS_DO_P	22/12/2023		Aceito

Endereço: Av. Presidente Antonio Carlos, 6627 2º Andar Sala 2005 Campus Pampulha

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Continuação do Parecer: 6.683.329

Básicas do Projeto	ETO_2263219.pdf	14:18:21		Aceito
Outros	FICHA_DE_AVALIACAO.pdf	22/12/2023 12:37:18	Christina Danielli Coelho de Moraes Faria	Aceito
Outros	FICHA_DE_AVALIACAO.pdf	22/12/2023 12:37:18	Christina Danielli Coelho de Moraes Faria	Postado
Outros	PARECER_CAMARA_DEPARTAMENT AL.pdf	22/12/2023 12:37:02	Christina Danielli Coelho de Moraes Faria	Aceito
Outros	PARECER_CAMARA_DEPARTAMENT AL.pdf	22/12/2023 12:37:02	Christina Danielli Coelho de Moraes Faria	Postado
Outros	ANUENCIA_LABORATORIO_NEUROL AB.pdf	22/12/2023 12:36:36	Christina Danielli Coelho de Moraes Faria	Aceito
Outros	ANUENCIA_LABORATORIO_NEUROL AB.pdf	22/12/2023 12:36:36	Christina Danielli Coelho de Moraes Faria	Postado
Projeto Detalhado / Brochura Investigador	PROJETO_DE_PESQUISA.pdf	22/12/2023 12:36:07	Christina Danielli Coelho de Moraes Faria	Aceito
Projeto Detalhado / Brochura Investigador	PROJETO_DE_PESQUISA.pdf	22/12/2023 12:36:07	Christina Danielli Coelho de Moraes Faria	Postado
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE.pdf	22/12/2023 12:35:20	Christina Danielli Coelho de Moraes Faria	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE.pdf	22/12/2023 12:35:20	Christina Danielli Coelho de Moraes Faria	Postado
Orçamento	ORCAMENTO.pdf	22/12/2023 12:35:11	Christina Danielli Coelho de Moraes Faria	Aceito
Orçamento	ORCAMENTO.pdf	22/12/2023 12:35:11	Christina Danielli Coelho de Moraes Faria	Postado
Cronograma	CRONOGRAMA.pdf	22/12/2023 12:35:00	Christina Danielli Coelho de Moraes Faria	Aceito
Cronograma	CRONOGRAMA.pdf	22/12/2023 12:35:00	Christina Danielli Coelho de Moraes Faria	Postado
Folha de Rosto	FOLHA_DE_ROSTO.pdf	22/12/2023 12:29:42	Christina Danielli Coelho de Moraes	Aceito

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Folha de Rosto	FOLHA_DE_ROSTO.pdf	22/12/2023 12:29:42	Faria	Aceito
Folha de Rosto	FOLHA_DE_ROSTO.pdf	22/12/2023 12:29:42	Christina Danielli Coelho de Moraes Faria	Postado

Situação do Parecer:

Aprovado

Necessita Apreciação da CONEP:

Não

BELO HORIZONTE, 04 de Março de 2024

Assinado por:
Corinne Davis Rodrigues
(Coordenador(a))

Endereço: Av. Presidente Antonio Carlos, 6627 2º. Andar Sala 2005 Campus Pampulha

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MINICURRÍCULO DO DISCENTE

Formação acadêmica/titulação:

- 2021 - Atual: Doutorado em andamento em Ciências da Reabilitação, Universidade Federal de Minas Gerais (UFMG) (Brasil) (bolsista: Fundação de Amparo à Pesquisa do Estado de Minas Gerais, FAPEMIG), com período sanduíche em *University College Dublin* (UCD) (Irlanda) (financiamentos: Coordenação de Aperfeiçoamento de Pessoal de Nível Superior (Programa Print/CAPES) e *Worldwide Universities Network* (WUN)).
- 2019 – 2021: Mestrado em Ciências da Reabilitação, UFMG (Brasil) (bolsista: Fundação de Amparo à Pesquisa do Estado de Minas Gerais, FAPEMIG).
- 2014 – 2019: Graduação em Fisioterapia, UFMG (Brasil).

Formação Complementar:

- 2024: Elementos Gramaticais da Língua Inglesa no Texto Acadêmico - Nível de Profi. Universidade Federal de Campina Grande, UFCG, Brasil.
- 2023: Curso de Comunicação e Escrita Científica. American Chemical Society, Estados Unidos.
- 2023: From Zero to NVivo 12. Udemey, UDEMY, Brasil.
- 2022 – 2023: Implementation of the HEARTS Technical Package in Primary Health Care. Pan American Health Organization, PAHO, Estados Unidos.
- 2022 – 2023: Sistema GRADE: graduação da certeza no conjunto final da evidência e força. Faculdade de Educação em Ciências da Saúde, FECS, Brasil.
- 2022: Workshop PRINCÍPIOS DA NEUROIMAGEM. Escola de Educação Física, Fisioterapia e Terapia Ocupacional-UFMG, EEEFTO, Brasil.
- 2021: Extensão universitária em Interpretação do Teste de Exercício Cardiorrespiratório na Prática Clínica. Universidade Federal de São Paulo, UNIFESP, Brasil.
- 2021: Mendeley, fichamentos e referências automáticas. Udemey, UDEMY, Brasil.
- 2021: CAPACITAÇÃO DO TELEATENDIMENTO EM FISIOTERAPIA. Centro de Estudos em Reabilitação Traumatológica, CERTRO, Brasil.
- 2021: Referências bibliográficas com EndNote Web. Udemey, UDEMY, Brasil.
- 2021: Introduction to Systematic Review and Meta-Analysis. Johns Hopkins University, JHU, Estados Unidos.
- 2021: Tecnologia na Educação, Ensino Híbrido e Inovação Pedagógica. Universidade Federal do Ceará, UFC, Brasil.

Artigos completos publicados em periódicos:

1. PENICHE, P. C.; LENNON, O.; MAGALHAES, J. P.; *et al.* Telehealth intervention involving the HEARTS Technical Package and the additional use of an activity monitor to increase physical activity level post-stroke: Protocol for a feasibility randomized controlled trial. PLoS One, v. 20, p. e0320026, 2025.
2. HALL, P.; PENICHE, P. C.; HICKEY, J.; *et al.* Identifying mediators of healthy lifestyle adoption after stroke: a focus group study using a Theoretical Domains Framework guided analysis. BMC Neurology, v. 25, p. 135, 2025.
3. HALL, P.; ASABA, E.; PENICHE, P. C.; *et al.* Stakeholder engagement and the co-design of an intervention template to support healthy lifestyle participation after stroke. Design for Health, v. 1, p. 1-23, 2025.
4. PENICHE, P. C.; MORAIS, C. D. C.; HALL, P.; *et al.* Effectiveness of behavior change and self-management theoretically-informed telehealth interventions for stroke secondary prevention: An overview of systematic reviews. JOURNAL OF TELEMEDICINE AND TELECare, v. 1, p. 1357633X2412387, 2024.

5. REIS, M. T. F.; AGUIAR, L. T.; PENICHE, P. C.; *et al.* Maximum heart rate prediction equations based on field-tests with adequate clinical applicability for aerobic exercise prescription to individuals after stroke. *DISABILITY AND REHABILITATION*, v. 1, p. 1-7, 2024.
6. PENICHE, P. C.; MORAIS, C. D. C.; HALL, P.; *et al.* A Scoping Review of Patient and Public Involvement (PPI) in Empirical Stroke Research. *International Journal of Stroke*, v. 1, p. 174749302412626, 2024.
7. SILVA, L. C.; FARIA, C. D. C. M.; PENICHE, P. C.; *et al.* Validity of the two-minute walk test to assess exercise capacity and estimate cardiorespiratory fitness in individuals after stroke: a cross-sectional study. *Topics in Stroke Rehabilitation*, p. 1-10, 2023.
8. REIS, M. T. F.; AGUIAR, L. T.; PENICHE, P. C.; *et al.* Are age-predicted equations valid in predicting maximum heart rate in individuals after stroke?. *DISABILITY AND REHABILITATION*, v. 8, p. 1-7, 2023.
9. PENICHE, P. C.; PINTO, A. P. S.; RIBEIRO, R. L. M. N.; *et al.* Recruitment, retention, attendance, and adherence of a randomized controlled trial to evaluate the effects of task-specific training with individuals post stroke. *FISIOTERAPIA E PESQUISA*, v. 29, p. 22-28, 2022.
10. BRITO, S. A. F.; SCIANNI, A. A.; PENICHE, P. C.; *et al.* Measurement properties of outcome measures used in neurological telerehabilitation: A systematic review protocol. *PLoS One*, v. 17, p. e0265841, 2022.
11. PENICHE, P. C.; AGUIAR, L. T.; REIS, M. T. F.; *et al.* An equation with clinical applicability and adequate validity to predict the maximum oxygen consumption of individuals post-stroke. *ARCHIVES OF PHYSICAL MEDICINE AND REHABILITATION*, v. 000, p. 1-7, 2022.
12. BRITO, S. A. F.; SCIANNI, A. A.; PENICHE, P. C.; *et al.* Measurement properties of outcome measures used in neurological telerehabilitation: a systematic review using COSMIN checklist. *CLINICAL REHABILITATION*, v. 37, p. 415-435, 2022.
13. SILVA, S. M.; DIAZ-QUIJANO, F. A.; PENICHE, P. C.; *et al.* Does Residing in Environments of Different Metropolises in a Developing Country exert an Impact on Disability after Stroke?. *Disability, CBR & Inclusive Development*, v. 32, p. 142-159, 2021.
14. PENICHE, P. C.; AGUIAR, L. T.; REIS, M. T. F.; *et al.* The Distance Covered in Field Tests is more Explained by Walking Capacity than by Cardiorespiratory Fitness after Stroke. *Journal of Stroke & Cerebrovascular Diseases*, v. 30, p. 105995, 2021.

Artigos submetidos: 3

Capítulos de livros publicados: 12

Revisor de periódico:

- 2021 – Atual: FISIOTERAPIA EM MOVIMENTO
- 2021 - Atual: Revista Interdisciplinar Ciências Médicas
- 2024 – Atual: Journal of Bodywork & Movement Therapies
- 2024 – Atual: American Journal of Health Promotion
- 2025 - Atual: Disability, CBR & Inclusive Development

Prêmios e títulos:

- 2025: Primeiro Lugar na categoria Iniciação Científica - II CONVERGIR, Conselho Regional de Fisioterapia e Terapia Ocupacional da 4ª Região (CREFITO-4 MG).

- 2025: Terceiro Lugar na categoria Iniciação Científica - II CONVERGIR, Conselho Regional de Fisioterapia e Terapia Ocupacional da 4ª Região (CREFITO-4 MG).
- 2025: Primeiro Lugar na categoria Tema Livre - II CONVERGIR, Conselho Regional de Fisioterapia e Terapia Ocupacional da 4ª Região (CREFITO-4 MG).
- 2024: HIGHLY COMMENDED SCIENTIFIC ABSTRACT: 2024 European Life After Stroke Forum, Stroke Alliance for Europe.
- 2022: Projeto de pesquisa aprovado em primeiro lugar na seleção interna da UFMG para o Worldwide University Network (WUN) Research Development Fund, Universidade Federal de Minas Gerais (UFMG) e Worldwide University Network (WUN).
- 2022: Projeto de pesquisa contemplado pelo Worldwide University Network (WUN) Research Development Fund 2022 (Edital RDF/2022), Worldwide University Network (WUN).
- 2022: Projeto de pesquisa contemplado com bolsa de doutorado-sanduíche da CAPES/PRINT - Chamada Interna PRPG 04/2022, Coordenação de Aperfeiçoamento de Pessoal de Nível Superior (CAPES).
- 2021: 1º lugar entre os melhores trabalhos no VI Congresso Brasileiro de Fisioterapia Neurofuncional e I Simpósio Internacional de Saúde Funcional, Associação Brasileira de Fisioterapia Neurofuncional.

Resumos publicados em anais de congressos: 36

Apresentações de trabalho e palestras: 22

Bancas:

Participação em bancas de trabalhos de conclusão: 5

Participação em bancas de comissões julgadoras: 5

Orientações e supervisões concluídas:

Monografia de conclusão de curso de aperfeiçoamento/especialização: 5

Trabalho de conclusão de curso de graduação: 1

Orientações e supervisões em andamento:

Monografia de conclusão de curso de aperfeiçoamento/especialização: 2

Trabalho de conclusão de curso de graduação: 1

Participação em eventos, congressos, exposições e feiras: 14

Organização de eventos, congressos, exposições e feiras: 1