

BMJ Open Telerehabilitation for lower extremity recovery poststroke: a systematic review and meta-analysis protocol

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ABSTRACT

Introduction Approximately 30% of individuals with stroke report unmet lower extremity recovery needs after formal hospital-based rehabilitation programmes have ended. Telerehabilitation can mitigate issues surrounding accessibility of rehabilitation services by providing ongoing support to promote recovery, however, no review exists that is specific to telerehabilitation for lower extremity recovery. This paper describes the protocol of a systematic review and meta-analysis that aims to describe and evaluate the effectiveness of lower extremity-focused telerehabilitation interventions on clinical outcomes poststroke.

Methods and analysis A systematic review of relevant electronic databases (MEDLINE, Embase, CINAHL, PsycINFO, Web of Science, Google Scholar, PEDro, PubMed and Cochrane Library) between inception and February 2022 will be undertaken to identify eligible interventional studies published in English that compared telerehabilitation focusing on lower extremity recovery to another intervention or usual care for individuals living in the community with stroke. Clinical outcomes examined will include those related to physical function and impairment, activities and participation that are typically assessed in clinical practice and research. Two reviewers will independently screen results, identify studies to be included for review, extract data and assess risk of bias. Meta-analyses will be performed if sufficient data exist. Sensitivity analyses will be performed by removing studies with low methodological quality, and subgroup analyses will be performed if data allow by stratifying papers based on salient demographic or stroke factors and comparing results. The reporting of the review will follow the recommendations of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement. The quality of evidence regarding various outcomes for telerehabilitation for lower extremity recovery poststroke will be assessed according to the Grading of Recommendation, Assessment, Development and Evaluation approach.

Ethics and dissemination No ethical approval or informed consent is needed for this systematic review. The findings of this review will be disseminated via peer-reviewed publications and conference presentations.

PROSPERO registration number CRD42021246886.

INTRODUCTION

Stroke is a leading cause of disease burden and death worldwide¹ with over 10 million

Strengths and limitations of this study

- This is the first review of the literature examining telerehabilitation interventions specific for lower extremity recovery poststroke, and the results will identify rehabilitation techniques and strategies that may be delivered using technology specific to improving lower extremity function.
- The overall effects of telerehabilitation will be estimated by meta-analysing outcomes data and the quality of the body of literature will be evaluated using Grading of Recommendation, Assessment, Development and Evaluation.
- Grey literature, including theses and protocols of ongoing studies, will not be included which may decrease the comprehensiveness of this review.
- All studies included will be assessed for study quality, including randomised controlled trials, non-randomised controlled trials and single-group pre-post studies.
- This systematic review protocol will be reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement.

new strokes and 6.5 million stroke deaths each year.² As the population ages, the prevalence of stroke is anticipated to increase 20% over the next 10 years.³ The most common and widely recognised deficit caused by stroke is motor impairment resulting in a loss or limitation of functional mobility, that can be seen in up to 80% of individuals with stroke.⁴ Lower extremity motor impairment, including haemiparesis, has been shown to lead to activity limitations, such as mobility,⁵ and participation restrictions,⁶ such as engaging in life roles (eg, relationships, community involvement). Additionally, there is a high risk of falls among stroke survivors with such impairment. Specifically, the occurrence of falls while walking can be as high as 73% among those who recover some ability to walk poststroke, with most falls occurring within the first few months of returning home from rehabilitation.^{7–9} Thus, regaining lower extremity function and walking ability is a



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priority for most stroke survivors,¹⁰ as optimal recovery may be associated with better long-term health and well-being outcomes.⁵

Despite evidence supporting the importance of continued rehabilitation for lower extremity recovery, stroke survivors face substantial barriers, such as limited finances, travel distance (distance between home and rehabilitation centre) and transportation issues (eg, unable to resume driving, lack of transit options),^{11–13} in attending ongoing rehabilitation after hospital discharge. Moreover, due to decreasing length of stays for inpatient stroke rehabilitation,^{14–16} alternative methods for ongoing, accessible and cost-effective rehabilitation programmes that extend opportunities for lower extremity recovery beyond hospital settings are becoming increasingly important.

Telerehabilitation, defined as the delivery of rehabilitation services using information and communication technologies,¹⁷ is a possible solution to mitigate issues surrounding accessibility of rehabilitation services and provide additional support during the transition back to the community. Telerehabilitation is also more cost-efficient when compared with traditional inpatient or person-to-person rehabilitation.¹⁸ The rapid growth in internet use and personal mobile devices has opened an array of possibilities for stroke survivors to remotely access specialised rehabilitation from their homes and communities (ie, telerehabilitation). Unfortunately, there is a paucity of research investigating telerehabilitation for the delivery of interventions for lower extremity recovery. Typically, programmes for lower-extremity recovery that focus on mobility and balance have been delivered in-person to manage safety issues and risks of falls. Thus, while telerehabilitation interventions have been used effectively for check-in sessions, education and counselling after stroke,^{19,20} there is minimal evidence on the use of telerehabilitation for lower extremity recovery poststroke. Furthermore, while telerehabilitation reviews exist,^{20–23} none have a specific focus on lower extremity recovery poststroke, largely because, up until recently, there has not been enough literature on the topic area. In fact, findings from various telerehabilitation investigations are just now beginning to emerge on lower-extremity recovery outcomes.^{24–26}

In this paper, we report on the protocol of a systematic review and meta-analysis that will:

1. Describe telerehabilitation interventions for lower extremity recovery following stroke; and
2. Quantitatively assess the effect of telerehabilitation programmes on clinical outcomes in the areas of physical function and impairment, activities and participation.

METHODS AND ANALYSES

Study design and registration

The systematic review will be conducted and reported according to the guidelines of the Preferred Reporting Items for Systematic Reviews and Meta-Analysis Protocol

(PRISMA),²⁷ as shown in online supplemental figure 1 of appendix A. In accordance with the PRISMA guidelines, the protocol is registered with the International Prospective Register of Systematic Reviews (PROSPERO) (Registration ID: CRD42021246886).

Eligibility criteria

Studies for review will be selected using the following eligibility criteria, categorised by study design, participants, interventions, comparators and outcomes.

Study design

This review aims to both describe and quantitatively assess the effects of telerehabilitation interventions poststroke, therefore, we will include randomised controlled trials (RCTs) as the primary study design, including cluster RCTs. However, non-RCT interventional studies, such as non-RCTs, will also be included for a comprehensive overview of all telerehabilitation interventions focusing on lower extremity recovery. For mixed-method studies, only the quantitative data will be used in the review for analysis. Only studies published in peer-reviewed journals and in English will be included in this study. Observational or descriptive study designs, including cohort studies, case series, case reports and cross-sectional studies will be excluded. Study protocols, reviews and abstract-only records will also be excluded.

Participants

The review will include research on community-living individuals with stroke, ≥ 19 years of age. Studies may include patients with all levels of stroke severity, which may be defined using validated and routinely used stroke-specific health measures such as the National Institutes of Health Stroke Scale²⁸ or Modified Rankin Scale (mRS).^{29,30} If studies report on mixed samples, we will only include the study for review if results on the stroke sample are provided, or if the sample is comprised of at least 50% stroke survivors.

Types of interventions

The review will include studies that involve the use of telerehabilitation to promote recovery of the lower extremity poststroke. For the purposes of this review, telerehabilitation will be defined as the remote delivery of rehabilitation services via information and communication technologies (telecommunication)¹⁷ which includes, but are not limited to, the telephone, internet, video-conferencing, mobile devices and monitoring via sensors or wearable devices. The interventions may be delivered by rehabilitation staff (eg, physiotherapists, occupational therapists) or by people who have received training by rehabilitation staff, such as paid or unpaid carers of individuals with stroke. Interventions that use a combination of telerehabilitation and in-person rehabilitation will be included, provided that at least 50% of the intervention (eg, number of sessions) is delivered via telerehabilitation. The review will include studies that are completed during any phase of the poststroke recovery process in the

community and in any physical or geographical location. We will exclude interventions that only have one session, or those with a primary focus on stroke sequelae other than lower extremity impairment (eg, upper extremity, cognition, communication, swallowing).

Comparisons or control

The review will include studies that have a comparator, which can be any of the following: another type of telerehabilitation, usual care or no intervention. Usual care can be defined as the rehabilitation that a patient who had stroke would normally receive as part of undergoing stroke rehabilitation.

Outcome measures

The review will include studies that focus on the outcomes of physical function and impairment, activities and participation that are associated with lower extremity recovery and typically measured pre–post rehabilitation intervention. Assessments that may be used, but not limited to, include the Timed Up and Go, 6-minute Walk Test, Fugl-Meyer Assessment, Berg Balance Scale, Stroke Impact Scale, Activities-specific Balance Confidence Scale, Reintegration to Normal Living Index and gait speed.

Information sources

We will search EMBASE, MEDLINE, PsycINFO, CINAHL, Web of Science, Google Scholar, PEDro, PubMed and Cochrane Library (including Cochrane Review Group Registers and Cochrane Central Register of Controlled Trials) databases systematically and comprehensively from their inception to February 2022. The reference list of all papers included for review will also be examined for additional studies of interest. PROSPERO will also be searched for ongoing or recently completed systematic reviews.

Search strategy

The search strategy for MEDLINE (online supplemental table 1 of appendix B) has been developed in collaboration with a university librarian and will be adapted for use in other databases. Terms include stroke, rehabilitation, telerehabilitation and lower extremity. Search terms were established using Medical Subject Headings and/or keywords.

Data management and selection process

We will use a multistage process for study selection.^{31 32} All retrieved studies will be imported into Covidence³³ and duplicate studies will be removed through the programme. First, two researchers will independently screen all titles that generally appear to meet the review's inclusion/exclusion criteria. Then, the same researchers will independently review all abstracts of each paper and identify papers for full-text review. Third, the researchers will review the full text of papers to finalise the study selection. Discrepancies at each stage of study selection will be resolved via group discussion or consulting with a

third investigator. We will document all removed studies with specific reasons regarding their exclusion.

Data extraction

Data from all eligible papers identified through the study selection process will be extracted by the two review authors who will independently perform data extraction using a study-specific data extraction form. The form focuses on general study characteristics, study methods, participant characteristics, intervention description, outcomes and results. The form will be piloted independently by the research team. The lead author will train a research assistant on data extraction. Both the lead author and the research assistant will then extract three studies independently and discuss any differences to ensure consistency with data extraction for the remaining studies. The corresponding authors of each study included for review will be contacted by email to obtain missing data or further information, if necessary.

Risk of bias

Study quality and risk of bias for the included studies will be performed independently by two review authors. We will assess study quality of the randomised controlled trials using both the 11-item Physiotherapy Evidence Database Scale (PEDro)³⁴ and the Cochrane Risk of Bias 2 Tool (CROB).³⁵ Research indicates that the agreement (intra-class correlation coefficient=0.285) between the summary scores of the two tools provide complimentary, yet distinct information.³⁶ The PEDro scale is used to assess methodological quality of trials using an 11-item checklist. The first item assesses external validity, and the remaining 10 items assess internal validity to calculate the final score which ranges from 0 to 10, with a higher score indicating better methodological quality.³⁷ Studies will be classified as poor (1–3 points), fair (4–5 points), good (6–8 points) and excellent (9–10 points).³⁸ The CROB is used to assess and report risk of bias for seven items across five domains: randomisation process, deviations from intended interventions, missing outcome data, measurement of the outcome and selection of the reported results. Each domain item is rated as 'high risk', 'some concerns' or 'low risk' of bias and can be summarised with an overall risk-of-bias judgement, which typically corresponds to the worst risk of bias in any domains.³⁹ Two review researchers will independently assess each studies' methodological quality using the PEDro scale and rate each domain of the CROB. Discrepancies will be resolved through discussion and/or by a third researcher. For non-RCTs, study quality will be assessed using the Johanna Briggs Institute Critical Appraisal Tool⁴⁰ and single-group pre–post studies will be assessed using the NIH Study Quality Assessment.⁴¹

Reporting bias will also be examined using a Funnel plot and an Egger regression test.⁴² A funnel plot is a scatter plot of estimated treatment effects from individual studies (x-axis) against a measure of sample size (y-axis). If there is little or no bias, the results from smaller sample size studies would scatter widely at the bottom of the graph

with the spread narrowing among larger studies. Publication bias may show as asymmetrical funnel plots and can be used as a mean to examine small study effects.⁴³ The Egger regression test is an alternative way of quantifying publication bias. The test regresses the standardised effect sizes on their precision and in the absence of publication bias, the regression intercept would be 0.⁴⁴

Descriptive summary

All interventional studies included for review will be described with the following: study design, participants, intervention, comparator (eg, another telerehabilitation intervention, no care, usual care), interveners (eg, therapist, caregiver) and outcomes (where reported). This review will assess whether interventions were sufficiently reported according to the Template for Intervention Description and Replication (TIDieR) checklist, a 12-item checklist originally created to improve the completeness of intervention reporting, of the included studies.⁴⁵ The lead author and a research assistant will independently complete the TIDieR checklist for three included studies, compare responses and discuss and clarify any discrepancies to ensure consistency. The analysis will be carried out on the body of literature by summarising key characteristics of the studies in the areas of study design, sample, intervention and control groups and outcomes.

Meta-analysis

Between-group meta-analyses will be performed on all outcomes that have pre–post or change data from at least two RCTs that demonstrate sufficient homogeneity across studies in terms of outcomes. Authors will be contacted if the change data of the outcomes relevant to the review are not reported. The results for the individual outcomes will be pooled quantitatively using either fixed or random effects meta-analysis models. RevMan V.5.4⁴⁶ will be used for meta-analyses. Continuous values will be expressed as a mean difference if studies all report the outcome using the same scale, or the standardised mean difference (SMD) if different scales are used, between baseline and postintervention along with 95% CIs. The SMD is the difference in mean outcome between groups divided by the SD of outcome among the participants at baseline.⁴⁷ As there are numerous measures used to measure similar lower extremity outcomes, it is important to assess the summary outcome by standardising the results to a uniform scale before they can be combined. The measures being combined will conceptually be assessing the same constructs (eg, self-efficacy, participation). Dichotomous values will be expressed as risk ratios and 95% CI.⁴⁷

Heterogeneity

Heterogeneity refers to the variability in the intervention effects being evaluated in the different studies. Clinical heterogeneity can be defined as differences in participant characteristics, types of timing of outcome measurements and intervention characteristics⁴⁸ and will be determined subjectively by the reviewers.

I^2 statistic will be used to determine statistical heterogeneity across the included studies. Fixed-effect models will be used if the I^2 is less than 50% (heterogeneity is not important or is moderate).⁴⁷ Random effect models will be used in all other cases. We will control for heterogeneity in random effect models using the DerSimonian and Laird method available in RevMan V.5.4⁴⁶ to weigh studies based on the extent of their heterogeneity.³⁰

Sensitivity analysis

To determine how robust the findings are from the main analyses, we will perform sensitivity analyses by excluding studies of low quality as determined by a PEDro score of 3 or less⁴⁹ and/or studies with a ‘high’ risk of bias as determined by the CROB.

Subgroup analysis

Several different sociodemographic factors have been shown to moderate stroke outcomes. For example, female sex has been found to be mildly unfavourable in recovery,⁵⁰ therefore a subgroup analysis will be performed for each outcome by sex if the data allow (critical number of studies ($n=2$) report based on sex). In addition, other factors such as age,^{51–59} severity of stroke^{55 59 60} and number of comorbidities^{61–63} have shown mixed evidence in influencing poststroke recovery, therefore a subgroup analysis will be carried out for each of the factors if data allow. The stroke severity will be dichotomised by severe (eg, mRS 3–5) and mild (eg, mRS 0–2).^{64 65} Finally, if data allow, we will perform subgroup analyses to examine differences in outcomes by the different types of interveners (eg, therapists, family members), and the technology used for the delivery of telerehabilitation (eg, mobile device, virtual reality).

Quality of the evidence

Assessment of the strength of the evidence for each outcome will be performed using the Grading of Recommendations Assessment, Development and Evaluation (GRADE)^{66 67} approach. The GRADE domains include risk of bias,⁶⁸ imprecision,⁶⁹ inconsistency,⁷⁰ indirectness⁷¹ and publication bias⁷² for rating down and could be rated up⁷³ for large magnitude of effect, dose–response gradient and the presence of any residual confounding effects that would decrease the magnitude of effect.

Patient and public involvement

No patients were involved in the writing of this systematic review protocol. However, the results of this review will be disseminated to patients with stroke who have lower extremity impairments.

DISCUSSION

This study will systematically review the research evidence of telerehabilitation for lower extremity recovery post-stroke and quantify the effects on physical function and impairment, activity and participation outcomes.

Issues with lower extremity recovery poststroke negatively impacts a patient's quality of life, activities of daily living and social participation.^{4 74 75} Our review and assessment of the existing literature on telerehabilitation interventions for lower extremity recovery will help shape future development in stroke telerehabilitation specifically for lower extremity recovery. Importantly, our results will inform future research as well as clinical practice; it will be used to identify knowledge gaps, factors influencing treatment efficacy and inform experimental design of new telerehabilitation studies.

Ethics and dissemination

No ethical approval or informed consent is needed for this systematic review. The findings of this review will be disseminated via peer-reviewed publications and conference presentations. The findings will also be distributed to stroke recovery groups via infographics and lay summaries.

Protocol amendments

Any amendments will be documented with a thorough description of the change(s), date changed and the rationale.

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Contributors BS is the guarantor of the review. SP, AT, CP and BS were involved in the design of the protocol for the systematic review. SP conceptualised and drafted the manuscript. All authors read and approved the final manuscript.

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Competing interests None declared.

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