

BMJ Open Efficacy of interventions to improve physical activity levels in individuals with stroke: a systematic review protocol

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ABSTRACT

Introduction: Stroke is a leading health problem worldwide and an important cause of disability. Stroke survivors show low levels of physical activity, and increases in physical activity levels may improve function and health status. Therefore, the aims are to identify which interventions that have been employed to increase physical activity levels with stroke survivors, to verify their efficacy and to identify the gaps in the literature.

Methods and analysis: A systematic review of randomised controlled trials that investigated the efficacy of interventions aiming at increasing physical activity levels of stroke survivors will be conducted. Electronic searches will be performed in the MEDLINE, Physiotherapy Evidence Database (PEDro), Excerpta Medica (EMBASE), Literatura Latino-Americana e do Caribe em Ciências da Saúde (LILACS) and Scientific Electronic Library Online (SCIELO) databases. Hand searches of the reference lists of the included studies or relevant reviews will also be employed. Two independent reviewers will screen all the retrieved titles, abstracts and full texts. A third reviewer will be referred to solve any disagreements. The quality of the included studies will be assessed by the PEDro Rating Scale. This systematic review will also include a qualitative synthesis. Meta-analyses will be performed, if the studies are sufficiently homogeneous. This review will follow the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) statement. The quality of the evidence regarding physical activity will be assessed, according to the Grading of Recommendations Assessment, Development and Evaluation (GRADE).

Discussion: This systematic review will provide information on which interventions are effective for increasing physical activity levels of stroke survivors. This evidence may be important for clinical decision-making and will allow the identification of gaps in the literature that may be useful for the definition of future research goals and the planning of new trials.

Trial registration number: CRD42016037750.

INTRODUCTION

Stroke is a leading health problem worldwide and an important cause of long-term

Strengths and limitations of this study

- This systematic review protocol will be reported in accordance with the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) statement.
- The three most complete databases for reports of randomised controlled trials will be searched.
- The quality of the included studies will be assessed by the PEDro Rating Scale.
- The quality of the evidence will be assessed, based on the Grading of Recommendations Assessment, Development and Evaluation (GRADE).
- This systematic review will not include interventions based on invasive procedures, drug and nutrition therapies, neither other neurological populations besides stroke.

disabilities.^{1 2} Although stroke mortality rate has decreased, the majority of the growth of the global stroke burden is coming from developing countries and it is expected to increase as a result of demographic changes, such the increases in the ageing population.^{1 2} Stroke survivors are more likely to require help with activities and to have restrictions in participation than matched controls.³ In addition, stroke survivors are at higher risks of having other cardiovascular diseases (CVDs).² Therefore, it is essential to develop interventions to recover and promote health and function, as well as to prevent secondary diseases in poststroke survivors.

Physical activity is defined as any bodily movement produced by skeletal muscles that result in energy expenditure, such as those performed during activities of daily living, at work, at home, during leisure activities or transport.⁴ Stroke survivors have low levels of physical activity at hospital and community settings.^{5 6} The quantity, duration and intensity of physical activities are reduced, even in high functioning community-dwelling stroke

survivors, when matched with a healthy elderly.⁷ According to a population-based study, community-dwelling stroke survivors have the highest proportion of physical inactivity, when compared with older adults with diabetes, musculoskeletal, cardiovascular, respiratory or other neurological chronic diseases.⁸

One of the major consequences of the disabilities after stroke is a chronic sedentary lifestyle.⁹ Common disabilities observed after stroke, including muscular weakness,¹⁰ reduced cardiorespiratory fitness,¹¹ fatigue,¹² physical mobility limitations,^{13 14} low perceptions of quality of life¹⁵ and restrictions in social participation,³ may lead to low physical activity lifestyles.⁹ Low levels of physical activity, in turn, have a negative impact on these disabilities and are related to health problems and, therefore, create a vicious cycle.⁹

Increase in physical activity levels can improve function and health in individuals after stroke.⁹ Furthermore, increases in physical activity levels could reduce the recurrence of stroke and other CVDs.¹⁶ Recently, the American Heart Association and the American Stroke Association published a scientific statement with recommendations of physical activity for stroke survivors,⁹ and there is a consensus that increases in physical activity levels are important for public health systems worldwide.^{9 17} However, according to the best of our knowledge, no broad systematic reviews on this topic have been conducted. There was found only two specific systematic reviews that investigated the efficacy of interventions on physical activity levels in stroke survivors: one targeted behavioural change¹⁸ and the other self-management programmes.¹⁹ The results of both reviews showed, in general, improvements in physical activity levels after tailored counselling¹⁸ and self-management programmes.¹⁹ Nevertheless, the risk of bias in the included studies was high in both reviews.^{18 19} Therefore, the overall efficacy of those interventions to improve physical activity levels in stroke survivors remains uncertain. In addition, these reviews had strict eligibility criteria, which may have prevented the inclusion of other relevant studies.^{18 19} For instance, they included studies that had follow-up measures at 3 months or longer¹⁸ and that only included community-dwelling participants.¹⁹ Therefore, the aims of the present systematic review are to identify which interventions have been employed to increase physical activity levels and to verify the efficacy of these interventions in individuals with stroke. The ultimate goal is to identify the gaps in the literature to allow for the planning and development of new clinical trials.

METHODS AND ANALYSES

Study design

This systematic review protocol will be reported in accordance with the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) (see Research Checklist),^{20 21} and the results will be reported

following the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) statement.^{22 23}

Study registration

On the basis of the PRISMA-P guidelines, this systematic review protocol was registered with the International Prospective Register of Systematic Reviews (PROSPERO) on 14 April 2016 (registration number: CRD42016037750; <http://www.crd.york.ac.uk/PROSPERO/>).

Eligibility criteria

Types of study

All randomised controlled trials (RCTs) that investigated the efficacy of interventions aiming at increasing physical activity levels in stroke survivors will be included in this systematic review. Quasi-RCTs, controlled clinical trials, cross-sectional studies, case series and case reports will be excluded.

Participants

All RCTs, in which participants were adults (≥ 18 years of age) and survived a stroke, will be included, without further restrictions. The authors of the studies that included mixed groups will be contacted for specific data related to the stroke survivors. When specific data are not available, the study will be excluded. Studies with participants with transient ischaemic attack will also not be included.

Types of interventions

All RCT that employed any type and mode of delivery, including, but not limited to, aerobic, strength exercises, counselling, self-management or behavioural interventions, in isolation or in combination, aimed at increasing physical activity levels, will be included. Trials will be excluded if the experimental interventions were invasive procedures, drug and nutrition therapies.

Comparisons or control

No restrictions will be made on the comparisons and/or the control group.

Outcome measures

Studies that quantified physical activity levels by any method, such as self-report assessment tools (eg, self-report questionnaires, diaries/logs or recall interviews)²⁴ or by direct measures (eg, accelerometers, pedometers, doubly labeled water, multisensor tools or direct observations) will be included.^{24 25} Physical activity levels could be reported as energy expenditure, steps per day, time of physical activity per day, number of transitions, time spent upright or others. Trials reporting walking or exercise capacity, gait patterns or ability to perform activities of daily living (eg, Barthel or Functional Independence Measure scores), which are not measurements of physical activity levels, will be excluded. Studies reporting only sedentary time will also be excluded.

Search strategy for the identification of relevant studies

Electronic searches will be conducted in the MEDLINE (via PubMed), Physiotherapy Evidence Database (PEDro), Excerpta Medica (EMBASE), Literatura Latino-Americana e do Caribe em Ciências da Saúde (LILACS) and Scientific Electronic Library Online (SCIELO) databases, from their inception to February 2016, without any language restrictions. The MEDLINE, PEDro and EMBASE databases were chosen because they are the most complete databases for reports of RCT.²⁶ The LILACS and SCIELO databases were chosen because they contain articles published in the Portuguese or Spanish languages. Hand searches of the reference lists of the included studies or identified relevant reviews will be employed. The search strategy will include terms related to stroke, RCT and physical activity levels. The search strategy related to stroke and RCT, which will be employed at the MEDLINE database, will follow that of a recent Cochrane Systematic Review²⁷ and the Cochrane Handbook for Systematic Reviews of Interventions,²⁸ respectively. The search strategy related to physical activity levels will be a combination of terms employed on three previously published systematic reviews.^{24 29 30} See online supplementary file 1 for the MEDLINE full-search strategy. The search strategy for the MEDLINE will be adapted to suit the other databases.

Screening of the studies

Duplicate studies will be removed. The main author (LTA) will search all databases and extract the titles and abstracts. Two independent reviewers (LTA, JCM) will screen all the retrieved titles and abstracts from the electronic search, according to the previously described inclusion criteria. Full texts will be screened by the same reviewers (LTA, JCM), independently. A third reviewer (CDCMF) will be referred to solve any disagreements. All the reasons for exclusion of ineligible studies will be recorded. The results of the screening process will be provided in details using the PRISMA information flow.²¹

Data extraction

The two independent reviewers (LTA, JCM) will extract the data, following recommended guidelines. Data extraction will include: (1) study details: authors and year of publication; (2) study characteristics: inclusion/exclusion criteria and setting; (3) sample characteristics: number of participants, age, sex, type and time since the onset of the stroke; (4) methods: design and allocation, blinding, sampling, time points when data were collected, loss to follow-up, recruitment and retention rates, comparison/control group; (5) interventions: description of intervention, duration, frequency, intensity, length and supervision and (6) outcomes: description, measurement instruments, unit of measurement and intervention effects on the outcome. Any additional information that may express conflict of interest or bias

will also be extracted. The correspondencing author of the studies with missing or incomplete data will be contacted for further information. Disagreements will be discussed with the third reviewer (CDCMF).

Risk of bias

The quality of the included RCT will be assessed by extracting the PEDro scores from the PEDro database (<http://www.pedro.org.au>). The PEDro Rating Scale is an 11-item checklist, which gives scores that range from 0 to 10, designed for rating the methodological quality of trials. The RCTs, which have not been assessed by the PEDro rating scale, will be scored by the reviewers (LTA, JCM). Once again, disagreements will be discussed with the third reviewer (CDCMF). The scores on the individual items of the PEDro scale of all included trial will be reported in a table. In an attempt to determine if reporting bias is present in the included trials, the trial register's 'ClinicalTrials.gov', '<http://www.anzctr.org.au>' and '<http://www.clinicaltrialsregister.eu/ctr-search/search>' will be screened to assess whether selective reporting is present.

Quality of evidence

The quality of the evidence of the studies will be assessed based on the Grading of Recommendations Assessment, Development and Evaluation (GRADE).³¹ The quality of the studies will be judged as high (further research is very unlikely to change the confidence in the effect estimates), moderate (further research is likely to have an important impact on the confidence in the effect and may change the estimate), low (further research is very likely to have an important impact on the confidence in the effect and is likely to change the estimate) and very low (any estimate of the effect is very uncertain).³¹

Strategy for data synthesis

This systematic review will also include a qualitative synthesis, which will provide information, in text and tables, to summarise the results of the included studies. A narrative synthesis will be performed to explore the results and associations within and between the included trials. Forest-plots and meta-analyses will be conducted if the studies are sufficiently homogeneous regarding the interventions and outcomes and if sufficient data are available, to synthesise the direction, size and consistency of the possible effects, using the Review Manager software (RevMan) (Review Manager (RevMan) [Computer program]. Version 5.3. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014).

Analyses of subgroups or subsets

If sufficient data are available, subgroups analyses will be carried out. These analyses will assess differences between the stroke phases (eg, acute, subacute or chronic), physical activity measurements (eg, subjective

vs objective instruments), type, duration and delivery of the intervention, group comparisons, quality and risk of bias.

DISCUSSION

According to the best of our knowledge, this systematic review is the first to investigate the efficacy of broad types of interventions aimed at increasing physical activity levels in stroke survivors. Previous systematic reviews with the aim to examine the efficacy of interventions on physical activity levels in poststroke survivors have investigated only two specific types of interventions: targeted behavioural change¹⁸ and self-management programmes.¹⁹ However, the efficacy of those interventions to increase physical activity levels in poststroke survivors continue to be unclear, due to the fact that the risk of bias of the included trials was high in both reviews.^{18 19} Moreover, important trials might not have been included because of the stringent eligibility criteria of these reviews.^{18 19} These factors limit the interpretation of the findings regarding the impacts of interventions on physical activity levels in poststroke survivors. Considering that physical inactivity is a major risk for recurrence of stroke and other CVDs and may affect health and function,^{2 9 16} it is important to investigate the impact of different types of interventions on physical activity levels in poststroke survivors.

The results of this systematic review will provide comprehensive and rigorous evidence regarding which types of interventions, and/or specific protocols have been investigated and are effective for increasing physical activity levels of stroke survivors. The information from the qualitative synthesis, which will be developed to explore the results and relations within and between the included studies, will be important for clinical decision-making aiming at improving function and health status of stroke survivors. Moreover, if sufficiently homogeneous data to conduct meta-analyses are available, clinicians will have information regarding the expected effect size associated with a given intervention.

Furthermore, this systematic review may allow the identification of gaps in the literature, regarding the types and specific intervention protocols, group comparisons, measurement instruments, short-term and long-term effects and different stroke phases (eg, acute, sub-acute or chronic). This information will be useful for the definition of future research goals and the planning of new research trials. The results from this systematic review will be spread by scientific publication and presentations in scientific events.

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Contributors The guarantor of this study is CDCMF. All authors contributed to the conception and design of the study, development of the search strategy, the establishment of the inclusion and exclusion criteria, data extraction criteria, analyses and interpretation. LTA and JCM were involved in the data collection and writing. CDCMF, SN, RRB and LFT-S provided critical revision of the paper. All authors read and provided final approval of the version to be published.

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Data sharing statement We, authors, agree that, should the article be accepted, the *BMJ Open* shall take over the authors' rights relating to this article, which shall become the property of the Journal.

Protocol amendments Protocol amendments will be documented with the date of each amendment and with a description of the change and the rationale.

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