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Activity monitors for increasing physical activity in adult stroke survivors (Protocol)

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Activity monitors for increasing physical activity in adult stroke survivors

Elizabeth A Lynch[1,2,3], Karen Borschmann[2,4,5], Michele L Callisaya[6], Natalie A Fini[5,7], Heidi Janssen[2,8,9], Liam Johnson[4,10], Taryn M Jones[11], Sharon Kramer[4], Suzanne Kuys[12], Niruthikha Mahendran[13], Dawn B Simpson[6], Coralie English[2,8,9], on behalf of the ACTIOnS Collaboration[14]

[1]Sansom Institute for Health Research, University of South Australia, Adelaide, Australia. [2]NHMRC Centre of Research Excellence in Stroke Rehabilitation and Brain Recovery, Florey Institute of Neuroscience and Mental Health & Hunter Medical Research Institute, Melbourne and Newcastle, Australia. [3]NHMRC Centre of Research Excellence in Stroke and Brain Recovery, The Florey Institute of Neuroscience and Mental Health, Melbourne, Australia. [4]Stroke Division, Florey Institute of Neuroscience and Mental Health, Melbourne, Australia. [5]School of Allied Health, La Trobe University, Melbourne, Australia. [6]Menzies Institute for Medical Research, University of Tasmania, Hobart, Australia. [7]Physiotherapy Department, Caulfield Hospital, Alfred Health, Melbourne, Australia. [8]School of Health Sciences, and Priority Research Centre for Stroke and Brain Injury, University of Newcastle, Newcastle, Australia. [9]Hunter Medical Research Institute, Newcastle, Australia. [10]Clinical Exercise Science Research Program, Institute of Sport, Exercise and Active Living, Victoria University, Melbourne, Australia. [11]Faculty of Medicine and Health Sciences, Macquarie University, Sydney, Australia. [12]School of Physiotherapy, Australian Catholic University, Brisbane, Australia. [13]Discipline of Physiotherapy, Faculty of Health, University of Canberra, Canberra, Australia. [14]Melbourne; Adelaide; Newcastle; Hobart; Sydney; Brisbane; Canberra, Australia

Contact address: Elizabeth A Lynch, Sansom Institute for Health Research, University of South Australia, Adelaide, South Australia, Australia. elizabeth.lynch@adelaide.edu.au.

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ABSTRACT

This is a protocol for a Cochrane Review (Intervention). The objectives are as follows:

To summarise the available evidence regarding the effectiveness of commercially available wearable devices and smart phone applications for increasing physical activity levels for people with stroke.

BACKGROUND

Description of the condition

Between 1990 and 2010 absolute numbers of people living with stroke increased by 84% worldwide, and stroke is now the third leading cause of disability globally (Feigin 2014). As such, the disease burden of stroke is substantial. It has been estimated that 91% of the burden of stroke is attributable to modifiable risk factors such as smoking, poor diet, and low levels of physical activity (Feigin 2016). A low level of physical activity (less than four hours per week) is the second highest population-attributable risk factor

for stroke, second only to hypertension (O'Donnell 2016). The promotion of physical activity, which has been defined as body movement produced by skeletal muscles resulting in energy expenditure (Caspersen 1985), is therefore an important health intervention for people with stroke.

The association between health and physical activity is well established. Prolonged, unbroken bouts of sitting is a distinct health risk independent of time engaged in regular exercise (Healy 2008). There is evidence from cross-sectional and longitudinal studies that high sitting time and low levels of physical activity contribute to poor glycaemic control (Owen 2010). Three systematic reviews and meta-analyses of observational studies have confirmed that, after adjusting for other demographic and behavioural risk factors, physical activity is inversely associated with all-cause mortality in men and women (Nocon 2008; Löllgen 2009; Woodcock 2011). Yet despite this knowledge, populations worldwide are becoming more sedentary, and physical inactivity has been labelled a global pandemic (Kohl 2012).

In addition to overcoming the sedentary lifestyles and habits prevalent in many modern societies, people with stroke have additional barriers to physical activity such as weakness, sensory dysfunction, reduced balance, and fatigue (Billinger 2014). Directly after a stroke, people should be admitted to hospital for co-ordinated care and commencement of rehabilitation (SUTC 2013). Early rehabilitation after stroke is frequently focused on the recovery of physical independence (Pollock 2014). Recovery after stroke is enhanced by active practice of specific tasks, and greater improvements are seen when people with stroke spend more time in active practice (Veerbeek 2014). Yet findings from research conducted around the world indicate that people in the first few weeks and months after stroke are physically inactive in hospital settings with around 80% of the day spent inactive (sitting or lying) (West 2012). These high levels of inactivity are concerning because recovering the ability to walk independently is an important goal of people with stroke. The reported paucity of standing and walking practice in the early phase after stroke potentially limits the opportunities of people with stroke to optimise functional recovery, particularly for standing and walking goals. Further, physical inactivity may lead to an increased risk of hospital-acquired complications, such as pressure ulcers, pneumonia, and cardiac compromise (Lindgren 2004).

Physical activity levels of people with stroke remain lower than their age-matched counterparts even when they return to living in the community (English 2016). Community-dwelling stroke survivors spend the vast majority of their waking time sitting down (English 2014). Promisingly, early research suggests that increasing physical activity in people with stroke is feasible, and that an increase in physical activity levels after stroke may have a positive impact on fatigue, mood, community participation, and quality of life (QoL) (Graven 2011; Duncan 2015).

Description of the intervention

For this review, we will consider an activity monitor to be any wearable or portable electronic device that provides feedback (either real-time or terminal) on physical activity. Activity monitors can be used independently by people with stroke or as an adjunct to therapy. Activity monitors include accelerometers and physical activity applications and these may be combined with global positioning systems. Feedback from a physical activity monitor can include objective measures of activity (e.g. step count, time spent in moderate intensity activity), graphs of daily activity, or encouragement on activity goals (e.g. encouragement to reach 10,000 steps per day, or reminders to move if sitting for a defined time).

Accelerometers are non-invasive activity monitors that record 'activity counts' based on acceleration detected across various movement planes (e.g. X, Y, Z planes). The objective measures of activity provided by accelerometers are dependent on the individual device, and include step count, activity duration, total activity counts, and energy expenditure. Accelerometers are classified as 'uniaxial', 'biaxial', or 'triaxial' depending on the number of movement planes across which they detect acceleration. Examples of accelerometers include Fitbit Charge HR, Actigraph, and Sensewear Armband.

Physical activity applications are typically installed on mobile smart devices which contain powerful embedded sensors, including triaxial accelerometers, global positioning system (GPS), cameras, orientation sensors, and gyroscopes that can be used to deliver continuous and automated real-time data to measure and interpret physical activity (Bort-Roig 2014). Applications downloaded on smart devices feature real-time feedback based on the user's activity profile, and some applications include an immersive storyline to engage the user in physical activity (Higgins 2016). Illustrations and animations are commonly used to describe how an activity/exercise is to be correctly performed, and some devices can be paired with wearable devices to further enhance the experience and data generated (Higgins 2016). Examples of physical activity applications include Strava Running, Runkeeper, and Fitbit.

GPS technology is now inbuilt into many mobile phones as well as wearable physical activity monitors and measures activity based on the location of the person. An example of a physical activity GPS is Garmin Forerunner.

How the intervention might work

Activity monitors are cheap and readily available to the public. They provide users with easy-to-understand, timely, and contextually relevant information about their physical activity behaviours. Further, many physical activity monitors have been designed to set goals and provide rewards, which are important elements in changing (and maintaining the change in) behaviour (Glynn 2013). Some applications have been designed to act as 'virtual coaches' to encourage and inspire the user. In addition, the capacity for

the user's behaviour to be shared via the connectivity capabilities of smart devices can promote social support, feedback, and competition via social networking platforms (Nakhasi 2014). Meta-analyses have shown that activity monitors can positively influence multiple health behaviours, including physical activity (Fanning 2012).

Activity monitors are increasingly being used to study physical activity in stroke survivors (Fini 2015). Use of these devices has the potential to be a relatively cheap and easy method of motivating people with stroke both in the clinical and community setting to increase physical activity levels for the purposes of maximising post-stroke physical function (i.e. walking) and reducing the risk of recurrent stroke (via regular exercise).

Why it is important to do this review

Despite the benefits of time spent in physical activity post-stroke, people who have had a stroke spend the majority of their day inactive, both during their inpatient rehabilitation (West 2012) and once living back in the community (English 2014). Commercially available wearable activity monitoring devices and smart phone applications provide immediate feedback to users on their physical activity levels, and if found to be effective in increasing physical activity, these have the potential to benefit all people with stroke. Understanding how effective such devices are in increasing physical activity after stroke will be useful for clinicians and researchers working in stroke prevention and rehabilitation, and for people with stroke who would like to improve their physical activity levels and general well-being.

It is not yet understood whether physical activity monitors alone, or with therapist support are effective and feasible in increasing physical activity after stroke. Further, investigation of characteristics of people with stroke (e.g. age, stroke severity) which may influence a person's ability to use an activity monitor independently or to engage in behaviour change in response to activity monitor feedback is required. Finally, factors related to the activity monitor intervention, such as type of monitor, setting, duration of intervention, intensity, dose, frequency, and mode of feedback for optimum improvements in physical activity after stroke need to be determined.

OBJECTIVES

To summarise the available evidence regarding the effectiveness of commercially available wearable devices and smart phone applications for increasing physical activity levels for people with stroke.

METHODS

Criteria for considering studies for this review

Types of studies

We will include randomised controlled trials (RCTs) and randomised cross-over trials.

Types of participants

Participants will be adults (aged 18 and over) with a diagnosis of stroke, who are in hospital settings or living in the community. If we identify studies with a mixed population including people with stroke, we will contact the study's authors and request data from just people with stroke so their data can be included.

Types of interventions

We will include interventions that examine the effectiveness or feasibility of the use of activity monitors for increasing physical activity levels within hospital or community settings in the review. We will exclude upper limb activity monitor interventions that have been designed to increase upper limb activity.

Variations of the intervention will include the type and frequency of feedback delivered (including whether timing was set or controlled by participants), the duration of intervention, and the type of activity monitor used.

We will include studies that compare use of:

- activity monitor versus no intervention;
- activity monitor versus other intervention;
- activity monitor versus different activity monitor intervention;
- use of activity monitor plus other intervention (e.g. a prescribed exercise program) versus other intervention alone.

We will exclude studies which compare use of activity monitor plus other intervention versus no treatment, when the effect of the activity monitor intervention cannot be determined. As our intention is to include studies that use physical activity monitors to promote physical activity, we will exclude studies when the activity monitor is used solely as a measurement tool.

Types of outcome measures

Primary outcomes

- Steps per day. Steps per day is relevant to people with stroke because it is associated with Activities and Participation domains of the International Classification of Functioning (Eng 2007).

- Time spent in moderate-vigorous physical activity (MVPA) at the end of the intervention period (short term), three months' post-intervention (medium term), and 12 months' post-

intervention (long term). We will measure time in MVPA in minutes per day and percentage of waking hours. We will include two methods of calculating MVPA with devices:

- using metabolic equivalents (METS): 3 METS or greater, where 1 MET is defined as the energy cost of sitting quietly (Haskell 2007);
- using activity count cut-off points: for example, 1952 counts per minute or greater (using the equations from Freedson and colleagues) (Freedson 1998).

Time in MVPA is important because MVPA has a vital role in the prevention of cardiovascular disease and stroke (Tremblay 2010; McDonnell 2013; Billinger 2014). Further, MVPA is inversely associated with all-cause mortality in men and women, after adjustment for other demographic and behavioural risk factors (Nocon 2008; Löllgen 2009; Woodcock 2011). Achieving a total physical activity level of 150 minutes per week of MVPA has been associated with a relative risk reduction (RRR) in all-cause mortality of 16%, and a RRR of 26% was reported for the higher threshold of 300 minutes of MVPA per week (Samitz 2011). Current guidelines recommend that stroke survivors complete at least 150 minutes per week of at least moderate-intensity physical activity (Billinger 2014).

Secondary outcomes

We will include further objective measures of physical activity as secondary outcomes.

- Sedentary time (measured in minutes per day and percentage of waking hours).
- Time spent in light physical activity (measured in minutes per day and percentage of waking hours).
- Walking duration (measured in minutes per day and percentage of waking hours).

These measures can assist in providing a complete picture of physical activity and include measures of intensity, frequency, and duration (Fini 2015).

We will also include self-reported measures of physical activity levels as secondary outcomes in terms of type of activity and context in which activity is undertaken.

We will include other measures as secondary outcomes.

- Fatigue (if a trial used multiple fatigue outcome measures, we will include the main outcome measure as specified by trial investigators. Where trial investigators have not specified the main outcome, priority will be given to Fatigue Assessment Scale and Fatigue Severity Scale).
- Mood (e.g. Hospital Anxiety and Depression Scale, General Health Questionnaire 12 Item, Brief Assessment Schedule Depression Cards, Patient Health Questionnaire 9 items).
- Quality of life (QoL) (e.g. Stroke Specific Quality of Life Scale, Stroke Impact Scale-16, EuroQol).
- Community participation (e.g. World Health Organization (WHO) Disability Assessment Schedule).
- Adverse events such as falls and hospitalisations.
- Death.

Fatigue, mood, community participation, and QoL are altered following stroke (Hackett 2005; Graven 2011; Duncan 2015), and an increase in physical activity may have a positive impact on these factors (Graven 2011; Duncan 2015).

Search methods for identification of studies

See the 'Specialized register' section in the Cochrane Stroke Group module. We will search for trials in all languages and arrange for the translation of relevant articles where necessary.

Electronic searches

We will search the following databases:

- Cochrane Stroke Group Trials Register (most recently updated);
- Cochrane Central Register of Controlled Trials (CENTRAL) (latest issue);
- MEDLINE (Ovid) (from 1946) (Appendix 1);
- Embase (Ovid) (from 1980);
- CINAHL (EBSCO) (from 1982);
- SPORTDiscus (EBSCO) (from 1949).

We developed the MEDLINE search strategy with the help of the Cochrane Stroke Group Information Specialist, which will be adapted for the other databases as necessary (Appendix 1). We will not limit searches to any language or type of publication.

Additionally, we will search the following ongoing trials registers:

- WHO International Clinical Trials Registry Platform (www.who.int/ictrp/en/);
- Clinicaltrials.gov (www.clinicaltrials.gov);
- EU Clinical Trial Register (www.clinicaltrialsregister.eu);
- ISRCTN Registry (www.isrctn.com);
- Australian and New Zealand Clinical Trial Registry (www.anzctr.org.au);
- Stroke Trials Registry (www.strokecenter.org/trials).

Searching other resources

To identify any further published, unpublished, or ongoing trials successfully, we will:

- search the reference lists of relevant articles and use the Web of Science cited reference search for forward tracking of references;
- search Google Scholar (scholar.google.com);
- attempt to contact trial authors to obtain further data if required.

Data collection and analysis

Selection of studies

Two or more review authors (HJ, NF, DS) will independently screen titles and abstracts of the references obtained as a result of our searching activities and will exclude obviously irrelevant reports. We will retrieve the full-text articles for the remaining references and two or more review authors (HJ, NF, DS) will independently screen the full-text articles and identify studies for inclusion, and identify and record reasons for exclusion of the ineligible studies. We will resolve any disagreements through discussion or, if required, we will consult a fourth review author (LJ). We will collate multiple reports of the same study so that each study, not each reference, is the unit of interest in the review. We will record the selection process and complete a PRISMA flow diagram.

Data extraction and management

Two or more review authors (NF, DS, KB) will independently extract data from included studies and record this information on a data extraction form developed specifically for this study. We will pilot the data extraction form on three studies to ensure clarity and comprehensiveness of data collection. We will extract the following data: type of study, participant population, study setting, details of interventions and co-interventions, time frame, and details of outcomes and their definitions. We will use headings from the TIDieR checklist to guide extraction of data regarding the interventions and co-interventions (Hoffmann 2014). We will compare the extracted results and will resolve any discrepancies by discussion.

Assessment of risk of bias in included studies

Two or more review authors (SKr, LJ, DS) will independently assess risk of bias for each study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We will resolve any disagreements by discussion or by involving a fourth review author (EL). We will assess the risk of bias according to the following domains.

- Random sequence generation.
- Allocation concealment.
- Blinding of participants and personnel.
- Blinding of outcome assessment.
- Incomplete outcome data.
- Selective outcome reporting.
- Other bias (e.g. carryover bias in cross-over trials, contamination between groups).

We will grade the risk of bias for each domain as high, low, or unclear. Low risk of bias indicates the study appears to be free from bias for the domain. We will grade a domain as having an unclear risk of bias when there is a risk of bias but there is insufficient information available to determine whether an important risk of bias is present, or there is a lack of clarity whether an identified problem will introduce bias. When there is at least one important risk of bias for a domain, we will identify the domain as having a high risk of bias. We will report information for each domain for each study together with a justification for our judgement in the 'Risk of bias' tables.

Measures of treatment effect

We will express continuous data as mean differences (MDs) with 95% confidence intervals (CIs) for data measured in the same way between trials, or standardised mean differences (SMDs) with 95% CIs to combine data when different scales were used for measurement. We will express dichotomous data as risk ratios (RRs) with 95% CI.

Unit of analysis issues

We will include all studies or trials with cluster-randomisation as well as individually randomised trials. We will determine whether or not to combine the results of individual RCTs and cluster-RCTs by performing a subgroup analysis separating individual RCTs and cluster-RCTs. If there is no significant difference between the results of the individual RCTs and cluster-RCTs, as indicated by a non-statistically significant result in the test of subgroup difference, we will consider it reasonable to combine the results from all included studies. We will include cross-over trials in the review and use only data from the first phase of included trials.

Dealing with missing data

We will follow the methods for sensitivity analysis described in the *Cochrane Handbook for Systematic Reviews of Interventions* for dealing with missing data (Higgins 2011). We will assess and report the dropout rates of each study, and use the principle of intention-to-treat analyses whereby we will analyse all participants according to group allocation. We will contact study authors to request data in an appropriate format to enable data syntheses and meta-analyses if such data are not reported in the retrieved paper. We will consider missing data as part of the assessment of risk of bias within included studies.

Assessment of heterogeneity

We will visually inspect the forest plots for any evidence of heterogeneity. We will use the I^2 statistic to measure heterogeneity among the trials in each analysis, with an I^2 statistic of 50% or higher indicating moderate to substantial heterogeneity. Due to the wide variety of devices considered and the broad eligibility criteria set for participants, we will use a random-effects model.

Assessment of reporting biases

We will use funnel plots to detect reporting biases (such as publication bias). We will assess funnel plot asymmetry visually.

Data synthesis

Where we consider two or more studies to be similar in terms of participant population and intervention received, we will conduct a meta-analysis by pooling the appropriate data using Review Manager 5 (RevMan 2014). We will describe findings narratively when studies do not allow for data to be pooled.

Subgroup analysis and investigation of heterogeneity

We intend to explore heterogeneity by additional subgroup analysis if data are available.

- Setting (hospital or community).
- Type of activity monitor (similar pedometer versus more complex body worn activity monitor).
- Frequency of feedback (real time versus terminal).
- Participant-specific factors (to facilitate identification of people with stroke most likely to respond to activity monitor interventions):
    - age 18 to 64 years, 65 years and over;
    - walking ability (independent or requiring assistance);
    - time since stroke (within one month, between one and six months, more than six months);
    - gait speed;
    - gait endurance.

Sensitivity analysis

We will judge study methods using Cochrane's tool for assessing risk of bias (Higgins 2011). We will perform sensitivity analyses to assess the robustness of the findings by excluding the studies from the analysis which are at high risk of bias .

'Summary of findings' table

We will create a 'Summary of findings' table including the following outcomes (steps per day, time spent in MVPA, sedentary time, time spent in light physical activity, walking duration, and adverse events). Two or more review authors (NF, DS, KB) will independently rate the quality of evidence regarding the studies that contribute data to the meta-analyses for each outcome using the GRADE approach (www.gradeworkinggroup.org/) and the GRADEpro Guideline Development Tool (GRADEpro GDT 2015). We will provide footnotes or comments to justify all decisions to downgrade or upgrade the quality of studies. If meta-analysis is not possible, we will present results in a narrative 'Summary of findings' table format.

An empty 'Summary of findings' table for our first comparison (physical activity intervention versus no treatment) is provided below. When more than one study is included for the other comparisons (physical activity monitor intervention versus other treatment, physical activity monitor intervention versus different activity monitor intervention, and physical activity monitor intervention plus other intervention versus other intervention alone), we will add relevant sections to the 'Summary of findings' table.

Population: people with stroke
Settings: hospital, community or home setting
Intervention: physical activity monitor intervention
Comparison: no treatment

Outcomes	Illustrative comparative risks (95% CI)		Relative effect (95% CI)	No of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	No treatment	Physical activity monitor intervention				
Steps per day	-	-	-	-	-	-
Time in MVPA	-	-	-	-	-	-
Sedentary time	-	-	-	-	-	-

(*Continued*)

Time in light physical activity	-	-	-	-	-	-
Walking duration	-	-	-	-	-	-
Adverse events	-	-	-	-	-	-

CI: confidence interval; MVPA: moderate-vigorous physical activity.

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* *Indicates the major publication for the study*

APPENDICES

Appendix 1. MEDLINE search strategy

MEDLINE (Ovid) search strategy
1. cerebrovascular disorders/ or basal ganglia cerebrovascular disease/ or exp brain ischemia/ or exp carotid artery diseases/ or exp cerebral small vessel diseases/ or exp intracranial arterial diseases/ or exp "intracranial embolism and thrombosis"/ or exp intracranial hemorrhages/ or stroke/ or exp brain infarction/ or stroke, lacunar/ or vasospasm, intracranial/ or vertebral artery dissection/
2. (stroke$ or poststroke or apoplex$ or cerebral vasc$ or brain vasc$ or cerebrovasc$ or cva$ or SAH).tw.
3. ((brain or cerebr$ or cerebell$ or vertebrobasil$ or hemispher$ or intracran$ or intracerebral or infratentorial or supratentorial or middle cerebral artery or MCA$ or anterior circulation or posterior circulation or basilar artery or vertebral artery or space-occupying) adj5 (isch?emi$ or infarct$ or thrombo$ or emboli$ or occlus$ or hypoxi$)).tw.
4. ((brain$ or cerebr$ or cerebell$ or intracerebral or intracran$ or parenchymal or intraparenchymal or intraventricular or infratentorial or supratentorial or basal gangli$ or putaminal or putamen or posterior fossa or hemispher$ or subarachnoid) adj
5 (h?emorrhag$ or h?ematoma$ or bleed$)).tw. 5. hemiplegia/ or exp paresis/ or exp Gait Disorders, Neurologic/
6. (hemipleg$ or hemipar$ or paresis or paraparesis or paretic).tw.
7. or/1-6
8. feedback/ or exp feedback, physiological/ or feedback, sensory/
9. monitoring, physiologic/ or exp monitoring, ambulatory/
10. exp accelerometry/ or actigraphy/
11. ((physical or physiolog$ or perform$ or fit$ or train$ or activ$ or endur$ or exercise) adj3 (track$ or monitor$ or measur$ or device$ or app$)).tw.
12. ((step$ or walk$) adj3 (count$ or meter$ or daily)).tw.
13. (pedometer$ or actigraph$ or acceleromet$).tw.
14. telemedicine/
15. Mobile Applications/ or cell phones/ or smartphone/or exp Computers, Handheld/
16. ((cell$ or smart$ or mobile or android or internet or web) adj3 (comput$ or device or app$ or phone)).tw.
17. or/8-16
18. Randomized Controlled Trials as Topic/
19. Random Allocation/
20. Controlled Clinical Trials as Topic/
21. control groups/
22. clinical trials as topic/ or clinical trials, phase i as topic/ or clinical trials, phase ii as topic/ or clinical trials, phase iii as topic/ or clinical trials, phase iv as topic/

23. double-blind method/
24. single-blind method/
25. Placebos/
26. placebo effect/
27. cross-over studies/
28. randomized controlled trial.pt.
29. controlled clinical trial.pt.
30. (clinical trial or clinical trial phase i or clinical trial phase ii or clinical trial phase iii or clinical trial phase iv).pt.
31. (random$ or RCT or RCTs).tw.
32. (controlled adj5 (trial$ or stud$)).tw.
33. (clinical$ adj5 trial$).tw.
34. ((control or treatment or experiment$ or intervention) adj5 (group$ or subject$ or patient$)).tw.
35. (quasi-random$ or quasi random$ or pseudo-random$ or pseudo random$).tw.
36. ((control or experiment$ or conservative) adj5 (treatment or therapy or procedure or manage$)).tw.
37. ((singl$ or doubl$ or tripl$ or trebl$) adj5 (blind$ or mask$)).tw.
38. (cross-over or cross over or crossover).tw.
39. (placebo$ or sham).tw.
40. trial.ti.
41. (assign$ or allocat$).tw.
42. controls.tw.
43. or/18-42
44. 7 and 17 and 43

Appendix 2. Trial register search strategy

1. Stroke AND “activity monitor”
2. Stroke AND “mobile phone”
3. Stroke AND “app”

CONTRIBUTIONS OF AUTHORS

EL drafted the ’Background’ and ’Description of the condition’ sections, and co-ordinated review team.

TJ, LJ, and NM drafted the ’Description of the intervention’ and ’How the intervention might work’ sections.

HJ drafted the ’Why it is important to do this review’ section.

EL and HJ the drafted ’Types of studies’, ’Types of participants’, and ’Types of interventions’ sections.

NF and KB drafted the ’Types of outcome measures’ section.

SKr developed search strategy.

SKu and CE drafted the ’Measures of treatment effect’, ’Unit of analysis issues’, and ’Dealing with missing data’ sections.

MC drafted ’Assessment of reporting biases’ and ’Sensitivity analysis’ sections.

DS drafted ’Subgroup analysis and investigation of heterogeneity’ section.

CE, SKu, HJ, MC, NF, EL, and DS conceptualised the review.

All authors read and reviewed the completed draft.

DECLARATIONS OF INTEREST

EL: none known.

KB: none known.

MC: none known.

NF: none known.

HJ: none known.

LJ: none known.

TJ: none known.

SKr: none known.

SKu: none known.

NM: none known.

DS: none known.

CE: none known.