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Reducing sedentary behaviour after stroke

Submission date
17/02/2020

Recruitment status
No longer recruiting

Registration date
01/04/2020

Overall study status
Completed

Last Edited
26/11/2024

Condition category
Circulatory System

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Time spent in sedentary behaviour (sitting/lying down) has recently emerged as an important topic. Too much time spent in sedentary behaviours is linked with ill health and mortality. This seems to be independent of physical activity – a short burst of activity such as an exercise class will not offset the detrimental health effects of many hours of sitting. Survivors of stroke are among the most sedentary individuals in the population, spending up to 80% of their waking day sitting or lying down. Interventions to reduce sitting time have enormous potential, would be low cost and may be more achievable than a structured exercise programme, particularly in stroke survivors afraid of another stroke or falling. This study's focus is on reducing sitting time in survivors of stroke in their own homes once they have been discharged from the hospital and therapy services. However, to achieve this the researchers feel it is important that stroke survivors are appropriately informed and supported in reducing sedentary behaviour from the time of their stroke, learning techniques which they can continue at home when no longer in receipt of therapy. Through a review of the evidence, observations of practice and joint work between stroke survivors, their carers, and healthcare professionals, ideas and action plans for reducing time spent sitting/lying (an intervention) have been developed. The initial intervention was tested and optimised in three services. The aim of this pragmatic pilot cluster Randomised Controlled Trial (cRCT) with embedded process and economic evaluations is to undertake a preliminary exploration of the developed intervention.

Who can participate?
Stroke in-patients aged 16 years or over at the time of stroke, requiring manual contact of no more than one person to stand to prevent falling with planned discharge into the community.

What does the study involve?
The intervention will be delivered by NHS stroke services across the UK. NHS stroke services randomly allocated to the intervention group will be trained to deliver the intervention alongside current practice, whilst those allocated to the control group will continue to deliver current practice. The study aims to recruit 300-400 stroke survivors in 15 NHS stroke services. Patients with a planned discharge home will be recruited by researchers based on the referring stroke units. Outcomes will be assessed at 6, 12 and 24 months after stroke survivors' recruitment and registration to the trial. The primary endpoint is the ability in extended activities of daily living measured using the Nottingham Extended Activities of Daily Living (NEADL) scale at 12 months post-registration. A key secondary outcome is sedentary behaviour

in total sitting time at 12 months (measured by the activity monitor activPAL); other secondary outcomes are
listed in the outcome section of this record. Endpoint analyses will be exploratory and provide preliminary estimates of the intervention effect.

A parallel and embedded process evaluation will explore and understand the implementation of the developed intervention and how it is experienced and understood by providers and recipients. This will include a range of methods including documentary analysis, non-participant observation and semi-structured interviews with a sample of trial participants and intervention providers.

What are the possible benefits and risks of participating?
The intervention is a quality improvement initiative which aims to reduce sedentary behaviour in stroke survivors. Patients admitted to stroke services allocated to the intervention may therefore benefit from the intervention. Aside from the possible effects of the intervention, participating in the study would bring about no direct or immediate benefit to stroke survivors, carers or stroke service managers, therapists or other multidisciplinary team members. However, the aim of the study is to gather data to inform the development and preliminary evaluation of an intervention to reduce sedentary behaviours for people who have had a stroke and in the future, therefore all participants would be making a contribution to these efforts to reduce sedentary behaviour after stroke and improve outcomes. There is some evidence that interview participants may derive some benefit from talking about their experiences.

For stroke survivor participants, there is a risk that some may find wearing the activity monitors burdensome and/or may experience a skin reaction/itchiness or discomfort depending on the method of attachment. Colleagues have undertaken large studies with older people where the ActivPAL activity monitor was successfully used. The researchers will follow their standard operating procedures. Completion of the paper-based outcome assessments may be time consuming, but they have been tested in a feasibility study and the researchers will provide advice and help where required.

Some of the questions in the semi-structured interviews (conducted as part of the embedded process evaluation) may cover topics that the interviewee may find distressing. They will be made aware of this before consenting to take part. At the time of the interview, it will be made clear that participants may pause and/or terminate the interview at any time. Non-participant observations of the provision of care/therapy provided to individual patients (also part of the process evaluation) may be perceived as intrusive by staff and/or patients and caregivers. All participants would be made aware before giving consent of the ways in which researchers would carry out their observations. That is, research fellows will seek verbal permission to observe on each and every occasion (in addition to written consent for more focused observations of individual sessions), locate themselves so as not to hinder the conduct of the care provision /therapy session, not speak during this time unless requested to do so by the patient, carer or staff member, have due regard for privacy and dignity and maintain confidentiality at all times. No episodes of personal care would be observed. Research fellows will cease observations if requested to do so by patients, their carers, and/or stroke service staff.

Where is the study run from?
Bradford Teaching Hospitals NHS Foundation Trust and the University of Leeds (UK)

When is the study starting and how long is it expected to run for?
December 2019 to December 2024

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Prof. Anne Forster
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Study website
https://www.bradfordresearch.nhs.uk/our-research-teams/academic-unit-for-ageing-and-stroke-research/our-research/stroke-research/recreate/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
271111

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 44047, IRAS 271111

Study information

Scientific Title
A multicentre pilot cluster randomised controlled trial evaluating an intervention to reduce sedentary behaviour in stroke survivors incorporating an embedded process evaluation

Acronym
RECREATE

Study objectives
Current study hypothesis as of 25/04/2023:
This study is the fifth of five workstreams in a National Institute for Health Research-funded seven-year research programme, which seeks to develop and evaluate strategies for reducing sedentary behaviour in people after stroke to improve outcomes. The researchers are developing and evaluating a complex intervention to target sedentary behaviour after stroke.

Building on the intervention developed through a co-production process in Workstream 3 and tested for feasibility in Workstream 4, they will undertake a pragmatic multicentre pilot cluster randomised controlled trial evaluating an intervention aiming to reduce sedentary behaviour after stroke, incorporating embedded process and economic evaluations.

Previous study hypothesis:
This study is the fifth of five workstreams in a National Institute for Health Research funded seven-year research programme, which seeks to develop and evaluate strategies for reducing sedentary behaviour in people after stroke to improve outcomes. The researchers are developing and evaluating a complex intervention to target sedentary behaviour after stroke.

Building on the intervention developed through a co-production process in Workstream 3 and tested for feasibility in Workstream 4, they will undertake a multicentre cluster randomised controlled trial evaluating the clinical and cost-effectiveness of the intervention incorporating an internal pilot phase and embedded process evaluation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 30/12/2019, Yorkshire and the Humber – Bradford Leeds REC (St Luke's Hospital, Extension Block, Little Horton Lane, Bradford, BD5 0NA, UK; +44 (0)207 1048 088; nrescommittee.yorkandhumber-bradfordleeds@nhs.net), REC ref: 19/YH/0403

Study design
Randomized; Both; Design type: Treatment, Process of Care, Education or Self-Management, Psychological & Behavioural, Complex Intervention, Physical, Rehabilitation, Qualitative

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Stroke

Interventions
Current interventions as of 25/04/2023:
The intervention will be delivered by NHS stroke services across the UK. NHS stroke services randomised to the intervention group will be trained to deliver the intervention alongside current practice, whilst those randomised to the control group will continue to deliver only current practice. The intervention ('Get Set Go') aims to reduce sedentary behaviour after stroke. It was developed using coproduction methods, following significant systematic review and qualitative work, and is underpinned by behaviour change theory. It is intended to begin early after stroke (in the in-patient setting) and continue into the community, and designed to fit into existing rehabilitation and recovery pathways.

Previous interventions:
The intervention will be delivered by NHS stroke services across the UK. NHS stroke services randomised to the intervention group will be trained to deliver the intervention, whilst those randomised to the control group will continue to deliver current practice. The trial aims to recruit 1,156 patients in 34 NHS stroke services. Patients with planned discharge home will be recruited by researchers based on the referring stroke units. Outcomes will be assessed at 6, 12 and 24 months after stroke survivors recruitment and registration to the trial. The primary outcome is ability in extended activities of daily living (ADL) measured using the Nottingham Extended ADL Scale at 12 months following participant recruitment. The key secondary outcome

is measurement of sedentary behaviour in total sitting time at 12 months (measured by the activity monitor activPAL). Other secondary outcomes include cost-effectiveness, health status and occurrence of major vascular events. A parallel and embedded process evaluation will explore and understand the implementation of the intervention and how it is experienced and understood by providers and recipients.

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measure as of 25/04/2023:
Participant-reported physical and social independence measured using the Nottingham Extended Activities of Daily Living scale (NEADL) at 12 months post-registration

Previous primary outcome measure:
Physical and social independence measured using the Nottingham Extended Activities of Daily Living (NEADL) at baseline, 6, 12 and 24 months

Secondary outcome measures
Current secondary outcome measures as of 25/04/2023:
Key secondary outcome measure:
Sedentary behaviour (mean daily sedentary time in minutes) at 12 months, measured using an activity monitor (ActivPAL)

Other secondary outcomes measured at baseline, 6-, 12- and 24- months post-registration (unless stated otherwise) for stroke survivor participants are:
1. EADLs measured by the Nottingham Extended Activities of Daily Living scale (NEADL) at baseline, 6 and 24 months
2. Sedentary behaviour measured by an activPAL activity monitor at baseline, 6, and 24 months
3. Physical and psychological functioning measured using the World Health Organisation Disability Assessment Schedule 2.0 (12-item; WHODAS 2.0-short)
4. Mental well-being measured using the Warwick-Edinburgh Mental Well-being Scale (WEMWBS)
5. Health status measured using the European Quality of Life 5-Dimension Health Questionnaire (5 levels; EQ-5D-5L)
6. Quality-Adjusted Life Year (QALY) gains
7. Fatigue measured using the Fatigue Assessment Scale (FAS)
8. Death
9. Falls and use of a walking aid at baseline, 12 weeks post-discharge, and at 6, 12 and 24 months
10. Use of a walking aid measured using participant-reported data at baseline, 12 weeks post-discharge, 6, 12 and 24 months
11. Self-reported sedentary behaviour measured using the Measure of Older Adults' Sedentary Time (MOST) and a Sedentary Behaviour Visual Analogue Scale
12. Social participation measured using social questions
13. Self-reported health and social care service use and informal care inputs measured by a Client Services Receipt Inventory (CSRI) specifically adapted for this trial from versions used in previous stroke rehabilitation trials
14. Costs from a health and social care perspective, and a societal perspective that further includes informal care
15. Institutionalisation, hospital re-admission, and emergency department attendance rates at 6, 12 and 24 months
16. Cardiovascular risk markers: Height (baseline only) and weight for Body Mass Index (BMI)

waist circumference, blood pressure (BP)
17. Total major vascular events: Composite measure of non-fatal stroke, non-fatal myocardial infarction or death due to any vascular cause (including unexplained sudden death)

Previous secondary outcome measures:
1. Sedentary behaviour measured by an activPAL activity monitor at Baseline, 6, 12 and 24 months

Participant-reported outcome measures:
2. Physical and psychological functioning measured using WHODAS 2.0 at baseline, 6, 12 and 24 months
3. Mental wellbeing measured using Warwick-Edinburgh Mental Well-being Scale (WEMWBS) at baseline, 6, 12 and 24 months
4. Health-related QoL measured using EQ-5D-L at baseline, 6, 12 and 24 months
5. Fatigue measured using Fatigue Assessment Scale (FAS) at Baseline, 6, 12 and 24 months
6. Use of a walking aid measured using participant-reported data at baseline, 6, 12 and 24 months
7. Sedentary behaviour measured using Measure of Older Adults' Sedentary Time (MOST) at Baseline, 6, 12 and 24 months
8. Sedentary behaviour measured using Sedentary Behaviour Visual Analogue Scale at Baseline, 6, 12 and 24 months
9. Social participation measured using social questions at baseline, 6, 12 and 24 months
10. Falls and injury measured using questions on falls and whether or not they led to injury measured at baseline, 6, 12 and 24 months (at baseline this will be related to in hospital falls and for the 6 months prior to hospital admission)

Additional outcomes to be collected include:
11. Use of health and social care measured using client service receipt inventories at baseline, 6, 12 and 24 months
12. Risk markers for cardiovascular disease: height and weight, waist circumference and blood pressure measured during visits at baseline, 6, 12 and 24 months
13. Total major vascular events, comprising composite of non-fatal stroke, non-fatal myocardial infarction or death due to any vascular cause (from health records through NHS Digital or directly from recruiting hospitals) at 24 months

Family/friend/carer-reported outcome measures:
14. Caregiver burden measured using Caregiver Burden Scale at Baseline, 6, 12 and 24 months

Overall study start date
31/12/2019

Completion date
01/12/2024

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 25/04/2023:
All stroke survivors with the following characteristics are eligible for this trial:
1. Are aged 16 years or over at the time of stroke
2. New or recurrent clinically diagnosed ischaemic or haemorrhagic (excluding subarachnoid haemorrhage) stroke

3. Require manual contact of no more than one person to stand to prevent falling. Manual contact consists of continuous or intermittent light touch to assist balance or coordination (i.e. not to support body weight)
4. Planned discharge to live in the community (not to a care home)
5. Provide written informed consent or Consultee agreement

Thus, the study will include a range of abilities from people who need help with balance /coordination to stand to those able to walk independently anywhere.

Family/friends /carer will be eligible for the study provided they are:
1. Aged 16 years or over
2. A family member/close friend/carer of a stroke survivor participating in the study and identified by the stroke survivor as someone they engage with on a regular basis (meet at least once a fortnight)
3. Able and willing to provide written informed consent

Previous participant inclusion criteria:
All stroke survivors with the following characteristics are eligible for this trial:
1. New or recurrent clinically diagnosed ischaemic or haemorrhagic (excluding subarachnoid haemorrhage) stroke
2. Requires manual contact of no more than one person to stand to prevent falling. Manual contact consists of continuous or intermittent light touch to assist balance or coordination in keeping with Functional Ambulatory Categories [Holden et al, 1984] (FAC) 3-6
3. Planned discharge to live in the community (not to a care home)
4. Provide written informed consent or Consultee agreement

Thus, the study will include a range of abilities from people who need help with balance /coordination to walk (FAC score=3) to those able to walk independently anywhere (FAC score=6)

Family/friends /carer will be eligible for the study provided they are:
1. Aged 16 years or over
2. A family member/close friend/carer of a stroke survivor participating in the study and identified by the stroke survivor as someone they engage with on a regular basis (meet at least once a fortnight)
3. Able and willing to provide written informed consent

Participant type(s)
Mixed

Age group
Adult

Lower age limit
16 Years

Sex
Both

Target number of participants
We originally planned a large multi-centre RCT with 34 stroke services each recruiting 34 participants. However, site recruitment was slower than expected due to issues related to the

COVID-19 pandemic. Therefore, we are conducting a large external pilot trial. We aim to recruit 300-400 participants across 15 stroke services. As the study will not have a formal power calculation and effectiveness will not be evaluated, all analyses will be of an exploratory nature.

Total final enrolment
334

Key exclusion criteria
Current participant exclusion criteria as of 25/04/2023:
Stroke survivors will be excluded from the trial if they:
1. Are in receipt of palliative care
2. Are discharged outside the defined geographical area supported by the associated community service(s) participating in the trial Family members/friends/carers will be excluded from the trial if the person with stroke does not consent to the trial

Previous participant exclusion criteria:
Stroke survivors will be excluded from the trial if they:
1. Are in receipt of palliative care
2. Have an FAC score of 1 (unable to stand without the help of a hoist or two people) or an FAC score of 2 (need continuous support to walk), as they will be unable to amend their behaviour without substantial help
3. Are discharged outside the area supported by the associated community service(s) participating in the trial

Family members/friends/carers will be excluded from the trial if the person with stroke does not consent to the trial

Date of first enrolment
01/06/2020

Date of final enrolment
30/04/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Bradford Institute for Health Research
Temple Bank House
Bradford Royal Infirmary
Duckworth Lane
Bradford
United Kingdom
BD9 6RJ

Study participating centre
University of Leeds
Clinical Trials Research Unit
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United Kingdom
LS2 9JT

Sponsor information

Organisation
Bradford Teaching Hospitals NHS Foundation Trust

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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: RP-PG-0615-20019

Results and Publications

Publication and dissemination plan
1. The study protocol will be available from the Chief Investigator
2. Peer-reviewed scientific journals
3. Conference presentation
4. Publication on website
5. Submission to regulatory authorities

Intention to publish date
31/03/2025

Individual participant data (IPD) sharing plan
De-identified individual participant data datasets generated and/or analysed during the current study will be available upon request from the Clinical Trials Research Unit, University of Leeds (contact CTRU-DataAccess@leeds.ac.uk in the first instance). Data will be made available at the end of the trial, i.e. usually when all primary and secondary endpoints have been met and all key analyses are complete. Data will remain available from then on for as long as CTRU retains the data.
CTRU makes data available by a 'controlled access' approach. Data will only be released for legitimate secondary research purposes, where the Chief Investigator, Sponsor and CTRU agree that the proposed use has scientific value and will be carried out to a high standard (in terms of scientific rigour and information governance and security) and that there are resources available to satisfy the request. Data will only be released in line with participants' consent, all applicable laws relating to data protection and confidentiality, and any contractual obligations to which the CTRU is subject. No individual participant data will be released before an appropriate agreement is in place setting out the conditions of release. The agreement will govern data retention, usually stipulating that data recipients must delete their copy of the released data at the end of the planned project.
The CTRU encourages a collaborative approach to data sharing and believes it is best practice for researchers who generated datasets to be involved in subsequent uses of those datasets. Recipients of trial data for secondary research will also receive data dictionaries, copies of key trial documents and any other information required to understand and reuse the released datasets.
The conditions of release for aggregate data may differ from those applying to individual participant data. Requests for aggregate data should also be sent to the above email address to discuss and agree suitable requirements for release.

IPD sharing plan summary
Available on request

Study outputs
Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Protocol article		30/07/2023	31/07/2023	Yes	No
Protocol article	protocol for the process evaluation	12/09/2023	14/09/2023	Yes	No