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PARAS: A feasibility study of an intervention targeting Physical Activity Routines After Stroke

Submission date
15/10/2018

Recruitment status
No longer recruiting

Registration date
24/10/2018

Overall study status
Completed

Last Edited
02/11/2022

Condition category
Nervous System Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English Summary
Background and study aims
Research shows that many stroke survivors are not active and spend large amounts of time sitting or lying down. Not being active after stroke can limit function, health and quality of life. This study will assess whether it is possible to deliver a programme where healthcare professionals support stroke survivors to manage their own long-term physical activity levels.

Who can participate?
Up to 12 healthcare professionals working in community stroke teams in the North East of England will be recruited. The health care professionals will be trained to deliver the programme to up to 45 adult stroke survivors who they are working with in the community. The stroke survivors taking part must understand what is involved in the study and be able to safely manage their own activity with support from a healthcare professional.

What does the study involve?
The healthcare professionals will be trained on how to deliver the programme. During the programme (delivered over at least two sessions) the professionals will support stroke survivors to set goals, make plans, identify ways to cope with barriers and measure activity levels. Information and tools will be provided on an individual basis to help participants be more active and feedback will be provided on progress. How confident and skillful the professionals are in programme delivery and what they think of the programme will be measured. The stroke survivor's well-being, tiredness and how they move will be measured before the programme and on review. Information will be collected on how the programme was used e.g. what goals were set, what tools were used. The stroke survivors will also be asked what they think of the programme.

What are the possible benefits and risks of participating in the study?
Healthcare professionals who take part in the study will be trained on how to deliver the programme and can use the skills they develop in other areas of their work. Developing the skills may however take some time. Stroke survivors will be provided with tools and support to help them to move more or sit less. They can use the skills and tools they learn after the study has finished. Stroke survivors will be asked to feedback on their experiences of the programme which will help to guide future research and support for more people with stroke. Stroke

survivors who take part may experience a bit of pain and discomfort when they first start to move more but they will be advised on this by their healthcare professional.

Where is the study run from?
The study is being run from Newcastle University and Northumbria Healthcare NHS Foundation Trust. There are three community stroke teams taking part in the study based at North Tyneside General Hospital, South Tyneside District Hospital and Sunderland Royal Hospital

When is the study starting and how long is it expected to run for?
June 2018 to March 2020

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

Who is the main study contact?
Dr Sarah Moore
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
39098

Study information

Scientific Title
A feasibility, acceptability and fidelity study of a multifaceted behaviour change intervention targeting free-living physical activity and sedentary behaviour after stroke

Study hypothesis
It will be feasible to deliver a multifaceted behaviour change intervention targeting free-living physical activity and sedentary behaviour after stroke in community stroke care

Ethics approval required
Old ethics approval format

Ethics approval(s)
North East - Tyne & Wear South Research Ethics Committee, 12/09/2018, ref: 18/LO/1135

Study design
Interventional non-randomised feasibility study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Community

Study type(s)
Treatment

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

Condition
Physical activity in people who have had a stroke

Interventions
At the baseline, the following socio-demographic and health information measures will be collected from the stroke survivors: age (years), sex (male/female), pre-morbid walking status (independent/walks with an aid), marital status (single, married/remarried, separated, widowed, divorced), occupation pre-stroke (e.g. school teacher, retired), current work status (full-time paid, part-time paid, causal, registered sick/disabled, retired, unemployed, student), medical history (diabetes, arthritis etc.), geographical location (post code) education (year count); date of stroke; assistive device use (no device/stick/tripod/elbow crutches/zimmer frame/delta frame /four wheeled walker/wheelchair/other). The following will also be completed: Rivermead Mobility Index, Fatigue Assessment Scale, Warwick-Edinburgh Mental Well-being Scale (WEMWBS).
Participants will undergo a stroke survivor supported self management intervention programme. This multifaceted theory and evidence based behaviour change intervention comprises of two distinct but related components:

1. A healthcare professional (HCP) supported self-management programme targeting the free-living physical activity and sedentary behaviour of stroke survivors
2. A training programme targeting the consultation behaviour of HCPs who are supporting the self-management programme.
Healthcare professionals will support the stroke survivors to undertake a self-managed intervention programme targeting physical activity and sedentary behaviour. The programme incorporates a number of different evidence based techniques that have been selected based on our developmental work to target unwanted physical activity and sedentary behaviour. The intervention programme will be delivered by HCPs who have been recruited to the study and trained in delivery. The HCPs will deliver the initial session face-to-face with the recruited stroke survivors. During this session they will use the intervention programme materials (e.g. workbook, laminated discussion cards) to facilitate the delivery of the supported self-management programme. The intervention programme will focus on goal setting; action planning; barrier identification; coping planning and feedback on physical activity and sedentary behaviour. Follow-up sessions will either be delivered face-to-face or by telephone according to the needs of the stroke survivor. During these sessions the goal setting process will be reviewed and updated. When the intervention is delivered will vary dependent on needs of the stroke survivor/health care professional's opinion on the best timing/availability of resources. Stroke survivors will have contact with their trained HCP on at least two occasions. The first session/s will target goal setting using the workbook and other tools, there will then be a review session timed to coincide with the review date for physical activity/sedentary behaviour goals. There is no upper limit to the number of HCP supported sessions. The number of sessions will be defined by the stroke survivors' support needs/availability of resources. They may increase their levels of fatigue through increasing their physical activity, but this will be monitored at baseline and during review sessions. Well-being, mobility and progress will also be reviewed by the healthcare professionals who will be able to provide the participants with advice and adapt the programme accordingly.
During review sessions the stroke survivors will be asked to repeat the measures of fatigue, well-being and mobility that were assessed at baseline and to review progress and plan for future management.
In order to improve and assess the fidelity of the delivery of the intervention, baseline and review sessions will be audio-recorded. The content of the first two intervention sessions will be reviewed by the research team to enable feedback to be provided to the HCPS on intervention delivery. The healthcare professionals will be reassured that this feedback will be confidential and used to improve their skills only not as a comparison to others. The audio-recorded data will be stored securely at the research sites after patient visits in locked filing cabinets behind locked doors. The research team will be alerted to visit the research sites to download this data. The downloaded data which will be taken straight back to the central research office where it will be stored securely on a password protected computer. We have used this methodology in previous studies of a similar nature and healthcare professionals were accepting of the process and data was stored securely.
The study will last for a duration of 18 months.

Intervention Type
Behavioural

Primary outcome measure
The overall aim of this study is to assess the feasibility, acceptability and fidelity of a theory- and evidence-based multifaceted behaviour change intervention targeting free-living physical activity and sedentary behaviour after stroke.
In order to assess the feasibility, acceptability and fidelity of the intervention the following

outcomes will be collected at the baseline and at the review:
1. Stroke survivor and healthcare professional study recruitment and attrition rates, calculated as rate per month
2. Feasibility of intervention delivery, described using:
2.1. The number of and time taken (minutes) for face-to-face/telephone intervention delivery
2.2. The application of the different intervention components applied (e.g. self-monitoring tools, activity selection)
2.3. Safety reporting
3. Completeness of baseline and review descriptive data to determine the feasibility of the inclusion criteria and of potential outcome measures. Baseline demographics will be collected and at baseline and reviews (the timing of the reviews is individualised to the participant) the following measures will be made:
3.1. Warwick-Edinburgh Mental Well-Being Scale
3.2. Fatigue Assessment Scale
3.3. Rivermead Mobility Assessment
4. Views of stroke survivors and healthcare professionals on the acceptability of the intervention and study protocol, assessed using a questionnaire and interview
5. Fidelity of delivery, receipt and enactment of the intervention, assessed through analysis of audio recordings of healthcare profressional delivered sessions and intervention documentation

Secondary outcome measures
N/A

Overall study start date
01/06/2018

Overall study end date
31/03/2020

Eligibility

Participant inclusion criteria
Stroke survivors:
1. Adult community dwelling stroke survivors
2. Currently receiving outpatient/community stroke rehabilitation in the study catchment area
3. Capacity to provide informed consent
4. Capability to undertake a supported self-management physical activity intervention programme (e.g. not requiring high levels of hands on therapy for function)
5. Agreement by the therapist and patient that there is capacity for increased activity/less sedentary behaviour

Healthcare professionals:
1. Currently working as a healthcare professional (e.g. physiotherapists, occupational therapists and rehabilitation assistants) delivering home/community based stroke rehabilitation
2. Capacity and willingness to undertake intervention training, delivery and assessment throughout study duration
3. Ability to deliver the intervention programme to up to five stroke survivors

Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 57; UK Sample Size: 57

Total final enrolment
30

Participant exclusion criteria
Stroke survivors:
1. Contraindications for undertaking physical activity e.g. presence of unstable heart disease
2. Advised by GP/Consultant not to undertake physical activity for health reasons

Recruitment start date
03/10/2018

Recruitment end date
31/10/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
North Tyneside General Hospital
Rake Lane
North Shields
United Kingdom
NE29 8NH

Study participating centre
Sunderland Royal Hospital
Kayll Road
Sunderland
United Kingdom
SR4 7TP

Study participating centre

South Tyneside District Hospital
Harton Lane
South Shields
United Kingdom
NE34 0PL

Sponsor information

Organisation
Northumbria Healthcare NHS Foundation Trust

Sponsor details
Rake Lane
North Shields
England
United Kingdom
NE29 8NH

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01gfeyd95

Funder(s)

Funder type
Government

Funder Name
NIHR Trainees Co-ordinating Centre (TCC); Grant Codes: ICA-CL-2015-01-012

Results and Publications

Publication and dissemination plan
The study will be presented at national and international conferences, and reported in peer-reviewed journals (October 2019-March 2020). Reports will be written for the study sponsor and regulatory bodies (yearly throughout the study). A summary of the results will be sent to study participants. Anonymised data will be provided to research databases as requested (e.g. the Cochrane Collaboration, the Virtual International Stroke Trials Archive (VISTA) to enable future meta-analyses)). The results will also be presented at local patient and public involvement groups and to local community stroke teams.

Intention to publish date
31/03/2021

Individual participant data (IPD) sharing plan
The researchers will share anonymised data (referenced only with study number) with approved collaborators both nationally and internationally (inside and outside of the EU) for scientifically sound, peer-reviewed studies. Data sharing offers a more open approach to maximise the impact of the study for the health and wellbeing of the population. Data sharing will be managed by a data management committee according to the following procedures:
1. Collaborators interested in accessing data from the study will send the data management committee an expression of interest, for example, using a data request form or via research platforms data portals.
2. The committee will then review the data request. If required, the data management committee may request changes to the proposed study by collaborators. The data management committee may then approve or reject the proposed study.
3. A data use agreement will be drafted and signed by both parties.
4. As agreed by the data managing committee and collaborators, and according to signed data agreement forms, anonymised data will be transferred to the collaborators.
Data will be securely transferred to collaborators. Data will be securely stored by collaborators for a fixed duration, as stated in the signed data use agreement. Only anonymous and unidentifiable data will be sent.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	29/04/2020	06/01/2021	Yes	No
Results article		03/09/2022	05/09/2022	Yes	No
Other publications	Intervention development study	12/05/2022	02/11/2022	Yes	No
HRA research summary			28/06/2023	No	No