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We Walk: development of a family-centred intervention to promote regular outdoor walking after stroke (Phase 2)

Submission date
17/07/2019

Recruitment status
No longer recruiting

Registration date
24/07/2019

Overall study status
Completed

Last Edited
16/06/2022

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Many stroke survivors have low levels of physical activity and fitness, raising the risk of further stroke, heart disease, falls and poor mobility. Regular physical activity, including walking, reduces these risks. However, many survivors have inactive lifestyles. The aims of the study are to undertake preliminary testing and refinement of a theory-based, person-centred intervention to enhance the uptake and maintenance of regular outdoor walking after stroke. The intervention will be tested with stroke survivors, their family members or friends (walking buddies) in preparation for testing in larger studies. The intervention was developed in phase 1 of the study together with stroke survivors, their family members and health professionals who work with stroke survivors. The Behaviour Change wheel and the Theoretical Domains Framework (TDF) were used to identify behaviour change techniques (BCTs), which will be used to deliver the intervention.

Who can participate?
Patients aged over 18 who have had a stroke and who can walk outdoors (with or without a walking aid), with a family member or friend (walking buddy)

What does the study involve?
The intervention is delivered over 12 weeks by a researcher and includes four visits to the home and three phone/Skype calls. As the intervention is still under development, no comparator group will be used. Action research methods are used to seek stroke survivors' and walking buddies' views on the intervention, to record and reflect on their experiences, and to refine the intervention. The refined intervention is then tried, and feedback on those refinements is sought in the next round of action research. The action research process involves regular contacts between the researcher and study participants to identify adaptations and required refinements. At the end of study, professionals, survivors and peer dyads are brought together at three events to discuss the findings from the study, i.e. recruitment, acceptability of the intervention, and methods for delivery in subsequent studies. These discussions inform final intervention adaptations to intervention design for testing in a future trial.

What are the possible benefits and risks of participating?
The researchers cannot guarantee any benefits, but walking may help with the recovery of walking after stroke. Getting out and about may help stroke survivors and their buddies feel better and improve their wellbeing. Possible disadvantages of participation are that walking outside after a stroke can be hard, particularly in the early days when there may be concerns about the stroke survivors' balance or risk of falling. This may cause some anxiety, to the stroke survivor and his or her walking buddy. However, survivors will not be expected to take part in the programme until they have already had practice at walking outside after having the stroke. The researchers will ask questions about how the stroke has affected participants, and how they have managed since having the stroke. Some people may find these questions upsetting. The researcher will stop any meeting if the survivors or their walking buddy do not wish to continue. The researchers will also advise on how professional support can be accessed if desired.

Where is the study run from?
The study is run from the University of Dundee, Scotland. Collaborators are based at the University of New Brunswick, Queen Margaret University, Edinburgh and Glasgow Caledonian University.

When is the study starting and how long is it expected to run for?
The study started in May 2018 (Phase 1, to design the intervention). Phase 2 will begin in August 2019 and will run until December 2020.

Who is funding the study?
The Chief Scientist Office, Scotland

Who is the main contact?
Dr Jacqui Morris
J.Y.Morris @dundee.ac.uk

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
HIPS/17/03

Study information

Scientific Title
We Walk: development of a family-centred and peer-support behavioural intervention to promote regular outdoor walking after stroke (Phase 2)

Acronym
We Walk (Phase 2)

Study objectives
A behavioural intervention, where stroke survivors work with walking buddies within a dyad, will help stroke survivors walk more in their own communities.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/05/2019, North of Scotland Research Ethics Service (Summerfield House, 2 Eday Road, Aberdeen, AB15 6RE, UK; Tel: +44 (0)1224 558458; Email: nosres@nhs.net), ref 19/NS/0077

Study design
Intervention development study

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
People who have had a stroke and are ambulant

Interventions
Intervention development study to design a behaviour change intervention in conjunction with stroke survivors, their family members and friends, and health professionals. The study will undertake preliminary testing of this novel intervention, which will be further developed and refined during the study using participatory action research with stroke survivor/walking buddy dyads.

The novel behaviour change intervention will be delivered to the stroke survivor/walking buddy dyads by a researcher over a 12-week period. Intervention delivery will include 4 visits to the home and 3 phone/Skype calls. The intervention is designed to increase walking among stroke survivors by using dyadic planning to facilitate goal setting, action planning and self-monitoring of outdoor walking.

This is an intervention development study, so no comparator group will be used.

Intervention Type
Behavioural

Primary outcome(s)
Engagement of the dyad with the intervention, assessed by exploration of participants' use and experiences of goal setting, action planning and self-monitoring of outdoor walking during the intervention period. Ongoing evaluation of the intervention through action research during intervention delivery will seek participants views on necessary adaptations. These will be tested and evaluated in subsequent rounds of action research, to refine the intervention.

Key secondary outcome(s))
Acceptability of the intervention, assessed using semi-structured interviews at the end of the intervention period

Completion date
31/12/2020

Eligibility

Key inclusion criteria
1. Community-dwelling stroke survivors who are ambulant (in indoor and outdoor environments), over 18 years of age, who can provide informed consent, and have no contraindications to increasing their walking. Potential participants will be asked to nominate a family member or friend who would be willing to take part in the study with him/her as part of a dyad.
2. Family members/friends (walking buddies) nominated by the stroke survivor, who are aged over 18 years, can provide informed consent and are willing to work with the stroke survivor as part of a dyad

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment

Key exclusion criteria
1. Stroke survivors who:
1.1. Cannot walk outdoors (with or without a walking aid)
1.2. Have medical conditions contraindicating increased walking
1.3. Cannot communicate verbally (over the telephone or face to face)
1.4. Are unable to give informed consent
2. Potential participants (stroke survivors, family members/peers) who are unable to participate in the study over a 12-week period

Date of first enrolment
01/08/2019

Date of final enrolment
09/03/2020

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
School of Nursing and Health Sciences
University of Dundee
11 Airlie Place
Dundee
United Kingdom
DD14HJ

Sponsor information

Organisation
University of Dundee/NHS Tayside (joint sponsors)

ROR
https://ror.org/03h2bxq36

Funder(s)

Funder type

Government

Funder Name
Chief Scientist Office, Scottish Government Health and Social Care Directorate

Alternative Name(s)
Chief Scientist Office, Scottish Government Health Directorate CSO, Chief Scientist Office, Scottish Government Health Directorates, Chief Scientist Office of the Scottish Government Health Directorates, Scottish Government Health and Social Care Directorate of the Chief Scientist Office, Scottish Government Health Directorate Chief Scientist Office, The Chief Scientist Office, CSO

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Jacqui Morris (j.y.morris@dundee.ac.uk). Type of data: structured Interview transcripts. The researchers will be using the data to inform future studies, so envisage that it would be two years after the end of the study, 31/07/2022, before they would be willing to share the data, and it will be available for five years thereafter. Only researchers who are undertaking intervention development studies of behavioural interventions after stroke, and wish to investigate appropriate adaptations for intervention acceptability by undertaking secondary analysis, may access the data on request to the principal investigator, for qualitative data analysis using framework method or other relevant analysis approaches. Consent was obtained in the participant consent forms by asking the participant to agree to the statement “information about me may be used in other research, but the information will not use my name.” All transcripts will be anonymised with any identifying information removed.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		14/06/2022	16/06/2022	Yes	No
Funder report results			09/03/2022	No	No
HRA research summary			28/06/2023	No	No