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Changing physical activity behaviour in people with MS: the iStep-MS trial

Submission date
30/04/2017

Recruitment status
No longer recruiting

Registration date
03/05/2017

Overall study status
Completed

Last Edited
10/06/2024

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Multiple sclerosis (MS) is one of the most common diseases of the central nervous system (brain and spinal cord). Healthy nerves are coated in a fatty casing (myelin sheath) which helps messages to travel quickly and smoothly along nerves. When a person is suffering from MS, the immune system, which normally helps to protect against infection, attacks the myelin sheath, stripping it from the nerves (demyelination). This demyelination means that messages cannot travel along the nerves effectively, causing a range of symptoms including problems with balance and coordination and weakness in the arms or legs. Physical activity has multiple benefits for people with MS including improvements in physical, mental and social wellbeing. Despite the benefits of physical activity, the majority of people with MS don't do very much physical activity. The main aims of this project are to develop a new way to help adults with MS to increase the amount of physical activity they do and reduce the amount of time they spend in sedentary behaviours (i.e. time spent in sitting and lying); and to determine if this approach is safe, enjoyable and easy to follow.

Who can participate?
People with MS who are able to walk independently with or without a walking aid within their house.

What does the study involve?
This project is being carried out in two phases. In phase 1 an programme is developed to increase physical activity levels and reduce sedentary behaviour among people with MS. This programme is based upon an intervention that has been successfully implemented among older adults in a primary care (GP level) setting. The researchers plan to work closely with a cognitive-behavioural therapy specialist and people with MS to develop the intervention over four months. The programme consists of physical activity sessions that incorporate behaviour-change techniques supported by a handbook, pedometer step-count feedback, and an individual physical activity diary. Once the programme has been developed the researchers train physiotherapists at the Berkshire MS Therapy Centre to deliver the physical activity consultations.
In phase 2 of the study the researchers conduct a trial to test how safe and easy it is to follow the programme, and also to see if it is possible to carry out a large trial to investigate if the

programme is effective. Participants are randomly allocated to one of those groups. Those in the first group continue as normal for the duration of the study. Those in the second group receive four sessions with a physiotherapist over three months. Physiotherapists use established techniques during the sessions, such as education about the consequences of physical inactivity, goal-setting, self-monitoring, creating action plans, and identifying social support, that have been shown to help people change their physical activity behaviour. In order to determine if the programme is safe and feasible for both the participants taking part and the physiotherapists delivering the programme, participant attendance is monitored and participants complete a range of questionnaires about their wellbeing.

What are the possible benefits and risks?
Participants may increase the amount of physical activity they do and reduce the amount of time they spend in sedentary behaviour after participating in the intervention, which may make them feel better and more energetic. There is a small risk that people may find the data collection procedures, in particular some aspects of the questionnaires that discuss fatigue or quality of life tiring or distressing. A very small number of people are sensitive to the adhesive tape used for the activity monitors, which is similar to that on a sticking plaster. Some people may find they are more tired or have muscle soreness from increasing the amount of activity they do.

Where is the study run from?
Berkshire MS Therapy Centre (UK)

When is the study starting?
January 2017 to December 2018

Who is funding the study?
Multiple Sclerosis Society (UK)

Who is the main contact?
Dr Jennifer Ryan
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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
ref 53

Study information

Scientific Title
A randomised controlled trial to assess the safety, feasibility and acceptability of a behaviour-change intervention to change physical activity behaviour in people with MS: the iStep-MS trial

Acronym
iStep-MS

Study objectives
The aim of this study is to determine the safety, feasibility and acceptability of a behaviour-change intervention that aims to increase physical activity and reduce sedentary behaviour among people with multiple sclerosis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Brunel University London's College of Health and Life Sciences Research Ethics Committee, 10 /04/2017

Study design
Single-centre randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Other

Participant information sheet

Health condition(s) or problem(s) studied

Multiple sclerosis

Interventions
Following baseline assessments, participants will be randomly allocated to one of two groups in a 1:1 ratio. Allocation will be performed by an individual independent to the study according to a computer-generated random schedule in permuted blocks of 2 or 4. The allocation sequence will be placed in sequentially numbered, opaque, sealed envelopes. Following baseline assessments, the Research Fellow will open the envelope that corresponds to the participant (according to the order in which they are assessed) and inform the participant if they are in the intervention group or control group. Participants and therapists (who will provide the intervention) will not be blinded to group allocation.

Intervention group: Participants allocated to the intervention group will receive a behaviour-change intervention, which is comprised of four sessions with a physiotherapist delivered over three months. Sessions 1 and 3 will be approximately 45 minutes in duration. Sessions 2 and 4 will be approximately 30 minutes in duration. Participants will receive a handbook, which physiotherapists will use to guide them through each session. Participants will complete sections of the handbook with the physiotherapist during each session. The handbook will also contain information for participants to read prior to attending each session and diaries to record the goals they've set at each session and note if they achieved the goal. Participants will also receive a pedometer to monitor their step count for at least one week before each session. Physiotherapists will use established behaviour-change techniques during the sessions, such as education about the consequences of physical inactivity, goal-setting, self-monitoring, creating action plans, and identifying social support, to help participants to change their physical activity behaviour.

Control group: Participants allocated to the control group will receive usual care only.

Intervention Type
Behavioural

Primary outcome measure
All participants will be assessed at baseline (week 0), 3 months (week 12), and 9 months (week 36).

Safety:
1. Fatigue is assessed using the Modified Fatigue Impact Scale
2. Pain is assessed using the question regarding pain on the EQ-5D-5L
3. Number and type of adverse events and serious adverse events including falls and relapses throughout the duration of the participants' involvement in the trial (9 months). Participants will specifically asked if they have experienced a fall, relapse or other adverse event since their last contact with the research team at each assessment point (week 12 and week 36).

Feasibility and acceptability
1. Attendance of participants at each intervention session
2. Completion of the handbook and diaries
3. Fidelity to the intervention using audio-recordings of 10% of each session (i.e. 1, 2, 3, and 4) for each therapist
4. Physiotherapist reported experience of delivering the intervention through semi-structured

interviews
5. Participant reported experience of receiving the intervention through semi-structured interviews with 15 participants purposively sampled from the intervention group

Feasibility of conducting a definitive trial:
1. Monitoring recruitment and retention rates
2. Identifying reasons for non-participation using a questionnaire distributed to people who refused to participate in the trial
3. Determining the feasibility and acceptability of randomisation by interviewing a random selection of 10 participants in the control group
4. Monitoring the completion rate of outcome measures relating to the effectiveness of the trial

Secondary outcome measures
The following outcomes will be assessed in all participants at baseline (week 0), 3 months (week 12), and 9 months (week 36). These outcomes are the proposed outcomes that will be used to determine the effectiveness of the intervention if a definitive trial is conducted.
1. Light, moderate and vigorous physical activity assessed by the Actigraph GT3x+ accelerometer
2. Sedentary behaviour assessed by ActivPAL3µ activity monitor
3. Self-reported physical activity and sedentary behaviour assessed by the International Physical Activity Questionnaire short-form
4. Fatigue assessed by the Modified Fatigue Impact Scale
5. Walking capability assessed by the Twelve Item MS Walking Scale
6. Self-efficacy assessed by the Multiple Sclerosis Self-Efficacy Scale
7. Quality of life as assessed by the EQ-5D-5L
8. Health service use assessed by the Adapted Client Service Receipt Inventory
9. Participation assessed by the Impact on Participation and Autonomy Questionnaire

Overall study start date
02/01/2017

Completion date
31/12/2018

Eligibility

Key inclusion criteria
1. A self-reported diagnosis of MS
2. Relapse free for the past 3 months
3. Independently ambulatory at a minimum within their home environment, with or without a walking aid
4. Free of unstable medical condition e.g. unstable angina
5. Ability to travel to the Berkshire MS therapy centre for the intervention
6. Fluent in English to a standard sufficient for completion of the trial assessment and intervention
7. An ability to comprehend and follow all instructions relating to participation in the study including providing informed consent, completing the outcome measures, or participating in the intervention

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
60

Total final enrolment
60

Key exclusion criteria
1. Pregnancy
2. Already participating in an interventional study

Date of first enrolment
15/05/2017

Date of final enrolment
30/04/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Berkshire MS Therapy Centre
Bradbury House
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Reading
United Kingdom
RG30 2JP

Sponsor information

Organisation
Brunel University London

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Sponsor type
University/education

ROR
https://ror.org/00dn4t376

Funder(s)

Funder type
Charity

Funder Name
Multiple Sclerosis Society

Alternative Name(s)
Multiple Sclerosis Society of Great Britain and Northern Ireland, The MS Society, MS Society UK, Multiple Sclerosis Society UK, MS Society

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
This project will result in the publication of four articles in high impact peer-reviewed journals and four conference presentations between December 2018 and December 2019.

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publically available repository (Figshare).

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		31/01/2019	23/06/2020	Yes	No
Other publications	Users' experiences	06/03/2020	16/02/2021	Yes	No
Protocol article		15/11/2017	25/08/2022	Yes	No
Other publications	Users' experiences	09/06/2020	10/06/2024	Yes	No