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Action Imagery and Observation in Neurorehabilitation for Parkinson's Disease (ACTION-PD)

Submission date
25/05/2018

Recruitment status
No longer recruiting

Registration date
13/06/2018

Overall study status
Completed

Last Edited
03/08/2021

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
When we see or imagine a movement, the areas of the brain that control our own movement are activated, preparing us to make the movement ourselves. Observing or imagining movements can improve daily activities following stroke and boost performance in athletes. Although these processes may also improve movement in people with Parkinson's, there is little research on this. Moreover, observation and imagination are more effective when combined, but they have not been used together to help people with Parkinson's. We are developing a home-based therapy to improve hand movement control through observing, imagining and performing everyday actions from videos. This is based on new scientific research including our investigations of imitation of simple hand movements in Parkinson's. It is also informed by health professionals and people with Parkinson's. The therapy is personalised, allowing individuals to choose which actions to train and to plan a flexible training schedule. This is a new and cost-effective approach to rehabilitation for Parkinson's. It has the potential to enhance current interventions used by therapists and equip people with effective everyday movement strategies.
This study aims to assess whether the home-based therapy is feasible (e.g., easy to use) and identify possible benefits to movement (e.g. dexterity), daily activities and well-being. This will provide the groundwork needed to develop the therapy further and obtain funding for a larger trial. Feedback from participants who carry out the training contributes to this further development.

Who can participate?
Adults aged 35 – 75 years with Parkinson's disease

What does the study involve?
All participants are asked to attend an assessment session at the University of Manchester (behavioural measurement of hand and eye movements and general assessments of movement, thinking and mood). They are then randomly assigned to one of two groups (Intervention group or Control group). Those in the Intervention group are asked to undertake home-based training as described below, while participants in the Control group are asked to carry on with their

normal activities, without any intervention, and receive a weekly phone call from the researcher. The intervention group receives the therapy, which involves watching videos of everyday actions, imagining the actions and then physically performing them. With the help of the researcher, they choose which actions to practice. The training takes place in their home using a tablet computer which is provided for the duration of the trial. They are asked to train for approximately 120 minutes (2 hours) a week for a period of 6 weeks, although this can be flexible to accommodate other commitments, or changes in your symptoms. Full training and instructions are provided and the researcher remains in contact during the training period. The tablet computer automatically records how much training is carried out and difficulty ratings for each action. Participants are also invited to record additional comments about the training. Once a week they are asked to complete a brief survey on how the training is going, their mood and activity levels during that week. After the 6-week period, both groups attend a final assessment session at the University of Manchester, which involves the same tasks and questionnaires as the initial assessment.
Finally, participants in the Intervention group are invited to take part in an interview at their home to discuss their experience of the training.

What are the possible benefits and risks of participating?
It is possible that participants in the Intervention group may obtain some direct benefits from carrying out the training in this study. However, as this is an early version of the therapy, further improvements may be required, which will be informed by the findings of this study. Participants in both intervention and control groups are contributing to the further development of the therapy by helping us to identify potential benefits that are specific to the training programme. There are no direct risks from participating in the study.

Where is the study run from?
University of Manchester (UK)

When is the study starting and how long is it expected to run for?
March 2016 to December 2018

Who is funding the study?
Medical Research Council Confidence in Concept, University of Manchester (UK)

Who is the main contact?
Dr Ellen Poliakoff (scientific)
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 3

Study information

Scientific Title
Action Imagery and Observation in Neurorehabilitation for Parkinson’s Disease (ACTION-PD): Pilot RCT

Acronym
ACTION-PD

Study objectives
The aim is to establish the feasibility and acceptability of the therapy and general trial design, as well as collect preliminary outcome data.
The hypothesis is that the intervention will improve manual dexterity in Parkinson's.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee North West – Greater Manchester South, 08/03/2016, ref: 16/NW /0085

Study design
Single-centre pilot interventional randomised controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Quality of life

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

Health condition(s) or problem(s) studied
Parkinson's disease

Interventions
This pilot RCT tests feasibility as well as identifying potential outcomes of ACTION-PD, which involves watching videos of everyday actions, imagining the actions and then physically performing them. All participants identify 6 hand actions that they would be interested to train from a library of everyday actions compiled through our preliminary research, including input from people with Parkinson's, as well as from existing literature and clinical tools.
During baseline assessment, they are measured (kinematics and video) performing their chosen 6 actions in the laboratory as well as 2 core actions
1. Opening a water bottle and pouring water into a glass
2. Opening a jar, taking a spoon of sugar and transferring to a cup.
We also measure self-reported dexterity (DextQ-24), Quality of Life (PDQ-39), motor imagery ability (KVIQ and hand rotation task) and self-reported use of motor imagery. These measures are repeated immediately following the 6 week intervention period.

Following baseline assessment, participants are randomly allocated by an independent administrator to an intervention group or a control group.
For those in the intervention group, the researcher visits the participant at home to provide the tablet computer with selected videos, as well as written instructions and an 'accessory kit' containing the objects needed to practice the actions during training. Participants are given 3 out of their 6 chosen actions to train as well as the two core actions, to allow standardised assessment of performance. Participants are asked to train for 120 minutes per week for 6 weeks (based on adherence rates in preliminary testing). Participants may choose to split the training according to individual preference. Participants are given a copy of the training instructions, which are also be available via the app. Time spent in training and actions practiced is captured automatically by the software, and participants are asked to provide minimal extra information (e.g., time of most recent medication dose). Participants observe videos depicting actions from both first-person and third-person perspectives. They are asked to engage in imagery while observing the action, and then to perform the action. A brief weekly survey is presented by the app; this is used to collect subjective ratings of progress, activity levels and mood throughout the intervention.
Participants are given the option to receive a reminder via SMS on their agreed training days, and all participants are contacted weekly by the research team.
The control group do not receive any intervention, but continue with any usual care/treatment, and are contacted weekly by the researchers to maintain engagement.

Intervention Type
Behavioural

Primary outcome measure
Self-reported manual dexterity is measured using DextQ-24 questionnaire before and after the 6 week intervention

Secondary outcome measures
1. Feasibility and acceptability is assessed using usage data, subjective ratings of performance and interviews at the end of the study
2. Quality of Life is measured using the total score of the PDQ-39 questionnaire before and after the 6 week intervention
3. Motor imagery ability is measured using the Kinaesthetic and Visual Imagery Questionnaire (KVIQ) before and after the 6 week intervention
4. Reported use of motor imagery is measured using a short bespoke questionnaire before and after the 6 week intervention
5. Kinematic measures of hand action (time to completion, smoothness) are measured using a polhemus motion tracker and video recording before and after the 6 week intervention

Overall study start date
01/03/2016

Completion date
31/12/2018

Eligibility

Key inclusion criteria
1. Age 35-75
2. Diagnosis of idiopathic Parkinson’s disease
3. Mild to moderate symptoms (Hoehn & Yahr stage I-III)
4. Participants receiving medication for symptoms of PD must be on a stable medication regime for at least 4 weeks prior to the start of the study
5. Self-reported difficulty in performing fine hand movements

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
20

Total final enrolment
10

Key exclusion criteria
1. Auditory impairment or level of English language ability prohibiting understanding of verbal instructions

2. Visual impairment that prevents participants from viewing images on a computer screen with or without corrective lenses
3. Marked cognitive impairment (based on Addenbrookes Cognitive Examination)
4. History of neurological illness other than Parkinson's disease
5. Presence or significant history of psychiatric illness
6. History of serious head injury

Date of first enrolment
01/03/2018

Date of final enrolment
30/08/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Manchester
United Kingdom
M13 9PL

Sponsor information

Organisation
University of Manchester

Sponsor details
Faculty of Biology, Medicine and Health
The University of Manchester
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Sponsor type
University/education

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council Confidence in Concept (University of Manchester)

Results and Publications

Publication and dissemination plan
Planned publication in a high quality peer reviewed journal.

Intention to publish date
30/09/2019

Individual participant data (IPD) sharing plan
The anonymised datasets that are generated and analysed during this study will be included in the subsequent publication of the results.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		23/07/2021	03/08/2021	Yes	No
HRA research summary			28/06/2023	No	No