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Supporting activity engagement in people with Huntington's disease

Submission date
13/03/2014

Recruitment status
No longer recruiting

Registration date
13/03/2014

Overall study status
Completed

Last Edited
21/02/2018

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
Huntington's disease (HD) is an inherited nervous-system-related disease, which over time causes problems with movement, thinking and behaviour and ultimately difficulties in undertaking usual activities of daily living. We know that keeping active (both physically and socially) is important for any person who suffers with a long-term health condition. This can become very difficult for people with HD given the complex and varied problems that they are faced with on a daily basis. This study aims to analyse two different home-based programmes that have been specifically developed for people with HD, each of which has different attributes, either social or physical.

Who can participate?
People with HD can participate in this study.

What does the study involve?
Participants will be asked to attend three research assessments (focussing on movement, thinking and activities of daily living) over a 6-month period at their local HD clinics. After the first assessment, they will be randomly allocated to one of two programmes that will be based in the home. In between the second and third assessment, all participants will continue with their normal activities. At the end of the study, each participant will be offered a brief version of the other programme.

What are the possible benefits and risks of participating?
There may, or may not be, direct benefits to anyone taking part in this study. The study is being undertaken to find out whether or not the activity programmes are beneficial to people with HD. By taking part, participants will be helping us to answer this question, which may be of benefit to people with HD in the future. The assessments and interventions are unlikely to cause any undue stress and there are no clear risks assoicated with participating in the study.

Where is the study run from?
The study is managed by the South East Wales Trials Unit, based in Cardiff. Participants are being recruited from the following sites in the UK:
1. Ashgrove House, NHS Grampian, Aberdeen

2. The Barberry, Birmingham and Solihull Mental Health Foundation NHS Trust, Birmingham
3. Southampton General Hospital, University Hospital Southampton NHS Foundation Trust, Southampton
4. Southmead Hospital, North Bristol NHS Trust, Bristol
5. St Mary's Hospital, Central Manchester University Hospitals NHS Foundation Trust, Manchester
6. Sheffield Clinical Genetics Service, Sheffield Children's NHS Foundation Trust, Sheffield
7. The Bennett Centre, North Staffordshire Combined Healthcare NHS Trust, Stoke-on-Trent
8. Cardiff University, Cardiff

When is the study starting and how long is it expected to run for?
May 2014 to March 2016

Who is funding the study?
National Institute for Health and Social Care Research (UK)

Who is the main contact?
Dr Monica Busse
busseme@cardiff.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Monica Busse

ORCID ID
http://orcid.org/0000-0002-5331-5909

Contact details
Heath Park
Cardiff
United Kingdom
CF14 4XN
-
busseme@cardiff.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
16354

Study information

Scientific Title
Supporting activity ENGAGEment in people with Huntington's Disease: a phase II evaluation

Acronym
ENGAGE-HD

Study objectives
The main objective of the trial is to evaluate the feasibility, acceptability and potential benefit of a home-based physical activity intervention programme targeted for people with early-mid stage HD when compared to an equivalent contact time social interaction intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East Wales Research Ethics Committee B, 26/02/2014; ref. 14/WA/0034

Study design
Randomised; Interventional; Design type: Process of Care

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

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
Topic: Dementias and Neurodegenerative Diseases Research Network; Subtopic: Huntingtons Disease; Disease: Huntington's disease

Interventions
ENGAGE-HD: Participants enrolled in the ENGAGE-HD Physical Activity Intervention will receive 6 home visits and interim phone calls over a course of 16 weeks (weeks 1, 2, 3, 6, 10 and 14). They will be supported in developing an individualized lifestyle approach to enhancing physical activity through interactions with trained physical activity coaches along with resources that include a.purpose development workbook and an exercise DVD.

The alternate intervention is a social contact intervention. A minimisation technique will be used for randomisation to allow for balancing of a range of important variables.

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measures as of 09/12/2014:
The primary feasibility outcome will include an evaluation of eligibility, recruitment and retention rates (in line with CONSORT recommendations) as well as monitoring of completion of outcome measures and assessments.

Previous primary outcome measures:
Physical Performance Test; Timepoint(s): baseline, 16 weeks and 24 weeks

Secondary outcome measures
Added 09/12/2014:
A range of secondary measures will be explored in terms of short-term benefit (timepoints: baseline, 16 weeks and 24 weeks). The main assessment of short-term benefit will be provided by the Physical Performance Test (PPT)

Added 13/03/2017:
Measures of participation and health:
1. Individualised quality of life, measured using the schedule for the evaluation of individual quality of life—direct weighting (SEIQoL-DW) at follow up assessment (week +26)
2. Self-efficacy, measured using the Lorig self-efficacy scale at baseline (week 0), primary outcome assessment (week +16), follow up assessment (week +26)
3. Health service use, measured using the Client Services Receipt Inventory at baseline (week 0), primary outcome assessment (week +16), follow up assessment (week +26)
4. Health utility, measured using EQ-5D-5L and ICE-CAP-A at baseline (week 0), primary outcome assessment (week +16), follow up assessment (week +26)

Measures of activity:
1. Functional activity, measured using the Physical Performance Test (PPT) at baseline (week 0), primary outcome assessment (week +16), follow up assessment (week +26)
2. Usual pattern of mobility, measured using the Life Space Assessment at baseline (week 0), follow up assessment (week +26)
3. Physical activity, measured using the International Physical Activity Questionnaire (Short Form) at baseline (week 0), follow up assessment (week +26)
4. Walking ability, measured using the six minute walk test and the Timed Up and Go Test at baseline (week 0), primary outcome assessment (week +16), follow up assessment (week +26)
5. Self-reported falls, including the frequency, circumstance and severity of any falls at baseline (week 0), primary outcome assessment (week +16), follow up assessment (week +26)

Measures of body function:
1. Disease-specific clinical measure of motor impairment, measured using the Unified Huntington Disease Rating Scale (UHDRS) modified motor scale at baseline (week 0), primary outcome assessment (week +16), follow up assessment (week +26)
2. Cognitive impairment, measured using the Symbol Digit Modality Test (SDMT) and Category Verbal Fluency at baseline (week 0), primary outcome assessment (week +16), follow up assessment (week +26)
3. Lower extremity strength and endurance, measured using the Timed 15 Repetition Chair Stand Test (15RCST) at baseline (week 0), primary outcome assessment (week +16), follow up assessment (week +26)

Behavioural outcomes:
1. Measures of autonomy/supportive interactions, measured using the PAS Healthcare Climate Questionnaire at primary outcome assessment (week +16)

Overall study start date
01/05/2014

Completion date
31/03/2016

Eligibility

Key inclusion criteria
Current inclusion criteria as of 14/10/2014:
1. Diagnosis of manifest HD, confirmed by genetic testing
2. Self-reported or physician-reported difficulties with walking and/or balance (but still able to walk with minimal assistance)
3. Above the age of 18
4. Stable medication regime for 4 weeks prior to initiation of trial, and anticipated to be able to maintain a stable regime for the course of trial
5. Enrolled on EHDN Registry/ENROLL-HD study [or if not enrolled, that the clinician is able to provide a recent specialist HD clinical assessment that includes a UHDRS TMS score, full medical history and a record of the CAG length (longer allele)]

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Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 62; UK Sample Size: 62

Key exclusion criteria

1. Any physical or psychiatric condition that would prohibit the participant from completing the intervention or the full battery of assessments
2. Unable to understand or communicate in spoken English
3. Currently involved in any interventional trial or within 4 weeks of completing an interventional trial

Date of first enrolment
23/06/2014

Date of final enrolment
21/08/2015

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Cardiff University
Cardiff
United Kingdom
CF10 3XQ

Study participating centre
Ashgrove House
NHS Grampian
Aberdeen
United Kingdom
-

Study participating centre
The Barberry
Birmingham and Solihull Mental Health Foundation NHS Trust
Birmingham
United Kingdom
-

Study participating centre
Southampton General Hospital
University Hospital Southampton NHS Foundation Trust

Southampton
United Kingdom
-

Study participating centre
Southmead Hospital
North Bristol NHS Trust
Bristol
United Kingdom
-

Study participating centre
St Mary's Hospital
Central Manchester University Hospitals NHS Foundation Trust
Manchester
United Kingdom
-

Study participating centre
Sheffield Clinical Genetics Service
Sheffield Children's NHS Foundation Trust
Sheffield
United Kingdom
-

Study participating centre
The Bennett Centre
North Staffordshire Combined Healthcare NHS Trust
Stoke-on-Trent
United Kingdom
-

Sponsor information

Organisation
Cardiff University (UK)

Sponsor details

Institute of Medical Genetics
Cardiff
Wales
United Kingdom
CF10 3XQ

Sponsor type
University/education

ROR
https://ror.org/03kk7td41

Funder(s)

Funder type
Government

Funder Name
National Institute of Social Care and Health Research; Grant Codes: SPON 1249-13

Results and Publications

Publication and dissemination plan
The results have been presented at the Annual EHDN plenary meeting in the Hague in September 2016. The main study results paper is also now in press and a results and dissemination event was held for site staff and participants from sites.

Intention to publish date
13/05/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available so as to protect the identity of participants with a rare disease.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	12/12/2014		Yes	No
Results article	results	17/11/2016		Yes	No
HRA research summary			28/06/2023	No	No