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Community-based Exercise Therapies for Huntington's Disease

Submission date	Recruitment status
21/04/2011	No longer recruiting
Registration date	**Overall study status**
21/04/2011	Completed
Last Edited	**Condition category**
18/11/2013	Mental and Behavioural Disorders

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
9371

Study information

Scientific Title
Can community supported exercise benefit subjective wellbeing, physical activity levels and abilities in people with Huntington's disease? A randomised feasibility study and process evaluation

Acronym
COMMET-HD

Study objectives
Keeping physically active is known to result in considerable health benefits. We know that gym based exercises can be of benefit to physically able individuals as well as people with uncomplicated Long Term Neurological Conditions (LTNCs) such as Muscular Dystrophy, Parkinsons Disease, Motor Neurone Disease and Multiple Sclerosis. Little is known about ways to support and encourage involvement in regular exercise in the more complex LTNCs such as Huntingtons disease (HD), a progressive condition in which individuals suffer mobility deficits, cognitive decline, and psychiatric illness.

This study aims to evaluate a gym-based supported exercise programme in terms of acceptability and potential benefit to people with HD. People with early stage HD will be provided with a graded exercise programme that will involve exercising three times a week for 3 months. One of the weekly sessions will take place in a gym based setting under supervision and the other two will be participant directed and focussed around a guided walking programme.

We will record how often people do the prescribed exercise, how they feel about it and whether there are any changes in health and wellbeing. We then plan use to this and evidence from other LTNCs to help develop practical methods to improve uptake of exercise for people with complex LTNCs in community leisure facilities.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Research Ethics Committee ref:10/WSE02/74; 22/12/2010

Study design
Randomised interventional trial

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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Dementias and Neurodegenerative Diseases Research Network

Interventions
1. Participants will be allocated to an intervention or a control group
2. Those allocated to the intervention group will be asked to exercise once a week in a community based gym under supervision of a member of the research team and to undertake an additional guided exercise session twice a week for the duration of the intervention.
3. The control group will be asked to continue as normal and will be offered the intervention at the end of the study provided results give no indication to questions
4. Follow Up Length: 9 month(s)

Intervention Type
Other

Phase
Phase I

Primary outcome measure
A number of outcomes that are representative of participation restriction, activity limitation as

Secondary outcome measures

Overall study start date
28/02/2011

Completion date
31/05/2011

Eligibility

Key inclusion criteria
1. The diagnosis of Huntington's Disease (HD), confirmed by genetic testing and neurological examination (this is a routine requirement for any of the participants enrolled in the Registry study)
2. The ability to walk independently as primary means of mobility and willing to travel to the exercise centre for the intervention
3. The capacity to give informed consent
4. A total functional capacity (TFC) score of at least 7
5. A Unified Huntington's Disease Rating Scales (UHDRS) Transcranial Magnetic Stimulation (TMS) score of at least 5
6. Have maintained a stable medical regime for 4 weeks prior to initiation of study and are able to maintain a stable regime for the course of the study
7. Either gender

Participant type(s)

Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 30; UK Sample Size: 30; Description: Thirty patients with early stage HD will be recruited to the study. Fifteen will be randomised to each arm of the study.

Key exclusion criteria
1. Have a history of additional prior major neurological condition, such as stroke
2. Have an orthopaedic condition that independently limits mobility
3. Have cardiac precautions that would prevent the subject from completing the exercise programme or completing the full battery of outcome measures
4. Demonstrate uncontrolled psychiatric symptoms
5. Are pregnant
6. Demonstrate any contraindication to exercise

Date of first enrolment
28/02/2011

Date of final enrolment
31/05/2011

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Department of Physiotherapy
Cardiff
United Kingdom
CF14 4XN

Sponsor information

Organisation
Cardiff University (UK)

Sponsor details
7th Floor
30-36 Newport Road
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CF24 0DE

Sponsor type
University/education

ROR
https://ror.org/03kk7td41

Funder(s)

Funder type
Government

Funder Name
Wales Office of Research and Development for Health and Social Care (WORD) Grant Codes: HA09/028

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2012		Yes	No
Results article	results	01/12/2013		Yes	No
HRA research summary			28/06/2023	No	No