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Benefits of Exercise in Early Psychosis

Submission date
14/10/2013

Recruitment status
No longer recruiting

Registration date
10/12/2013

Overall study status
Completed

Last Edited
22/02/2016

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
We are interested in helping people who are experiencing a first episode of psychosis. It is important to help these people, as in many cases appropriate treatment means they can recover and get back to work. At the moment, the main treatments for psychosis are medications and talking therapies. For some people these treatments can help, but they have drawbacks. For instance, medications are not ideal as they have bad side-effects and do not really treat some of the problems with thinking and motivation that people with psychosis have. They are also not very good for the body; having side-effects such as weight gain and diabetes. Talking therapies can be useful but often they do not improve quality of life and distress. Talking therapies can also be costly, and not everybody wants to talk about their problems. It is known that exercise has beneficial effects on the body as it also boosts mood and wellbeing. However, we still do not know if exercise could help people with a first episode of psychosis. The aim of the study is therefore to see if exercise would be feasible and help people with psychosis.

Who can participate?
We would be looking for people who are currently receiving help from an NHS Early Intervention Service, experiencing certain psychological difficulties and aged 18-35. We cannot include people who are aged below 18 or above 35, pregnant, experiencing a physical health condition which makes exercise a problem or do not have speak English.

What does the study involve?
The study involves participants initially taking some psychological tests which will assess symptoms and their thinking abilities. We will also assess their mood and quality of life. Participants will have their brain scanned and also have tests of muscle strength and cardio fitness. Some blood will also be taken. After this, participants will have a personalised exercise plan developed for them in conjunction with the study team. Participants will then engage in the exercise plan for 10 weeks. At the end, we will measure the same things we did at the beginning.

What are the possible benefits and risks of participating?
If people feel pressurised into undertaking new activities they can sometimes find that certain psychological difficulties get worse or come back. However, the aim of this study is to help people explore new physical activities they want to do while taking care to minimise the risk of any psychological difficulties. Participants can talk to their Care Co-ordinator, GP, or psychiatrist about participation in this study, and any concerns they may have. There is potential risk of injury

during physical exercise. This will be minimised with the correct use of warming up and cooling down techniques.

Where is the study run from?
Greater Manchester area (UK)

When is the study starting and how long is it expected to run for?
November 2013 to November 2014

Who is funding the study?
The project is being funded by Greater Manchester West NHS Mental Health Trust (UK)

Who is the main contact?
Professor Alison Yung
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Contact information

Type(s)
Scientific

Contact name
Prof Alison Yung

Contact details
Institute of Brain Behaviour & Mental Health
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Investigating the Benefits of Exercise in Early Psychosis: a feasibility study

Acronym
iBEEP

Study objectives
The aim of this project is to conduct a feasibility trial of exercise in early psychosis, in order to examine its effects on brain structure and function, positive and negative psychotic symptoms, mood and anxiety and physical health. The goal is to inform a definitive and cost effectiveness of the randomised controlled trial of physical exercise as a treatment in the first episode group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North Manchester REC – submission pending

Study design
Within subject before and after feasibility trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

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
Psychosis; Schizophrenia

Interventions
The intervention is a 10-week personalized exercise programme in line with the volume of activity recommended by the NHS. We will work with participants to identify suitable exercise activities (.e.g. football, boxing) and accompany them to these activities. At the end of the 10 weeks, we will re-adiminister the same tests we do in the beginning, to see if there are any significant changes.

Intervention Type
Behavioural

Primary outcome measure
1. Acceptability and feasibility
These will be assessed by analysing referral and recruitment rates, drop out rates and completion of assessment protocols. This includes assessment of number and proportion consenting to pre- and post-intervention physical and mental health assessments, fitness assessments, cognitive testing and brain scans, and numbers completing the exercise

intervention. This will be assessed at the end of the study, by looking at consent and attrition rates (01/11/2014).

Secondary outcome measures
1. Positive and negative psychotic symptoms, depressed mood, anxiety, social functioning and quality of life will be assessed at baseline and at the end of the 10 week intervention. These will be assessed with the Postive and Negative Symptoms Scale (PANSS), the Beck Depression Inventory II (BDI-II), the Social Interaction Anxiety Scale (SIAS), the Social and Occupational Functioning Assessment Scale (SOFAS) the WHODAS (39) and the WHO Quality of Life 26 item version (WHOQoL Bref) respectively.
2. Cognitive function will be assessed at baseline and after the 10 week intervention. Participants will be seated at a laptop computer and will complete a series of computerised tasks. These tasks are very similar to the types of tests included in popular "brain training" packages available on the internet or on handheld gaming devices. In each task participants will be presented with stimuli (which will be either words, pictures, faces or shapes) and will be asked to make decisions about those stimuli. The different tests will assess a range of mental processes; for example, memory, planning and attention to information.
3. Change in brain structure relative to baseline: We will acquire structural images on the 3T Philips scanner at the Wellcome Trust CRF, using T1 weighted imaging sequences optimized for voxel based morphometry analysis. Individuals will be scanned before and after the intervention and we will use voxel based
morphometry within SPM12 (statistical parametric mapping: www.fil.ion.ucl.ac.uk/spm) to explore grey matter changes. We will use a region of interest approach to explore changes in the hippocampus and temporal gyri.
4. Resting state brain connectivity: Functional imaging data will be acquired in the same scanning sessions as the structural data. Participants will be asked to rest with their eyes closed for 8.5 minutes. During this time, 256 images will be acquired using an echo-planar T2* imaging sequence. Images will be spatially pre-processed and then analysed using the functional connectivity toolbox within SPM.
5. Weight, height, body mass index (BMI), blood pressure and waist circumference will be assessed by standard procedures by the research team at baseline and at the end of the 12 week intervention. Hba1c, lipoproteins and inflammatory markers will be measured by blood test using 12 ml venous blood.
6. Aerobic fitness: sub-maximal exercise assessment will be conducted during incremental exercise on a cycle ergometer. Participants will wear a heart rate monitor and will breathe through a mouth-piece so that O2 and CO2 from expired gas can be measured using a metabolic cart. Outcome measurements from this assessment will include the assessment of the respiratory exchange ratio to indicate substrate utilization (greater fat oxidation indicates better health status), heart rate at an exercise intensity of 50 Watts (lower heart rate after training indicates increased stroke volume) and increased VO2submax indicates better overall health status.

Overall study start date
01/11/2013

Completion date
01/11/2014

Eligibility

Key inclusion criteria

1. Currently receiving help from an NHS Early Intervention Service
2. Experiencing certain psychological difficulties
3. Aged 18-35

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
35 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Aged below 18 or above 35
2. Pregnant
3. Experiencing a physical health condition which makes exercise a problem
4. Does not have sufficient English language

Date of first enrolment
01/11/2013

Date of final enrolment
01/11/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Manchester
Manchester
United Kingdom
M13 9PL

Sponsor information

Organisation
University of Manchester (UK)

Sponsor details
c/o Nallan Thakker
Oxford Road
Manchester
England
United Kingdom
M13 9PL

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Greater Manchester West Mental Health NHS Foundation Trust (UK)

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	20/02/2016		Yes	No