ISRCTN16900744 https://doi.org/10.1186/ISRCTN16900744

A pragmatic randomised controlled trial to evaluate physical activity as a treatment for depression

Submission date
15/02/2007

Recruitment status
No longer recruiting

Registration date
16/02/2007

Overall study status
Completed

Last Edited
07/06/2016

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
There is some evidence that exercise can improve outcome in depression but the current evidence is rather limited and the studies have been too small to provide accurate estimates of any possible benefit. Exercise on prescription is used to describe arrangements whereby a doctor will recommend to a patient that they carry out a systematic programme of exercise. They have mostly been provided for people with cardiovascular (heart) disease. The aim of this study is to investigate whether exercise on prescription affects outcome in depression when used in addition to the usual care of depression that is usually treated with antidepressants.

Who can participate?
Patients aged 18-69 with mild/moderate depression

What does the study involve?
Participants are randomly allocated to one of two groups. One group receives exercise on prescription in addition to usual care. The other group receives usual care. We measure depression over 24 months and also measure antidepressant use, quality of life and costs.

What are the possible benefits and risks of participating?
Not provided at time of registration

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

When is the study starting and how long is it expected to run for?
August 2006 to January 2011

Who is funding the study?
Health Technology Assessment Programme (UK)

Who is the main contact?
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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
HTA 03/45/07

Study information

Scientific Title
A pragmatic randomised controlled TRial to Evaluate physical Activity as a treatment for Depression

Acronym
TREAD

Study objectives
Current study hypothesis as of 10/04/2012
Does facilitated physical activity, in addition to usual care in primary health care, change the outcome in depression and alter the subsequent use of antidepressant medication?

Previous study hypothesis
Does physical activity, in addition to usual care in primary health care, change the outcome in depression and alter the subsequent use of antidepressant medication?

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/034507
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0013/51007/PRO-03-45-07.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Midlands Multi-centre Research Ethics Committee, 20/10/2005, ref: 05/MRE07/42

Study design
Two-arm multi-centre pragmatic randomised controlled trial with randomisation at the level of the individual participant

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Mild/moderate depression

Interventions
Current interventions as of 10/04/2012
The TREAD intervention aims to increase self-esteem, confidence and social interaction as well as the take-up of physical activity, through the use of motivational techniques and drawing upon the theories of social cognition and self-determination. It comprises a series of face-to-face meetings and telephone contacts, negotiated between participants and a designated Physical Activity Facilitator (PAF) over a 8-month period.

Previous interventions
The TREAD intervention aims to increase self-esteem, confidence and social interaction as well as the take-up of physical activity, through the use of motivational techniques and drawing upon the theories of social cognition and self-determination. It comprises a series of face-to-face meetings and telephone contacts, negotiated between participants and a designated Physical Activity Facilitator (PAF) over a 12-month period.

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measures as of 10/04/2012:
Change in clinical symptoms of depression assessed using Beck Depression Inventory at 4-months post-randomisation.

Previous primary outcome measures:
Change in clinical symptoms of depression assessed using Beck Depression Inventory at 3-months post-randomisation.

Secondary outcome measures
Current secondary outcome measures as of 10/04/2012:
A number of secondary outcomes will be measured at various points throughout the trial (4-months, 8-months, 12-months post-randomisation) including change in use of anti-depressants, uptake of physical activity, exercise efficacy and quality of life .

Previous secondary outcome measures:
A number of secondary outcomes will be measured at various points throughout the trial (3-months, 12-months, 24-months post-randomisation) including change in use of anti-depressants, uptake of physical activity, physical self-perceptions, exercise efficacy, psychiatric co-morbidity, quality of life and social support.

Overall study start date
01/08/2006

Completion date
31/01/2011

Eligibility

Key inclusion criteria
Patients aged 18-69 diagnosed by GPs as having a new episode of mild/moderate depression (ICD-10 diagnosis and a score of 14 or more on Beck Depression Inventory)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
69 Years

Sex
Both

Target number of participants
361

Key exclusion criteria
1. Physical contraindications to exercise
2. Inability to complete self-administered questionnaires
3. Psychosis
4. Serious drug or alcohol abuse
5. Pregnancy at time of randomisation

Date of first enrolment
01/08/2006

Date of final enrolment
31/01/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Bristol
Bristol
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BS8 2BN

Sponsor information

Organisation
University of Bristol (UK)

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Research, Enterprise and Development office
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Sponsor type
University/education

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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?

Protocol article	protocol	12/11/2010	Yes	No
Other publications	rationale and development	01/12/2010	Yes	No
Results article	results	01/04/2011	Yes	No
Results article	cost-effectiveness results	01/06/2012	Yes	No
Results article	results	06/06/2012	Yes	No