

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

Submission date 15/02/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 16/02/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 07/06/2016	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> 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?

Prof. Glyn Lewis

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Contact information

Type(s)

Scientific

Contact name

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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

United Kingdom

BS8 2BN

Sponsor information**Organisation**

University of Bristol (UK)

Sponsor details

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?
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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