

The effectiveness of exercise as a treatment for post-natal depression

Submission date 04/06/2009	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input checked="" type="checkbox"/> Protocol
Registration date 27/07/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 31/08/2018	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Amanda Daley

Contact details
Primary Care Clinical Sciences
School of Medical and Dental Sciences
University of Birmingham
Birmingham
United Kingdom
B15 2TT
-
a.daley@bham.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

The effectiveness of exercise as a treatment for post-natal depression: a randomised controlled trial with a nested qualitative study

Acronym

PAM-PeRS

Study objectives

Participants randomised to the exercise plus usual care group will report lower post-natal depression scores than the usual care only group

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial with a nested qualitative study

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 the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Post-natal depression

Interventions

The intervention will last 6 months. Women randomised to the exercise intervention will be offered two (40 - 60 minutes) personal home-based exercise consultations in the first two months and two further supportive phone calls that promote exercise in the following two months. Participants will also be mailed information on local opportunities to exercise with updates sent on three occasions during the six-month intervention.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Post-natal depression. Measured at baseline, 6 months and 12 months.

Secondary outcome measures

1. Physical activity
2. Body weight
3. Vitality
4. Quality of life
5. Body image
6. Self-efficacy for exercise

Measured at baseline, 6 months and 12 months.

Overall study start date

12/11/2009

Completion date

11/11/2012

Eligibility**Key inclusion criteria**

1. An International Classification of Diseases, 10th Edition (ICD-10) diagnosis of depression, following screening using the Edinburgh Postnatal Depression Scale (EPDS) at 6 and 8 - 10 weeks and the Clinical Interview Schedule - Revised (CIS-R) at 8 - 10 weeks after giving birth
2. Non-pregnant at baseline
3. Not experiencing psychotic symptoms
4. Not dependent on illicit drugs or alcohol
5. Aged greater than or equal to 18 years
6. Currently inactive (defined as not meeting the current public health guidelines for physical activity, i.e. less than 150 minutes of moderate intensity physical activity per week in previous six weeks)

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

208

Key exclusion criteria

1. Not proficient in English at a level to complete research assessments
2. General Practitioner (GP) considers patient unsuitable for the trial
3. Women whose babies have died

Date of first enrolment

12/11/2009

Date of final enrolment

11/11/2012

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Primary Care Clinical Sciences

Birmingham

United Kingdom

B15 2TT

Sponsor information**Organisation**

University of Birmingham (UK)

Sponsor details

Contracts and Governance

Research and Enterprise Services

Birmingham

England

United Kingdom

B30 2EH

+44 (0)121 414 7618

b.w.laverty@bham.ac.uk

Sponsor type

University/education

Website

<http://www.bham.ac.uk/>

ROR

<https://ror.org/03angcq70>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research (NIHR) (UK) - National School of Primary Care Research

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	09/06/2012		Yes	No
Results article	results	01/04/2020		Yes	No