

Trial of physical activity for smoking cessation during pregnancy

Submission date 17/07/2008	Recruitment status No longer recruiting	☒ Prospectively registered ☒ Protocol
Registration date 21/07/2008	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 19/01/2017	Condition category Mental and Behavioural Disorders	☐ Individual participant data

Plain English summary of protocol

Background and study aims

We are carrying out a study of pregnant smokers to see if exercise can help pregnant women stop smoking. To do this we will compare the effect on quit rates at end of pregnancy for two treatments:

1. Usual stop smoking support
2. Usual stop smoking support plus a physical activity intervention

Who can participate?

Pregnant women who currently smoke at least one cigarette a day and least five cigarettes daily before pregnancy, are 10- 24 weeks into their pregnancy, are motivated to quit smoking, and are aged 16-50 years.

What does the study involve?

Participants will be allocated to one of two groups. One group will receive 6 sessions of stop smoking support and the other group will receive this stop smoking support plus 14 physical activity sessions (involving exercise on a treadmill and counselling about increasing physical activity levels).

What are the possible benefits and risks of participating?

The benefit of participating would be that you receive one-to-one advice on how to stop smoking which will increase your chances of stopping smoking. Information from this study may help other pregnant women to stop smoking. Unless you have been advised by your doctor or midwife not to take exercise, there are no disadvantages and risks of taking part. If you have been advised by your doctor or midwife not to take exercise you will not be able to take part.

Where is the study run from?

The study is run from St George's University of London, who are sponsoring the trial. Recruitment, however, takes place at 12 UK hospitals:

1. St George's, London
2. Epsom & St Helier
3. Croydon University Hospital
4. Kingston

5. Imperial (St Mary's, Hammersmith, Chelsea & Queen Charlottes)
6. Chelsea & Westminster
7. Guys & St Thomas'
8. Crawley
9. Kings College London
10. Medway Maritime Hospital
11. West Middlesex University Hospital
12. Leighton Hospital, Mid-Cheshire Hospital Trust

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

Recruitment started in April 2009 and we aim to finish recruiting by November 2012. We will follow-up participants at the end of their pregnancy and six months after to check their progress. We aim to finish this by July 2013.

Who is funding the study?

National Institute of Health Research Health Technology Assessment (NIHR HTA) programme

Who is the main contact?

Dr Michael Ussher
mussher@sgul.ac.uk

Contact information

Type(s)

Scientific

Contact name

Dr Michael Ussher

Contact details

Division of Community Health Sciences
St George's University of London
Cranmer Terrace
London
United Kingdom
SW17 0RE
+44 (0)20 8725 5605
mussher@sgul.ac.uk

Additional identifiers

Protocol serial number

HTA 07/01/14

Study information

Scientific Title

Pragmatic randomised controlled trial of physical activity as an aid to smoking cessation during pregnancy

Acronym

LEAP (London Exercise And Pregnant smokers) Trial

Study objectives

This study is assessing whether taking part in a physical activity programme enhances rates of smoking abstinence at end of pregnancy.

More details can be found at: <https://www.journalslibrary.nihr.ac.uk/programmes/hta/070114/#/>

Ethics approval required

Old ethics approval format

Ethics approval(s)

Wandsworth LREC, 14/10/2008, ref: 08/H0803/177

Primary study design

Interventional

Study design

Pragmatic randomised controlled trial

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Smoking addiction

Interventions

Physical activity intervention: 14 sessions of supervised exercise (30 mins of brisk walking on a treadmill) plus physical activity counselling over 8 weeks plus 6 sessions of behavioural support for smoking cessation over 6 weeks.

Control: Six sessions of behavioural support for smoking cessation over 6 weeks

Intervention Type

Behavioural

Primary outcome(s)

Prolonged smoking abstinence at end of pregnancy validated by expired CO and saliva cotinine

Key secondary outcome(s)

1. Reports of physical activity, recorded throughout treatment, at end of pregnancy and six months after birth
2. Withdrawal symptoms, assessed during treatment
3. Desire to smoke, assessed during treatment
4. Self-efficacy for physical activity and for quitting smoking, assessed throughout treatment, at end of pregnancy and six months after birth
5. Depression, measured by the Edinburgh Post-natal Depression Scale throughout treatment, at end of pregnancy and six months after birth
6. Weight/ body mass index (BMI), assessed throughout treatment, at end of pregnancy and six months after birth

Completion date

30/04/2013

Eligibility

Key inclusion criteria

1. Pregnant women, no more than 24 weeks pregnant
2. 16 to 50 years of age
3. Currently smoking at least one cigarette a day
4. Report smoking at least ten cigarettes daily before pregnancy
5. Motivated to quit smoking

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

1. Injury or illness that might be exacerbated by exercise. If they have been advised by their doctor or midwife not to take exercise during pregnancy or if they have any cautions for taking exercise a consultant Obstetrician and Gynecologist at their hospital will be consulted to check that it is safe for them to take part in the trial
2. Women who wish to use nicotine replacement therapy (NRT)

Date of first enrolment

01/04/2009

Date of final enrolment

01/11/2012

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

St George's University of London
London

United Kingdom
SW17 0RE

Study participating centre
Epsom and St Helier University Hospitals NHS Trust
Surrey
United Kingdom
SM5 1AA

Study participating centre
Croydon University Hospital
Surrey
United Kingdom
CR7 7YE

Study participating centre
Kingston Hospital
Kingston upon Thames
United Kingdom
KT2 7QB

Study participating centre
Imperial College Healthcare NHS Trust (St Mary's, Hammersmith, Chelsea & Queen Charlotte's)
London
United Kingdom
W2 1NY

Study participating centre
Chelsea and Westminster Hospital
London
United Kingdom
SW10 9NH

Study participating centre
Guy's and St Thomas' NHS Foundation Trust
London
United Kingdom
SE1 7EH

Study participating centre

Crawley Hospital

Crawley
United Kingdom
RH11 7DH

Study participating centre

King's College Hospital

London
United Kingdom
SE5 9RS

Study participating centre

Medway Maritime Hospital

Gillingham
United Kingdom
ME7 5NY

Study participating centre

West Middlesex University Hospital

Middlesex
United Kingdom
TW7 6AF

Study participating centre

Leighton Hospital, Mid-Cheshire Hospital Trust

Cheshire
United Kingdom
CW1 4QJ

Sponsor information

Organisation

St George's, University of London (UK)

ROR

<https://ror.org/040f08y74>

Funder(s)

Funder type

Government

Funder Name

Health Technology Assessment Programme

Alternative Name(s)

NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	14/05/2015		Yes	No
Results article	results	01/10/2015		Yes	No
Protocol article	protocol	04/10/2012		Yes	No
Other publications	process evaluation	17/01/2017		Yes	No