

# Trial of physical activity for smoking cessation during pregnancy

<b>Submission date</b> 17/07/2008	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 21/07/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 19/01/2017	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> 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

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## 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

**Study design**

Pragmatic randomised controlled trial

**Primary study design**

Interventional

**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?
<a href="#">Results article</a>	results	14/05/2015		Yes	No
<a href="#">Results article</a>	results	01/10/2015		Yes	No
<a href="#">Protocol article</a>	protocol	04/10/2012		Yes	No
<a href="#">Other publications</a>	process evaluation	17/01/2017		Yes	No