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Trial of physical activity for smoking cessation during pregnancy

Submission date
17/07/2008

Recruitment status
No longer recruiting

Registration date
21/07/2008

Overall study status
Completed

Last Edited
19/01/2017

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

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

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

Secondary outcome measures
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

Overall study start date
01/02/2009

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

Age group
Adult

Sex
Female

Target number of participants
866

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
England

United Kingdom

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)

Sponsor details
Cranmer Terrace
London
England
United Kingdom
SW17 0RE
+44 (0)20 8725 5000
awithers@sgul.ac.uk

Sponsor type
University/education

Website
http://www.sgul.ac.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, 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	04/10/2012		Yes	No
Results article	results	14/05/2015		Yes	No
Results article	results	01/10/2015		Yes	No
Other publications	process evaluation	17/01/2017		Yes	No