ISRCTN49741320 https://doi.org/10.1186/ISRCTN49741320

Stopping smoking to optimise pregnancy

Submission date	Recruitment status	[ ] Prospectively registered
26/05/2016	Stopped	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
26/05/2016	Stopped	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
19/09/2018	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol

Plain English summary as of 18/09/2018:
Background and study aims
About 13% of women having babies in the Coombe Hospital smoke cigarettes. This is associated with an increased risk of having a baby weighing less than 2.5kg at birth, and of having a baby before he or she is due to be born (premature birth). Both low birth weight and preterm birth are the leading causes of health problems for babies, including failure of the baby to reach its growth potential, or even stillbirth. Smoking can lead to an increased risk of pregnancy-related problems for the mother as well, including separation of the placenta from the wall of the womb, causing bleeding. It has been shown that there is a relationship between the number of cigarettes smoked per day and the amount of risk placed on the pregnancy. Stopping smoking has well-known benefits, as does “cutting down”. There is, however, no proven cost effective way to help women to cut down or stop smoking during pregnancy. The aim of this study is to assess whether receiving smoking cessation advice and social media support via a secret website is more effective than the usual way of delivering smoking cessation advice (with pamphlets at the first pregnancy visit, and through doctors). We also hope to show that smoking cessation will result in fewer pregnancies complicated by a low birthweight baby or a baby born too early.

Who can participate?
Pregnant women aged over 18 who smoke

What does the study involve?
Participants are randomly allocated to either the control group or the intervention group. The control group receive standard antenatal care in which they receive routine advice on diet, exercise and smoking cessation. The intervention group receive standard antenatal care along with an individualised counselling session and social media support via a private website. The individualised counselling session includes advice on how to quit smoking, smoking cessation resources and the benefits of smoking cessation. At the first antenatal appointment the women are also invited to join a website for smoking cessation support which includes reasons to stop smoking, methods to stop smoking and also allows for interaction between members of the group. Participants are seen by the research team once at less than 24 weeks gestation and at one other time point in pregnancy to have measurements (weight, height, body composition), a urine test, a breath test, and to complete food diaries and questionnaires.

What are the possible benefits and risks of participating?
The possible benefits of participation include increased knowledge of the health risks, adverse pregnancy outcomes and financial cost of continuing to smoke during pregnancy. There are no known adverse risks of participation.

Where is the study run from?
The Coombe Women and Infants University Hospital (Ireland)

When is the study starting and how long is it expected to run for?
June 2015 to March 2018

Who is funding the study?
Coombe Women and Infants University Hospital (Ireland)

Who is the main contact?
Ciara Reynolds

Previous plain English summary:
Background and study aims
About 13% of women having babies in the Coombe Hospital smoke cigarettes. This is associated with an increased risk of having a baby weighing less than 2.5kg at birth, and of having a baby before he or she is due to be born (premature birth). Both low birth weight and preterm birth are the leading causes of health problems for babies, including failure of the baby to reach its growth potential, or even stillbirth. Smoking can lead to an increased risk of pregnancy-related problems for the mother as well, including high blood pressure or separation of the placenta from the wall of the womb, causing bleeding. It has been shown that there is a relationship between the number of cigarettes smoked per day and the amount of risk placed on the pregnancy. Stopping smoking has well-known benefits, as does “cutting down”. There is, however, no proven cost effective way to help women to cut down or stop smoking during pregnancy. The aim of this study is to assess whether receiving smoking cessation advice and social media support via a secret website is more effective than the usual way of delivering smoking cessation advice (with pamphlets at the first pregnancy visit, and through doctors). We also hope to show that smoking cessation will result in fewer pregnancies complicated by a low birthweight baby or a baby born too early.

Who can participate?
Pregnant women aged over 18 who smoke

What does the study involve?
Participants are randomly allocated to either the control group or the intervention group. The control group receive standard antenatal care in which they receive routine advice on diet, exercise and smoking cessation. The intervention group receive standard antenatal care along with an individualised counselling session and social media support via a private website. The individualised counselling session includes advice on how to quit smoking, smoking cessation resources and the benefits of smoking cessation. At the 24 weeks gestation antenatal appointment the women are also invited to join a website for smoking cessation support which includes reasons to stop smoking, methods to stop smoking and also allows for interaction between members of the group. Participants are seen by the research team once at less than 24 weeks gestation, at one other time point in pregnancy, at delivery, and 6 weeks after delivery, to have measurements (weight, height, body composition), a urine test, a breath test, and to complete food diaries and questionnaires.

What are the possible benefits and risks of participating?
The possible benefits of participation include increased knowledge of the health risks, adverse pregnancy outcomes and financial cost of continuing to smoke during pregnancy. There are no known adverse risks of participation.

Where is the study run from?
The Coombe Women and Infants University Hospital (Ireland)

When is the study starting and how long is it expected to run for?
June 2015 to March 2018

Who is funding the study?
Coombe Women and Infants University Hospital (Ireland)

Who is the main contact?
Ciara Reynolds

Contact information

Type(s)
Public

Contact name
Miss Ciara Reynolds

Contact details
Coombe Women and Infants University Hospital
Cork Street
Dublin 8
Dublin
Ireland
8

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Stopping Smoking To Optimise Pregnancy (SSTOP): a randomised controlled trial

Acronym

SSTOP

Study objectives
The hypothesis is that smoking cessation support, including an individualised counselling session and social media support via a private website (intervention group), will result in more women completely ceasing smoking compared with women receiving routine antenatal care alone (usual care group).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Coombe Women and Infant University Hospital Research Ethics Committee, 14/10/2015, Ref: 17-2015

Study design
Single-centre interventional randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

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
Smoking cessation in pregnant women

Interventions
Interventions as of 18/09/2018:
The control group will receive standard antenatal care in which they will receive routine advice on diet, exercise and smoking cessation.

Women allocated to the intervention group will receive standard antenatal care along with an individualised counselling session and social media support via a private website. The individualised counselling session will include advice on how to quit smoking, smoking cessation resources and benefits of smoking cessation. At the first antenatal appointment the women will also be invited to join a website for smoking cessation support which will include pregnancy specific and evidence based information on reasons to cease smoking, methods to cease smoking and will also allow for interaction between members of the group.

Previous interventions:
The control group will receive standard antenatal care in which they will receive routine advice on diet, exercise and smoking cessation.

Women allocated to the intervention group will receive standard antenatal care along with an individualised counselling session and social media support via a private website. The individualised counselling session will include advice on how to quit smoking, smoking cessation resources and benefits of smoking cessation. At the 24 weeks gestation antenatal appointment the women will also be invited to join a website for smoking cessation support which will include pregnancy specific and evidence based information on reasons to cease smoking, methods to cease smoking and will also allow for interaction between members of the group.

Intervention Type
Behavioural

Primary outcome measure
Primary outcome measure as of 18/09/2018:
Smoking cessation measured using urine samples and carbon monoxide breath tests. These will be collected at <17 weeks gestation and two months post recruitment.

Previous primary outcome measure:
Smoking cessation measured using urine samples and carbon monoxide breath tests. These will be collected at <24 weeks gestation, two months post recruitment, at delivery and 6 weeks postnatal.

Secondary outcome measures
Secondary outcome measure as of 19/09/2018:
1. Perceived stress score will be collected by questionnaire at <17 weeks gestation and two months post recruitment
2. Nicotine dependency will be collected by questionnaire at <17 weeks gestation and two months post recruitment
3. Preterm birth collected post-delivery from hospital's computerised system
4. Birthweight collected post-delivery from hospital's computerised system
5. Perinatal mortality collected post-delivery from hospital's computerised system
6. NICU admissions collected post-delivery from hospital's computerised system

Previous secondary outcome measure:
1. Perceived stress score will be collected by questionnaire at <24 weeks gestation, two months post recruitment, at delivery and 6 weeks postnatal
2. Nicotine dependency will be collected by questionnaire at <24 weeks gestation, two months post recruitment, at delivery and 6 weeks postnatal
3. Preterm birth collected post-delivery from hospital's computerised system
4. Birthweight collected post-delivery from hospital's computerised system
5. Perinatal mortality collected post-delivery from hospital's computerised system
6. NICU admissions collected post-delivery from hospital's computerised system

Overall study start date
02/06/2015

Completion date
30/09/2016

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
Participant inclusion criteria as of 18/09/2018:
1. Age >18 years
2. <17 weeks gestation
3. Fluent in English
4. Ongoing singleton pregnancy
5. Self-reported smoker
6. Able to give written informed consent

Previous participant inclusion criteria:
1. Age >18 years
2. <24 weeks gestation
3. Fluent in English
4. Ongoing singleton pregnancy
5. Self-reported smoker
6. Able to give written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
220 pregnant women

Key exclusion criteria
Participant exclusion criteria as of 18/09/2018:
1. Age <18 years
2. >17 weeks gestation
3. Non-English speaking
4. Multiple pregnancy
5. Non-smoker
6. Unable to give written informed consent

Previous participant exclusion criteria:
1. Age <18 years
2. >24 weeks gestation
3. Non-English speaking

4. Multiple pregnancy
5. Non-smoker
6. Unable to give written informed consent

Date of first enrolment
01/05/2016

Date of final enrolment
30/09/2016

Locations

Countries of recruitment
Ireland

Study participating centre
The Coombe Women and Infants University Hospital
Cork Street
Dublin
Ireland
4

Sponsor information

Organisation
Coombe Women and Infants University Hospital (Ireland)

Sponsor details
Cork Street
Dublin 8
Dublin
Ireland
8

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00bx71042

Funder(s)

Funder type

Hospital/treatment centre

Funder Name
Coombe Women and Infants University Hospital (Ireland)

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date
01/03/2019

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available