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Health education for the prevention of secondhand smoke exposure among pregnant women visiting the antenatal clinic at a university hospital

Submission date
22/02/2016

Recruitment status
No longer recruiting

Registration date
11/04/2016

Overall study status
Completed

Last Edited
07/04/2016

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
One of the biggest public health threats in the world is smoking. It is a major preventable cause of disease and death all over the world. Every year, six million persons die due to the effects of tobacco. Worldwide, 40% of men and nearly 9% of women smoke tobacco. In Saudi Arabia 13% to 38% of males and 1-16% of females are smokers (although this varies with age and social status).
Although the number pregnant women in Saudi Arabia is very low (0.6%), a significantly number (31%) are frequently exposed to secondhand smoke (SHS). Tobacco smoke that is exhaled by a smoker contains more than 4000 chemicals known to be toxic or carcinogenic (i.e. known to cause cancer). SHS can affect a developing baby (fetus) directly by crossing the placenta. It is associated with premature labor, low birth weight (LBW), stillbirth, shorter infant length, smaller head size and congenital malformations (i.e. birth defects). The amount of nicotine in the air in a household where people smoke is 17 times that of a household with non-smokers. Studies have shown that many pregnant women have limited knowledge about SHS can affect the health of their unborn baby. Health education plays a key role in increasing pregnant women awareness about SHS and its harmful effect on their babies. The aim of this study is to look at whether face-to-face counselling and written information (in the form of a leaflet) about SHS for pregnant women is a more effective way of increasing their knowledge about the health risks involved than just providing written information.

Who can participate?
Women who are less than 25 weeks pregnant, do not smoke but live with someone who does smoke.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in group 1 are given one 15-20 minute session of face-to-face counseling and a leaflet about the health risks of SHS. Those in group 2 are given the leaflet only. All participants are asked to complete questionnaires before

the study begins and again 4 weeks later. These questionnaires are designed to measure whether or not the women gain a better understanding of the risks of SHS, whether they take steps to reduce the amount of SHS they are exposed to and also whether they become less exposed to SHS.

What are the possible benefits and risks of participating?
There are no risks to taking part in this study.

Where is the study run from?
King Khalid University Hospital (Saudi Arabia)

When is the study starting and how long is it expected to run for?
September 2015 to September 2016

Who is funding the study?
King Saud University (Saudi Arabia)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Ref.No.15/0393/IRB

Study information

Scientific Title
The effectiveness of health education for the prevention of secondhand smoke exposure among pregnant women visiting the antenatal clinic at a university hospital: a randomized controlled trial

Study objectives
1. It is hypothesized that both methods of health education will be effective at improving the pregnant women knowledge about SHS exposure and its adverse effects compared to pre-education knowledge by 20-50%
2. It is hypothesized that women counseling is more effective than written information in improving pregnant women knowledge about SHS exposure
3. It is hypothesized that counseling will be effective at reducing SHS exposure among pregnant women by 20-50%

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board at King Saudi University, 29/10/2015, ref: 15/0393/IRB

Study design
Open-label randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Secondhand smoke exposure in pregnant women

Interventions
Face-to face counseling (one session which takes 15-20 minutes) and written information (leaflet) compared to only written information about health risks of exposure to secondhand smoke for pregnant women.

Intervention Type

Other

Primary outcome measure
1. Reduction in time of pregnant woman exposure to secondhand smoke
2. Increased knowledge about health risks of exposure to secondhand smoke on the pregnant woman and her unborn child
3. Improvement of behavior of avoidance of secondhand smoke exposure by pregnant women

All outcomes will be measured using pre/post intervention validated questionnaire. The outcomes will be measured 4 weeks after interventions.

Secondary outcome measures
1. Rate of quitting of person/persons smoking in the presence of the pregnant woman
2. All outcomes will be measured using pre/post intervention validated questionnaire

The outcomes will be measured 4 weeks after interventions.

Overall study start date
01/09/2015

Completion date
30/09/2016

Eligibility

Key inclusion criteria
1. Arabic speaking pregnant non –smoker women
2. <25 weeks of pregnancy to give time for the intervention (1 month) and the follow up
3. Living with smoking person (husband, brother, father, son, father- in- low, house helper or other)
4. Literate
5. Willing to participate in the study

Participant type(s)
Other

Age group
Adult

Sex
Female

Target number of participants
The total number of the participants will be 100 pregnant women (50 women in each arm)

Key exclusion criteria
Women with unknown smoking status

Date of first enrolment
01/03/2016

Date of final enrolment
01/07/2016

Locations

Countries of recruitment
Saudi Arabia

Study participating centre
King Khalid University Hospital
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Sponsor information

Organisation
King Saud University, Deanship of Scientific Research

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Sponsor type
University/education

ROR
https://ror.org/02f81g417

Funder(s)

Funder type
University/education

Funder Name
King Saud University

Alternative Name(s)
, KSU

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Saudi Arabia

Results and Publications

Publication and dissemination plan
We expecting to finish data collection by Mid-July 2016. We planning to finalize data analysis by mid- August will send the manuscript for publication by end of September. As the information of this study is of paramount importance to maternal care in Saudi Arabia will organize sessions for dissemination of the results of the trial, after publication, and will invite all stakeholders including senior obstetricians, officials of maternal and child health directorates from the Ministry of Health and members of the public including mothers and fathers and the press. These seminars will be organized through King Saud University.

Intention to publish date
31/10/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request