

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	<input type="checkbox"/> Prospectively registered
Registration date 11/04/2016	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 07/04/2016	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

Protocol serial number
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

Study type(s)

Prevention

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(s)

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.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

P.O Box 2925, (internal code 34)

Riyadh

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11461

Sponsor information

Organisation

King Saud University, Deanship of Scientific Research

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request