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Intervention for mothers during pregnancy to reduce exposure to second-hand smoke

Submission date
11/02/2024

Recruitment status
No longer recruiting

Registration date
19/02/2024

Overall study status
Completed

Last Edited
18/03/2025

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
This study looks at a special program designed to help pregnant women in India and Bangladesh avoid second-hand smoke at home. Second-hand smoke can be harmful, especially to unborn babies, leading to health problems after birth. The researchers wanted to see if this program, which includes various supportive materials and advice, could make a difference in reducing smoke exposure.

Who can participate?
Pregnant women who don't use tobacco themselves but are around second-hand smoke, confirmed by a saliva test, were invited to join the study. They had to be within the first 20 weeks of their pregnancy to participate.

What does the study involve?
Participants were divided into two groups. One group received a comprehensive package that included educational booklets, personalized messages, feedback on their exposure levels, and one-on-one consultations. The other group got just an educational leaflet. The main goal was to see if this approach could lower the levels of smoke exposure, as measured by a saliva test, three months later. The study also looked at how much the women knew about the risks of second-hand smoke, their confidence in asking family members to smoke less, and how ready they thought their families were to make these changes.

What are the possible benefits and risks of participating?
The big hope was that this program would lead to healthier environments for pregnant women, reducing the risks associated with second-hand smoke. There weren't any significant risks involved in participating, as the study mainly focused on providing information and support.

Where is the study run from?
The research was carried out in two locations: Comilla in Bangladesh and Bangalore in India. These sites were chosen to recruit and study the women involved.

When is the study starting and how long is it expected to run for?
December 2015 to June 2017

Who is funding the study?
1. Medical Research Council (MRC) (UK)
2. Department of Biotechnology (DBT) (India)
It's important to note that these funders didn't influence how the study was conducted or reported.

Who is the main contact?
Atif Rahman, atif.rahman@liverpool.ac.uk

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Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Protocol v1

Study information

Scientific Title
Intervention for Mothers during Pregnancy to Reduce Exposure to Second-hand Smoke (IMPRESS): a pilot randomized controlled trial in Bangladesh and India

Acronym
IMPRESS

Study objectives
The aims were to examine the feasibility and acceptability of
1. The study design, measures and methods including delivery of a multicomponent intervention to reduce home exposure to second-hand smoke (SHS) among non-smoking pregnant women
2. The intervention in reducing home exposure to SHS among non-smoking pregnant women from two low- and middle-income countries (LMICs), India and Bangladesh
3. To estimate the standard deviation of the proposed primary outcome measure, to inform sample size calculation for a prospective definitive trial

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 01/03/2016, University of Liverpool (Foundation Building, Brownlow Hill, Liverpool, L69 7ZX, United Kingdom; +44 (0)151 794 2000; iphresearch@liverpool.ac.uk), ref: N/A

2. approved 16/12/2015, National Institute of Mental Health and Neuro Sciences (NIMHANS) (Hosur Road / Marigowda Road, (Lakkasandra, Wilson Garden), Bangalore, 560029, India; +91 (0) 80 26995000; dirstaff@nimhans.ac.in), ref: N/A

Study design
Pilot randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention, Quality of life

Health condition(s) or problem(s) studied
Second-hand smoke

Interventions
Multicomponent behavioural intervention

Participants were divided into two groups. Simple 1:1 randomization using computer-generated sequence of random numbers was used. One group received a comprehensive package that

included educational booklets, personalized messages, feedback on their exposure levels, and one-on-one consultations. The other group received an educational leaflet. The duration of the intervention was 2 months in the Bangalore site as this had an additional component of voice calls. The duration of follow-up was 3 months.

Intervention Type
Behavioural

Primary outcome(s)
Saliva cotinine levels measured using NicAlert® test at baseline and 3-month follow-up

Key secondary outcome(s))
Women's knowledge of SHS; attitudes to SHS and behaviours to reduce SHS exposure; perceived confidence in negotiating change with husbands and other family members and perceived readiness of their husband to change, measured using researcher-administered knowledge, attitude and behaviour questionnaire at baseline and 3 months

Completion date
01/06/2017

Eligibility

Key inclusion criteria
1. Women within 20 weeks of pregnancy attending the selected clinics
2. Over 18 years old, reported SHS exposure by their husbands at home
3. Resident in the area and were NicAlert positive

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
50 years

Sex
Female

Total final enrolment
101

Key exclusion criteria
Women using tobacco (smoking or chewing tobacco)

Date of first enrolment
01/11/2016

Date of final enrolment
01/06/2017

Locations

Countries of recruitment
Bangladesh

India

Study participating centre
National Institute of Mental Health and Neuro Sciences
NIMHANS
Bangalore
India
560029

Study participating centre
Ark Foundation
Suite C3-4, House, 6 Rd 109
Dhaka
Bangladesh
1212

Sponsor information

Organisation
University of Liverpool

ROR
https://ror.org/04xs57h96

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
DBT India

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr Veena A. Satyanarayana (veenas@nimhans.ac.in). The dataset will be shared comprising baseline and follow-up data in Excel format. Written informed consent was sought from participants consenting to participate in the trial. Datasets were pseudo-anonymized before analysis. No individual-level data will be shared in the publication.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		17/04/2024	18/03/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes