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Smoking Prevention in South Asia

Submission date
18/01/2013

Recruitment status
No longer recruiting

Registration date
05/02/2013

Overall study status
Completed

Last Edited
10/09/2015

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims
This initial study is focused on testing the feasibility and reliability of an intervention to help empower newly diagnosed patients of tuberculosis (TB) of lungs, who are non- smokers but are exposed to second hand smoke at home, to architect smoke free homes. The level of exposure to second hand smoke will be measured through urine cotinine tests. According to the guidelines issued by the National Tuberculosis Program in Pakistan, all newly diagnosed patients of tuberculosis undergo routine examination/care and a course of anti TB drugs spanning six months. The TB patients return to the hospital each month for examination and free anti TB drugs. The main aim of the study is to develop a behaviour change intervention 'Smoke Free Homes' designed on theories of behaviour change and aimed at encouraging families of newly registered TB patients to implement smoking restrictions at home.

Who can participate?
You can enter this study if you have been diagnosed with pulmonary tuberculosis, are 10 years old or older, are a non-smoker, and have at least one smoker residing in your home.

What does the study involve?
All eligible patients will be randomly allocated to one of the following two groups:
Group 1: Individual Based Care (SFH materials- flip chart and pamphlet)
Group 2: Individual Based Care (SFH materials) plus Supplementary Support (mobile phone text message 'SMS' to smoker at home OR letter on weekly basis)
Each eligible patient will voluntarily submit a urine sample for testing level of cotinine, to confirm second hand exposure to tobacco smoke. The research team will collect another urine sample at the end of second month to compare against the baseline. The research team will use Nic alert dip sticks to measure the cotinine level in urine- level 1 and 2 indicate exposure to tobacco smoke while level 0 indicates no exposure.
The research team will also record the TB outcomes of each patient at six months. The national TB guidelines say nothing to educate TB patients to protect themselves from second hand tobacco smoke. Previous studies haven confirmed a strong association between exposure to second hand smoke and poor TB outcomes.

What are the possible benefits and risks of participating?
You will not have any monetary benefit from taking part in this study, and it is unlikely to change your treatment plan in any way. However, you will receive useful information that will have good

impact on your TB treatment. Also the results of the study will be used to design a feasible 'Smoke Free Home' intervention to help people with TB of lungs to protect themselves from exposure to second hand smoke. As there are no treatments in this study, there are no side effects.

Where is the study run from?
District Rawalpindi, District Sialkot and Punjab Province, Pakistan.

When is the study starting and how long is it expected to run for?
November 2012 to April 2013.

Who is funding the study?
NHS Leeds, UK

Who is the main contact?
Dr Nauman Safdar
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
4-87/12/NBC-100/RDC/

Study information

Scientific Title
A pilot individual randomized controlled trial empowering tuberculosis patients to architect smoke free homes

Acronym
SPISA

Study objectives
The study hypothesis is to improve tuberculosis (TB) outcomes among those TB patients that are exposed to second hand smoke and reduce the risk of TB transmission to other members of the household by encouraging families to make homes smoke free.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Bioethics Committee (NBC) Pakistan , August 2012, 4-87/12/NBC-100/RDC/

Study design
Small-scale pilot individual randomised controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Prevention of exposure to second hand smoke in the home

Interventions
Individual Based Care (Smoke Free Home materials-A flip chart and pamphlet based on taxonomy of behaviour change (Michie et al) to empower TB patients' to architect SFH and Supplementary Support (mobile phone text message 'SMS' to smoker at home OR letter on weekly basis)

All eligible patients will be randomized to the following two arms:
Arm 1: Individual Based Care (SFH materials- flip chart and pamphlet)
Arm 2: Individual Based Care (SFH materials) plus Supplementary Support (mobile phone text message 'SMS' to smoker at home OR letter on weekly basis)

The research assistant, after registering the TB patient, will deliver the information in the flip chart and provide a pamphlet and explain its use. He will also arrange for the urine cotinine test. However he himself will be blinded to the result of the test. He will follow up the patient after one month and deliver the intervention again.

In case the patient is randomized to the Arm 2, the co-investigator will send weekly text messages to the smoker at home, for 8 weeks. The research assistant will be blinded to this intervention.

The research assistant will follow up the patients once he/she returns for the second time in the second month. This time the research assistant will deliver the intervention again and arrange for the urine cotinine test.

The research assistant will conduct a third follow up in the 6th month and also note the TB outcome for the patient.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Smoke free home of non-smoker TB patient by validating through urine cotinine test, measured twice, first at baseline when the TB patient is registered and then at the second monthly follow up.

Key secondary outcome(s))
1. TB patients cure rates measured in the sixth month during the third follow-up by noting the TB outcome.
2. In addition we will measure a number of other variables, which will be built into our trial registration form, gender, urban/rural, barriers, recruitment rates, rate and reasons for refusal, etc
3. Implementation of smoking restrictions as measured by questionnaires before and after intervention

Completion date
30/04/2013

Eligibility

Key inclusion criteria
1. Should be a registered case of new pulmonary TB, either sputum smear positive or negative (new TB patients are defined as those who have no history of prior TB treatment or who received less than 1 month of anti-TB drugs, regardless of whether their smear or
culture results are positive or not).
2. Aged more than 10 years, no upper age limit
3. Should be a non-smoker
4. Have not taken part in a 'Smoke Free Homes' activity before
5. Residing within the same district
6. Lives with at least one other person who smokes tobacco

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria

1. Not a new pulmonary TB case
2. Patient is a smoker confirmed by carbon monoxide (CO) meter
3. Has taken part in a 'Smoke Free Homes' activity before
4. Residing in another district
5. Aged less than 10 years
6. Does not live with a person who smokes tobacco on a regular basis
7. Patient does not consent to participate in the study

Date of first enrolment
01/11/2012

Date of final enrolment
30/04/2013

Locations

Countries of recruitment
Pakistan

Study participating centre
House 862
Islamabad
Pakistan
44000

Sponsor information

Organisation
University of York (UK)

ROR
https://ror.org/04m01e293

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
NHS Leeds (UK) ref: R14401

Results and Publications

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?
Results article	results	01/02/2015		Yes	No
Protocol article	protocol	24/10/2013		Yes	No