

# An intervention to stop tobacco use among patients suspected of tuberculosis (TB)

<b>Submission date</b> 05/12/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 17/03/2009	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 16/07/2013	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
1

## Study information

**Scientific Title**  
An intervention to stop tobacco use among patients suspected of tuberculosis (TB): an evaluation of an integrated approach

## **Acronym**

TATO

## **Study objectives**

1. What is the effect of an intervention, based on the World Health Organization (WHO) 'five steps to quit' model and consisting of training of health professionals, a desk-guide, a desktop patient education tool and leaflet, on patients' point and continuous abstinence from tobacco use? [Effect evaluation]
2. To what extent do the health professionals communicate risks of tobacco use and benefits of its cessation to their patients? What are their experiences and opinions about this strategy? [Process evaluation]
3. How do patients experience the intervention for tobacco addiction? [Ethical evaluation]
4. What is the incremental cost-effectiveness ratio of the intervention for tobacco addiction compared to usual care? [Economic evaluation]

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Research Ethics Committees of TB programme and Pakistan Medical Research Council, approval pending as of 05/12/2008.

## **Study design**

Cluster randomised controlled trial

## **Primary study design**

Interventional

## **Study type(s)**

Quality of life

## **Health condition(s) or problem(s) studied**

Tuberculosis and tobacco use

## **Interventions**

A total of 22 primary care health centres will be selected (11 each for control and intervention arms) and 50 patients recruited with suspected tuberculosis in each of these centres.

In the intervention arm, recruited patients will be given the 'five steps to quit' model. This is based on the evidence-based recommendations for treatment of tobacco addiction published by WHO in 2001. Participants will be:

1. Asked about the status of nicotine use
2. Advised about the benefits of stopping nicotine use
3. Assessed for their motivation to stop its use
4. Assisted in stop attempts through various therapeutic options
5. Provided with an information leaflet
6. Asked to arrange a follow-up

In the control arm, patients will be provided with education leaflets only.

The trial will continue for six months and a review at 1 and 6 months will take place to assess smoking status and clinical outcomes in both arms.

### **Intervention Type**

Other

### **Phase**

Not Applicable

### **Primary outcome(s)**

1. Point abstinence at 4 weeks: the proportion of trial participants who have completely given up all forms of nicotine use at four weeks after the completion of NRT, bupropion and/or brief counselling therapy
2. Continuous abstinence up to 6 months: proportion of trial participants who remained abstinent from 4 weeks onwards up to six months
3. We will also measure tobacco use, e.g. number of cigarettes smoked per day to estimate any reduction in tobacco use secondary to the intervention

### **Key secondary outcome(s)**

1. Incidence of various adverse affects secondary to therapy
2. Economic outcomes assessed in terms of healthcare cost to get one person to stop smoking at four weeks. Healthcare cost will include the treatment cost, the average duration of health professionals' time spent with the patients during assessment, advice and counselling.
3. Process outcomes include:
  - 3.1. The proportion of tobacco users who decide to quit and registered to receive 'five steps to quit' intervention
  - 3.2. The proportion of people registered who continue follow-up for the full period planned

### **Completion date**

30/11/2011

## **Eligibility**

### **Key inclusion criteria**

In each health centre, we will approach adult patients (greater than or equal to 18 years, either sex), who cough for three or more weeks and are therefore suspected and screened for pulmonary tuberculosis.

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

Does not meet inclusion criteria

**Date of first enrolment**

01/12/2008

**Date of final enrolment**

30/11/2011

**Locations****Countries of recruitment**

United Kingdom

England

Pakistan

**Study participating centre**

**Nuffield Centre for International Health and Development**

Leeds

United Kingdom

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**Sponsor information****Organisation**

International Development Research Centre (IDRC) (Canada)

**ROR**

<https://ror.org/0445x0472>

**Funder(s)****Funder type**

Research organisation

**Funder Name**

International Development Research Centre (IDRC) (Canada) (ref: 104825-002)

## Alternative Name(s)

Centre de recherches pour le développement international, IDRC.CRDI, le Centre de recherches pour le développement international (CRDI), el Centro Internacional de Investigaciones para el Desarrollo (IDRC), International Development Research Centre: IDRC, El Centro Internacional de Investigaciones para el Desarrollo, IDRC, CRDI

## Funding Body Type

Government organisation

## Funding Body Subtype

National government

## Location

Canada

# Results and Publications

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary

#### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	07/05/2013		Yes	No
<a href="#">Protocol article</a>	protocol	25/03/2010		Yes	No