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# Increasing tuberculosis case detection and reducing gender disparities through sputum submission instructions: a randomised controlled trial in Pakistan

**Submission date**
13/09/2005

**Recruitment status**
No longer recruiting

**Registration date**
03/11/2005

**Overall study status**
Completed

**Last Edited**
06/07/2007

**Condition category**
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

## Study information

**Scientific Title**

**Study objectives**

Giving women instructions on how to provide sputum samples will increase the yield of smear positive tuberculosis diagnoses in a chest clinic.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Not provided at time of registration

## Primary study design
Interventional

## Study design
Randomised controlled trial

## Study type(s)
Diagnostic

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

## Interventions
Patients in the intervention arm were referred to a designated room at the TB centre where they received guidance from a female health worker who was trained by the researcher and a senior TB control officer to provide sputum submission instructions. The female health worker was not involved in recruitment or randomisation. The following points were explained in detail to patients:
1. The importance of submitting sputum rather than saliva, and a description of visual difference between the two
2. The technique that should be used to produce a good sputum specimen (take three deep breaths, followed by a deep cough to bring up sputum from your lungs)
3. The necessity of filling at least one-quarter of the container (5 ml), shown by pointing out the required level on a demonstration container
4. The importance of providing one spot specimen and returning the next day with another specimen which has been expectorated on awakening that morning

Following instructions, which lasted between 2-3 min, patients in the intervention group were directed to the laboratory to obtain sputum submission containers.

Control group: usual procedure

## Intervention Type
Other

## Phase
Not Specified

## Primary outcome(s)
The primary outcome measure was specimen smear-positivity.

### Key secondary outcome(s)
The secondary outcome, specimen quality, was determined by visual assessment of specimens and microscopic assessment of Ziehl-Neelsen (ZN) stained smears, using a modification of the rating system of Bartlett.
Specimens with a purulent/mucoid/blood-stained visual appearance and/or containing polymorphoneutrophils (PMNs) on microscopic inspection were designated sputum.
Specimens with a clear/watery appearance containing squamous epithelial cells, but no PMNs were designated saliva.

### Completion date
01/09/2005

## Eligibility

### Key inclusion criteria
New male and female tuberculosis (TB) suspects, who were referred by TB centre physicians for initial diagnostic sputum testing, were eligible to participate in the trial. According to the National Tuberculosis Control programme guidelines, the criteria for enrolment were:
1. History of a cough for >3 weeks and/or fever for 1 month
2. Blood in sputum
3. Night sweats
4. Weight loss
5. Loss of appetite

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
All

### Key exclusion criteria
1. Age over 75 or below 14 years
2. History of TB diagnosis or treatment
3. Intake of oral steroids in the 3 months leading up to presentation

### Date of first enrolment
01/07/2005

### Date of final enrolment
01/09/2005

## Locations

### Countries of recruitment

United Kingdom

England

Pakistan

**Study participating centre**
**Keppel Street**
London
United Kingdom
WC1E 7HT

# Sponsor information

**Organisation**
London School of Hygiene and Tropical Medicine (UK)

**ROR**
https://ror.org/00a0jsq62

# Funder(s)

**Funder type**
Government

**Funder Name**
Department for International Development (DFID) (UK) - Knowledge Programme on Tuberculosis

# 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 | 09/06/2007 | | Yes | No |