Tobacco cessation within TB programmes: A ‘real world’ solution for countries with dual burden of disease.

Grant Agreement no. 680995
Collaborative Project
EU H2020 Programme
Health
Medical Research and the Challenge of Ageing
Project duration: 1st November 2015 to 31st October 2019 (48 months)
Indicative budget: € 12 million, Allocated budget: € 11.959.375
TB and Tobacco - syndemic

- Tobacco use – 6 million deaths a year
- TB – 1.7 million deaths a year
- Tobacco use is high in TB high-burden countries
- Increases risk and worsens outcomes
- 15% of TB disease burden due to tobacco
- 40 million excess TB deaths down to tobacco (2010-2050)

Aims and objectives

To reduce the burden of lung diseases in LMIC by integrating inexpensive tobacco cessation strategies of proven efficacy into TB control programmes (Bangladesh, Nepal, and Pakistan)

Effectiveness goal

Implementation goal
Advantages of tobacco cessation in TB

- **Health benefit**: Greater health benefits than in general population
- **Opportunity**: Opportunity of ‘teachable moments’
- **Potential**: Potential to ‘piggy back’ on TB program's infrastructure

Ambition

- **Global**: Multi-country study
- **Outcomes**: Cessation and clinical outcomes
- **Diversity**: Diverse methods & evaluations
- **Scale up and sustain ability**: Post-trial follow-up
Potential impact

- Improving outcomes in lung diseases
- Improving health of the most vulnerable
- Knowledge translation into policy

Low-cost options for tobacco cessation

Millennium Development Goals

Enhance competitiveness & growth
Summary

Importance
- Important understudied topic

Quality
- Rigorous approach to evaluate and implement interventions

Capacity
- Support to deliver the programme is in place

Benefit
- Potential for global impact

Work package (WP) 7
Management and Coordination
### Consortium (TB and Tobacco)

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### Management Structure

- **Study Advisory Panels (SAPs)**
- **Independent Steering Committee (ISC)**
- **Study Management Team (SMT)**
- **Work Package Management Teams (WPMTs)**
- **Local Management Teams (LMTs)**
The structure of the proposed work plan

Work Packages

Qualitative
WP1: Development and Feasibility
WP4: Process Evaluation
WP5: Context Evaluation

Quantitative
WP2: Effect Evaluation
WP3: Economic Evaluation

WP6: Scale up and Sustainability
WP7: Management and Coordination

Total Project Duration: 4 Years
The Research Team

International Partners

- University of York, UK
- University of Leeds
- The University of Edinburgh
- Heinrich-heine-universitaet Duesseldorf
- General University Hospital, Prague

Implementing Partners

Pakistan  Bangladesh  Nepal

- National TB Control Program - Pakistan
- The Initiative - Pakistan

APPROVALS  NBC Pakistan (PMRC) and DRAP

Country Coordinating Teams

National TB Control Program - Pakistan

- Dr Razia
- Mabbooob ul Haq

The Initiative - Pakistan

- Sonia Mansoor
- Data Manager
- Aam Mohal
- Office Manager
- Sohail
- Field Monitoring and Evaluation Team
- Maryam Noor
- Dr Amina
- Dr Amina
- Dr Amina
Implementation goal

**Behavioural Support (BS)** was to adapt the delivery of tobacco cessation strategies (BS Counselling) to the local context.

**The BS Materials:**
- Flipbook to guide counselling: TB messages and tobacco: 8 pages
- Leaflet: Tobacco only, to reinforce counselling messages and to increase motivation to quit among those not able to admit or quit.
- Poster: To advertise the cessation service.

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Effectiveness goal

**Cytisine Trial (TB & Tobacco Trial)**
- To test whether a medicine called cytisine can help TB patients to quit tobacco.
- In order to test the drug, we will compare it to an inactive course of capsules that look identical to cytisine, called a ‘placebo’.
- Patients will have an equal chance of being given cytisine or the placebo. They will not know whether they have been given the placebo or the cytisine.
- We will then see how many in each group have been able to quit tobacco use after 6 months.
Primary Objective

To assess the effectiveness and cost-effectiveness of cytisine when added to behavioural support for tobacco cessation compared to behavioural support alone on tobacco cessation in TB patients who smoke tobacco on a daily basis.

Primary Outcome

Continuous abstinence at six months (self-report of tobacco use not more than five cigarettes/bidis/water pipe sessions/chew after the quit date), which is biochemically verified by CO level of <10ppm and cotinine dip-stick level of < 3 in urine (Level 3 =100-200ng/mL cotinine), if using smokeless tobacco as well.
Research Design

This phase III drug trial is a 30-month Parallel group, double-blind, randomised, placebo-controlled trial comparing arm 1 (active) versus arm 2 (placebo):

Arm 1: Cytisine + BS  
Arm 2: Placebo + BS

Patients will be randomly allocated in a 1:1 ratio to active or placebo treatment.

Cytisine and placebo tablets labelled and repackaged at coordinating centre will be identical in appearance to ensure blinding.

Trial Sites

TB diagnostic and management centres in Pakistan (IRB and approval from MS)

1. Government Tb hospital, Sargodha
2. Infectious Diseases hospital, Bilal Gunj, Lahore
3. Gulab Devi Chest Hospital, Lahore
4. Federal Government Tuberculosis center, RWP
5. DHQ Teaching Hospital, Bannu
6. PIMS, Islamabad
7. Samli Sanatorium, Murree
8. LRH Teaching Hospital, Peshawar
9. Mayo Hospital, Lahore

Study Participants/Screening

• Recruitment/Identifying participants
  We will recruit from:
  Hospitals (Doctors, paramedic/nurses, Health Workers (HW), other clinical staff and laboratory technicians engaged in TB care and management at the Health Centre (HC) will identify TB patients)

• Screening for Eligibility

• Consenting and Enrolling Participants

• Participants Randomization and Allocation
  We will individually randomise 1004 participants to one of the two arms of the trial.
Newly diagnosed Pulmonary TB patients who smoke tobacco on a daily basis

Eligibility Consent

Recruited Randomized 1:1 Questionnaire Filled

Cyticine + Behavioral Support (n=500)  Placebo + Behavioral Support (n=500)

Follow up Day 5, Week 5, 9, 12 and Month 6, 12

Contact Information

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