





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





TB and Tobacco

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

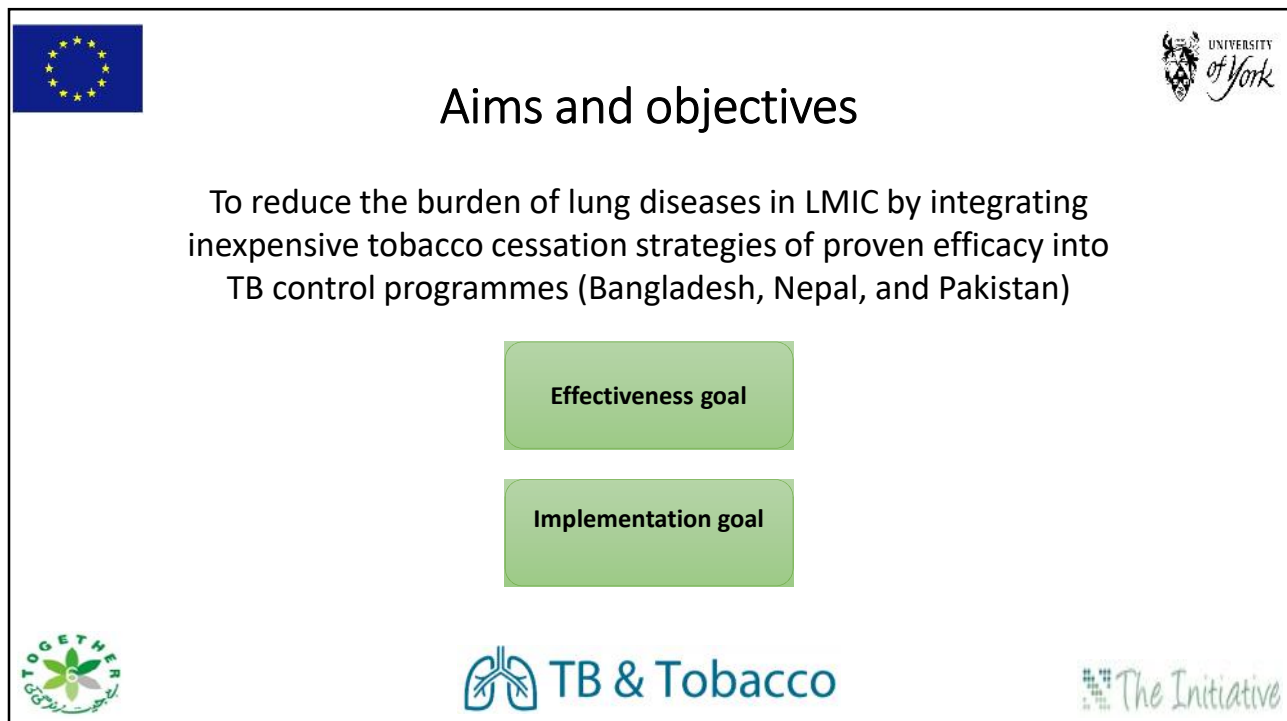
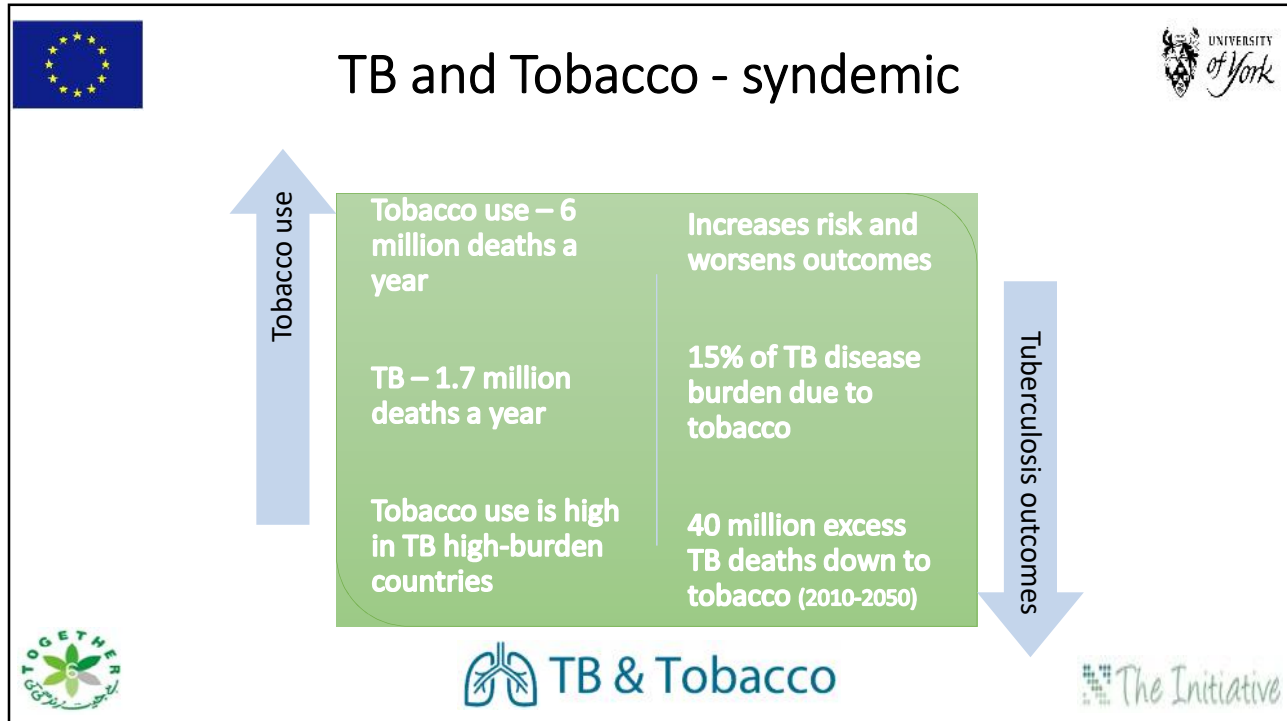
Health



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















Advantages of tobacco cessation in TB



| | |
|----------------|--|
| Health benefit | <ul style="list-style-type: none"> • Greater health benefits than in general population |
| Opportunity | <ul style="list-style-type: none"> • Opportunity of 'teachable moments' |
| Potential | <ul style="list-style-type: none"> • Potential to 'piggy back' on TB program's infrastructure |

Ambition






| | |
|------------------------------|---|
| Global | <ul style="list-style-type: none"> • Multi-country study |
| Outcomes | <ul style="list-style-type: none"> • Cessation and clinical outcomes |
| Diversity | <ul style="list-style-type: none"> • Diverse methods & evaluations |
| Scale up and sustain ability | <ul style="list-style-type: none"> • Post-trial follow-up |




Potential impact



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

Potential impact







- Low-cost
 - Low cost options for tobacco cessation
- MDG
 - Millennium Development Goals
- Competitive
 - Enhance competitiveness & growth




Summary


| | |
|------------|---|
| Importance | <ul style="list-style-type: none"> • Important <u>understudied</u> topic |
| Quality | <ul style="list-style-type: none"> • Rigorous approach to evaluate and implement interventions |
| Capacity | <ul style="list-style-type: none"> • Support to deliver the programme is in place |
| Benefit | <ul style="list-style-type: none"> • Potential for global impact |


Work package (WP) 7

Management and Coordination




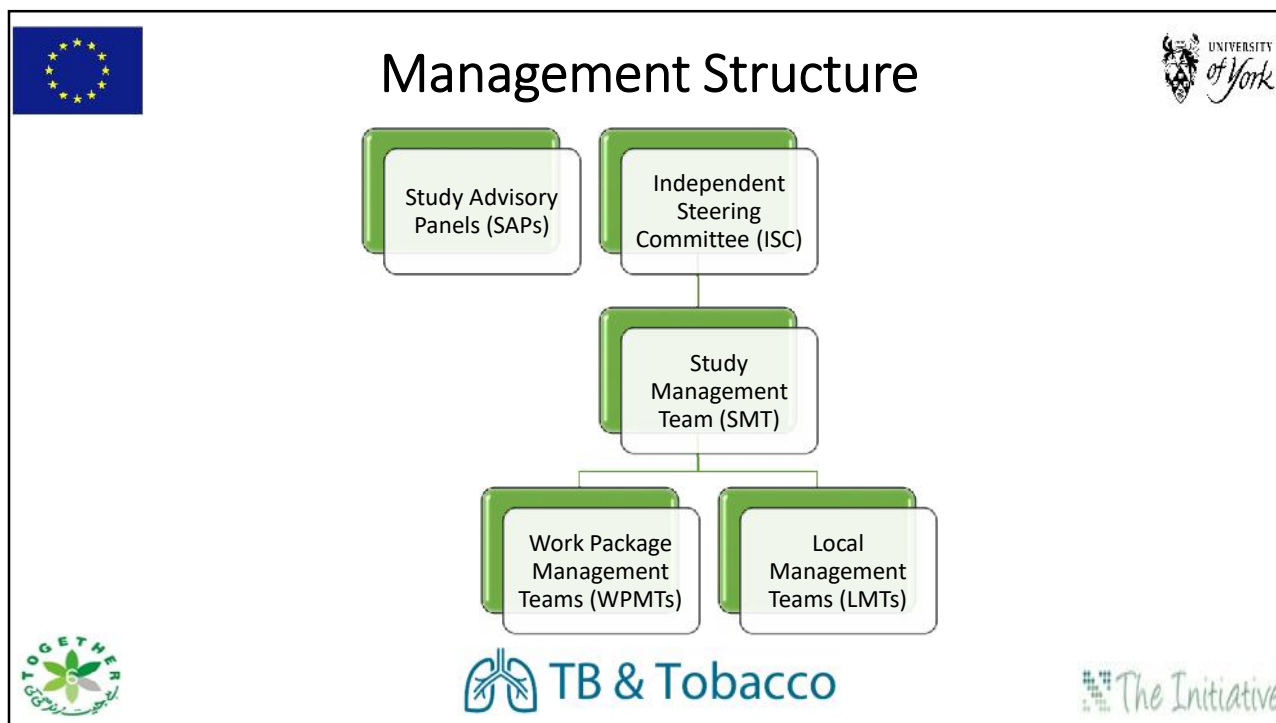




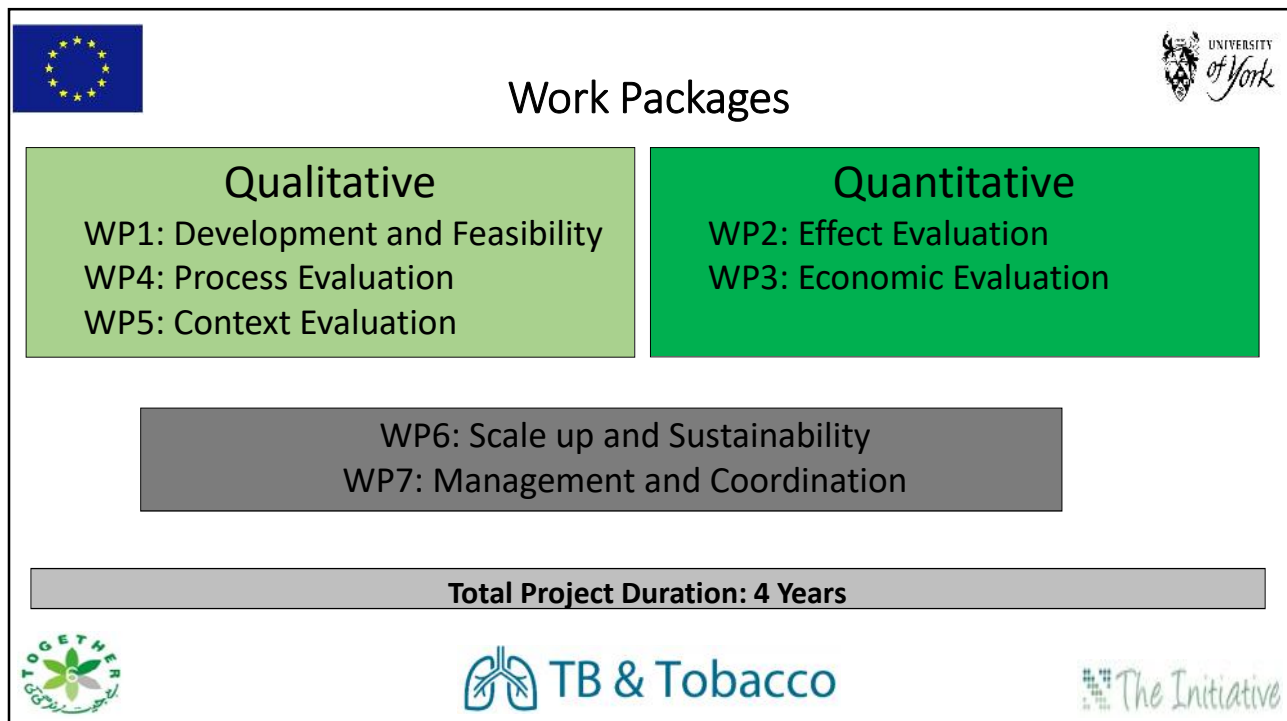
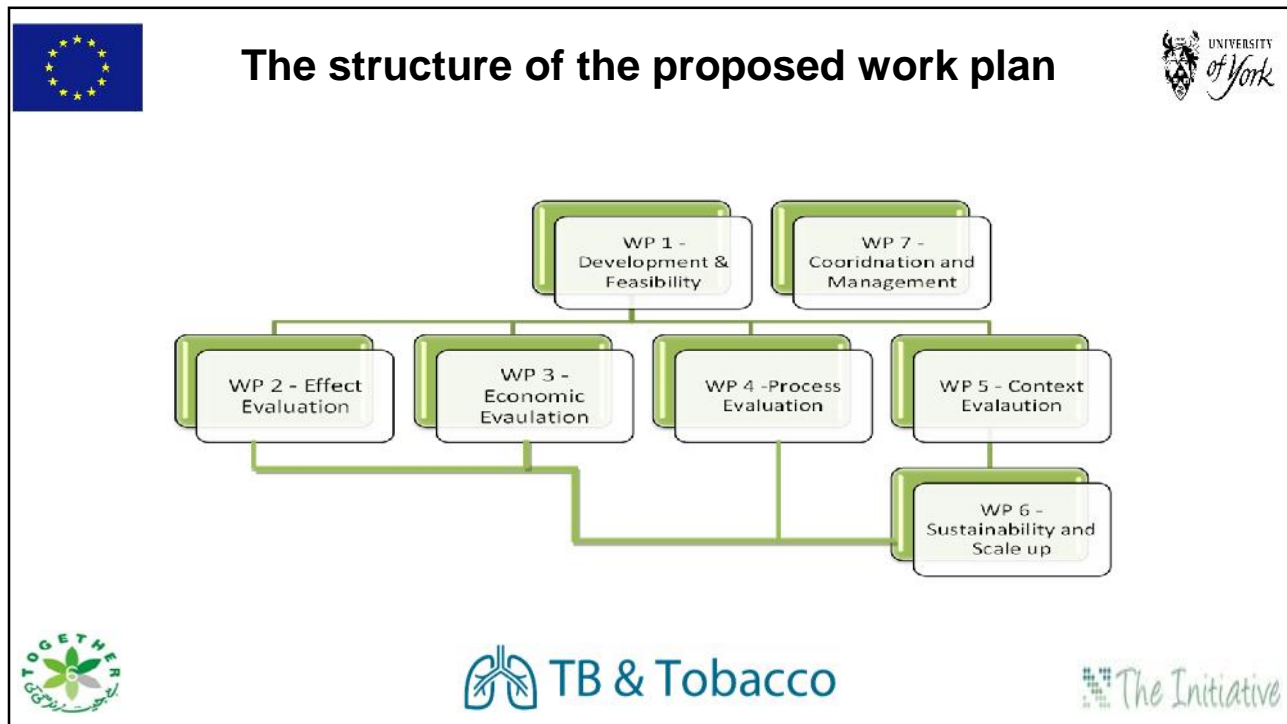


Consortium (TB and Tobacco)



| No | Participant organisation | Expertise | Contribution |
|-----|---------------------------------------|--|--|
| P1* | University of York, York | Tobacco cessation trials in LMIC | Effect and Economic evaluation |
| P2 | ARK Foundation, Dhaka | TB and tobacco control (BD) | PI Bangladesh |
| P3 | HERD, Kathmandu | TB & health systems | PI Nepal |
| P4 | National TB Programme, Islamabad | TB programme | Policy & practice lead |
| P5 | The Initiative, Islamabad | Tobacco control (PK) | PI Pakistan |
| P6 | Heinrich-Heine-University, Düsseldorf | Smoking cessation in respiratory illnesses | Process Evaluation |
| P7 | University of Edinburgh, Edinburgh | Lung health & primary care | Advisory |
| P8 | University of Leeds, Leeds | TB & health services delivery | Development, Scale-up and Sustainability |
| P9 | General University Hospital, Prague | Tobacco cessation in diverse settings | Context Evaluation |





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

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

APPROVALS NBC Pakistan (PMRC) and DRAP


Bangladesh

Nepal












Country Coordinating Teams



National TB Control Program - Pakistan




Dr Razia




Mahboob ul Haq


The Initiative - Pakistan




Sonia Mansoor
Data Manager




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Qualitative Researcher






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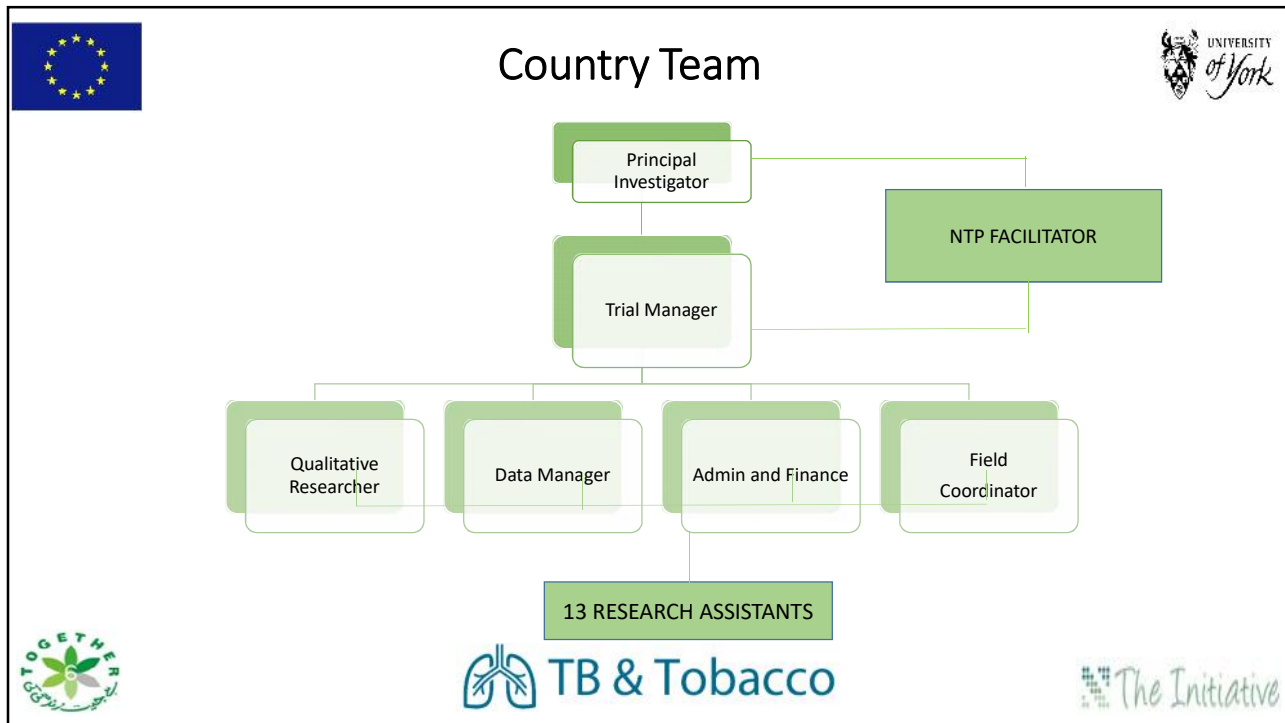
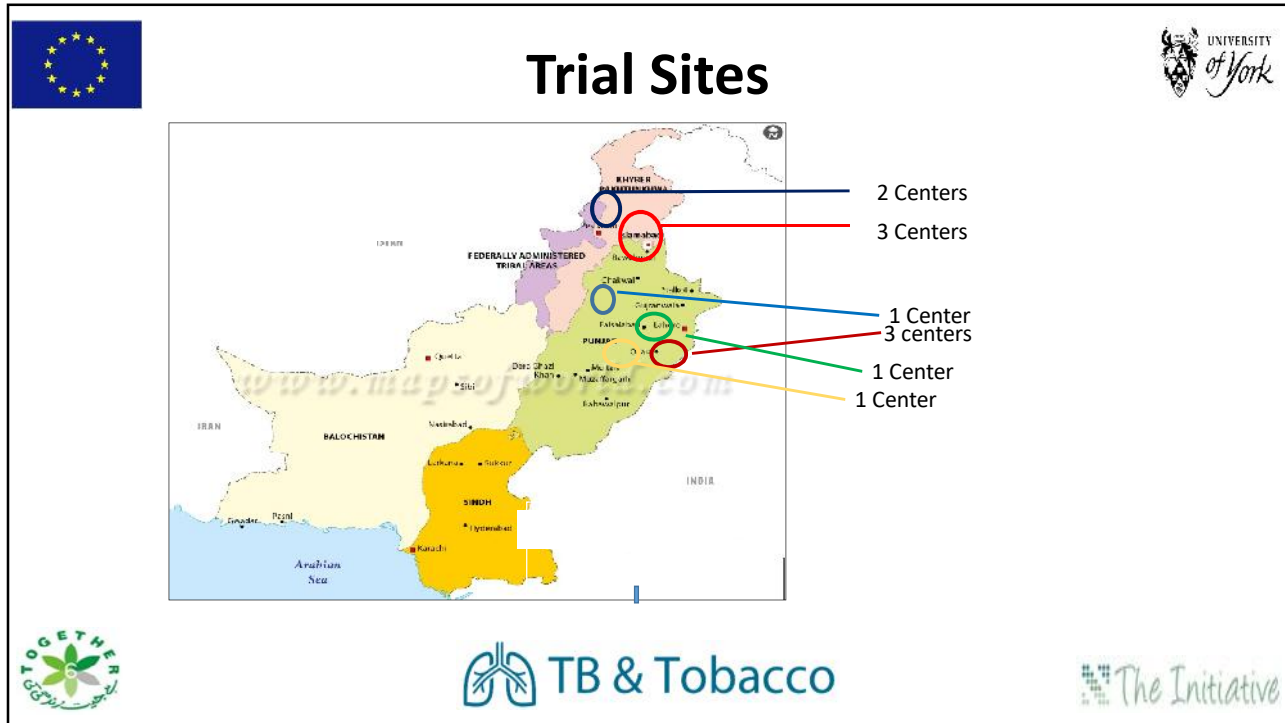




Sohail
Field Monitoring and Evaluation



Dr Amina








Implementation goal


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

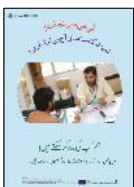
The BS Materials:


- 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.























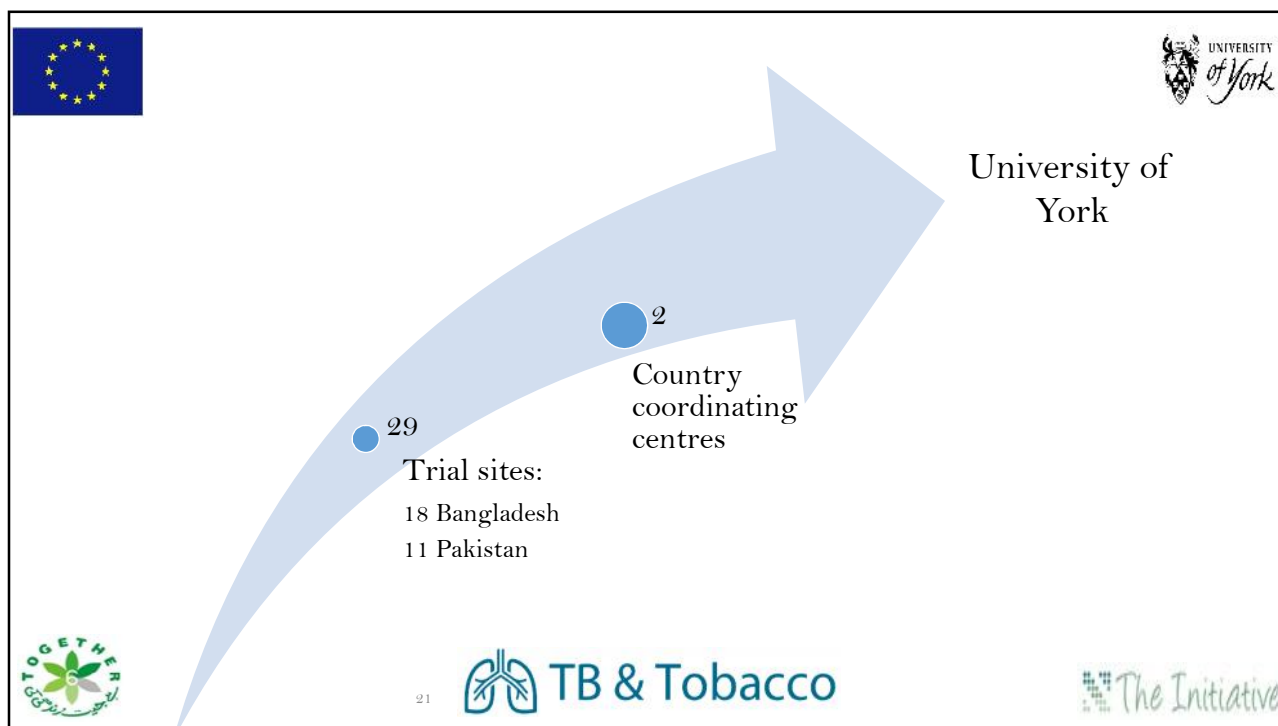



Effectiveness goal

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



WP2
Effect Evaluation
(Double-Blind, randomized, Parallel Group, Placebo-Controlled Trial)

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.

TOGETHER

TB & Tobacco

The Initiative

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

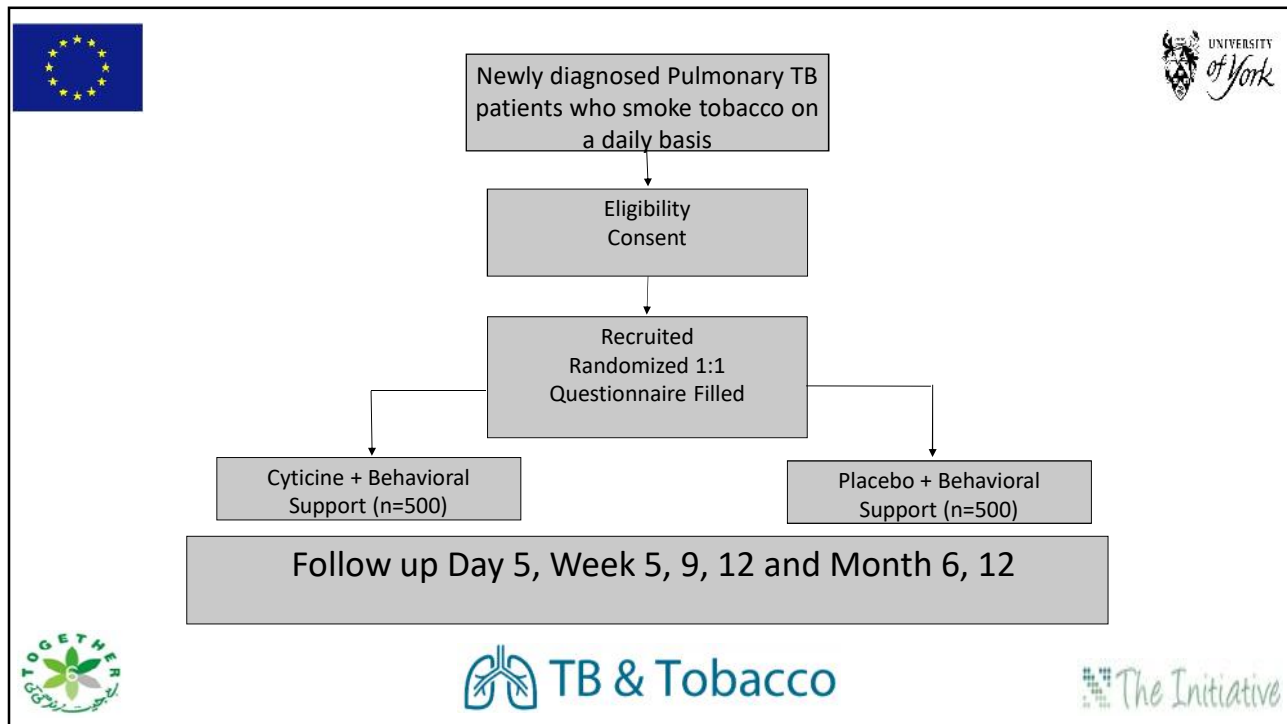


Study Participants/Screening

- **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.



Contact Information

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| <p>National TB Control Program- Pakistan</p> <p>Research Unit Dr. Razia Kaneez Fatima Chief Data Officer/PI</p> <p>Phone: +92-51-8438077-9 Email: drrazia@ntp.gov.pk www.ntp.gov.pk</p> | <p>The Initiative – Pakistan</p> <p>Dr. Amina Khan Executive Coordinator/TM</p> <p>Phone: +92-51-8732651 Email: aminakhan67@gmail.com info@theinitiative.org.pk www.theinitiative.org.pk</p> |
|--|--|

The contact information section provides details for the National TB Control Program- Pakistan and The Initiative – Pakistan. It includes names, titles, phone numbers, email addresses, and websites for the research units. The diagram also features logos for the European Union, University of York, TOGETHER, TB & Tobacco, and The Initiative.