

Brief Advice and Breathing EXercises (BABEX) for quitting tobacco use in low income communities in India

Submission date 15/05/2012	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 07/06/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 07/10/2016	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Tobacco use is a risk factor for six out of eight leading causes of death in the world including heart, respiratory diseases and cancers. Tobacco use leads to an estimated 5.4 million deaths globally every year. Since tobacco use is so harmful, there is a continued need to develop and assess interventions to promote quitting of tobacco use. In India there is an urgent need for low cost interventions (programs) that can be delivered to the 275 million tobacco users. There are only 19 tobacco cessation clinics (TCC) in the country established by the Government of India so far which is not adequate to meet the existing need. In the Indian context, it is important to identify a low cost method to aid tobacco use quitting which can be made available and accessible to the massive number of tobacco users in the country. Brief advice delivered by trained personnel is a low cost method for stopping tobacco use which is effective and can be delivered to a large number of tobacco users. There is reason to believe that such brief advice can work even better by including training in yogic breathing exercises. Such advice delivered by outreach in the community is likely to be very cost effective. The aim of this study is to test how well brief advice and a single session of training in yogic breathing exercises work to stop tobacco use among adult tobacco users living in low income communities in India.

Who can participate?

Tobacco users will be identified by a household survey in 28 low income communities. Participants will be included in the study if they are current tobacco users, 23 years or more of age and willing to provide consent.

What does the study involve?

All participants will be divided into two groups (arms): one treatment arm in which brief advice and training in yogic breathing exercises (YBA) will be given to participating tobacco users and a comparison arm in which very brief advice (VBA) simply stressing the need to quit would be given. Participants in 14 slum areas will be put in the yogic breathing exercises group and participants in the other 14 slum areas to the very brief advice group. After obtaining consent, participants will be interviewed by field investigators in their homes regarding their tobacco usage and then either offered very brief advice or offered brief advice and single session

training on yogic breathing exercises. The participants will be visited at their homes again for follow up one month and 7 months after the initial advice to assess whether they have been successful in stopping tobacco use or not. Additionally about half of the consenting participants will be selected and offered a saliva test. Those who report to have stopped at the 7 months follow up will be verified by a saliva test to measure levels of cotinine which is expected to be raised in tobacco users.

What are the possible benefits and risks of participating?

There are no direct benefits for participants except being able to stop tobacco use free of cost and lead healthier lives if the method works for them. In addition, their participation could potentially benefit millions of tobacco users in the country to stop tobacco use. There are almost no risks to participants as no drug or medication is being given and training on only simple beginner level yogic breathing exercises already recommended by Yoga gurus and used by thousands in India will be used. The training will include any specific precautions to be taken if applicable.

Where is the study run from?

The study will be run from the Public Health Foundation of India (PHFI), in New Delhi, India.

When is study starting and how long is it expected to run for?

The study is expected to start enrolling participants by August 2012. It is expected to be completed within 15 months from the first enrolment.

Who is funding the study?

Wellcome Trust (UK) and Public Health Foundation of India (PHFI)

Who is the main contact?

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

3051/002

Study information

Scientific Title

Cluster randomized trial of a brief tobacco cessation intervention for low income communities in India

Acronym

BABEX

Study objectives

To evaluate the effectiveness of brief advice plus training on yogic breathing on tobacco users in low income communities in India to promote cessation of tobacco use. Even a small effect size of 5% over control would make the intervention very cost effective.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Research Ethics Committee, University College London, 20/10/2011, ref: 3051/ 002
2. Institutional Ethics Committee, Public Health Foundation of India, 23/02/2012, ref: TRC-IEC-122/11

Study design

Community-based cluster randomised trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Tobacco users

Interventions

Intervention arm:

1. Obtain informed consent
2. Complete questionnaire by interview and offer the intervention.
3. Provide brief advice based on a script with personalized modifications
4. Provide training on breathing exercises using a standard video
5. Help the tobacco user practice the breathing exercises briefly in your presence to ensure understanding
6. Inform regarding the follow up after one month and six months

Control arm:

1. Obtain informed consent
2. Complete questionnaire by interview
3. Provide Very Brief Advice based on a script
4. Inform regarding follow up after one month and six months

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Self reported abstinence from tobacco use in the 6 months preceding the follow up
 2. Salivary cotinine concentration of less than 20ng/ml at that point using a Enzyme-linked immunosorbent (ELISA) assay
- Measured at 7 months

Secondary outcome measures

1. One week self reported point prevalence abstinence from tobacco use at one month follow up
2. Attempts to stop tobacco use between the intervention and the 1 month follow up
3. One week point prevalence abstinence at the follow up at 7 months confirmed by saliva cotinine assessment

Overall study start date

30/07/2012

Completion date

30/09/2013

Eligibility

Key inclusion criteria

1. Adults, aged 23+ years of age (the age limit is necessary to avoid contamination with a previous research study with participants up to 21 years)
2. Current self reported tobacco users of any tobacco containing product and providing consent for the study

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

A total of 850 tobacco users (425 in each arm) are proposed to be recruited across 28 clusters

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

30/07/2012

Date of final enrolment

30/09/2013

Locations**Countries of recruitment**

England

India

United Kingdom

Study participating centre

University College London

London

United Kingdom

WC1E 6BT

Sponsor information**Organisation**

University College London (UK)

Sponsor details

Health Behaviour Research Centre

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Sponsor type

University/education

Website

<http://www.ucl.ac.uk/>

ROR

<https://ror.org/02jx3x895>

Funder(s)

Funder type

Research organisation

Funder Name

Public Health Foundation of India (India)

Alternative Name(s)

PHFI

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

India

Funder Name

Wellcome Trust (ref: 6936)

Alternative Name(s)

Funding Body Type

Private sector organisation

Funding Body Subtype

International organizations

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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	01/02/2017		Yes	No