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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

Registration date
07/06/2012

Overall study status
Completed

Last Edited
07/10/2016

Condition category
Mental and Behavioural Disorders

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

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

India

Study participating centre
University College London
London
United Kingdom
WC1E 6BT

Sponsor information

Organisation
University College London (UK)

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Research organisation

Funder Name
Public Health Foundation of India (India)

Alternative Name(s)
The Public Health Foundation of India, Public Health Foundation of India (PHFI), 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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2017		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes