Randomized Controlled Trial for Smartphone based Smoking Cessation Program

Indian Institute of Technology, Bombay

Background

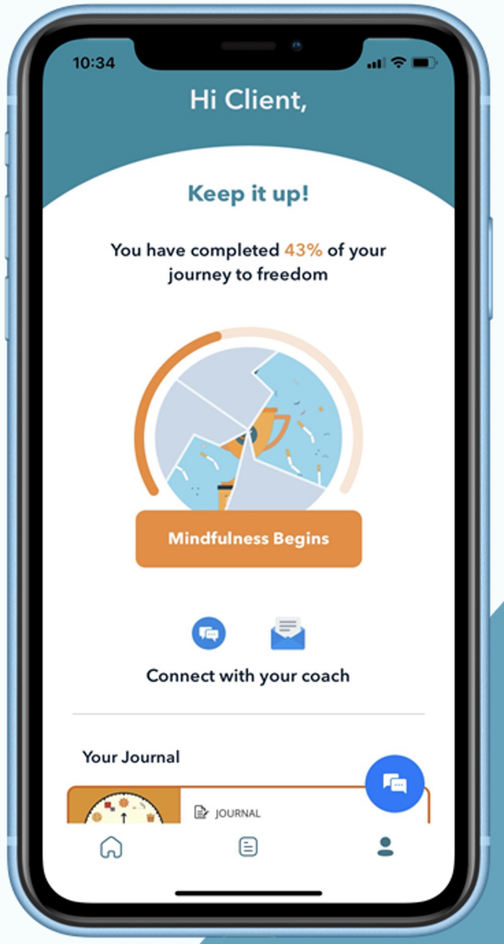
- Tobacco smoking is a leading cause of preventable death worldwide.
- Most tobacco cessation programs are unaffordable or inaccessible.
- Digital interventions are a promising alternative.
- The study presents a ‘zero human intervention’ solution using text and video-based content: A ‘Quit Smoking App’

Hypothesis

- To reverse the user’s psychological addiction to nicotine using behavioral techniques like positive psychology, cognitive behavioral therapy, and mindfulness.
- No use of pharmaceutical interventions like oral supplements, medications or nicotine replacement therapies.
- Requires 6-10 hours over 6-10 days to complete.

Quit Smoking App – Key Features

- 6-day program with daily content – mental exercises, interactive journal, chat-based support from expert coaches.
- No cravings after quitting.
- No lifestyle changes needed.
- No weight gain post quitting.
- Affordable (~2 packs of cigarettes in most countries).



Objectives

- To assess the impact of A ‘Quit Smoking App’ program on short and long-term smoking cessation.
- To determine the level of engagement with the ‘Quit Smoking app’.
- To assess the feasibility of the ‘Quit Smoking App’ program.

Study Design

- 2-arm, single blinded, randomized controlled trial.
- Min 500 Participants: 250 (Intervention Group – IG) + 250 (Control Group – CG).
- Adult everyday smokers with ~1 cigarette per day (have smoked at least 100 cigarettes).
- Sample size based on literature with 12% success rate of mobile app-based cessation therapies.

Study Design

- The IG group will be assigned to the **Quit Smoking app** program.
- The CG group will be given brief advice to quit smoking.
- Point Prevalence Abstinence (PPA) & Prolonged Abstinence (PA) - self-reported via phone/online/in-person at 7-day, 30-day, 3-month, and 6-month time points.

Study Design

- Self-reported data will be verified via non-invasive testing of saliva cotinine (at 30-day & 6-month points).
- Publication of initial results after obtaining 30-day post quit data.
- Follow up publication after remaining time points.

Role of Human Participants

Adult participants who smoke at least 1 cigarette daily, and have smoked at least 100 cigarettes in total.

- Eligible participants will be randomly assigned:
  - **Quit Smoking** program (IG)
  - Basic advice on quitting smoking (CG)

enefits of **Quit smoking** pp

- Successfully quit smoking without cravings – impacts future health and wellbeing.
- Affordable and accessible as compared to most high efficacy smoking cessation programs.
- Success of the program will aid the creation of standardized large-scale, high-efficacy de-addiction interventions – affordable & accessible to global marginalized communities.
- Better understanding of the psychological aspects of nicotine addiction.

Study Population

- Participants from multicentric trial study centres across India:

-Participation with informed consent and meeting inclusion and exclusion criteria.

-All locations under the study area will be under the jurisdiction of an IEC (hospital or technology institute.

Participant Inclusion Criteria

- Adults over 18 years of age.
- Written informed consent by the participant.
- Proficient in written and spoken English.
- Must be an everyday smoker – 1 or more cigarettes per day on average & smoked at least 100 cigarettes.

Participant Inclusion Criteria

- Participant must have daily access to an Android or iOS smartphone.
- Can use a smartphone without difficulty.
- Salivary cotinine test positive on first visit (after meeting other Inclusion criteria).
- The participant's mouth is rinsed thoroughly with water 10 minutes before sample collection.

Participant Exclusion Criteria

- Have already quit smoking / Currently not smoking.
- Advised by doctor to not quit smoking cold-turkey.
- Severe mental or psychiatric illness.
- Inability to attend follow-up clinic visits during study period.
- Planned to use a smoking cessation aid / participate in any kind of smoking cessation activities outside the trial.

Participant Exclusion Criteria

- Consumed a major meal within 60 minutes before the test.
- Consumed alcohol within 12 hours before the test.
- Consumed foods like broccoli, cabbage, mustard, garlic, radishes, almonds and horseradish within 12 hours.
- Persons working with metal and related occupations including electroplating and precious metal refining.
- Tobacco workers.

Participant Recruitment Procedure

- Participants will be:

– interviewed at the study centre by investigators.

- given a questionnaire to obtain baseline de-identified data.

- asked to sign a written informed consent form in English language only.

- screened for inclusion and exclusion from the study.

- randomly sorted into IG or CG based on a computer program.

Study Procedure

- CG participants will be advised by investigators to stop smoking using self-control – 7 days, with telephonic counselling from the team.
- IG participants will be enrolled in the Quit Smoking program for 6 days.
- The team will telephonically check the adherence of the participants (IG and CG).
- Reminders will be sent **once a day to both groups**.

Study Procedure

- IG participants will receive access to the **Quit Smoking App** program and assistance (6–10 hours total content over 6–10 days).
- IG group will be provided text and video-based behavioral change techniques.
- Self-reporting of smoking cessation at 7, 30, 120, and 180 days.
- Salivary cotinine tests repeated after 30 and 180 day points.

Salivary Cotinine

- Salivary cotinine is a good marker for tobacco consumption detection.
- However, it may also be positive in passive or non-smokers.
- According to a study published in Indian J Psychiatry (Sharma et al., 2019), the mean cotinine levels in saliva is as follows:

  9.53 ng/mL - non-smokers (n = 26)

  18.31 ng/mL - passive smokers (n = 15)

  327.39 ng/mL - smokers (n = 49)

Salivary Cotinine Test

- Saliva samples will be collected using a POC test kit.
- The participant will be asked to chew the cotton stick for 2 minutes.
- Once placed back in a sterile tube, it will be tested using a POC device.
- The test will take place at the end of the ~30 minute interview.
- Salivary cotinine levels below 50 ng/mL will be considered as a negative test result (to eliminate bias due to passive smoking).

Undisclosed Features

Participants will not be informed about the external funding agency as they might assume it is part of a promotional campaign.

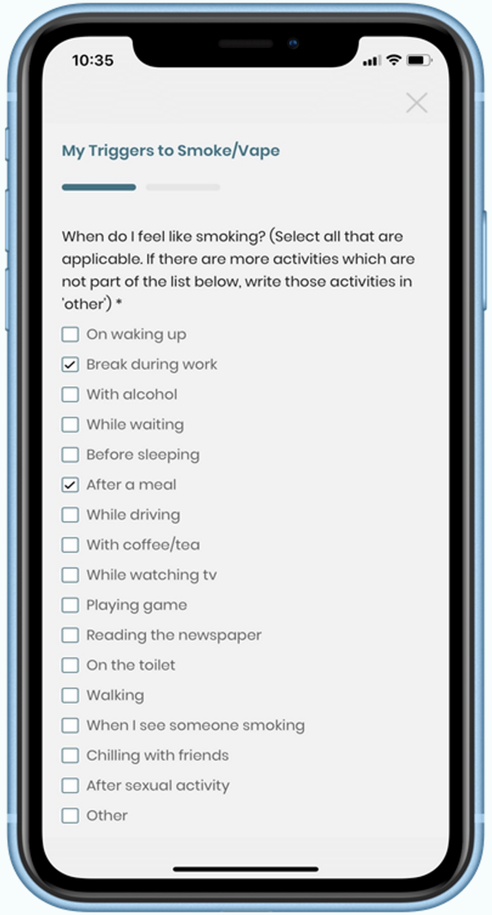
Type of Data Collected

- **Demographic data:** date of birth, sex, place of residence, occupation, marital status, number of children (if any), education, employment status.
- **Information regarding smoking activities**
- **Inclusion/Exclusion criteria:** English proficiency, access to smartphone, psychiatric/mental health problems, access to the clinic during study period, participation in other smoking cessation programs or aids.

Data Collection Procedure

- Initial eligibility interview
- Saliva cotinine tests
- Questionnaire
- Self-reported progress data via smartphone

All data will be collected via a Google form which will be password protected and accessible only to the investigators.



Associated Risks

There are no risks or harmful effects associated with this study.

Associated Benefits

- Ability to quit smoking without cravings.
- Significant positive impact on future health and wellbeing.
- Affordable and accessible.
- Better understanding of the psychological aspect of nicotine addiction.

Regulatory & Ethical Compliance

- Participants are recruited from Govt and private medical establishments with valid IEC approval and after taking Informed Consent Form (by the participants).
- The program is registered with the Clinical Trial Registry, India (CTRI)

Project Funding

- **Primary Sponsor: IIT Bombay to the Study Centres**

Publication of Study Results

- Publication of initial results after obtaining 30-day post quit data.
- Follow up publication after remaining time points.

Only demographic details will be used. No personal identifiable data will be utilized in these publications.

Study Timeline

- **Duration of the Quit Smoking App Programme:** 6-10 days.

- **Self-reporting of abstinence:**
  - after 7 days post abstinence or 7 days post completion of the program

    (whichever is earlier).

  - after 30 days or 30 days post completion of the program (whichever is earlier).

Study Timeline

- after 180 days or 180 days post completion of the program (whichever is earlier).

- **Salivary Cotinine Detection:**

-on day 1 (recruitment day).

-after day 30 and after day 180 (if the participant self-reports abstinence).

Thank You!