INFORMED CONSENT FORM

for: Randomized Controlled Trial for Smartphone based Smoking Cessation Program

Study Title: Randomized Controlled Trial for Smartphone based Smoking Cessation Program

Name of Principal Investigator:
Name of Organization:

Name of Sponsor: Primary sponsor to study centres: IIT Bombay to the study centres

Name of Proposal and version: Quit smoking, Version-1.0

PART I: Information Sheet

I. Introduction

We are a group of researchers from IIT Bombay (originator institute) and associated centres (as mentioned below). The principal investigator of the study is Prof Rohit Srivastava, Co-Pi is Dr Arnab Ghosh and list of centres and researchers are mentioned below:-

Sl	Name of the Institute	Name of the researchers
(a)	IIT Bombay Originating institute	PI: Prof Rohit Srivastava, Co-PI: Dr Arnab Ghosh
(b)	NRS Medical college	Dr Soumik Goswami, Dr Niladri Das
(c)	DYPUSM	Not yet confirmed. When the list is confirmed we will inform IITB IEC
(d)	KSHEMA	(Nitte University), Mangalore: Dr JONATHAN L, Dr. Satheesh Rao, DR. SHISHIR KUMAR, Dr Srinivasa Bhat, Mr Paul Parlees, and Mrs Agnieta
(e)	Code Wellness centre, Kolkata:	Dr Ananya Bhowmik PhD in clinical Nutrition, Dr Suman Mitra, MD Medicine.

We will be giving you a brief description of our study which is as follows: -

Brief description of the quit smoking mobile app programme: Tobacco smoking remains one of the leading causes of preventable death worldwide. The most effective tobacco cessation programs require personalized human intervention combined with costly pharmaceutical supplementation, making them unaffordable and/or inaccessible to most tobacco users. Thus, digital interventions, delivered through smartphones, offer a promising alternative to these traditional methods. We would like to understand whether text and video-based content, delivered via a smartphone application, with minimal to zero human intervention, can be used to reverse the psychological dependence on nicotine (via smoking or

vaping) at scale. To answer this, we propose to conduct a randomized controlled trial of the quit smoking smartphone-app based tobacco cessation program. The quit smokingProgram uses various behavioral change techniques like positive psychology, cognitive behavioral therapy, and mindfulness, delivered purely via text and video material available within the app, to reverse their user's psychological addiction to nicotine and manage their physical withdrawal symptoms once they quit. It does not include or recommend the use of any pharmaceutical interventions, like oral supplements, medications, or nicotine replacement therapies. The program requires around 6-10 hours over 6-10 days to complete.

Key features of the quit smoking app: - six-day program or course, daily content and mental exercises to create long lasting psychological habit change, interactive journal for clients to record their quitting journey, chat-based support from expert coaches, no self-control required to quit and no cravings after quitting, no lifestyle changes needed and no weight gain post quitting, affordable access to the program (~2 packs of cigarettes in most countries).

Background of present study: Tobacco smoking remains one of the leading causes of preventable death worldwide. The most effective tobacco cessation programs require personalized human intervention combined with costly pharmaceutical supplementation, making them unaffordable and/or inaccessible to most tobacco users. Thus, digital interventions, delivered through smartphones, offer a promising alternative to these traditional methods. We would like to understand whether text and video-based content, delivered via a smartphone application, with minimal to zero human intervention, can be used to reverse the psychological dependence on nicotine (via smoking or vaping) at scale. To answer this, we propose to conduct a randomized controlled trial of the quit smoking smartphone-app based tobacco cessation program.

Objectives of the clinical trial: The main objectives of the proposed study are:(1) To assess the impact of the quit smoking program on short-term and long-term smoking cessation, (2) To determine the level of engagement with the quit smoking smartphone app and (3) To assess the feasibility of the quit smoking program.

- **Proposed topic of research: "**Randomized Controlled Multicentric Trial for Smartphone based Smoking Cessation Program – quit smoking".

- **Objective of proposed research**

  A. To assess the impact of the quit smoking program on short-term and long-term smoking cessation.

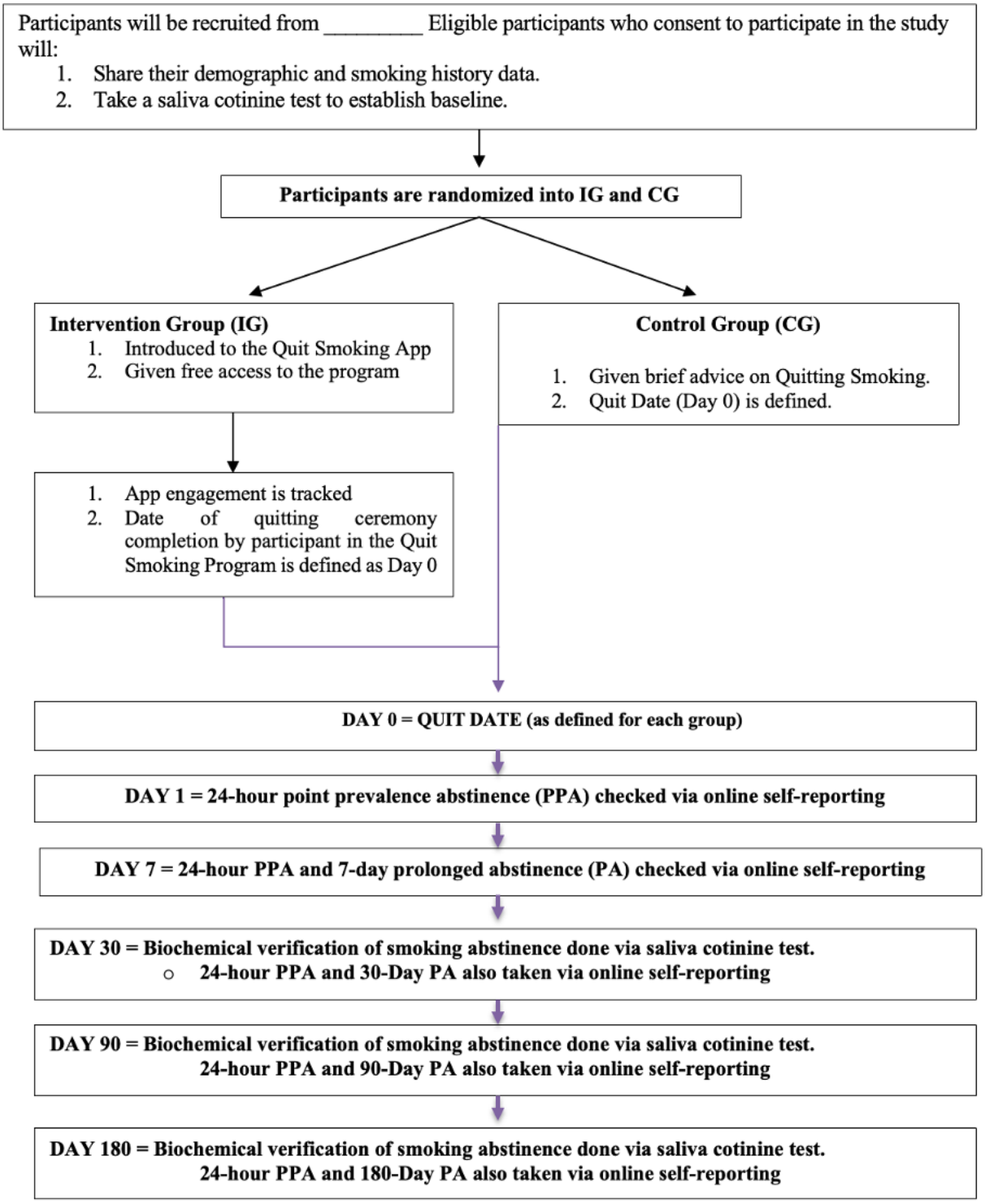
  B. To determine the level of engagement with the quit smoking smartphone app and

  C. To assess the feasibility of the quit smoking program.

Methodology: A two-arm, single-blinded, randomized controlled trial design on adult everyday smokers (at least 1 cigarette per day on average and have smoked at least 100 cigarettes). Eligible participants will

be randomly assigned to either do the quit smoking program [the IG] or will simply be given brief advice to quit smoking [the CG]. Both point prevalence (PPA) abstinence and prolonged abstinence (PA) outcomes will be recorded via self-reporting via phone, online or in-person at the 7-day, 30-day, 3-month, and 6-month timepoints post the quit date (in the case of the IG) or post the quit date defined in by the CG. At the 30-day and 6-month (180 days) time points we will also biochemically verify self-reported data by testing saliva cotinine (non-invasive test) in the participants.

Protocol



Expected outcome: We expect the quit smoking program is efficacious and feasible for both short term and long-term cessation of smoking

PART II: Certificate of Consent

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Print Name of Participant:

Signature of Participant:

Date:

If illiterate

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ AND Thumb print of participant

Signature of witness _____

Date _____

Day/month/year

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands the requirements of the study as outlined in the Information Sheet. I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Print Name of Researcher/person taking the consent: Signature:

Date:

Print Name of Principal Investigator: Signature:

Date: