Clinical Trial Details (PDF Generation Date :- Wed, 12 Apr 2023 14:55:52 GMT)

CTRI Number	Pending -
Last Modified On	
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Other (Specify) [Mobile application based digital therapeutic]
Study Design	Randomized, Parallel Group, Active Controlled Trial
Public Title of Study	Randomized Controlled Trial for Smartphone-based Smoking Cessation Program – QuitSure
Scientific Title of Study	Randomized Controlled Trial for Smartphone-based Smoking Cessation Program – QuitSure

Secondary IDs if Any

Secondary ID	Identifier

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
Name	Dr Rohit Srivastava
Designation	Professor
Affiliation	IIT BOMBAY
Address	NanoBios Lab Dept of Biosciences and Bioengineering IIT Bombay NanoBios Lab Dept of Biosciences and Bioengineering IIT Bombay Mumbai MAHARASHTRA 400076 India
Phone	9867980408
Fax	
Email	rsrivasta@iitb.ac.in

Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
Name	Dr Arnab Ghosh
Designation	Ph.D. Scholar
Affiliation	IIT BOMBAY
Address	NanoBios Lab Dept of Biosciences and Bioengineering IIT Bombay NanoBios Lab Dept of Biosciences and Bioengineering IIT Bombay Mumbai MAHARASHTRA 400076 India
Phone	9168219911
Fax	
Email	drarnab.edu@gmail.com

Details Contact Person (Public Query)

Details Contact Person (Public Query)	
Name	Dr Aniket Kundu
Designation	Project Manager
Affiliation	IIT BOMBAY
Address	NanoBios Lab Dept of Biosciences and Bioengineering IIT Bombay NanoBios Lab Dept of Biosciences and Bioengineering IIT Bombay Mumbai MAHARASHTRA 400076 India
Phone	8454937539
Fax	

Email	kunduaniket00@gmail.com

Source of Monetary or Material Support

Source of Monetary or Material Support

Primary Sponsor

Primary Sponsor Details	
Name	IIT BOMBAY
Address	Dr Rohit Srivastava NanoBios Lab Dept of Biosciences and Bioengineering IIT Bombay PIN 400076
Type of Sponsor	Research institution

Details of Secondary Sponsor

Name	Address
MS Rapidkart Online Private Limited	Bajaj Bhavan Cabin No 1 2nd Floor Jamnalal Bajaj Marg 226 Nariman Point Mumbai 400021 Registration Number U5210CMH2014PTC256711

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Lt Col SRIKRISHNA PRASAD PANDA	ARMED FORCES MEDICAL COLLEGE, PUNE	SHOLAPUR ROAD, WANOWRIE, PUNE-411040 Pune MAHARASHTRA	7972280934 drsppanda@gmail.com
Dr Ananya Bhowmik	Code Wellness Centre	321A Prince Anwar Shah Rd, beside Metropolis Lab Madar Tala Colony Lake Gardens Kolkata West Bengal PIN 700095 Kolkata WEST BENGAL	8100517024 ananya50@gmail.com
Dr Sanjiv Kale	DYPUSM Navi Mumbai	Vasantdada Patil Marg Sector 4 CBD Belapur Navi Mumbai Maharashtra 400614 Mumbai (Suburban) MAHARASHTRA	9820547252 sanjivkale58@gmail.com
Dr JONATHAN L	KSHEMA NITTE	6th Floor, University Enclave, Medical Sciences Complex, Deralakatte, Mangaluru, Karnataka 575018 Bangalore KARNATAKA	9008127372 jontysaba@gmail.com
DR NILADRI DAS	Nilratan Sarkar Medical College and Hospital,	Nilratan Sarkar Medical College and Hospital Kolkata Kolkata WEST BENGAL	7291906745 dr.niladridas90@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
IIT Bombay-Institute Ethics Committee	Approved	12/04/2023	Yes

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied	Health Type	Condition
	Healthy Human Volunteers	Tobacco Smoking addiction ICD-10-CM F17 (Nicotine dependence) ICD-10-CM Z72.0 (Tobacco use) ICD-10-CM Z87.891 (Personal history of nicotine dependence)

Intervention / Comparator Agent	Type	Name	Details
	Intervention	For Intervention group: QuitSure Mobile App usage for 7 days For Control Group: Brief advice to quit smoking Duration: 7 days	For Intervention group Name: QuitSure Mobile App usage for 7 days Duration: 7 days Mode of administration: Digital media/ phone/online/ Condition/Disease Targeted: Nicotine dependence/ Tobacco use/ Personal history of nicotine dependence Test for evaluation: Biochemical confirmation for nicotine use with Salivary Cotinine (non-invasive) test at the time of enrollment Self-declaration by the user of the app Quitsure, about their abstinence from smoking or tobacco use which ascertains their quitting status by biochemical verification with- Salivary Cotinine (non-invasive) test after 1, 3, and 6 months of completion of the app usage For Control Group Name: Brief advice to quit smoking Duration: 7 days Mode of administration: Digital media/ phone/online/in-person Condition/Disease Targeted: Nicotine dependence/ Tobacco use/ Personal history of nicotine dependence Test for evaluation: Biochemical confirmation for nicotine use with Salivary Cotinine (non-invasive) test at the time of enrollment Self-declaration by the participant in the control arm who has been given Brief advice to quit smoking, about their abstinence from smoking or tobacco use which ascertains their quitting status by biochemical verification with- Salivary Cotinine (non-invasive) test after 1, 3, and 6 months of completion of the app usage

Inclusion Criteria	Inclusion Criteria	
	Age From	18.00 Year(s)
	Age To	70.00 Year(s)
	Gender	Both
	Details	 (i) Smokes at least 1 cigarette per day on average and has smoked at least 100 cigarettes till date. (ii) Agrees to

		participate in a smoking cessation treatment program with written informed consent (iii) Must be an adult over 18 years of age (iv) Are, at minimum, proficient in the written and spoken English Language (v) Must be an everyday smoker: Should currently smoke 01 (one) or more cigarettes per day on an average (indicating sufficient dependence on nicotine) and have smoked at least 100 cigarettes (indicating sufficient exposure of the body to nicotine) on a regular basis. (vi) Have daily access to an Android or iOS smartphone. (vii) Salivary cotinine test positive on the first visit. (viii) Can use a smartphone without difficulty. (ix) Rinsed mouth thoroughly with water 10 minutes before sample is collected. (x) Inclusion criteria for controls: Age and gender matched controls.

Exclusion Criteria

	Exclusion Criteria	
Details	(i) Has already quit smoking and is currently not smoking. (ii) If a doctor has advised the participant not to quit cold-turkey. (iii) History of severe mental illness/ psychiatric illness or under current treatment for psychiatric illness such as schizophrenia or other primary psychotic disorders, BPAD, catatonia, OCD, dissociative disorders, eating disorders, personality disorders. (iv) Unable to attend follow-up clinic visits during the study period. (v) Started taking a smoking cessation medication within 1 year before the registration. (vi) Planned to use any smoking cessation aids and/or to participate in any kind of smoking-cessation activities (not limited to smoking cessation therapy) outside of the trial. (vii) Consumed a major meal within 60 minutes before the test. (viii) Consumed alcohol within 12 hours before the test. (ix) Consumed foods like broccoli, cabbage, mustard, garlic, radishes, almonds and horseradish within 12 hours. (x) Persons working with metal, the related occupations include electroplaters and people who refine precious metals. (xi) Tobacco workers.	

Method of Generating Random Sequence	Computer generated randomization
Method of Concealment	An Open list of random numbers
Blinding/Masking	Participant Blinded

Primary Outcome

Outcome	Timepoints
cessation of smoking of any form of nicotine and / or smokeless tobacco consumption.	cessation of smoking of any form of nicotine and / or smokeless tobacco consumption.

Secondary Outcome

Outcome	Timepoints
cessation of smoking of any form of nicotine and / or smokeless tobacco consumption.	1 year

Target Sample Size

Total Sample Size=500
Sample Size from India=500
Final Enrollment numbers achieved (Total)=Applicable only for Completed/Terminated trials
Final Enrollment numbers achieved (India)=Applicable only for Completed/Terminated trials

Phase of Trial	N/A
Date of First Enrollment (India)	15/05/2023
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**1 **Months=**0 **Days=**0
Recruitment Status of Trial (Global)	Not Yet Recruiting
Recruitment Status of Trial (India)	Not Yet Recruiting
Publication Details	NIL
Brief Summary	

The proposed topic of research: Randomized Controlled Trial for Smartphone-based Smoking Cessation Program – QuitSure

The objective of the proposed research:

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

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

C.   To assess the feasibility of the QuitSure program.

Background of the 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 QuitSure smartphone-app-based tobacco cessation 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 QuitSure 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 time points 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 time points we will also biochemically verify self-reported data by testing saliva cotinine (non-invasive test) in the participants.

Expected outcome: We expect the Quitsure program to be efficacious and feasible for both short-term and long-term cessation of smoking