ISRCTN50586181 https://doi.org/10.1186/ISRCTN50586181

Investigating the use of the Mindcotine® virtual reality smartphone app to help people to quit smoking

Submission date
19/09/2019

Recruitment status
No longer recruiting

Registration date
03/10/2019

Overall study status
Completed

Last Edited
31/07/2020

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Currently available tobacco cessation (quitting) programs are often not effective. Problems limiting their effectiveness include that they are not accessible and poor adherence, meaning that people don't follow the program to the end. Digital interventions offer a great opportunity to overcome these difficulties, yet virtual reality has not been used as a remote and self-administered tool to help increase adherence and effectiveness. This study aimed investigate participant adherence and smoking cessation outcomes of the digital intervention Mindcotine®. Participants followed a program combining virtual reality and mindfulness using their mobile phone at a convenient time for them.

Who can participate?
People living in Buenos Aires who are aged 24 to 65 years, who smoke at least 5 cigarettes a day and who have an Android mobile phone and access to the internet.

What does the study involve?
Participants were randomly allocated to one of two groups. One group received the Argentinian Ministry of Health manual on how to quit smoking. The other group received an app that delivered 21 days of virtual reality Mindful Exposure Therapy (VR-MET) sessions, daily surveys, and online peer-to-peer support moderated by psychologists. Participants in this group go through a training process of 21 days, having a 10-minute mindfulness session (inside of virtual environments or through a 2D video) during the morning, and taking a reflective moment at night to register the quantity of cigarettes smoked (or not), the main motives that triggered his /her behavior, and an open question to reflect. Also, during the day, the participant can have access to a community chat moderated by psychologists, a wristband to deviate his/her attention from the urge to smoke, and mindfulness audio to help him/her with anxiety when the urge arises. All participants were asked at 1 day following the end of treatment if they had smoked in the previous 24 hours and at 90 days after the end of treatment if they had smoked in the previous 90 days.

What are the possible benefits and risks of participating?
By becoming part of the study participants may quit smoking, which can greatly improve their quality of life and lifestyle. All of the participants will be practicing mindfulness techniques, which will change their relationship with themselves. By using virtual reality, they may suffer from "cybersickness", but this can be prevented by no longer using the virtual reality parts of the app.

Where is the study run from?
University of Flores (Argentina)

When is the study starting and how long is it expected to run for?
August 2017 to April 2018

Who is funding the study?
The University of Flores (Argentina), using a grant received from the Ministry of Production of the Argentine Nation, and Mindcotine Inc (USA)

Who is the main contact?
Emilio Goldenhersch, emiliogolden@gmail.com

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
17EX04

Study information

Scientific Title
Virtual reality smartphone-based smoking cessation: A pilot RCT on initial clinical efficacy and adherence

Acronym
Virtual reality smartphone-based smoking cessation program

Study objectives
Can a virtual reality smartphone-based smoking cessation program increase both adherence and abstinence rates among participating smokers compared to usual treatment and control group?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/04/2018, Institutional Review Board of the University of Flores (Av. Rivadavia 5741, C1406GLA Caballito, Buenos Aires, Argentina, ref: 17EX04.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Nicotine addiction

Interventions
The design of the study follows the recommendations for clinical trials in health using virtual reality, in particular Tier VR 2, focusing on acceptability, feasibility, tolerability, and initial clinical efficacy. We conducted a clinical trial with a control group, including baseline and follow-up assessments at days 1 and 90 post-treatment. Participants were randomized into TG (60) and CG (60) 1:1 using a blocked random assignment sequence.

The novel intervention combines exposure to smoking-related cues in ecological situations using virtual reality and mindfulness as a tool to cope with in-situ cravings, bodily sensations, affective states, and automatic reactions. Moreover, these virtual reality and mindfulness sessions are part of a classic CBT smoking cessation program that provides information on relevant topics on a daily basis through CBT notifications and community support among users moderated by psychologists and mindfulness facilitators.

The administration to the treatment group was carried out through an on-boarding process, establishing the framework of the experience and the basic principles of the use of VR. The treatment was remotely self-administered through the use of a mobile application. The application consists of a 21-day treatment that includes 2 main activities each day, which become available after completing the activities of the previous day. The control group received a quit smoking manual of the Argentine National Ministry of Health. All of the participants were asked to attend one of the university offices to receive the on-boarding process. The intervention group completed the on-boarding process, which included digital informed consent, and received an intervention kit, including a guideline that explains the use of the program, a unique ID to access the app, a cardboard headset, three stickers to declare smoke-free areas, and two wrist-bracelets working as a behavior replacement method to help decouple the craving so smokers could use it to snap their wrist with it when the craving is acknowledged. Participants were also instructed to download the mobile application from the Google Play Store. The participants were trained in assembling the cardboard headset, use of the app, completed the baseline assessment and received an explanation on the activities to be carried out during the 21-day intervention phase. The control group signed digital informed consent, received a quit smoking manual by mail, which was developed by the Office of the President of the Argentine Nation.

The elements of the program are:
1. Practice sessions in formal mindfulness: 6 sessions of mindfulness in video format of up to 10 min each, and 7 sessions in audio format of 3 to 10 min. This is based on the works of John Kabat-Zinn (1982) and Bowen and Marlatt (2009), where the user is given an initial introduction to mindfulness involving the recognition of bodily sensations, and the ability to practice non-reactively to emotions and thoughts related to smoking, from a compassionate and non-judgmental position.
2. Practice sessions in informal mindfulness using VR: Two sessions of Virtual Reality Mindful

Exposure Therapy (VR-MET), each lasting 10 min. A selection of 2 virtual contents that combine the awareness of the act of smoking and the recognition of craving, from a perspective of acceptance and commitment. This selection is the result of an adaptation of the previously conducted work synthesized by and including virtual environments used in cue exposure therapy. VR-MET design: Each of the virtual environments was created based on previous research that proved to elicit craving and was recorded with an Insta360Pro camera in locations in Mexico City (Mexico) and Buenos Aires (Argentina). The animated parts of the environments were created in Unreal Engine4, based on previous research to induce emotional states of tranquility and relaxation. Mindfulness audio of both environments were chosen to work consciously with craving-related acts ("RAIN": Recognize, Accept, Investigate, and Nourish; "Act of smoking": consciously review each moment of the act itself). Each video was repeated over a period of 14 days, with a total of 7 times each. This decision was based on previous research regarding the time of exposure in virtual environments and the space between them.
3. Daily self-reports: At the end of the day, each user reported on the app their total daily number of cigarettes, reasons that triggered cravings, and provided a written answer to the question: "What do you think has changed in your relationship to smoking as of today?" (Nightly reflections). This data was collected on the Typeform platform embedded in the app.
4. Peer-to-peer support: The app contained a group chat feature for exchange with all other participants. The group chat was moderated by a psychologist and a mindfulness facilitator to promote engagement and respond to participant questions.
5. Mindcotine® support: If participants were inactive for a certain amount of time, they received a text message (after 2 days) and a phone call (after 4 days) to encourage engagement within the program. Participants could contact for technical support by email any time as well.

Intervention Type
Behavioural

Primary outcome measure
Self-reported abstinence at 1 day after the end of the program. The question used for assessment was "Did you smoke tobacco in the last 24 hours?"

Secondary outcome measures
1. Sustained abstinence, i.e. self-reported abstinence at 90 days after the end of the program in the TG. The question used for assessment was "Did you smoke tobacco in the last 90 days?"
2. Adherence assessed using log file data collected using the platform Amplitude, which measured total use of the app of each participant. Full adherence was defined as the participant completing the treatment in the suggested time (i.e. 21 days without any breaks). Regular adherence was defined as participants completing all daily activities in up to 60 days; and depth of adherence as the total number of mindfulness training minutes.
3. Cigarette consumption reported by participants as the number of cigarettes they smoked each day during treatment, as part of their daily self-reports. The daily number of cigarettes was averaged every week to generate an average number for that period.
4. Craving was assessed using the Questionnaire for Smoking Urges (QSU), which consists of a 7-point Likert scale. This data was collected through an online survey at baseline, at the end of days 7 and 14, and on 1-day follow-up, as well as on 90-day follow-up. The internal consistency for the overall scale was adequate (= .87).
5. Mindfulness was assessed using the Five Facets Mindfulness Questionnaire (FFMQ). The five dimensions are: observing, describing, acting with awareness, not judging internal experience, and not reacting to internal experience. This data was collected through an online survey at baseline and at 1-day follow-up, as well as on day 90-day follow-up.
6. Readiness to quit was assessed using the Contemplation Ladder, which consists of 11 rungs

and 5 anchor statements reflecting the stages of change, designed to measure readiness to quit smoking. It was assessed through an online survey at baseline and at 1-day follow up.
7. Nicotine dependence was assessed using the Fagerström Test (Roa-Cubaque, Marcela, 2016), which consists of a 6-item self-report scale and observes responses suggestive of physiological dependence on nicotine. This data was collected through an online survey at the beginning of the program, at the end of day 7, 14, on 1-day follow-up and 90-day follow-up. The internal consistency for the overall scale was adequate (= .81).

Overall study start date
10/08/2017

Completion date
30/04/2018

Eligibility

Key inclusion criteria
1. Aged 24 to 65 years
2. Minimum consumption of 5 cigarettes per day
3. Score of 4-9 on the Contemplation Scale (CL)
4. Residents in the City of Buenos Aires
5. Own an Android mobile phone with gyroscope
6. Have data plan or Wi-Fi access
7. Expressed an interest in using VR as a method to quit smoking

Participant type(s)
All

Age group
Adult

Sex
Both

Target number of participants
120

Total final enrolment
120

Key exclusion criteria
1. Diagnosed with a current psychiatric disorder

Date of first enrolment
13/11/2017

Date of final enrolment
29/01/2018

Locations

Countries of recruitment
Argentina

Study participating centre
Universidad de Flores
Camacúa 11
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Sponsor information

Organisation
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Sponsor type
University/education

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ROR
https://ror.org/02hsdts66

Funder(s)

Funder type
University/education

Funder Name
University of Flores

Funder Name
Ministry of Production of the Argentine Nation. “Seed Fund” project number 3291022226

Funder Name
Mindcotine INC.

Results and Publications

Publication and dissemination plan
The plan for publication and dissemination includes having an RCT pilot article with the trial results in a well-known scientific journal by the end of the year. The journal may be of medical and internet research, addiction-related, or cyberpsychology.

Intention to publish date
15/12/2019

Individual participant data (IPD) sharing plan
Interested researchers should make a request to Emilio Goldenhersch (emiliogolden@gmail.com). The data stored are participant demographics, cigarette intake and responses to the questionnaires (FTND, FFMQ, QSU, CL). The data will become available for other researchers during the first 2 years after publication, at the discretion of the principal investigator. Access will be considered for researchers whose work is not directly related to any smoking cessation mobile apps or associated with companies that own their own smoking cessation mobile apps. The reason for this is that retrospective and comparative analysis with other populations will be performed by this research team, who do not want to compromise the dataset. The data will be shared using docsend (https://www.docsend.com) with a time-frame defined by both parties upon request.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Preprint results	results in preprint	29/07/2020	16/06/2020	No	No
Results article	results	29/07/2020	31/07/2020	Yes	No