BLENDED SMOKING CESSATION TREATMENT

No registrations found.

Ethical review	Positive opinion
Status	Other
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27150

Source
NTR

Brief title
LiveSmokefree-Study

Health condition

smoking
tobacco
treatment
blended
roken
stoppen
behandeling
tabak

Sponsors and support

Primary sponsor: Saxion University of Applied Sciences
Academie Mens & Maatschappij
M.H. Tromplaan 28
7513 KB Enschede
Source(s) of monetary or material Support: Saxion University of Applied Sciences
Academie Mens & Maatschappij
M.H. Tromplaan 28
7513 KB Enschede

Intervention

Outcome measures

Primary outcome

The primary outcome parameter is biochemically validated sustained abstinence at 15 months from the start of the smoking cessation treatment. Abstinence is defined as having salivary cotinine levels < 20ng/mL. Participants with a cotinine-value of > 20ng/mL are regarded as smokers as well as participants who are lost to follow-up.

Secondary outcome

Patient characteristics and medical history
Demographical data (sex, age, nationality, cultural background, marital status, children, housing, education, source of income, main activity) are collected using an online questionnaire. Medical history will be recorded from medical charts.

Internet Skills

Internet skills will be measured using an online questionnaire adapted from conceptual definitions for internet skills (van Deursen, Courtois, & van Dijk, 2014). This conceptual definition includes two major skill areas (medium-related Internet skills and content-related Internet skills) which a further spread into five minor skill areas. Medium-related Internet skills include operational and formal skills; content-related Internet skills include informational, communication and strategic skills. Based on a principle component analysis of formal and informational skills a 10 item questionnaire is used that measures internet skills with a 5-point Likert scale, resulting a score range from 10 (unskilled) to 50 (highly skilled).

Smoking status

The actual smoking status will be measured using an online questionnaire to record e.g. if the patient has already stopped smoking, quit day, if there were relapses, which kind of tobacco products (cigarettes, self-rolled cigarettes, cigarillos, e-cigarettes) are consumed when and how much.

Nicotine dependence (Fagerström)

Fagerström Test for Nicotine Dependence (FTND) (Heatherton et al., 1991) is the most commonly used tool for the assessment of nicotine dependency. The FTND was initially

developed to determine whether or not nicotine replacement therapy is needed to treat withdrawal syndrome. It is easily understood and rapidly applied. The scores obtained on the test permit the classification of nicotine dependence into five levels: very low (0 to 2 points); low (3 to 4 points); moderate (5 points); high (6 to 7 points); and very high (8 to 10 points). The instruments evaluates e.g. time from awakening to the day's first cigarette, smoking when bed-ridden with illness, and difficulty in refraining from smoking when it is forbidden.

Smoking history

Smoking history will be measured using an online questionnaire from the longitudinal Vlagtwedde-Vlaardingen Study (1965 to 1990) (Jansen et al., 1999) recording the age of first smoking attempts and the numbers of years and number of cigarettes/day that the patient was smoking in each decade.

Attitude, Social Influence, Self-Efficacy

The intention to stop smoking is determined by three cognitive constructs: Attitude, Social Influence and Self-Efficacy (de Vries, Dijkstra, & Kuhlman, 1988). These variables will be measured (Mudde, 2000) using online questionnaires.

Attitude refers to the overall evaluation of smoking cessation. It will be measured recording stop smoking expectations related to health, missing smoking, risk of lung cancer, ability to relax, self-satisfaction, and withdrawal symptoms.
Social influence refers to three distinctive constructs: social norms, perceived behaviour of others and direct support. It will be measured recording if the patient is stimulated to stop smoking by acquaintances, if his/her partners is a smoker and how many of his/her acquaintances are smokers.
Self-Efficacy refers to the confidence in the ability to refrain from smoking in specific high-risk situations, i.e the situations in which the quitter is tempted to relapse. It will be measured recording 6 typical relapse situations (e.g. stress, party).

Readiness to change

Readiness to change will be measured using a short form of the basic algorithm to detect the stage of change in smokers (DiClemente et al., 1991). The expected stop moment (e.g. within 1 month) offers the possibility to distinguish between the contemplation and preparation stage of change.

Stop Smoking History

Earlier attempts to stop smoking will be recorded using an online questionnaire asking if there were earlier stop smoking attempts, when the last stop smoking attempt was, how long the non-smoking phase was, and when the last stop smoking attempt was, which was successful for more than 24 hours.

Alcohol/substance (mis)use

Alcohol/substance and tobacco are often used together (Myers & Kelly, 2006). For example: People who smoke are much more likely to drink, and people who drink are much more likely to smoke (Bobo & Husten, 2000). To explore the interaction and to detect if there is a change in consumption of alcohol/substances while quitting smoking alcohol and substance (mis)use will be measured using short online questionnaires based on the Five-shot questionnaire on heavy drinking (Seppa et al., 1998). Only if a patients declares that he/she is consuming alcohol/substances at all additional questions will be asked to keep the burden for the patient as low as possible. The additional questions will record the frequency of alcohol and substances (i.e. (soft-)drugs) consumption, which (soft-)drugs are consumed, feelings of anger and guilt related to drinking, and if the patient drinks in the morning to cope with hangover.

MAP-HSS + special complaints of smokers

The MAP-HSS is a ten-item structured interview, which was adapted from the health scale of the Opiate Treatment Index (Darke, Ward, Zador, & Swift, 1991). Each item is scored on a five-point Likert-type scale, ranging from 0 (complaint never present in the previous 30 days) to 4 (complaint always present in the previous 30 days), resulting in a total scale-score ranging from 0 to 40. The scale is scored by summing the weights 0-4 across the 10 items. Internal reliability of the scale was satisfactory (alpha = 0.77) (Marsden et al., 1998).
In addition to MAP-HSS the patients are asked to scale 16 typical smoking related complaints (e.g. cold hands and feet, cough, pale skin, pain in the lung). A overall score of physical complaints will be calculated by adding MAP-HSS and the additional smoking related complaints.

DASS21

The DASS21 (Antony et al., 1998; Lovibond & Lovibond, 1995) is a set of three self-report scales designed to measure the negative emotional states of depression, anxiety and stress. Each of the three DASS scales contains 7 items. The Depression scale assesses dysphoria, hopelessness, devaluation of life, self-deprecation, lack of interest/involvement, anhedonia, and inertia. The Anxiety scale assesses autonomic arousal, skeletal muscle effects, situational anxiety, and subjective experience of anxious affect. The Stress scale is sensitive to levels of chronic non-specific arousal. It assesses difficulty relaxing, nervous arousal, and

being easily upset/agitated, irritable/over-reactive and impatient. Subjects are asked to use 4-point severity/frequency scales to rate the extent to which they have experienced each state over the past week. Scores for Depression, Anxiety and Stress are calculated by summing the scores for the relevant items..

Quality of Life (Euroqol 5D)

The EuroQol-5D (EuroQol, 1990) is a generic quality-of-life (QoL) instrument which consists of 5 domains: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. There are three response alternatives for each domain. The EQ-5D index is obtained by means of applying predetermined weights to the 5 domains. The EQ-5D index is a societal-based numerical quantification of the patients' health status which can range from 0 (death) to 1 (perfect health status). In addition to the 5 domains EuroQol-5D also offers an overall rating for quality of life by means of a visual analogue scale (VAS). The VAS is a vertical line from worst (0) to best state of health (100). EQ-5D is designed for self-completion by respondents.

Middle evaluation of treatment

Three month after the start of the treatment participants will be asked to report their experiences with the different aspects of the treatment program they have encountered so far. Participants can rate the importance of certain parts of the treatment and their gained insight in risk situations, moods and thoughts.

Long term evaluation of treatment

At the end of the treatment (6 month after start) and during the follow-up measurements (9 and 15 month after start) participants will be asked to report their experiences with the different aspects of the treatment program. Participants can rate satisfaction with the program by grading all separate types of contact, assessing the overall contact with their counsellors, and reporting their own perception of improvements. In addition they can report on adherence, results and benefits, gained insights, the use of co- interventions, and the use of NRT. Furthermore they are asked for improvement suggestions.

Exhaled CO

The measurement of exhaled carbon monoxide (CO) level provides an immediate, non-invasive method of assessing smoking status (Cropsey et al., 2014). A breath CO level of 5 ppm is taken as the cut-off between smokers and non smokers (5ppm or higher=smoker, less than 5ppm=non smoker). Breath CO monitoring is performed using a Micro III Smokerlyzer

(Bedfont Instruments: Kent, UK), a portable CO monitor. The patients are asked to exhale completely, inhale fully, and then hold their breath for 15 seconds. If the subjects are unable to hold their breath for 15 seconds, they are asked to hold it as long as possible. Following breath holding, the subjects were asked to inhale fully in order to sample the alveolar air.

Cotinine level

Saliva cotinine level will be measured as biochemical verifaction of tobacco use and cessation (Srnt Subcommittee on Biochemical Verification, 2002). A 0,5-1ml salivary sample is collected for cotinine assessment by means of a Salivette (Sarstedt AG & Co., Nümbrecht, Germany). Under supervision, patients have to chew on a cotton swab for one minute to stimulate the saliva flow rate. All saliva specimens are frozen until assayed and transported to the laboratory for the determination of the cotinine level using a gas chromatography technique.

Adherence

In order to find out how the online application is used in practice, real-time data about the usage (log data) will be collected to track individual use. These log files will be used for identifying user profiles and to gain insight into adherence to the application, usage patterns that emerge and what elements of the application are used. This information provides insight in how the application (both content and system) matches with its users.
Costs

All treatment related costs generated by the care providers and the patients: Costs will be calculated based on e.g. hours spent by the counsellors (including no shows) and overhead, travel costs of the patients and maintenance of the online infrastructure.

Study description

Background summary

Rationale:

Cigarette smoking causes a wide range of diseases. Smoking cessation can significantly reduce the risk of developing smoking-related diseases. Several face-to-face and online treatments have proven to be effective. Tailoring and interactivity play an important role in successful cessation treatment. Blending of online and face-to-face treatment that allows for tailoring and interactivity is expected to improve smoking cessation treatment. To the best of our knowledge this will be the first study comparing a face-to-face smoking cessation treatment and a blended online+face-to-face treatment.

Objective:

The primary objective of this research is to compare sustained abstinence of the blended smoking cessation treatment (BSCT) with the face-to-face treatment as usual (TAU). Secondary objectives are to detect the benefit of blended treatment concerning patients satisfaction and cost effectiveness, give advice for further improvement of smoking cessation treatment, and identify mechanisms underlying smoking cessation

Study design:

The study is a randomised controlled non-inferiority-trial with parallel group design. Patients will be randomly assigned to either the BSCT or TAU group based on a computer generated randomisation list.

Study population:

The study population comprises adults smokers that are willing to stop smoking.

Intervention (if applicable):

Both TAU and BSCT are based on the following evidence-based techniques: (1) pharmacotherapy, (2) cognitive behavioural therapy (CBT), (3) motivational interviewing, (4) self-control techniques and self-monitoring, and (5) relapse prevention. Both treatments will consist of 10 sessions within six months. All TAU sessions take place the outpatient smoking cessation clinic ("Stoppen met roken poli"; SRP) while BSCT sessions will partly take place at SRP (five sessions) and online via rokendebaas.nl (five sessions).

Main study parameters/endpoints:

The primary outcome parameter is sustained abstinence at 15 months from the start of the smoking cessation treatment. Abstinence is defined as having salivary cotinine levels < 20ng/mL. Participants with a cotinine-value of > 20ng/mL are regarded as smokers as well as participants who are lost to follow-up.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
The possibility of smoking cessation outweighs the minimal/eligible risks of (online) counselling in a controlled setting. The data collection will mostly be done using online questionnaires, which will ask for a small extra time (2 hours in total within 15 month). Compared to the usual smoking cessation treatment there will be no additional burden (e.g. physical examination) for this research except the cotinine salvia measurement at the 3 and 15 month follow up.

Study design

The main assessments are performed at entry and after 3, 6, 9, and 15 months. The biochemical measurements will be done when the patient is at SRP for a face-to-face session

in week 1 (Exhaled CO; baseline / month 0), week 14 (Exhaled CO & Cotinine level; month 3) and week 22 (Exhaled CO; month 5). All other assessments are done using online questionnaires which the participants can complete.

Intervention

Blended smoking cessation treatment (BSCT) is put into practice at the outpatient smoking cessation clinic (“Stoppen met roken poli”; SRP) which is part of the department of pulmonary medicine of Medisch Spectrum Twente (MST). The team of SRP consists of a pulmonologist and specially trained care professionals with a broad experience in face-to-face smoking cessation treatment. The face-to-face treatment as usual (TAU) resembles intensive counseling (SmokeStop Therapy) which has proven to be more cost effective than a standard, less intensive programme (Minimal Intervention Strategy for Lung patients [LMIS]) (Christenhusz et al., 2012). Additionally, in the currently running REDUQ Trial innovative smoking reduction techniques are being evaluated in an RCT in a population of smoking COPD patients (Pieterse, van der Palen, & Hagens, 2009). Several of these techniques are already implemented in the SRP. All these research projects were conducted in joint collaboration of the University of Twente and the MST, both partners in this research.

BSCT is developed in collaboration with Tactive which is the department for online addiction care and prevention at Tactus Addiction Treatment. Tactus Addiction Treatment currently offers six different online treatments aiming at alcohol, benzodiazepines, eating, cannabis, gambling, and smoking. The online smoking cessation treatment is carried out via the website http://www.rokendebaas.nl/. Rokendebaas.nl currently offers two types of online smoking cessation: an intensive treatment consisting 12 steps in 12 to 18 weeks and a 6 week short treatment. BSCT is based on the 6 week short treatment.

BSCT aims to improve the client-friendliness, quality and (cost) effectiveness of smoking cessation by combining elements of the face-to-face treatment as usual (TAU) of SRP and elements of the online treatment at rokendebaas.nl. Both TAU and BSCT are based on the following evidence-based techniques:

● pharmacotherapy

● cognitive behavioural therapy (CBT) like goal setting, formulating helpful thoughts, considering helpful behaviours, identifying decision moments, and making an action plan

● motivational interviewing

● self-control techniques and self-monitoring like pros and cons, self-monitoring of smoking behaviour in diary, description of the craving moments, identifying risky situations, and quitting as ultimate goal

● relapse prevention

In addition to TAU, BSCT includes daily online registration, online counselling and online homework via rokendebaas.nl. Both treatments will consist of 10 sessions within six months. All TAU sessions take place at SRP while BSCT sessions will partly take place at SRP (five sessions) and online via rokendebaas.nl (five sessions).

Contacts

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Eligibility criteria

Inclusion criteria

willing to quit smoking,

aged 18 or older,

current daily smoker

Exclusion criteria

no internet access,

not able to read or write Dutch language,

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	01-04-2015
Enrollment:	342
Type:	Unknown

Ethics review

Positive opinion

Date:	24-03-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47900
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4975
NTR-old	NTR5113
CCMO	NL50944.044.14
OMON	NL-OMON47900

Study results