Blended Smoking Cessation Treatment Evaluation of effectiveness of a blended face-to-face and web-based smoking cessation treatment versus treatment as usual (Randomised controlled trial)

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON47900

Source
ToetsingOnline

Brief title
LiveSmokefree-Study

Condition

- Other condition

Synonym
Tobacco addiction

Health condition

Addiction

Research involving
Human

Sponsors and support

Primary sponsor: Saxion Universtiy of Applied Sciences
Source(s) of monetary or material Support: Saxion University of Applied Sciences

Intervention

Keyword: blended, smoking, tobacco, treatment

Outcome measures

Primary outcome

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.

Secondary outcome

Secondery outcome parameters are:

Internet Skills

Smoking status

Nicotine dependence (Fagerström)

Smoking history

Attitude

Self-efficacy

Readiness to change

Stop Smoking History

Social support

Alcohol (mis)use

Substance (mis)use

MAP-HSS + special complaints of smokers

DASS21

Quality of Life (Euroqol 5D)

Middle evaluation of treatment

Long term evaluation of treatment

Adherence

Exhaled CO

User experience

Study description

Background summary

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 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 version derived from an face-to-face treatment and an online addiction treatment.

Study 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 explore mechanisms underlying smoking cessation, give advice for further improvement of smoking cessation, and to explore the benefit of blended treatment concerning patients

satisfaction and treatment costs.

Study design

The study is a randomized 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 randomization list.

Intervention

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).

Study burden and risks

The possibility of smoking cessation outweighs the minimal/eligible risks of (online) counselling in a controlled setting. BSCT may prove to be an alternative treatment option for smokers experiencing problems with quitting smoking, and a potentially greater number of individuals will be able to increase their chances of sustained cessation aided by BSCT. The data collection will mostly be done using online questionnaires.). Approximately 10 participants of the blended treatment group will be asked to take part in additional interviews (45 min). 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 15 month follow up.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

willing to quit smoking,
aged 18 or older,
current daily smoker
able to access internet websites and to receive emails

Exclusion criteria

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
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-05-2015
Enrollment:	344
Type:	Actual

Ethics review

Approved WMO Date:	09-04-2015
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	28-07-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	21-07-2016
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	10-07-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	20-08-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 27150
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL50944.044.14
OMON	NL-OMON27150