BLENDED SMOKING CESSATION TREATMENT

Gepubliceerd: 24-03-2015 Laatst bijgewerkt: 15-05-2024

Ethische beoordeling	Positief advies
Status	Anders
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27150

Bron
NTR

Verkorte titel
LiveSmokefree-Study

Aandoening

smoking
tobacco
treatment
blended
roken
stoppen
behandeling
tabak

Ondersteuning

Primaire sponsor: Saxion University of Applied Sciences
Academie Mens & Maatschappij
M.H. Tromplaan 28
7513 KB Enschede
Overige ondersteuning: Saxion University of Applied Sciences
Academie Mens & Maatschappij
M.H. Tromplaan 28
7513 KB Enschede

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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).

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

willing to quit smoking,

aged 18 or older,

current daily smoker

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

no internet access,

not able to read or write Dutch language,

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Anders
(Verwachte) startdatum:	01-04-2015
Aantal proefpersonen:	342
Type:	Onbekend

Ethische beoordeling

Positief advies

Datum:	24-03-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 47900
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4975

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

Resultaten