Effectiveness of an online smoking cessation self-help intervention. A randomized clinical trial.

Submission date	Recruitment status No longer recruiting	Prospectively registered		
12/09/2005		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
12/09/2005 Last Edited	Completed Condition category	☐ Results		
		Individual participant data		
28/01/2009	Mental and Behavioural Disorders	☐ Record updated in last year		

Plain English summary of protocol

Not provided at time of registration

Study website

http://www.stoppenmetrokenonderzoek.nl/home.html?where=home

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Study objectives

Compared to an online smoking cessation brochure, does participation in an online self-help smoking cessation program lead to:

- 1. A greater percentage successful quitters, three and six months after the start of the intervention
- 2. A greater percentage of quitting attempts

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Smoking cessation

Interventions

The online self-help smoking cessation program consists of three components:

- 1. Smoking cessation module containing exercises which are based on cognitive behavioural therapy
- 2. Discussion forum
- 3. State-of-the art information and tips about smoking cessation.

The control group gets access to an online smoking cessation brochure ('Quit smoking: why and how') which advises on smoking cessation and gives information about withdrawal symptoms. Each intervention can be used in accordance with their needs. Both interventions are developed by STIVORO.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

- 1. Abstinence
- 2. Smoking in the last 7 days (point prevalence)
- 3. Incidence of quitting attempts of 24 hours or longer

Secondary outcome measures

- 1. Decrease of the daily cigarette consumption
- 2. Number of quitting attempts of 24 hours or longer
- 3. Stage transition in the stage-of-change (motivational stage)

Overall study start date

01/08/2005

Completion date

31/07/2007

Eligibility

Key inclusion criteria

- 1. Patients that are 18 years or older
- 2. Currently smoking cigarettes or rolling tobacco
- 3. Intend to guit smoking within a month
- 4. Have access to the Internet

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

Target number of participants

1104

Key exclusion criteria

- 1. Patients that do not meet the inclusion criteria
- 2. Are already preparing a quitting attempt with the help of a counsellor or course
- 3. Are already preparing a quitting attempt with help of pharmacotherapy
- 4. Are involved in another (experimental) study with an interfering design or interfering goals

Date of first enrolment

01/08/2005

Date of final enrolment

31/07/2007

Locations

Countries of recruitment

Netherlands

Study participating centre

Trimbos Institute - The Netherlands Institute for Mental Health and Addiction

Utrecht Netherlands 3500 AS

Sponsor information

Organisation

Trimbos Institute (The Netherlands)

Sponsor details

Da Costakade 45 Postbus 725 Utrecht Netherlands 3500 AS

Sponsor type

Charity

ROR

https://ror.org/02amggm23

Funder(s)

Funder type

Funder Name

ZON-MW, The Netherlands Organization for Health Research and Development

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	22/01/2009		Yes	No