Comparing two e-Health programs for the GP-setting to target LSES and HSES smokers.

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21954

Source
NTR

Brief title
video & text computer tailoring; multiple tailoring

Health condition

smoking cessation, web-based tailored intervention

Sponsors and support

Primary sponsor: Maastricht University
Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

1. 7-day point prevalence abstinence from smoking (PPA);

2. Continued abstinence.

Secondary outcome

1. 24-hour point prevalence;

2. Smoking during the last month;

3. Number of quit attempts;

4. Overall tobacco consumption;

5. Self-efficacy;

6. Attitudes;

7. Intention to quit smoking.

Study description

Background summary

Background of the study:

SMOKING. Smoking tobacco is a major preventable cause of illness. Cessation of this addictive habit thus has many advantages. A challenge remains to reach smokers in general, and smokers not immediately motivated to quit and LSES smokers in particular.

Objective of the study:

STUDY 1: The main purpose of this study is to test the differential effects of a web-based text and a web based video driven computer tailored approach in LSES and HSES smokers (Study 1). The target group is not restricted to the usual target group (smokers motivated to quit within the next month), but includes a broader group with an intention to quit not all immediately but within the next six months.

The hypothesis is that the text driven messages will be more attractive and effective in motivating HSES smokers to quit, whereas video driven messages will be more attractive and effective in motivating LSES smokers to quit. For the LSES group we expect that the multiple video tailored condition will result in an 18% quit rate, and in an 8% quit rate in the text based condition, requiring 176 smokers in both conditions. For the HSES groups we expect quit rates of 22% in the text based condition and 12% in the video based condition, requiring

220 smokers.

STUDY 2: This study aims:

1. To assess the experiences of smoking patients concerning the two interventions;

2. To assess among smokers who have not yet quit and smokers who relapsed during the process their attitudes and intentions toward continued use after the study period;

3. To assess differences evaluation in between LSES and HSES users;

4. Assess the reactions of GPs and their
assistants concerning the protocol used in this study;

5. To explore the determinants of future adoption
of this protocol in GP practices.

STUDY 3: This study concerns and economic evaluation and will involve a combination of a cost-effectiveness analysis (CEA) and a cost-utility analysis (CUA). Modelling will be used to extrapolate outcomes to a lifetime horizon to also assess incremental costs per QALY gained. The budgetary impacts of each intervention will be estimated from insurer perspective.

Measurements at baseline, and follow-ups at 6, 12 months will be performed to test the effects of both programs.

The three conditions will be:

1. An experimental condition based on CT text advices;

2. An experimental condition based on CT video advices;

3. A control condition in which only a generic text advice will be provided.

Study population:

The target group will consist of smoking patients visiting the GP, aged 18+, willing to quit within 6 months. They need to have access to internet

and should be able to understand the dutch language sufficiently.

Participants will be recruited in two ways:

1. Through GP practices. Gp's and their assistants will attent smoking patient on the possibility to participate in the CT intervention;

2. Through massmedia. Advertisements will be placed in newspaper and on websites, in which smokers from the general public will be asked to participate in the CTY intervention.

Intervention:

Respondents in the two intervention groups will receive messages through 6 feedback sessions. Each feedback session will also result in a personalized summary report with a to-do action plan. This summary report can be printed for the
respondents in both conditions. The first session will be directly after the baseline questionnaire and will yield feedback on the main pros perceived, how to best obtain social support, how to increase
self-efficacy, and how to plan quitting.

Filling out the questionnaires takes about 30 minutes per session. There are no risks related to this study. Participation is voluntarily, without costs and participants have the right to stop at any moment.

Participants who completed the intervention and reported to have succesfully quit will be contacted for a cotinine test. A saliva specimen will be taken with a swap to test for cotinine. Participants will be visited on location for the test. No risks are related to the salivaswap or the cotininetest.

Study objective

The hypothesis is that the text driven messages will be more attractive and effective in motivating HSES smokers to quit, whereas video driven messages will be more attractive and effective in motivating LSES smokers to quit. For the LSES group we expect that the multiple video tailored condition will result in an 18% quit rate, and in an 8% quit rate in the text based condition. For the HSES groups we expect quit rates of 22% in the text based condition and 12% in the video based condition.

Study design

Baseline, 6 months, 12 months.

Intervention

Intervention:

Respondents in the multiple tailoring group (two experimental groups) will receive multiple computer tailoring feedback on different moments: Depending on a person's intention to quit smoking and the readiness to set a quit date within a month, respondents will receive personalized information on a number of occasions. Measurements at baseline, and follow-ups at 6, 12 months will be performed to test the effects of both programs. At the end of the baseline questionnaire, respondents are asked to fill in whether they are planning to quit within the following month. Depending on their answer, respondents are allocated to one of the two possible routing of the program.

Respondents with the intention to quit within the following month will follow route 1. Respondents are asked to choose a quit date and are invited seven days before their quit date to participate in the second session of the program. Respondents subsequently receive an invitation for the third session three days after their quit date. Additionally, respondents will receive an invitation for the fourth, fifth and sixth feedback sessions two, four and eight weeks after their chosen quit-date.

Respondents not intending to quit within the next month will follow route 2. One month after the baseline questionnaire respondents will be invited by the program to follow the second session. At session two they are asked again to indicate their intention to quit within the following session. Respondents prepared to quit are subsequently directed to route 1, as described above. Respondents not prepared to quit will receive their last invitation for the third session one month later.
Six and twelve months after filling out the baseline questionnaire, all respondents of the three conditions are asked to complete the follow-up measurements.

Respondents in the group that will receive usual care (control group) will receive no intervention but a generic text advice and only fill in the questionnaires at baseline, at six week follow-up and at six and 12 months follow-up.

Contacts

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Eligibility criteria

Inclusion criteria

1. Smoke;

2. Are 18 years or older;

3 Are able to understand Dutch sufficiently.

Exclusion criteria

1. Do not smoke;

2. Are younger than 18 years;

3. Are not able to understand Dutch sufficiently;

4. Respondents that refuse to sign the informed consent form are also excluded from participation.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2010
Enrollment:	1500
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL2954
NTR-old	NTR3102
Other	ZonMw : 200110007
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A