Effectiveness and feasibility of a web-based multiple tailored smoking cessation programme and tailored counseling by practice nurses

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A 10% point prevalence abstinence in the control condition (usual care) is expected. The web-based multiple tailored smoking cessation programme alone is expected to yield an additional 10% of abstinent respondents, while the combination of multiple...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27206

Bron
NTR

Verkorte titel
Multiple tailoring and counseling study

Aandoening

EN: Smoking behavior, smoking
NL: Rookgedrag, roken

Ondersteuning

Primaire sponsor: KWF Kankerbestrijding
Overige ondersteuning: KWF Kankerbestrijding

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main outcome parameters include:
- quit attempt
- point prevalence abstinence
- continued abstinence.

Toelichting onderzoek

Achtergrond van het onderzoek

Background of the study:

The smoking of tobacco continues to be a major preventable cause of illness (including several types of cancer) and premature death. Quitting smoking therefore improves smokers' life expectancy and quality of life. People surrounding the smoker benefit as well, as passive smoking rates decrease. In order to stimulate and aid smokers to quit, many different smoking cessation interventions have been developed. Stand-alone interventions have often limited success, suggesting multi-faceted approaches. Multiple tailored programmes and advice by general practitioners (GPs) concerning smoking cessation have proved to be effective stand-alone interventions.
However, multiple tailoring concerning smoking cessation is not offered to the general public and GPs indicate they are not using their full potential when it comes to smoking cessation advice to their patients. Practice nurses are a promising alternative, but so far it is not clear whether their advice is as effective as that of a GP or whether this approach will be adopted by general practice.

Objective of the study:

The main goal of this study is to test whether offering a web-based multiple computer-tailored programme and the additional effect of a tailored counseling protocol for practice nurses to adult smokers wanting to quit within six months (preparer or contemplator), results in a significant higher percentage of quit attempts, higher rates of point prevalence abstinence and of sustained abstinence compared to usual care in general practice.

Study design:

Randomized controlled trial (RCT).

Study population:

1200 healthy smoking adults (>= 18 years), motivated to quit smoking within the next six months (contemplators and preparers) and able to understand Dutch sufficiently.

Intervention:

Respondents in the multiple tailoring group (first experimental condition) will receive multiple computer tailoring feedback on four moments: baseline, six weeks, six months and two days after the quit date they set at baseline. At 12 months follow-up they will be asked to fill out one last questionnaire.
Respondents in the multiple tailoring and counseling by practice nurses group (second experimental condition) will receive multiple tailoring as in the first experimental condition, with an additional counseling meeting with a practice nurse. After receiving the first tailored feedback, respondents will be prompted to make an appointment with the practice nurse in their general practice for a counseling session. At 12 months follow-up they will be asked to fill out one last questionnaire.
Respondents in the group that will receive usual care (control group) will not receive any intervention and only fill in the questionnaires at baseline, at six week follow-up and at six and 12 months follow-up.

Primary study parameters/outcome of the study:

The main outcome parameters include quit attempt, point prevalence abstinence and continued abstinence.

Secondary study parameters/outcome of the study:

Secondary study parameters are overall tobacco consumption, self-efficacy, attitudes and intention to quit smoking.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

Participants in both experimental conditions will be offered four tailored feedback messages. To obtain this feedback, participants have to fill out a questionnaire at multiple points in time (at baseline, six weeks, six months and two days after the set quit date).
For the multiple tailoring only group, all four advices are internet-based and will be displayed on the participant's screen immediately after filling out the questionnaire. For the second experimental group, the second tailored advice is replaced by a tailored counseling session by a practice nurse. At 12 months after baseline, respondents are again asked to fill out an online questionnaire.
Participants in the control group will fill out questionnaires at baseline, six week, six and 12 months follow-up, without receiving any type of feedback.
Respondents' self-report to have refrained from smoking will be biochemically validated by means of a saliva swap/cotinine test at 12 months follow-up.
Participation in this study is voluntarily and without any risk.

Doel van het onderzoek

A 10% point prevalence abstinence in the control condition (usual care) is expected. The web-based multiple tailored smoking cessation programme alone is expected to yield an additional 10% of abstinent respondents, while the combination of multiple tailoring and tailored counseling by a practice nurse is hypothesized to result in another 10% increase in point prevalence abstinence.

Onderzoeksopzet

Baseline, 6 weeks, 6 months, 12 months.

Onderzoeksproduct en/of interventie

Respondents in the multiple tailoring group (first experimental condition) will receive multiple computer tailoring feedback on four moments: baseline, six weeks, six months and two days after the quit date they set at baseline. At 12 months follow-up they will be asked to fill out

one last questionnaire.

Respondents in the multiple tailoring and counseling by practice nurses group (second experimental condition) will receive multiple tailoring as in the first experimental condition, with an additional counseling meeting with a practice nurse. After receiving the first tailored feedback, respondents will be prompted to make an appointment with the practice nurse in their general practice for a counseling session. At 12 months follow-up they will be asked to fill out one last questionnaire.

Respondents in the group that will receive usual care (control group) will not receive any intervention and only fill in the questionnaires at baseline, at six week follow-up and at six and 12 months follow-up.

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Respondents are included in the study when they:

1. Smoke

2. Are 18 years or older

3. Are able to understand Dutch sufficiently.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Respondents are excluded from the study when they:

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.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	22-04-2009
Aantal proefpersonen:	1200
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	23-06-2008
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1303
NTR-old	NTR1351
Ander register	: KWF 2007-3834
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A