Using nicotine patches to support smoking cessation among adolescents.

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Rationale: There is increasing evidence that Nicotine Replacement Therapy (NRT) may help adolescents to successfully quit smoking. However data on the effectiveness and safety of NRT among adolescents are limited and a large clinical trial of...

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

Samenvatting

ID

NL-OMON22696

Bron
Nationaal Trial Register

Aandoening

Smoking adolescents.
Jongeren die roken.

Ondersteuning

Primaire sponsor: Utrecht University
Overige ondersteuning: The Netherlands Organisation for Health Research and Development
(ZonMw)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main primary endpoint will be prolonged abstinence 6 months after the quit date. In addition, the co-primary endpoint is abstinence 12 months after the quit date.

Toelichting onderzoek

Achtergrond van het onderzoek

N/A

Doel van het onderzoek

Rationale:

There is increasing evidence that Nicotine Replacement Therapy (NRT) may help adolescents to successfully quit smoking. However data on the effectiveness and safety of NRT among adolescents are limited and a large clinical trial of nicotine replacement therapy is warranted to be more conclusive about the effects of NRT among adolescents. The present study will be conducted in response to this need.

Objective:

The main aim of this study is to determine the effectiveness and safety of nicotine replacement therapy (NRT) in achieving long-term smoking cessation among young smokers aged 12 up to and including 18 years. Other aims of this study are to investigate the mediating and moderating processes through which NRT has an effect on smoking cessation.

Onderzoeksopzet

First, pretreatment measurements will take place during the meeting, in which we will measure nicotine dependence (using a scale derived from the mFTQ and the HONC), number of cigarettes adolescents smoke, general craving (Dijkstra & Borland, 2003), current craving (Heishman et al., 2003), latency to craving (DiFranza et al., in press), cue-induced craving (DiFranza et al., in press), number and duration of quit attempts, positive emotions about cessation, self-efficacy (Kremers et al. 2001), support of friends and family, perceived pro's and cons of smoking, motivation to quit smoking, depressive symptoms (Kandel & Davies, 1982), impulsivity (EATQR, Capaldi & Rothbart, 1992), physical activity, and alcohol and drug use.

Second, questionnaires during the treatment period and the two follow-up questionnaires consist of most of the previous mentioned measurements, namely current craving, positive emotions about cessation, self-efficacy, support of friends and family, motivation to quit smoking, depressive symptoms, physical activity, and alcohol and drug use. In addition, withdrawal (WSWS, Welsh et al., 1999), compliance, relapse, weightloss/increase in weight and side effects were also measured.

Onderzoeksproduct en/of interventie

One week before starting the treatment period participants will attend a meeting where they will receive information about this study, a short behavioural intervention aiming at quitting smoking and instructions for the use of NRT. At the end of this meeting, participants will receive a package of nicotine or placebo patches sufficient for the whole treatment period. Every morning a new patch is put on a clean, dry area of the skin. The nicotine doses and treatment duration will be determined according to the instructions of the producer on basis of the participant's intensity of smoking (number of cigarettes a day). This means that adolescents in the treatment condition who smoke more than 20 cigarettes a day will receive a higher nicotine patch dose and will continue use for 9 weeks (3 weeks TTS21, 3 weeks TTS14 and 3 weeks TTS7), whereas adolescents in the treatment condition who smoke less than 20 cigarettes a day will use a lower dose for a period of 6 weeks (3 weeks TTS14 and 3 weeks TTS7). The instruction for placebo patches is exactly the same.

The treatment period starts on monday the week after the meeting. Participants have to fill-out six online questionnaires, namely during the first quit day, and next during the 3rd day, the 5th day, the 7th day, the 14th day, and for the last time the first day after finishing treatment.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Not having a major physical health problem;

2. Smoking at least 7 cigarettes a day;

3. Having parents who are aware of their smoking behavior;

4. Motivated to quit smoking;

5. Aged from 12 up to and including 18 years.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Pregnancy, lactation;

2. Chronic skin conditions;

3. Current use of NRT or other smoking cessation medication (e.g. bupropion and Chantix);

4. Hypersensitivity to any ingredients in the patches.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	31-01-2011
Aantal proefpersonen:	360
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	22-08-2011
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	NL2885
NTR-old	NTR3031
Ander register	ZonMw / MEC University Medical Center Utrecht : 200110005 / 10-045;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A