Using nicotine patches to support smoking cessation among adolescents.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22696

Source
NTR

Health condition

Smoking adolescents.
Jongeren die roken.

Sponsors and support

Primary sponsor: Utrecht University
Source(s) of monetary or material Support: The Netherlands Organisation for Health Research and Development
(ZonMw)

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

A first secondary endpoint includes mediating effects of changes in nicotine dependence symptoms, craving, withdrawal symptoms, negative affect, hunger, and perceived self-efficacy. Also, we will check for possible moderating effects of demographic characteristics (e.g. age, gender, educational level, and ethnicity) and smoking characteristics (e.g. severity of nicotine dependence, number of cigarettes a day).

Study description

Background summary

N/A

Study objective

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.

Study design

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.

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-01-2011
Enrollment:	360
Type:	Actual

Ethics review

Positive opinion

Date:	22-08-2011
Application type:	First submission

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	NL2885
NTR-old	NTR3031
Other	ZonMw / MEC University Medical Center Utrecht : 200110005 / 10-045;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A