Using nicotine patches to support smoking cessation among adolescents.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON34738

Source
ToetsingOnline

Brief title
NRT for young people

Condition

- Other condition

Synonym
smoking

Health condition

(stoppen met) roken

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Utrecht
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: effectiveness, nicotine replacement therapy, RCT

Outcome measures

Primary outcome

Main primary endpoint is abstinence at 6 months after quitting, and a co-primary endpoint of abstinence at 12 months after quitting.

Secondary outcome

A first secondary endpoint includes mediating effects of changes in nicotine dependence symptoms such as 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). Finally, the acceptability and possible side effects of NRT are secondary endpoint.

Study description

Background summary

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.

Study 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. Also the acceptability and possible side effects of NRT will be measured.

Study design

A double blind, randomized, placebo-controlled trial will be conducted testing the effectiveness of nicotine patch therapy in comparison to a placebo condition.

Intervention

Participants will be recruited and randomly assigned (after stratification for gender and for intensity of smoking) to one of two conditions: (1) an active nicotine patch condition, and (2) a placebo patch condition (the control condition). The period of treatment will be about 6 to 9 weeks, depending on the number of cigarettes they smoke. Every day they will use a new patch (nicotine or placebo) with declining doses.

Study burden and risks

First, all participants will receive a behavioral intervention and will receive instructions for the use of NRT, which will last about 2 hours. During the treatment they have to fill-out 6 online questionnaires, which will each last about 15 minutes. Questionnaires can be filled-out at home. Also two more online questionnaires will take place at 6 and 12 months after quitting. Finally, to validate self-reported measures of abstinence, both at the 6 and the 12 month follow up measurement, a random selection of about 1/3 of the participants who reported to be abstinent for at least 7-days will receive a saliva-based cotinine test. For this test the participants have to give a saliva sample. The burden associated with particpation is limited, because participants only have to fill-out some online questionnaires, which they can do at home. Besides, we will visit them at their home for the cotinine test. The only risk for the participants is possible side-effects of the nicotine patches. However these are small and easy to prevent or diminish. Clearly, smoking cessation will be the main benefit for participants.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1) not having a major physical or mental health problem, 2) smoking > 10 cigarettes a day, 3) having parents who are aware of their smoking behaviour, 4) a minimal score of 6 on the modified Fagerstrom Tolerance Questionnaire (mFTQ), 5) planning to quit smoking within 1 à 2 months, and 6) aged from 12 upto and including 18 years.

Exclusion criteria

Pregnancy, lactation, chronic skin conditions, current use of NRT or other smoking cessation medication (e.g. bupropion and Chantix).
Taking narcotics, antidepressants, anxiolytic drugs, xanthine-derived bronchodilators, sympathomimetic agents, alpha-adrenergic blocking agents, St John's Wort, kava-kava or caffeine containing products prior to the start of the study.
Hypersensitivity to any ingredients in the patches.

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

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

Medical products/devices used

Product type:	Medicine
Brand name:	Nicotinell®
Generic name:	Nicotine Patches
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	04-02-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	28-09-2010
Application type:	First submission

Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	21-11-2011
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Not approved Date:	28-12-2011
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
EudraCT	EUCTR2009-017862-22-NL
CCMO	NL30912.041.10