

The implementation of 'Leuk Zonder Peuk', a smoking prevention program for primary school children

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|------------------------------|---------------------|
| Ethical review | Approved WMO |
| Status | Recruitment stopped |
| Health condition type | Lifestyle issues |
| Study type | Interventional |

Summary

ID

NL-OMON36403

Source

ToetsingOnline

Brief title

smoking prevention program (Leuk Zonder Peuk)

Condition

- Lifestyle issues

Synonym

Health promotion, smoking prevention

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Maastricht

Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: implementation, primary schools, smoking prevention, tailoring

Outcome measures

Primary outcome

The primary outcome measures will be: level of utilization of the Leuk Zonder Peuk website and ever smoking

Secondary outcome

Secondary outcome measures will be attitudes, self-efficacy, intention not to smoke, monthly smoking

Study description

Background summary

Smoking is a leading cause of morbidity and mortality. Tobacco use represents a major health risk and is a preventable cause of many chronic diseases, including coronary heart disease and various types of cancers. It is known from previous studies the earlier people start to smoke the more likely they will become regular smokers.

Especially the transition from primary school to secondary school is a period of risk to start smoking. In this period youngsters experience pressure and stress, and want to belong to a group. If someone offers them a cigarette they need positive attitudes, self-efficacy and skills to refuse that cigarette.

The present study will include primary school students from group 7 and will follow them to the first class of the secondary school. With computer tailored feedback we will give the youngsters (in the experimental group) information about their own attitudes, self-efficacy and social norms helping them not to start (experimenting with) smoking. Computer tailored feedback has shown to be effective in reaching adolescents, also in smoking prevention trials.

Furthermore, we will test the efficacy of a proactive approach using prompts in order to maintain interest and attention of the pupils. Several studies suggest that the utilization of a proactive approach will yield higher participation rates.

Study objective

The main goal of this study is to examine the effectiveness of a smoking prevention program for primary school children. The program should provide the pupils with attitudes, knowledge and skills to refuse cigarettes when they make the transition to secondary school.

In the intervention trial our goal is to assess what the effects of providing prompts will be on the intensity of use of Leuk Zonder Peuk in primary school children.

Study design

The design of the study is a Randomized Control Trial (RCT) with three equal groups (two experimental groups and one control group). The control group receives no tailored feedback reports. Both experimental groups will be compared with the control group and mutually (proactive group will be compared with the reactive group). One experimental group will be approach proactively to revisit a website, read their previous advices and get new advices. The other experimental group will not be stimulated to revisit the website.

Pupils in the proactive group receive three tailored feedback reports based on their answers in the online questionnaire. We will provide prompts to the pupils to encourage them to revisit the Leuk Zonder Peuk website. To prompt the pupils to (re)visit the web page we will use e-mails and SMS text messages.

Pupils in the reactive group will receive three tailored feedback reports, similar to those in the proactive group. Students in the reactive group are free to (re)visit the Leuk Zonder Peuk website, but they will not be prompted.

Students in the control group will not receive tailored feedback reports and will not be prompted to (re)visit the Leuk Zonder Peuk website. They only have to fill out the online questionnaire at the three measurement periods. Between the measurement periods they will not have access to the website of Leuk Zonder Peuk.

Intervention

The computer tailored intervention will consist of three groups: one control group and two experimental groups. All participants will fill out an online questionnaire regarding their attitudes, self-efficacy and other factors related to smoking. While the control group receives nothing, the two experimental groups will receive computer tailored feedback reports based on the answers they filled out in the online questionnaire. The difference between these two groups is that one group will be proactively prompted (via sms and e-mail) to revisit the website (prompt group), with information about smoking, whereas the other group will not be prompted (non-prompt group).

Study burden and risks

Participation in this study is voluntary and without any risk. The well-intentioned personal advices will only lead to positive health effects, when followed correctly. We will guarantee full confidentiality to our participants. The data will only be available to the researchers of Leuk Zonder Peuk.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)

Adolescents (16-17 years)

Children (2-11 years)

Inclusion criteria

Participants need to be primary school students in grade 7, who have access to a computer and internet at home

Exclusion criteria

- Parents refuse their child(ren) to participate
- Children refuse to participate
- Not being a primary school student in grade 7
- Special education schools
- Schools using the program 'ik (r)ook niet' (Stivoro)

Study design

Design

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

Primary purpose: Prevention

Recruitment

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|---------------------------|---------------------|
| NL | |
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 03-10-2011 |
| Enrollment: | 3600 |
| Type: | Actual |

Ethics review

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|--------------------|-----------------------------------|
| Approved WMO | |
| Date: | 10-05-2011 |
| Application type: | First submission |
| Review commission: | METC Z: Zuyderland-Zuyd (Heerlen) |

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 |
|-----------------|----------------|
| CCMO | NL32093.096.11 |