

Tobacco Use Prevention among Adolescents in primary Care

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Primary objective This study will serve as a pre-test of three strategies for GPs to opportunistically advice adolescents not to initiate or to quit smoking. The primary objective of the study is to assess the acceptability and feasibility of these...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON40708

Source

ToetsingOnline

Brief title

TUPAC

Condition

- Other condition

Synonym

Smoking

Health condition

Niet van toepassing; primair preventief onderzoek

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: COPD en Astma Huisartsen Advies Groep

Intervention

Keyword: Adolescents, General practice, Public Health, Tobacco control

Outcome measures

Primary outcome

Acceptability

Adolescents* evaluation of the strategy as assessed by a questionnaires at T1 (immediately after consultation) and T2 (two week follow-up):

- Condition 1: whether they found the advice clear, useful and relevant; what they particularly liked and disliked about the advice; whether they had given thought to the advice and how;
- Condition 2: condition 1 + how relevant they found the information and images regarding harmful consequences of smoking; what they particularly liked and disliked about the information and images; whether there was sufficient information or not enough (applies also for the images); whether the information covered the right topics and was new for them; whether they had given thought to the information and images and how
- Condition 3: condition 1 + how relevant they found the information on

specific situations which may be difficult to refuse an offer of a cigarette;
what they particularly liked and disliked about the information and formulating
an action plan; whether there was enough information or not enough; whether
they formulated an action plan (if applicable, why not); whether they had used
their action plan (T2) or were planning to use it in the future (T1 and
T2).

GPs* evaluation of the strategy as assessed by a questionnaire
post-intervention:

- How easy the strategy was;
- How effective they found it;
- How it could be improved;
- If they will continue to use the strategy.

Feasibility:

- The proportion of GPs approached and agreed to participate
- The proportion of adolescents approached and included into the study
- Subjects* response rates to the follow-up questionnaires
- Duration of intervention

Secondary outcome

Adolescent*s behavioural attributes (T0, T1 & T2):

- Intention to refrain from or to quit smoking
- Attitude towards smoking
- Perceived risk of smoking

- Social norm
- Perceived self-efficacy to resist smoking

GP-adolescent interaction:

- Video-recordings of consultation (random sample)

Adolescent*s socio-demographic characteristics (T0):

- Gender
- Age
- Educational level

Other measures:

- If parents were present during consultation (T1)
- Action plans (T1 condition 3)

Study description

Background summary

Background

Active smoking during adolescence has potential harmful effects on later social, emotional, and physical well-being. Extensive research shows a link between youth tobacco use and an increased health risk, including respiratory problems, coronary heart disease and cancer in later adulthood. In the Netherlands, most children in primary school and the early years of secondary school show a healthy behavioural lifestyle; the prevalence of young daily smokers is relatively low between the ages of 10 and 15 (0%-10%). However, among adolescents aged 16 to 19 year the prevalence increases to 12%-27%. Moreover, the majority of Dutch teenagers in this age range has experimented with cigarette smoking (50-61%) and around one in every three teenagers indicates having smoked in the previous four weeks (26%-35%). Therefore, this

period is crucial in the development of regular smoking behaviours. Moreover, 90% of the adult smokers start with smoking during adolescence, which indicates the importance of tobacco control interventions during adolescence.

General practice and smoking cessation intervention

General practice provides an unique setting to inform adolescents about the risks of smoking, motivate them to quit or not to start smoking and to offer quit smoking support. In general, current guidelines recommend GPs to proactively ask patients about their smoking behaviour, provide tailored information about risks, and to create and maintain records on the patients' current smoking status which allow GPs to address the patients' smoking status regularly in the future (NHG-Standaard Stoppen met roken). GPs are subsequently recommended to provide pharmacological and behavioural support to smokers who are motivated to quit or to refer them to a skilled practice nurse who provides quit smoking cessation. However, no guidelines for the treatment of tobacco use by adolescents are currently available in general practice.

Tobacco control among adolescents

Reducing the prevalence of smoking among adolescents can occur by two means: 1) increasing the number of adolescents who give up smoking, and 2) decreasing the number of adolescents who initiate smoking. In the last decade, several tobacco control strategies are developed and used in school-based intervention studies which resulted in a reduced smoking initiation rate among adolescents. However, adolescents who already regularly smoke are also interested in quitting; study findings show a lifetime cessation attempt prevalence of 71% among these young smokers. Yet, high relapse rates are common in this age group and studies show that adolescents' plans for quitting are often relatively vague and far in the future. Since adolescents indicate that they want to discuss their smoking behaviour with their healthcare provider, GPs could play a key role in tobacco use prevention among adolescents. Moreover, recent studies urge efforts to increase the proportion of physicians who screen and counsel adolescents about unhealthy behaviour, including smoking behaviour.

GP advice for smoking cessation

A meta-analysis of 17 studies has shown that a single tailored advice of a physician has small but significant effects on quit rates compared to no advice among adult smokers. It is however unknown if these effects are also present among adolescent smokers. A recent study showed that adolescents who had tried to quit smoking in the past 12 months were two times more likely to report having been asked about smoking or advised to quit by a healthcare professional. Therefore, it can be suggested that routinely providing such minimal interventions in general practice has beneficial effects on adolescent smoking abstinence and initiation.

Action plans

Recent years, multiple school-based tobacco prevention interventions aimed to increase skills among adolescents to resist social influences that encourage

smoking. An often used strategy learns adolescents how to refuse the offer of a cigarette in potential difficult situations by forming simple *if-then* plans, also called action plans or implementation intentions. This planning strategy is shown to be effective within school-based settings and reduces smoking initiation rates to 0% compared to a control condition in which 6% of the adolescents initiated smoking. In addition, this strategy is shown to increase abstinence rates among smokers to 19% compared to abstinence rates of only 2% in a control condition.

Threatening health messages

Other tobacco control interventions focus on increasing the perceived risks of adolescents with regard to the harmful consequences of smoking. Such interventions often include threatening health messages or images to increase the adolescent's perceived risk with regard to the harmful consequences of smoking. It is shown that adolescents rate this strategy as effective in preventing them from smoking, especially in younger adolescents. For this reason, it is suggested that threatening health warnings or images may play an important role in preventing smoking initiation among adolescents.

Study objective

Primary objective

This study will serve as a pre-test of three strategies for GPs to opportunistically advise adolescents not to initiate or to quit smoking. The primary objective of the study is to assess the acceptability and feasibility of these strategies as evaluated by GPs and adolescents.

Secondary objectives

The secondary objective of the study is to explore the short-term effectiveness of the proposed GP strategies on adolescent's attitude towards smoking, perceived self-efficacy to refrain from smoking, and on adolescent's intention to refrain from or to quit smoking.

It is hypothesized that all three strategies will lead to a more positive attitude towards smoking, perceived self-efficacy and a higher intention of adolescents to refrain from or to quit smoking. Yet, based on promising results of previous school-based interventions among adolescents, it is hypothesized that adolescents who form action plans with help of their GP will report the highest intention to refrain from or to start smoking compared to the other two strategies.

Study design

This study will serve as a pre-test of three GP strategies aimed at tobacco use prevention among adolescents. The results of this study will be used to refine the potential most effective, acceptable and feasible strategy and to proceed with a pragmatic (cluster) randomized controlled trial to examine the long-term

effectiveness of this strategy. The present study is built out of two parts, a quantitative and qualitative part.

Quantitative part

The first part of the study will consist of a quasi-experimental, pre-post study. This study will consist of three conditions in which GPs will routinely implement one of three strategies during consultations with adolescents aged 12 to 19 years. The three strategies correspond to current GP guidelines for smoking cessation care (condition 1 and 2) or are proven effective in a school-based setting (condition 3). The three strategies are aimed to routinely identify the smoking status of adolescents and to create awareness among the adolescents about potential harmful consequences of smoking and peer pressure with regard to initiating smoking. In each condition, the participating GP will implement one of three strategies in all consultations with adolescents during a period of three months. Because the present study will serve as a pre-test of these strategies, GPs will not be randomized and no control group will be included in the study. Yet, the first condition in which GPs will only provide the adolescent with a single advice will serve as a reference group. Figure 1 present the flow chart of the study.

Qualitative part

GPs who participate in the above-mentioned study will be asked to video-tape a sample of consultations with adolescents. The video-recordings will be used to assess the delivery of the strategies. Analyses of the communication will be used to provide more insight in the interaction between GPs and adolescent patients during the consultations. These insights may provide practical tools for GPs on how unsolicited conversations about smoking with adolescents may be best introduced and which reactions of adolescents can be anticipated

Intervention

The three tobacco control strategies will focus on routinely implementing tasks of GPs as outlined in the current guideline for the treatment of tobacco use of the Dutch College of General Practitioners (NHG-Standaard Stoppen met roken). Since recent studies have suggested that these tasks should be limited to asking about smoking, advising to quit and arranging follow-up support (*A-A-A approach*), the strategies outlined in the present study will follow this suggestion. Overall, GPs will identify the subjects' smoking status, inform the about risks of smoking or potential difficult situation to refuse a cigarette and advise to quit or not to start smoking. If the adolescents smokes, GPs will refer him/her to a practice nurse or to external smoking cessation support, as outlined in current GP guidelines.

Condition 1

During the intervention period, GPs in this condition will ask the subject about his/her attitude about smoking and provides a short advice. The smoking status will be registered in the electronic patient medical record by the GP

regardless of the subjects* reason of consultation. Depending on the smoking status of the subject the following scenario*s may occur within this condition:

Subject is a regular smoker (smokes at least once a week):

The GP advises to quit smoking, tailored to relevant characteristics of the subject.

Subject is a non-smoker, but has previously (tried to) smoke(d) at least once :

The GP advises not to initiate smoking or experiment with smoking anymore in the future. The advice will be tailored to relevant characteristics of the subject.

Subject is a non-smoker and has never smoked before:

The GP praises for not having smoked and advises not to initiate or experiment with smoking in the future, tailored to relevant characteristics of the subject.

Condition 2

Alike condition 1, GPs in this condition will assess and register the smoking status of the subject and provide a tailored advice based on the subject*s smoking status (see: condition 1). In addition, the GP in this condition discusses the potential harmful short- and long term consequences of smoking, using graphic images of these harmful consequences (see: appendix 1). These images are planned to be used as pictorial warnings on cigarette packages in the European Union.

Condition 3

Alike condition 1, GPs* in this condition will assess and register the smoking status of the subject and provides tailored advice based on the smoking status (see: condition 1). Subsequently, the GP will provide information about specific situations which may be difficult to refuse an offer of a cigarette (school break, party, etc.). In addition, the GP will suggest that an a priori action plan on how to refuse a cigarette in such situations can be very helpful. The GP instructs the subject to formulate an action plan using a questionnaire in the waiting room.

All three conditions

The parents (or relevant others) of the subject may also be present during the intervention. Although the smoking status of the parents is likely to be discussed as well, the GP will focus on the smoking behaviour of the subject.

Study burden and risks

This study is carried out in minors because the research questions specifically relate to adolescents aged 12 to 19 years. Participation entails minimal burden; adolescents complete three questionnaires (pre, post, and follow-up). The risks of participating in the study are negligible; the tobacco control

strategies are part of current evidence-based healthcare.

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

- Aged 12 to 19 (birth year 2001 to 1994)
- Willing to participate in study procedures
- Visiting the participating GP during the intervention period
- Able to read and write the Dutch language

Exclusion criteria

- Poor cognitive function
- Mental disorder
- Substance dependence
- Illiteracy
- If parents of minor subjects (aged 12 to 17 years) raise objections

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Prevention

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 09-10-2014

Enrollment: 180

Type: Actual

Ethics review

Approved WMO

Date: 06-10-2014

Application type: First submission

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

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	NL47714.058.14