

Evaluation of school-based counselling for tobacco use prevention and cessation among adolescents

Submission date 26/11/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 08/01/2009	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 08/01/2009	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Cluster randomised controlled trial of tobacco prevention and cessation among students in junior high grades

Acronym

SOTIS

Study objectives

To evaluate whether structured counselling conducted by school nurses, based on motivational interview and tailored on stage of tobacco use, achieves higher rates of tobacco abstinence than usual counselling, both among the youths undergoing the intervention and at the school level as a whole.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Regional Ethical Board in Stockholm gave approval on the 3rd September 2008 (ref: 2008/1081-31/5)

Study design

Cluster randomised controlled trial, with schools as units of randomisation

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet (Swedish only)

Health condition(s) or problem(s) studied

Tobacco use and dependence

Interventions

Structured individual counselling based on motivational interview and stage of tobacco use (1 - 5 sessions) versus usual nurse-administered counselling (one session, unstructured).

The opening counselling is scheduled to be approximately 5 minutes, depending on the average between the time needed for a non-user of tobacco and that needed for a user. The following

counselling occasions (1 - 4) are scheduled only for users, and determined to last an average of 15 minutes. The intervention is tailored on stage of use, therefore the total duration is not equal for all subjects. The follow-up will also vary, depending on time of recruitment (November 2008 - May 2009). All tobacco users undergoing intervention will be surveyed for tobacco use in May 2009.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Prevalence of abstainers from tobacco among students receiving the counselling, assessed by personal interview by the school nurses at each counselling occasion and at the end of follow-up (May 2009). Data will be registered on a paper data form (SOTIK4).

Secondary outcome measures

Prevalence of abstainers from tobacco in the whole students population, assessed during a survey employing a structured questionnaire (SOTIK3), administered to all students in a random sample of classes in each school, before the intervention start (October 2008) and at the end of the school year (May 2009).

Overall study start date

01/09/2008

Completion date

30/06/2009

Eligibility**Key inclusion criteria**

All students (aged 13 - 15 years, either sex) in junior high grades in the randomised school

Participant type(s)

Patient

Age group

Child

Lower age limit

13 Years

Upper age limit

15 Years

Sex

Both

Target number of participants

3200 (intervention and control arm together)

Key exclusion criteria

Refusal to participate

Date of first enrolment

01/09/2008

Date of final enrolment

30/06/2009

Locations

Countries of recruitment

Sweden

Study participating centre

Department of Public Health Sciences

Stockholm

Sweden

17176

Sponsor information

Organisation

Stockholm County Council (Sweden)

Sponsor details

Health Care Board (Hälso- och Sjukvårdsnämnden)

Box 6909

Stockholm

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102 39

cecilia.lindvall@sll.se

Sponsor type

Government

Website

<http://www.sll.se/>

ROR

<https://ror.org/02zrae794>

Funder(s)

Funder type

Government

Funder Name

Stockholm County Council (Sweden) - Public Health Grant (ref: HSN 0802-0318)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration