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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Maria Rosaria Galanti

Contact details
Department of Public Health Sciences
Karolinska Institutet
Stockholm
Sweden
17176
+46 (0)8 524 801 11
rosaria.galanti@ki.se

Additional identifiers

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 abstainers 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)

Primary study design
Interventional

Study design
Cluster randomised controlled trial, with schools as units of randomisation

Study type(s)
Quality of life

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(s)
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).

Key secondary outcome(s)

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).

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
13 Years

Upper age limit
15 Years

Sex
All

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration