

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

<b>Submission date</b> 26/11/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 08/01/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 08/01/2009	<b>Condition category</b> 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

**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

**Protocol serial number**  
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

**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