

# PREdictive value of the Self-triagecard and Chlamydia trachomatis positivity rate in vocational School students

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON27434

### Source

Nationaal Trial Register

### Brief title

PRESS-study

### Health condition

Chlamydia trachomatis, Neisseria Gonorrhoeae, sexual behaviour

## Sponsors and support

**Primary sponsor:** Public Health Service South Limburg

**Source(s) of monetary or material Support:** Public Health Service South Limburg

## Intervention

## Outcome measures

### Primary outcome

1. Chlamydia trachomatis positivity rate (prevalence) in both groups (intervention group and control group)

## 2. Effectivity of the self-triagecard:

Agreement between score of the self-triage card and Chlamydia trachomatis positivity rate

## 3. Feasibility of the self-triagecard:

Differences between the intervention and the control group in willingness to Chlamydia trachomatis testing and the difference in the intended test uptake

## 4. Chlamydia trachomatis serovar distribution of Chlamydia trachomatis positive vocational school participants to identify networks.

### **Secondary outcome**

Neisseria Gonorrhoea positivity rate (prevalence) in both groups

## **Study description**

### **Background summary**

Rationale:

Chlamydia trachomatis (CT) is the most prevalent bacterial sexual transmitted disease (STDs) with major public health consequences due to its frequent asymptomatic nature, its high prevalence among adolescents and its reproductive morbidity. The incidence of CT infections is currently increasing. Especially CT positivity rates on schools for low and intermediate education (vocational schools; in Dutch MBO/ROC - regionale opleidingscentra) seem to be high. In the present study we will address this potential risk group, vocational school students, to assess prevalence of CT. We will also test for Neisseria Gonorrhoea (GC) because of the increased prevalence of GC in the region South Limburg. This has never been studied before in the Netherlands. Both CT and GC tests will be done in FCU or SVS. Unfortunately, reluctance of at risk populations to attend appropriate care and fear of invasive gynecologic examination hamper effective STD control. Despite the presence of - easy to perform and acceptable - sampling methods (self-taken vaginal swab (SVS) and first catch urine (FCU)) and easy treatment (one dose azytromycin), identification of CT-infection (CT test compliance) is still hampered by the compliance to test for STD.

In the current study, we assess the feasibility of a self-triagecard to increase the CT-test rate in a potential high risk population (vocational school students).

We hypothesize that the self-triagecard is a usefull instrument for detecting CT infections.

Objective:

This study assesses the prevalence of CT and GC in vocational school students and assesses

the validity and feasibility of the self-triagecard as a method to efficiently identify and treat CT positive youth and limit the spread of CT.

#### Study design:

Intervention study. The intervention is filling in a 7-item self-triagecard and obtaining test advice accordingly.

#### Study population:

Vocational school students (men and women) age 18-29 years old.

#### Main study parameters/endpoints:

1. CT and GC positivity rate (prevalence) in both groups (intervention group and control group)
2. Effectivity of the self-triagecard: Agreement between score of the self-triage card and CT positivity rate
3. Feasibility of the self-triagecard:  
Differences between the intervention and the control group in willingness to CT testing and the difference in the intended test uptake
4. CT serovar distribution of CT positive vocational school participants to identify networks.

#### Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

The major advantage is an accurate diagnosis for CT and GC and free treatment. In addition a STD education at school is provided. Procedures to take biological specimens are minimally invasive.

Possible disadvantages are the time-investment to fill out questionnaires and to take a biological sample (FCU/SVS). Possible stigmatization is greatly reduced because all students in the classroom receive the same STD education. This study is deemed to be mainly conducted by classrooms since the expected contamination-effect of the intervention (self-triagecard) is large and this will dilute any existing effect. However, to avoid any stigmatization or group pressure, we provide the opportunity to fill out questionnaires and

take biological materials outside the school/class and return them the next day. Students without sexual experience will also be included in the study to reduce potential stigmatisation in classes.

To ensure that it is not obvious to other subjects who does test and who does not test, all subjects are asked to return the test tubes, whether filled or not, in the given coded envelope.

### **Study objective**

The self-triagecard is usefull as a method to efficiently identify and treat Chlamydia trachomatis positive youth and limit the spread of Chlamydia trachomatis

### **Study design**

Measurements take place once for each participant

### **Intervention**

Intervention consist of the self-triagecard with CT test advise.

Interventiongroup recieves: class-education, questionnaire and self-triagecard with diagnostic CT (and GC) test

Control group recieves: class-education, questionnaire and diagnostic CT/ (GC) test

## **Contacts**

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## Eligibility criteria

### Inclusion criteria

Vocational school students (men and women) age 18-29 years old

### Exclusion criteria

Below 18 years of age

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	03-11-2008
Enrollment:	1400
Type:	Anticipated

## Ethics review

Positive opinion	
Date:	18-08-2008
Application type:	First submission

## Study registrations

### Followed up by the following (possibly more current) registration

ID: 31773

Bron: ToetsingOnline

Titel:

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

Register	ID
NTR-new	NL1350
NTR-old	NTR1410
CCMO	NL19525.068.07
ISRCTN	ISRCTN wordt niet meer aangevraagd
OMON	NL-OMON31773

## Study results

### Summary results

N/A