PREdictive value of the Self-triagecard and Chlamydia trachomatis positivity rate in vocational School students (PRESS-study)

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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.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON31773

Source
ToetsingOnline

Brief title
PRESS-study

Condition

- Other condition
- Chlamydial infectious disorders

Synonym
Chlamydia trachomatis, Neisseria Gonorrhoea, STD, venereal diseases

Health condition

seksueel overdraagbare aandoeningen: gonorroe

Research involving
Human

Sponsors and support

Primary sponsor: GGD Zuid Limburg
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Chlamydia trachomatis, prevention, STD, triage

Outcome measures

Primary outcome

1. CT 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.

Secondary outcome

GC prevalence in both groups

Study description

Background summary

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 seem to be high. One Rotterdam study showed a prevalence of 24.5% compared to our STD outpatient clinic and general sexual active 15-29 year-olds 8.9% vs. 2.3%. STD testing on schools showed highly acceptable in international studies although CT positivity rates are not generalizable to Dutch schools. Based on a previous Dutch population study, a prediction rule for CT infection was assessed with potential value on different screening settings. Based on this prediction rule we designed a self-triagecard for individuals to assess their risk profile on CT.

Study 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

Design of the study:
This is an intervention study . We will randomize itwo groups:
group 1) intervention group
Questionnaire and self-triagecard with diagnostic CT and GC test
group 2) non-intervention group
Questionnaire and diagnostic CT test

Intervention

The intervention is filling in a 7-item self-triagecard and obtaining testadvice accordingly.

Study burden and risks

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 grouppressure, 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.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Vocational school student
Age 18-29 years old

Exclusion criteria

Younger than 18 years old

Study design

Design

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

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-10-2008
Enrollment:	1400
Type:	Actual

Ethics review

Approved WMO

Date:	25-06-2008
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 27434
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL19525.068.07
OMON	NL-OMON27434