Chlamydia Screening Implementatie.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29621

Source
NTR

Brief title
CSI

Health condition

Chlamydia infection; Sexually transmitted infection; Screening intervention;
Chlamydia infectie; Seksueel overdraagbare aandoening; Screening

Sponsors and support

Primary sponsor: Jan van Bergen
STI AIDS Netherlands
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Source(s) of monetary or material Support: ZonMW for programme implementation; Ministry of Health for evaluation

Intervention

Outcome measures

Primary outcome

Participation rate and positivity rate, per block of clusters in the three regions, comparing the intervention and control blocks per region, after multiple screening invitations. Estimated

population prevalence based on positivity rates and participant profile.

Secondary outcome

Acceptability and reasons for non-response; reinfection rates at 6 months after initial Chlamydia infections. Process indicators, such as time to participation, response after reminders.

Study description

Background summary

Summary (from report to ZonMW, 12/2010)
The Internet-based Chlamydia Screening Implementation (CSI) program started in three regions (Amsterdam, Rotterdam and South-Limburg) in the Netherlands in April 2008. Young adults (16-29 years old, N=315.000) were invited to participate in two consecutive screening rounds with an interval of 1 year, by using municipal population registers, in 2008/2009 and 2009/2010. The third round was only partly completed at the time of analysis for the current evaluation (november 2010).

Objectives of the evaluation:

The objectives of the evaluation of the CSI programme described here, were to assess the coverage of the program (numbers of persons reached and participating) and the number of Chlamydia cases found (positivity rates), in order to study the impact of screening on the prevalence of chlamydia and its long-term reproductive sequelae. The longer-term impact was predicted by using mathematical modeling of epidemiological outcomes, which were further used to estimate the long-term cost-effectiveness of implementation of such a screening program. A process-evaluation has been performed earlier and reported in 2010.

Design of the screening roll-out was adapted for the purpose of evaluation.

To optimize the possibilities of an unbiased impact evaluation, the intervention was implemented within a stepped wedge design, i.e. a gradual roll-out in subpopulations representative for the total population, enabling comparisons at different stages of the implementation. Subpopulations or ‘blocks’ (a number of clusters in the stepped wedge design) were stratified for expected risk for Chlamydia, by equal proportions of clusters labeled as high, medium- and low-risk based on population characteristics (income level, ethnicity, age group).

Chlamydia Screening proved feasible and was well-perceived.

The evaluation has demonstrated that Internet-based population screening for chlamydia is achievable in the Netherlands. Home testing was acceptable to participants, the MHS managed the roll-out locally very well, IT- and logistic processes were appropriately developed, laboratories delivered reports on time and GPs and STI clinics fulfilled their crucial role in achieving successful treatment of positives.

Participation rates were low from the start and decreased with multiple screening rounds.

However, the participation rate was much lower than the 30% expected beforehand. The participation was 16% in the first screening round, or 20% when adjusted to the target population of sexually active. The participation rate declined to 12% in the second and 9% in the third round. This decline was higher for repeated invites (10% and 8% in round 2 and 3), but was also visible in newly invited groups.

In the blocks of the stepped wedge design, participation rates in block A (completed 3 rounds) gradually declined over three rounds, from A1 to A2 to A3, in all three regions; block B1 had similar participation rates to A1, whereas B2 rates were in between A2 and A3. Block C (only entering the screening in round 1) had participation rates lower than A1 and B1 but higher than A2 and B2. This indicates the lower participation rates in consecutive rounds were caused by a combination of overall reduced motivation and lower response at repeated invitations.

In three screening rounds, 24% of invitees participated at least once. Among participants in the first round, 30% participated again when invited for the second round; of people who participated already twice, 51% participated again in the 3rd round.

Higher participation was seen in lower risk demographic groups but associated with higher risk behavioral factors.

Participation was higher among women, older age groups (20-29), Dutch invitees, in low community risk areas and in high SES postcode areas. Participation rates differed between geographic clusters, independent of individual determinants.
Multivariate regression models for participation, including behavioral data from an online general questionnaire, confirmed the above ‘low risk factors’ were significantly associated with higher participation, but on the other hand also showed that some behavioral ‘high risk factors’, such as being in a relationship less than 1 year or being with someone from non-Dutch origin, and having a history of STI were also associated with higher participation rates.

Rates for repeated participation in the first and second round showed similar associations with demographic and behavioral factors. Men, invitees from Turkish/Moroccan origin or

under 20 years old were less likely to participate twice, while people having a relationship shorter than 1 year, with a non-Dutch partner or concurrent partners were more likely to participate again.

The level of individual sexual risk (calculated by summation of various behavioral risk variables) was higher in CSI participants compared to the average of the general sexually active population of the same age group (from RNG national survey). The level of sexual risk among participants in round 2 and 3 was higher than that in round 1, suggesting self-selection of groups at higher risk after repeated invitations. In contrast, the community related factors were less predictive of participation in the second and third screening round.

Positivity rate was overall 4%, declining from round 1 to 2 to 3.

A positivity rate of 4.2% was found among participants in round 1. The positivity rates declined in round 2 (4.1%) and round 2 (3.5%), although declines were not reaching a significant level. The positivity rates were higher in women, young people under 20 years old, non-Dutch ethnic groups (especially Surinamese/Antillean) and high community risk areas. The decline over the screening-rounds was visible in all three regions, in male and female participants and specifically in higher-risk groups such as high community risk areas, low SES and non-Dutch ethnic groups. People participating repeatedly reduced their chance to get Chlamydia more obviously (reduction from 5-7% to 2-3%).
In the blocks of the stepped wedge design, for positivity rates in block A, a declining trend was seen over three rounds, from A1 to A2 to A3, in Amsterdam and Limburg (Rotterdam A2 lower); and B2 rates were slightly lower than B1 (not in Rotterdam). Block C had positivity rates slightly lower than A1 but higher than A2 and B2 (not in Amsterdam). This indicates the lower positivity rates in consecutive rounds may have been an effect of the screening and could potentially spill-over to areas not (yet) included in the screening.

In multivariate regression models, the same demographic factors associated with lower screening uptake were also associated with higher chlamydia positivity, such as younger age, non-Dutch ethnic background, high community risk, low SES, in round 1 as well as round 2. Geographic clusters were not independently associated with positivity rate. Persons who had tested chlamydia positive in the previous round had a higher chance tot test positive again, especially when they had not participated in the re-screening after six months.

Chlamydia positives were treated adequately, their partners treated or notified but 10% was positive again in a retest.

In a questionnaire afterwards, more than 90% of positives said to have visited a doctor and

86% had taken treatment within 2 weeks after receiving the result of the test. To whom applicable, the majority indicated that their current partner had also been treated at the same time or ex-partners notified, mostly by contacting them directly or (12%) making use of the website for this.
Test packages for rescreening 6 months after the first test result were returned by two third of positives and one out of ten tested positive again.
The prevalence of self-reported (recent) PID was estimated at 1.6-1.9% among women answering this part of the questionnaire, not different between the three rounds.

CSI’s contribution to Chlamydia case finding in the regions.

By comparison of CSI-outcomes with data from surveillance of STI centers and GP networks, we estimated that the number of people tested doubled in the CSI-regions during the CSI-programme. The proportion of Chlamydia cases found in CSI programme was estimated at more than a quarter of all cases found in the screening regions during the course of the first screening round. This proportion reduced to about a sixth in round 3.

Screening procedures were well perceived by participants.

Participants were positive about the set-up of the screening. They appeared to have made informed choices about participating; they were knowledgeable about Chlamydia and participated mainly for their own health. Although some Ct-positives thought the waiting times were long and 10% had some personal problems, more than 95% of them were happy to have participated. Two thirds of the participants were willing to participate again in the next round. In reality we saw that only one third actually did so in round 2.

Non-participants had often made an informed choice not to participate.

Almost 70% of non-participants had justified reasons for non-participation: not yet sexually active, recently tested or no (self-perceived) risk of infection. The non-participants were also quite appreciative of the set-up of the screening, but potential barriers for participation were a negative attitude towards the idea of sending a sample by post (26-29% in round 1 and 2 mentioned this) or taking a sample at home (12-20%); the information provided was not clear to everyone (8%). Nearly half of the non-participants were willing to be tested in the future, especially when their perceived risk-status would change. In reality only 5% did so in round 2.

The majority of participants and non-participants stated they were more likely to participate when the interval between screening rounds was one year rather than two or three.

The selection by risk score in South-Limburg worked well.

The selection by risk score applied in South-Limburg excluded 37% in round 1 (cut-off point at score 6), 20% in round 2 (cut-off lowered to 5) and 22% in round 3. The higher the risk score, the more likely one was to test positive. The number of invitations needed per Ct-positive case (NNI) was higher in Limburg than in the two cities, but the number needed to screen per case (NNS) was similar as a result of the selection. With lower participation rates (round 3) both NNI and NNS rise.

Population prevalence estimates suggest a small decline during 3 year CSI in the cities.

The prevalence of Chlamydia in the whole population of 16-29 years was estimated by extrapolation of the CSI-results towards the whole population in a weighted analysis taking into account the main demographic characteristics. The population prevalence was estimated at 2.8% in Amsterdam, 3.9% in Rotterdam and 2.4% in South-Limburg during the first round in 2008. The estimated population prevalence declined over the screening rounds in Amsterdam and Rotterdam (in South-Limburg only the maximum estimate declined). These declines, however, were not statistically significant.

Block C (not previously screened) of the stepped wedge design showed a higher prevalence than block A3 (two previous screening rounds). Although differences were not statistically significant, a similar effect was visible in each region, suggesting at least short term impact of two screening rounds on population prevalence. A decline in prevalence was only visible in the age groups 20-24 and 25-29 years.

There was no visible impact of one screening round on the estimated population prevalence.

Modeling 10 years CSI: Screening will reduce Ct-prevalence by 20% if participation rate in round 3 stabilizes.

A model simulating the spread of Chlamydia over a population with specified sexual contact networks, chlamydia prevalence and baseline testing and treatment rates fitted for the urban CSI regions (Amsterdam and Rotterdam) and for South Limburg was used to estimate the Ct-prevalence among men and women in the period of 2001 to 2019, comparing the baseline situation (only regular testing at STI centers and GPs) with a 10 years CSI-programme intervention from 2008 onwards. Participation rates during 2008-2010, as based on CSI-outcomes, caused a direct effect on the prevalence (from 2.8 to 1.7% in the cities and from 1.9% to 1.2% in S-Limburg). Assuming the participation rate in CSI in round 3 can be maintained for the multiple screening rounds thereafter, the prediction shows that after 10 years of CSI, the difference in Ct-prevalence between baseline and CSI would be 0.6-0.7%. If the participation rate would drop further in 4th and 5th rounds before stabilizing, the difference would be only 0.4-0.5%. Alternative scenario’s of screening, i.e. screening women only, screening younger age groups only (16-24 years) and biennial screening, were less

effective in bringing down the prevalence in the simulation.

Cost-effectiveness evaluation.

The reduction in the number of incident cases of Chlamydia as a result of 10 years CSI-programme, predicted in the epidemiological model (with participation rates sustained after 3 rounds), was used estimate the number of major outcomes averted (MOA), in a disease progression model calculating the number of complications (PID, chronic pelvic pain, infertility, ectopic pregnancy and neonatal pneumonia/conjunctivitis) prevented by the screening. This included MOA both (1) directly, by treating the chlamydia cases detected (reduction of 50% of sequelae) and (2) indirectly, due to a reduced number of future Ct-cases by bringing down the transmission. The costs of the CSI programme were balanced with costs of Ct-cases and MOA, i.e. treatment, health care, hospitalizations, as well as productivity losses due to illness.

The first results of this economic model showed that for the cities, the cost per Ct-case was estimated at 630 EUR and the cost per MOA at 3,700 EUR. For South Limburg the costs per Ct-case were estimated at 930 the cost per MOA at 5,600 EUR. Rough estimates of cost per QALY are discussed.

Based on these (first) estimates, we can conclude that CSI is unlikely to be cost effective. The costs per MOA are higher than shown in previous research.

Conclusion and recommendations.

Given the low and declining participation rates, only a small impact on population prevalence is predicted, which does not support nationwide roll-out of the CSI-project in its present form. Although a substantial number of chlamydia infections was detected, the evidence for effectiveness of this screening programme (as measured as a lasting decline in population prevalence) is limited and systematic, internet-based screening in 16-29 year old persons, as implemented, as well as the alternative scenario’s (only women, only people < 25 years, two-yearly screening) are unlikely to be cost-effective.

Other recommendations are:

1. Extension of the screening programme with one year was decided to facilitate a potential future (adjusted) screening programme, but at the same time it will provide more insight in participation rates of following screening rounds and the long term impact of annual screening;

2. More research is needed on the effectiveness of modified screening scenarios in the

intervention areas or mixed models of opportunistic and Internet-based Chlamydia screening, which could still contain valuable elements of the CSI-programme, such as the CSI-website and developed IT-programme, automatic re-testing of Ct-positives, facilitated (ex)partner notification;

3. Strengthening the care of Ct-infected individuals (including partner notification and prompt treatment) is needed in order to reduce the high rate of reinfections.

Study objective

Systematic, population-based Chlamydia Screening will be able to bring down the prevalence of infections and incidence of longterm complications, provided participation rates are sufficient.

Study design

Start: April 2008; first invitation round finishes in februari 2009.

Second invitation round from march 2009, third invitation from march 2010 and fourth inviation from march 2011.

Intervention

The Chlamydia Screening Implementation (CSI) is implemented by the Public Health Services in Amsterdam, Rotterdam and South Limburg. STI AIDS Netherlands is coordinating the programme. In collaboration with these implementing parties, the Centre for Infectious Disease Control at the National Institute for Public Health and the Environment (RIVM) provides process and impact evaluations. The background and set-up of CSI in brief is:

1. Design: Selective, systematic, population-based screening, repeated annually;

2. Invitees: 315,000 people aged 16 to 29 years, obtained from the population register. The intervention is rolled out in a stepped wedge design, in a cluster-randomised order (cluster = town area or village); for evaluation purposes, clusters are randomized in three blocks comparable in proportion of clusters with high/medium/low community risk level (estimated by population income levels, proportion non-dutch ethnic groups and proportion in targeted age-group);

3. One of the three blocks of clusters is the 'control' block, where the intervention is only rolled-out after the second screening invitation has been sent to other blocks;

4. All targeted individuals are invited to participate to the screening with a personal letter;

5. Invitation letters containing the website address (www.chlamydiatest.nl) and a personal login code are sent by mail. Communication and screening procedures are Internet based. Home sampling kits (urine or vaginal swab) can be requested through this website;

6. Actual intervention: Chlamydia test; advice and referral letter for treatment (for Chlamydia-positive participants and current partners). Opportunity to notify former partners anonymously through the website (www.chlamydiatest.nl);

7. Follow-up: Repeated invitation in three consecutive periods of 1 year. Chlamydia-positive participants automatically receive a test package 6 months after the first test;

8. Laboratory procedures: Nucleic acid amplification techniques (NAAT) in three regional accredited laboratories.

Contacts

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Eligibility criteria

Inclusion criteria

All young persons from 16 to 29 years old, registered in the municipal register in Amsterdam, Rotterdam and part of South Limburg (Parkstad, around Heerlen). In Amsterdam and Rotterdam where the population is dense, all sexually active people are encouraged to participate, but in South Limburg where the population is less dense, eligibility for screening depends on the individual's score on a questionnaire (including e.g. sexual history, residence area, ethnic background, and symptoms) related to the expected Chlamydia risk.

Exclusion criteria

Excluded are persons younger than 16 years or older than 29 years and persons living outside the 3 trial regions. In South Limburg individuals with a low score on the selection questionnaire can not proceed further with participation (i.e. requesting a chlamydia test kit).

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2008
Enrollment:	315
Type:	Anticipated

Ethics review

Positive opinion

Date:	16-09-2011
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL2924
NTR-old	NTR3071
Other	METC VUmc / ZonMw : 2007/239 / 12.400.0001;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

Van den Broek IV, Hoebe CJ, van Bergen JE, Brouwers EE, de Feijter EM, Fennema JS, Götz HM, Koekenbier RH, van Ravesteijn SM, de Coul EL. Evaluation design of a systematic, selective, internet-based, Chlamydia screening implementation in the Netherlands, 2008-2010: implications of first results for the analysis. BMC Infect Dis. 2010 Apr 7;10:89.
Van Bergen JE, Fennema JS, van den Broek IV, Brouwers EE, de Feijter EM, Hoebe CJ, Koekenbier RH, de Coul EL, van Ravesteijn SM, Götz HM. Rationale, design, and results of the first screening round of a comprehensive, register-based, Chlamydia screening implementation programme in the Netherlands. BMC Infect Dis. 2010 Oct 7;10:293.
Greenland KE, Op de Coul EL, van Bergen JE, Brouwers EE, Fennema HJ, Götz HM, Hoebe CJ, Koekenbier RH, Pars LL, van Ravesteijn SM, van den Broek IV.
Acceptability of the Internet-Based Chlamydia Screening Implementation in the Netherlands and Insights Into Nonresponse. Sex Transm Dis. 2011 Jun;38(6):467-474.
Eline LM Op de Coul, Hannelore M Götz, Jan EAM van Bergen, Elfi EHG Brouwers, Johannes SA Fennema, Christian JPA Hoebe, Rik H Koekenbier, Sander M van Ravesteijn, Lydia L Pars, Marianne AB van der Sande, Ingrid VF van den Broek. Who participates in the Dutch Chlamydia Screening? A study on demographic and behavioural correlates of participation and positivity. STI, in press.