Home-sampling as a Tool in the Context of *Chlamydia trachomatis* Partner Notification: A Randomized Controlled Trial

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Chlamydia trachomatis is the most common known bacterial cause of sexually transmitted infection (STI) (1, 2) and an important cause of infertility in women and possibly in men (3, 4). Following a remarkable decrease in reported cases of *C. trachomatis*, there was a 10–15% annual increase in cases reported to the Swedish Centre of Communicable Disease Control between 1997 and 2005 (5). Increase in the incidence of chlamydia have also been reported in many other countries (6). In Sweden, partner notification of chlamydia-infected individuals is mandatory under legislation passed in 1988 and 2004 (7). One possible reason for this increase in Sweden could be that partner notification may not be fully effective in preventing transmission.

The aim of the present study was to evaluate whether home-sampling could decrease the delay between the time when partner tracing starts (i.e. the meeting between the index patient and a counsellor) and the date of testing (sampling) of sexual partners, compared with conventional testing of partners at a clinic.

MATERIALS AND METHODS

This Swedish multicentre study included sexually transmitted disease (STD) clinics in 3 towns (Norrköping, Motala and Västervik), and all *C. trachomatis*-infected individuals presenting between October 2006 and July 2007 were eligible and were invited to enrol in the study.

The primary index patient, i.e. the first individual diagnosed with *C. trachomatis* in a new sexual network, was randomized to either a conventional partner notification mode (in which the partners were asked either by the index patient or by the counsellor to attend a clinic for *C. trachomatis* testing) or to a mode in which a test kit for home self-sampling was posted to them by the counsellor or distributed via the index patient. When sexual partners infected with *C. trachomatis* became index patients, they were assigned to the same study branch as the primary index patient.

At the STD clinics an informed consent was given to the partner tracer. Written information about the study was sent with the letter requiring the partner to be tested for *C. trachomatis* at a clinic, according to the law, if the index person was randomized or assigned to the conventional clinic-testing study branch. Current sexual partners who were prescribed antibiotics were excluded from participation.

Sampling of female partners was carried out via combined first-catch urine (FCU) and vaginal samples. Sampling of male partners was via FCU. The sampling date was taken as the end-point.

The Kaplan–Meier approach was used in a 1 minus the survival probability calculation for determination of the time-period from being elicited as a sexual partner until *C. trachomatis* testing. In an overall analysis the differences between the median times were tested using the log-rank test in the comparisons between conventional clinic-testing and home-sampling. Stratified analyses were carried out for gender and for different sexual partner situations, where the latter was defined in 3 categories: current partner; ≤ 30 days, and > 30 days since sexual contact. Differences in proportions were tested with Pearson's χ^2 test. The significance level was set to 5% for all tests carried out.

RESULTS

Of the 920 index patients eligible for contact tracing, 833 individuals (505 women and 328 men) were eventually enrolled. As the intention was to cluster randomize index patients, approximately half (n =451, 54%) were randomized, i.e. individuals believed at the counselling conversation to be a primary index patient. During the study period 447 sexual networks were revealed, comprising 2,390 individuals. After the initial exclusion, there were 1,693 partners, of whom 1,528 (90.2%) were confirmed to have been tested. Eventually 660 partners were enrolled; 461 men (age range 14–60 years, median age 21 years) and 199 women (age range 14–39 years, median age 20 years). Home self-sampling mode comprised 55 women (14–39 years, median age 19 years) and 160 men (15–60 years, median age 21 years). Conventional clinic-testing tracing mode comprised 144 women (14–38 years, median 20 years) and 301 men (14–49 years, median 22 years) (Fig. S1; available from: http://www.medicaljournals.se/acta/content/?doi=10.2340/00015555-1624).

Since cluster-randomization was not possible in practice, many index patients were randomized instead of being assigned to the appropriate study arm. This occurred in almost all sexual networks comprising more than 4 index patients (the range of index patients per sexual network was 1–49, median 2). All calculations are therefore performed at the individual level and not at the cluster level. Analyses of median times to test for *C. trachomatis* showed a significant difference between conventional mode and home-sampling mode: 15 days in the conventional group and 10 days in the home-sampling group ($p < 0.001$) (Table I, Fig. 1). The difference was seen in the separate male stratum (conventional clinic-test mode = 16 days, home-sampling = 11 days) and in the female stratum (conventional clinic-test mode = 14 days, home-sampling mode = 7 days). Among persons who had current partners there was no difference in time to test between the 2 test modes ($p = 0.903$), whereas there were significant differences for those who had had a sexual contact within 30 days (conventional

Table I. *Kaplan-Meier comparison of time from being elicited by the index patient to the counsellor as a sexual partner to C. trachomatis testing, between conventional clinic-testing and home-sampling mode*

		Conventional test mode			Home-sampling			Comparisons between conventional test mode and home-sampling mode
	Total *n*	*n*	Median days	*p*-value	*n*	Median days	*p*-value	*p*-value
All	660	445	15	–	215	10	–	<0.001
Men	461	301	16	0.094	160	11	0.115	<0.001
Women	199	144	14		55	7		<0.001
Sexual partner situation[a]								
Current partner[a]	62	40	10	0.005	22	8	0.982	0.903
≤30 days	159	99	14		60	8		0.038
>30 days	433	301	18		214	11		<0.001

[a]Missing values: $n=6$.

clinic-test mode = 14 days, home-sampling mode = 8 days) ($p=0.038$) and those with > 30 days since sexual contact (conventional clinic-test mode = 18 days, home-sampling mode = 11 days) ($p<0.001$) (Table I).

DISCUSSION

The present study showed that home-sampling reduced the delay to testing of partners compared with conventional testing at a clinic. This is in line with results from a study with self-sampling in a partner notification context in Denmark, where partner notification is not mandatory and no testing is required (8). The benefit of the home-sampling mode was seen when the partners for tracing were not current. The reason that current partners were tested early may be that index patients themselves were involved in notifying the partner, which emphasizes the importance of co-operation between counsellor and index patient, as also reported by Trelle et al. (9). The median time to test was 14 and 16 days, for women and men respectively, tested at a clinic in the present study, which was similar to the results from a retrospective case note audit by Horton on 844 index patients in England (unpublished data provided to Clarke) (10).

Despite the fact that all chlamydia-infected persons in the catchment area were referred to the clinic for partner notification, it was often not possible to determine whether a chlamydia-infected individual was not a primary index patient. The revelation of sexual partners to an index patient is a process, and was often not concluded at the first meeting between the index patient and the counsellor. Thus the study was neither a cluster randomized trial nor a strict randomized controlled study (all index patients were not randomized), since only 46% of index patients were assigned to their cluster. The limited opening hours of the clinics for those partners assigned for conventional clinic testing could favour those assigned to home-sampling and may not reflect the actual readiness for testing.

In conclusion, home-sampling of sexual partners appears to be a successful strategy to significantly reduce the delay in testing cases in which the partner to be tested is not a current partner. Current sexual partners of a chlamydia-infected individual were tested within a short time-period irrespective of the tracing mode.

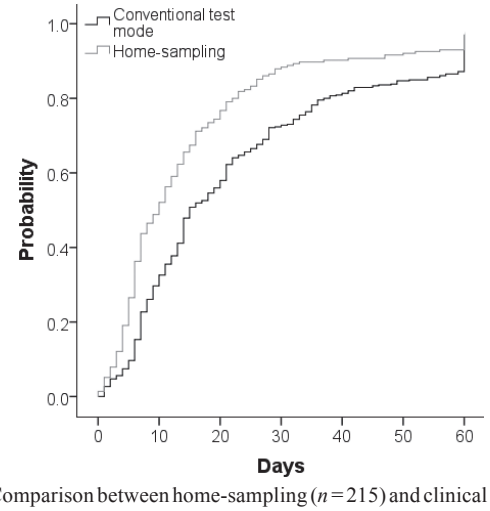

Fig. 1. Comparison between home-sampling ($n=215$) and clinical sampling mode ($n=445$) regarding the time from the date a sexual partner was revealed by the index patient at the counselling conversation to the date of testing. The Kaplan-Meier approach was used in a 1 minus the survival probability calculation.

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The regional research ethics committee of Linköping approved the study on 6 September 2006 (M 122-06).

The study was registered in a Swedish worldwide web site for medical research "FoU i Sverige" as document 27331, https://www.fou.nu/is/sverige/document/27331 in 2009 and at ClinicalTrial.gov number NCT01596946.

The authors declare no conflicts of interest.

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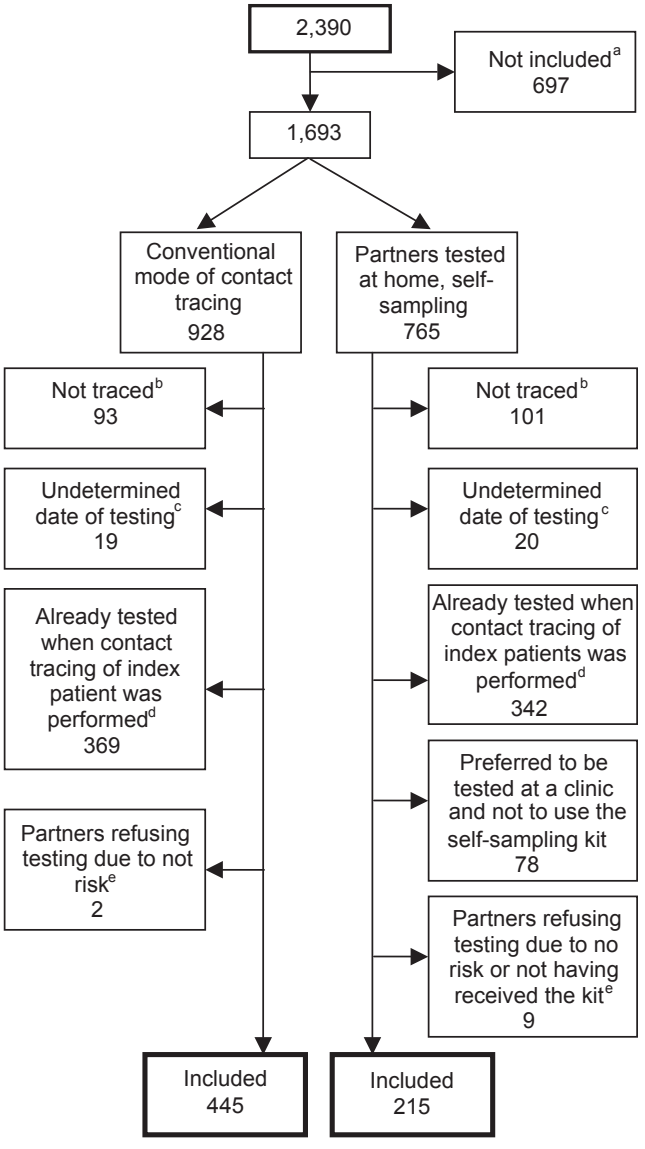

Fig. S1. Algorithm of partners ($n=2,390$) those eligible; those included ($n=1,693$); those primarily not included due to exclusion criteria ($n=697$); those partners secondarily excluded in the study for various specific reasons ($n=1,033$); and those included ($n=660$). [a]Not included because of exclusion criteria, such as living abroad ($n=86$); living in another county ($n=419$); being a man who has sex with men ($n=13$); randomization not properly performed or documented ($n=126$); index patients attending after inclusion of new sexual networks and not recognized as belonging to a prior network existing within the study, i.e. after primary index patients randomization had terminated ($n=50$); and 1 index patient did not want to participate in the study ($n=3$ partners). [b]Partners could not be identified, and thus could not be traced ($n=142$); although elicited partners were not traced because the counsellor deemed it implausible that the partner could be infected ($n=12$) or because the partner had died ($n=1$); partners not revealed by the index patient, but tested and *Chlamydia trachomatis*-positive and thus new index patients ($n=39$). [c]Partner performed the test, but the date of examination could not be determined ($n=39$). [d]Partners had already been tested at the time the index patient's eliciting of partners to the contact tracer had commenced ($n=711$). [e]Partners, when traced, claimed not to be at any risk of having contracted *C. trachomatis* ($n=4$); or the self-sampling kit was returned to sender or not delivered properly ($n=7$).