

A randomised controlled trial of computer-assisted interviewing in sexual health clinics

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ABSTRACT

Objectives To assess the impact of computer-assisted interview compared with pen and paper on disclosure of sexual behaviour, diagnostic testing by clinicians, infections diagnosed and referral for counselling.

Methods Two-centre parallel three-arm randomised controlled open trial. Computer-generated randomisation with allocation concealment using sealed envelopes.

Setting Two London teaching hospital sexual health clinics.

Participants 2351 clinic attenders over the age of 16 years.

Interventions Computer-assisted self-interview (CASI). Computer-assisted personal interview (CAPI). Pen and paper interview (PAPI).

Main Outcome Measures Diagnostic tests ordered, sexually transmitted infections (STI).

Secondary Outcomes Disclosure of sexual risk, referral for counselling.

Results 801, 763 and 787 patients randomly allocated to receive CASI, CAPI and PAPI. 795, 744 and 779 were available for intention-to-treat analysis. Significantly more diagnostic testing for hepatitis B and C and rectal samples in the CAPI arm (odds for more testing relative to PAPI 1.32; 95% CI 1.09 to 1.59). This pattern was not seen among CASI patients. HIV testing was significantly lower among CASI patients (odds for less testing relative to PAPI 0.73; 95% CI 0.59 to 0.90). STI diagnoses were not significantly different by trial arm. A summary measure of seven prespecified sensitive behaviours found greater reporting with CASI (OR 1.4; 95% CI 1.2 to 1.6) and CAPI (OR 1.4; 95% CI 1.2 to 1.7) compared with PAPI.

Conclusion CASI and CAPI can generate greater recording of risky behaviour than traditional PAPI. Increased disclosure did not increase STI diagnoses. Safeguards may be needed to ensure that clinicians are prompted to act upon disclosures made during self-interview.

Trial registration ISRCTN: 97674664.

Sexual health clinics combine treatment for sexually transmitted infections (STI) with preventive work (tracing partners, advising about risk reduction). These functions are guided by information about sexual behaviour disclosed by attenders. Experience gained in community-based surveys of sexual behaviour has indicated that the disclosure of stigmatised sexual behaviours may increase when individuals have the opportunity to provide information to a computer.^{1–3} Similar observations have been reported from sexual health clinics.^{9–12}

The consistency of these findings varies considerably across studies, some of which suggest that particular ethnic or age groups may respond differently,^{13–15} whereas other studies have highlighted inconsistencies between all forms of self-report and biomarkers.¹⁶ Computer-assisted self-interview (CASI) spares the interviewee the embarrassment of a face-to-face interview, makes it easier to introduce branching routes through a questionnaire, ensures all patients receive a standardised interview and offers greater scope to develop multilingual questionnaires.^{2, 3, 17–19} Greater internal consistency and fewer missed questions have been reported when using CASI compared with pen-and-paper questionnaires.^{9, 20} At present, face-to-face interviewing remains the norm in UK sexual health clinics despite growing evidence that individuals may prefer to disclose information about their sexual behaviour in ways they feel to be less threatening.²¹ Computer-assisted interviewing methods also offer the opportunity to save clinic time and to move to an electronic patient record (EPR), which are important for clinics implementing programmes of extended access and preparing for service-wide information technology developments within Britain's National Health Service.

The Computer Assisted Sexual Health Interviewing (CASHI) study was designed to investigate whether the increased disclosure associated with computer-assisted interviewing can deliver demonstrable benefits in relation to: (1) the investigation and diagnosis of STI; (2) the identification of other reproductive health issues for female attenders such as unplanned pregnancy and the need for emergency contraception; (3) referral to health advisors who undertake risk-reduction counselling. Qualitative research on the acceptability of computer use to patients and clinicians was also undertaken and is being reported separately.

METHODS

Subjects

The study was conducted at two large London sexual health clinics, the Mortimer Market Centre in a central London location, and the Courtyard Clinic, 9 miles away in south-west London. The Courtyard Clinic serves a younger population and offers more walk-in appointments. The Mortimer Market Centre is particularly favoured by gay men and offers more booked appointments. Male and female patients over the age of 16 years attending with a new clinical episode were eligible. Patients

were excluded if they had insufficient English or literacy to understand the recruitment process.

Interventions

Patients were randomly assigned to be interviewed in one of three ways:

1. CASI, using a tablet (touchscreen) computer in private. The electronic interview followed the format of the clinical proforma used by clinicians at each clinic for standard care. The patient would then be assessed by a clinician provided with a print-out generated from the interview.
2. Computer-assisted personal interview (CAPI), patient and clinician viewing the screen together, using the same interview as in CASI, but with data input by the clinician. On completion of the interview the clinician generated a print-out to place in the clinic notes.
3. Pen and paper interview (PAPI) with a clinician following the normal clinic practice of completing a proforma with the patient (usual care arm). The data from the clinic notes were subsequently transferred into same electronic format as the CASI and CAPI interviews by research staff.

The data collected in all trial arms were based on the existing clinical notes proforma in use at each clinic. Computer-assisted interviews were developed and administered using the questionnaire development system provided by the Nova Research Company (Bethesda, Maryland, USA).

Recruitment and randomisation

Recruitment alternated between male and female clinics at each site on a weekly basis. Recruitment started in June 2005 and closed in July 2006. One full-time researcher at each site approached consecutive patients in the waiting areas, inviting them to participate. Following patient consent, research staff opened sealed numbered envelopes prepared by the trial statistician to inform patients about their trial arm allocation. Randomly permuted blocks of varying size were used, stratified by site.

Clinical staff

Clinical staff at the two clinics involved in the study included all available nurse practitioners, junior doctors, staff grade physicians, specialist trainees and consultants. All staff were trained to use the electronic interview.

Laboratory testing

In this pragmatic trial, testing for *Neisseria gonorrhoeae*, *Chlamydia trachomatis*, *Trichomonas vaginalis*, hepatitis A, B and C and HIV was carried out according to established protocols in place at each clinic. The only variation was testing for *C. trachomatis* by nucleic acid amplification tests on throat and rectal samples and nucleic acid amplification tests for *N. gonorrhoeae* on rectal samples made available to male and female trial participants who disclosed rectal or pharyngeal exposure.

Outcome measures

The primary outcome measures were:

1. Patterns of STI diagnostic testing in each arm. Diagnostic testing patterns were classified as 'standard', 'standard with HIV test' or 'enhanced'. The 'standard' test comprised tests for gonorrhoea and chlamydia from urethral/cervical/urine samples, a test for trichomonas on a vaginal sample and a blood test for syphilis. 'Enhanced' testing included additional tests for hepatitis B or hepatitis C or rectal samples for gonorrhoea and chlamydia, reserved for participants disclosing higher risk behaviour.

2. STI diagnoses.

Secondary outcome measures were:

1. Uptake of testing for HIV, hepatitis B, hepatitis C, rectal gonorrhoea and chlamydia.
2. Rates of diagnosis of HIV, hepatitis B, hepatitis C, rectal gonorrhoea and chlamydia.
3. Identification of indications for post-coital contraception.
4. Referral to health advisers (sexual health counsellors).
5. Rates of disclosure of same-sex partners, concurrent relationships, multiple partners, involvement in sex work, non-use of condoms with casual partners and anal sex.

Sample size and statistical analysis

We calculated that 2300 patients would provide 80% power to demonstrate as statistically significant a 35% relative increase in enhanced screening from an assumed uptake of 20–27% or a 27% relative increase in STI diagnoses from a prevalence of 30–38%. The calculations were based on a significance level of 2%, reduced from the usual 5% level to account for the multiple testing arising from comparing three pairs of study arms.

Analysis was based on the study arm to which the patient was randomly assigned (intention to treat). The principal comparisons were the pairwise comparisons between study arms, with PAPI taken as the comparison arm as it is the current standard. The majority of outcomes are binary. For these the OR for one study arm relative to the other were used as the measure of effect, and these were adjusted for gender and clinic venue through logistic regression. For the first primary outcome (patterns of STI diagnostic testing), with three ordered categories, ordinal regression was used. The OR was also used as the measure of effect, calculated under an assumption of proportional odds. To measure the effect of an interview method relative to another for the behavioural outcomes, a summary OR was calculated, pooling information from seven outcomes. This was done using generalised estimating

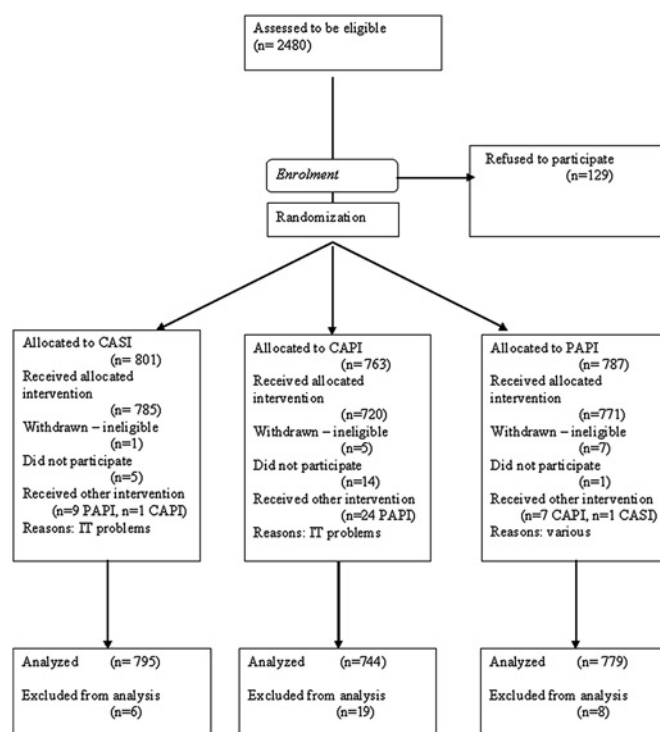


Figure 1 CASHI trial flow diagram. CAPI, computed-assisted personal interview; CASI, computer-assisted self-interview; PAPI, pen and paper interview.

Table 1 Demographic features of trial participants

	Mortimer market centre	Courtyard clinic	p Value
Patients randomly assigned	1079	1239	
Male	48.6%	48.8%	0.90
Non-UK origin	44.3%	32.3%	<0.001
Same-sex partner	27.5%	5.7%	<0.001
Age			<0.001
<25 years	28.9%	35.9%	
25–34 years	45.3%	46.1%	
>35 years	25.7%	17.9%	

equations, as was successfully applied to an earlier study to compare reporting between interview methods in the general population.²⁰ As a subsidiary analysis, OR were also calculated for each individual behavioural outcome, and testing for heterogeneity was performed to establish whether the difference between study arms was broadly similar across the seven behaviours or not. As a form of subgroup analysis, tests were carried out to see whether differences between arms varied by gender or by clinic.

RESULTS

Figure 1 shows the flow of patients through the study in each trial arm. The most common deviations from protocol were patients allocated to CAPI who received PAPI instead as a result of difficulties encountered by clinicians in using the CAPI programme.

Demographic features of 2318 subjects who participated (table 1), show patients at the Courtyard Clinic were significantly younger and patients at the Mortimer Market Centre significantly more likely to be of overseas origin or to report same-sex partners.

Primary outcomes

Testing for sexually transmitted infections

Screening tests for any STI were carried out at a significantly higher rate among patients in the CAPI arm compared with PAPI patients (OR 1.32; 95% CI 1.09 to 1.59) (see table 2).

Diagnosis of infection

Diagnosis of STI was highest in the CAPI arm (11%) but did not differ significantly between trial arms.

Secondary outcomes

Specific testing for hepatitis B (OR 1.65; 95% CI 1.28 to 2.13) and hepatitis C (OR 3.36; 95% CI 2.05 to 5.51) and rectal infections (OR 1.35; 95% CI 1.0 to 1.82) was conducted significantly more often in CAPI patients, whereas testing for HIV was significantly less in the CAPI arm (OR 0.73; 95% CI 0.59 to

0.90). There was no significant difference in the rates of diagnosis of these infections by trial arm. The number of women identifiable as potential candidates for post-coital contraception was significantly higher among CAPI patients (OR 2.14; 95% CI 1.46 to 3.13). Referral to health advisors did not differ significantly by trial arm (tables 3 and 4).

Table 4 displays secondary outcomes relating to the disclosure of risk behaviour. Of the seven risk behaviours selected before the study, three (having more than one partner in the past 3 months, having a history of concurrent sexual relationships and anal sex) were disclosed significantly more often in CAPI and CAPI than in controls.

A summary OR across all seven behaviours showed significantly higher reporting with CAPI (OR 1.41; 95% CI 1.20 to 1.65) and CAPI (OR 1.42; 95% CI 1.21 to 1.66) compared with PAPI, but no difference between CAPI and CAPI. A test for heterogeneity of the differences between arms across behaviours highlighted that differences were especially marked for the reporting of ever concurrent partnerships (see table 4). Excluding this behaviour, the summary OR were 1.21 (1.05 to 1.39) for CAPI and 1.26 (1.10 to 1.44) for CAPI compared with PAPI.

As a subgroup analysis we tested whether the differences between study arms varied by patient gender or by site across the various primary and secondary outcomes. We found only one statistically significant interaction, with a p value of 0.045, which may therefore have arisen by chance. The interaction found suggested that compared with PAPI, CAPI leads to more identifications of potential candidates for post-coital contraception among women at one site, but is similar to PAPI at the other.

Discussion

The CASHI study was designed to test the hypothesis, based on other studies^{9–12} that utilised CASI, that patients would disclose more sensitive and clinically useful information when offered the option of CASI, leading to more beneficial health outcomes. The odds of disclosure for seven key sensitive behaviours were found to be 40% greater when computer-assisted interviewing was compared with PAPI. Contrary to expectation, the CAPI interviews matched the CASI interviews for disclosure; the presence of a health worker did not reduce disclosure in the way that might be expected if social desirability was the major determinant of disclosure. The higher rate of diagnostic testing in the CAPI arm compared with the CASI arm, despite comparable disclosure of risky behaviour, was also unexpected. The extra testing observed did not lead to a higher rate of STI diagnosis. The lower rate of HIV testing in the CASI arm may be of concern to clinics aiming to encourage a high uptake of HIV testing among attenders.

The CASHI study goes beyond earlier studies of CASI,^{9–12} which have focused principally on disclosure, in extending its

Table 2 Primary outcomes—patterns of screening, STI diagnoses

Primary outcomes		PAPI		CAPI		CASI	
		N (%)	OR (95% CI)	N (%)	OR* (95% CI)	N (%)	OR* (95% CI)
Screening	Not tested	41 (5.3)	1	35 (4.7)	1.32† (1.09 to 1.59)	67 (8.4)	0.86† (0.72 to 1.03)
	Standard‡	169 (21.7)		148 (19.9)		189 (23.8)	
	Standard and HIV	370 (47.5)		301 (40.5)		325 (40.9)	
	Extended§	199 (25.6)		260 (35.0)		214 (26.9)	
Any STI positive test		78 (10.0)	1	82 (11.0)	1.12 (0.80 to 1.57)	80 (10.1)	0.96 (0.69 to 1.34)

*OR relative to pen and paper interview (PAPI) arm, adjusted for patient gender and recruitment clinic.

†Calculated under the proportional odds assumption, that is the higher the ratio the greater the proportion of patients tested more comprehensively.

‡Tests for gonorrhoea and chlamydia from urethral/cervical/urine samples, test for trichomonas on vaginal sample, blood test for syphilis.

§Indicates tests for hepatitis B or C, rectal tests for gonorrhoea or chlamydia.

CAPI, computer-assisted personal interview; CASI, computer-assisted self-interview; STI, sexually transmitted infection.

Table 3 Secondary outcomes—STI linked to high-risk behaviour, referral to health advisors, indications for emergency contraception

Secondary outcomes	PAPI		CAPI		CASI	
	N (%)	OR (95% CI)	N (%)	OR* (95% CI)	N (%)	OR* (95% CI)
1. STI targeted by enhanced screen†	45 (5.8)	1	43 (5.8)	1.01 (0.65 to 1.57)	37 (4.7)	0.74 (0.46 to 1.16)
2. HIV test uptake	540 (69.3)	1	512 (68.8)	0.98 (0.78 to 1.21)	498 (62.6)	0.73 (0.59 to 0.90)
3. HBV test uptake	127 (16.3)	1	180 (24.2)	1.65 (1.28 to 2.13)	134 (16.9)	1.02 (0.78 to 1.33)
4. HCV test uptake	22 (2.8)	1	66 (8.9)	3.36 (2.05 to 5.51)	26 (3.3)	1.17 (0.66 to 2.09)
5. Rectal sample taken	104 (13.4)	1	124 (16.7)	1.35 (1.00 to 1.82)	113 (14.2)	1.01 (0.75 to 1.37)
6. Possible indicator for EC‡ (women only)	49 (12.1)	1	65 (16.9)	1.49 (1.00 to 2.22)	90 (22.6)	2.14 (1.46 to 3.13)
7. Health advisor§ attendance	119 (15.3)	1	103 (13.8)	0.89 (0.67 to 1.19)	99 (12.5)	0.80 (0.60 to 1.06)

*OR relative to pen and paper interview (PAPI) arm, adjusted for patient gender and recruitment clinic.

†Hepatitis B virus (HBV), hepatitis C virus (HCV), rectal gonorrhoea, rectal chlamydia.

‡Unprotected vaginal sex in last week, or emergency contraception (EC) given as reason for attendance.

§The health advisor role includes counselling for safer sexual behaviour and partner notification.

CAPI, computer-assisted personal interview; CASI, computer-assisted self-interview; STI, sexually transmitted infection.

outcomes measures to clinician behaviour and subsequent health outcomes. The study supports the use of electronic formats to collect data from patients attending sexual health services in the UK. Although it was not able to demonstrate significantly improved health outcomes, CASI has shown that electronic formats encourage the disclosure of sensitive information and thus have the potential to improve patient management.

The following limitations apply to our findings:

1. Many different formats for electronic interviews are possible for gathering the same dataset, such as the wording of questions and whether respondents are given freedom to skip questions. Response rates are likely to vary with different electronic questionnaire formats.
2. Clinicians seeing patients recruited into the CASI and CAPI arms of the study were required to conduct consultations in a way that was new and different (and in the case of CAPI, rather unpopular). Had the study been conducted in an environment where these new approaches were more familiar and established, it is likely that more evolved working practices might have produced different results.
3. The power of the study to detect differences in STI diagnoses according to study arm will have been reduced by the 10% rates of STI among participants, which proved to be 20% lower than anticipated.

Our study is thus in broad agreement with earlier studies,^{9–12} which have demonstrated greater capture of sensitive information during computer assisted interviews and attributed this to a reduction in social desirability bias. By including the CAPI arm it became possible to examine separately the impact of computer

use per se and the impact of offering interview privacy on disclosure.

Two explanations should be considered for the high level of disclosure in the CAPI arm. First, patients knew information collected by CASI would be reviewed and discussed with them immediately afterwards by a clinician, so limiting the privacy element. Second, the impact of social desirability bias in a clinical setting might be substantially lower than that observed in community-based surveys of sexual behaviour. We suspect the overriding factor was the rigid structure of the electronic interview, which affords less scope than the pen and paper to skip embarrassing questions.⁹ This effect may have been large enough to mask any effects of social desirability bias. The greater use of diagnostic tests in the CAPI arm suggests that the ordering of extra tests might be more likely to occur when the clinician elicits a full history from the patient in person rather than relying on self-interview data. An additional reason for the divergent in the use of diagnostic tests in CAPI and CASI patients may have arisen from the fact that recommendations for tests were displayed at the end of the CAPI interviews to patient and clinician simultaneously, facilitating discussion, whereas CASI patients viewed this recommendation on their own, before their face-to-face consultation. We believe that safeguards could be introduced to alert clinicians if they do not follow recommended criteria for ordering tests. It would also be possible to re-design the CASI interview in a way that encourages the patient more strongly to commit to HIV testing and to draw the attention of clinicians to patients who have initially elected to opt out. Self-interview does to some extent remove an important opportunity for patient and clinician

Table 4 Secondary behaviour disclosure outcomes

Outcome	PAPI		CAPI		CASI	
	N (%)	OR (95% CI)	N (%)	OR* (95% CI)	N (%)	OR* (95% CI)
Two or more partners in past 3 months	247 (31.7)	1	271 (36.4)	1.26 (1.00 to 1.57)	308 (38.7)	1.35 (1.08 to 1.68)
Ever concurrent partnerships	62 (8.0)	1	145 (19.5)	2.88 (2.09 to 3.97)	127 (16.0)	2.19 (1.59 to 3.03)
Same-sex partner past 3 months	108 (13.9)	1	107 (14.4)	1.10 (0.78 to 1.54)	131 (16.5)	1.16 (0.83 to 1.61)
Sold sex in past 3 months	4 (0.5)	NA†	5 (0.7)	NA†	4 (0.5)	NA†
Paid for sex last 3 months	3 (0.8)	NA†	6 (1.7)	NA†	8 (2.0)	NA†
Unprotected sex with casual partner past 3 months	99 (12.7)	1	91 (12.2)	0.96 (0.70 to 1.31)	114 (14.3)	1.10 (0.82 to 1.49)
Anal sex in past 3 months	124 (15.9)	1	166 (22.3)	1.63 (1.24 to 2.15)	184 (23.1)	1.59 (1.21 to 2.09)
Summary OR (behaviours above)‡	—	1	—	1.42 (1.21 to 1.66)	—	1.41 (1.20 to 1.65)
IDU	7 (0.9)	NA†	7 (0.9)	NA†	2 (0.3)	NA†
Sex with IDU	6 (0.8)	NA†	9 (1.2)	NA†	4 (0.5)	NA†

*OR relative to pen and paper interview (PAPI) arm, adjusted for patient gender and recruitment clinic.

†Not calculated due to small numbers.

‡Calculated using the generalised estimating equation methodology, with robust variance estimation.

CAPI, computer-assisted personal interview; CASI, computer-assisted self-interview; IDU, injecting drug user.

Key messages

- Computer-assisted interviewing can encourage the disclosure of sexual risk-taking.
- This study noted a reduction in HIV testing among patients using CASI.
- Computer-assisted interviewing was linked to additional STI testing without increasing the rate of STI diagnosis in this study.

to build rapport.^{22 23} If it is embraced, mechanisms will be required to divert those patients who particularly want or need to talk through an issue face to face towards a more traditional clinical pathway.

The challenges for the future are to demonstrate whether computerised interviewing can offer cost-effective improvements in health outcomes in sexual health services, to optimise the instruments for data collection and their integration into clinical pathways and consultations, to ensure that the uptake of HIV testing is not diminished and to ensure that electronic data collection does not adversely affect patient–clinician interaction.

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Competing interests None.

Patient consent Obtained.

Ethics approval The study was given ethical approval by the Medical Research Ethics Committee for Wales.

Contributors The study was designed and established by JR, AC, JI, KM, MP and STS. Recruitment of patients and data collection was by PK, OM and JR. Data extraction was carried out by VJ. Data were analysed by VJ and AC. The paper was written by JR with comments and contributions from all authors. All contributors approved the final version submitted for publication. JR was the guarantor.

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