



Robustness of capturing behavioural and sexual lifestyle data for a complex clinical study using internet-based computer assisted self-interview



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Background

Sexual behaviour and vaginal practices impact on vaginal pathology, but accurately capturing such data for multi-site clinical studies is logistically difficult. Computer assisted self-interviews (CASI), are useful for capturing sensitive information¹ for community surveys but require programming expertise or expensive software. We piloted an open-source software designed internet-based CASI, using previously validated questions for the “eSTI² consortium: Investigating the Polymicrobial nature of Sexually transmitted infection (STI) syndromes” (PolySTI) study, a multi-site clinical study on the vaginal microbiome. Common correlates of bacterial vaginosis (BV), a common vaginal dysbiosis, were examined. Smoking and vaginal douching are associated with BV²; White ethnicity and combined hormonal contraceptives are inversely related to BV^{3,4}.

Methods

Women attending sexual and reproductive health clinics across four clinical sites in and around London, UK were recruited to the PolySTI, where data were collected using internet-based CASI.

The CASI question-structure was constructed from the third UK National Survey of Sexual Attitudes and Lifestyles⁵ using the LimeSurvey[®] open-source software⁶, consisting of 71 questions, and was delivered via a responsive algorithm. These covered demographics, sexual behaviour, vaginal practices, contraception, and life-time smoking history. Patients could decline questions and the CASI was delivered to participants online.

BV status was determined by Nugent scores from Gram-stained lateral vaginal swab smears.

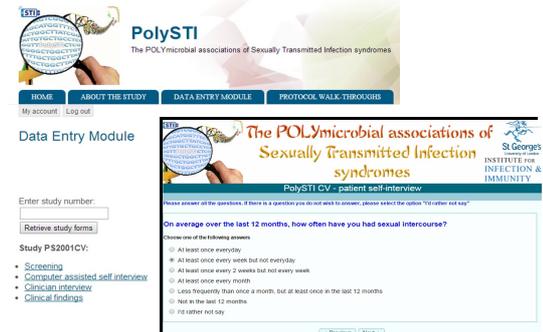


Fig.1. Screen shot of webpage and CASI

Results

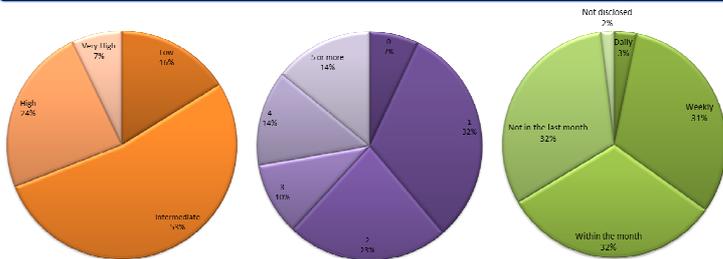


Fig.2. Risk of STI⁷ Fig.3. Sexual partners (1 year) Fig.4. Masturbation frequency

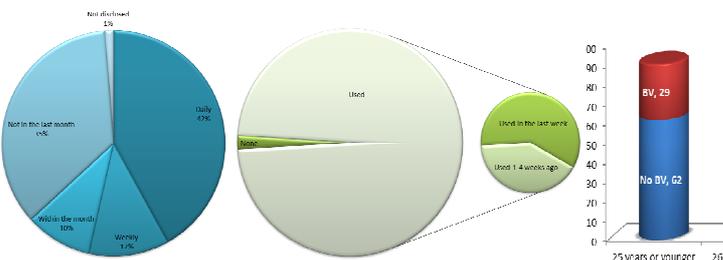


Fig.5. Vaginal douching Fig.6. Feminine care product in 1 month Fig.7. BV by age

- 155 women had available Nugent scores.
- Mean time to completing CASI was just over 5 minutes (Range: 1 minute 52 seconds-11 minutes 10 seconds 95% CI ± 17 seconds).
- There were no missing data.
- Most participants declined to answer “number of one-off partners” (14 participants, 9%).
- White ethnicity and combined hormonal contraceptives (CHC) were inversely related with BV (Odds ratios (OR): 0.33 [95%CI: 0.16-0.67] and 0.41 [0.17-0.97] respectively)
- Lifetime smoking of >1 pack-years and regular vaginal douching were directly related with BV (OR: 2.56 [1.21-5.41] and 2.03 [1.01-4.09] respectively).
- Nearly 50% of women reported daily vaginal douching and >90% reported using feminine care products in the preceding month.

Conclusion

The CASI delivered a complete dataset, the findings from which were consistent with published associations of BV, demonstrating robustness. Web-based CASI is an efficient method of collecting sensitive sexual and behavioural data within a complex clinical study, from patients recruited in busy clinical settings, and can be developed using open-source questionnaire software without the need for coding expertise. This is data from women only. Men may respond differently; future work is planned to compare CASI with NIH Chronic Prostatitis Symptom Index scores in men with prostatitis.

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