## **Sexually Transmitted Infections**

# The SPORTSMART STUDY: a pilot randomised controlled trial of sexually transmitted infection (STI) screening interventions targeting men in football club settings.

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The SPORTSMART STUDY: a pilot randomised controlled trial of sexually transmitted infection (STI) screening interventions targeting men in football club settings.

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#### **ABSTRACT**

## Background

Uptake of chlamydia screening by men in England has been substantially lower than by women. Non-traditional settings such as sports clubs offer opportunities to widen access. Involving people who are not medically trained to promote screening could optimise acceptability and cost.

#### Methods

We developed two interventions to explore the acceptability and feasibility of urine-based STI screening interventions targeting men in football clubs. We tested these interventions in a pilot cluster randomised control trial. Six clubs were randomly allocated two to each of three trial arms: team captain-led and poster STI screening promotion; sexual health advisor-led and poster STI screening promotion; or poster-only STI screening promotion (control / comparator). Primary outcome was test uptake.

#### Results

Across the three arms 153 men participated in the trial and 90 accepted the offer of screening (59%, 95% CI 35-79%). Acceptance rates varied by club, but were broadly comparable across the arms: captain-led: 28/56 (50%); health professional-led: 31/46 (67%); control: 31/51 (61%). No infections were identified. Process evaluation confirmed that interventions were delivered in a standardised way but the control arm was unintentionally "enhanced" by some team captains actively publicising screening events.

## Discussion

Compared with other UK-based community screening models, uptake was high but gaining access to clubs was not always easy. Use of sexual health advisers and team captains to promote screening did not appear to confer additional benefit over a poster-promoted approach. Although the interventions show potential, the broader implications of this strategy for UK male STI screening policy require further investigation.

#### **BACKGROUND**

Men's uptake of chlamydia screening within the English National Chlamydia Screening Programme, (NCSP) has been substantially lower than that reported in women (1). Among all 15-24 year old participants in the NCSP between July and September 2013, only 30% of tests were returned by men (1). Evidence suggests that although women of reproductive age bear the majority of adverse health consequences of chlamydial infection (2), the inclusion of men in screening efforts can be effective in reducing the population burden of infection (3,4), but this may be less cost-effective than other strategies (5).

Men's lower uptake of screening could be explained by differences in men's and women's health seeking behaviours, underpinned by different beliefs about health and illness (3, 6-8). However, growing evidence suggests that men are beginning to appreciate the rationale for STI screening and have clear preferences for how and where they would like to access it (7, 9-15). Men appear to find traditional health care settings such as genitourinary medicine (GUM) clinics and general practice most acceptable (11). To date there has been limited success in implementing effective male STI screening in primary care in England, (16-20), suggesting that offering men screening in other settings remains important. Sports settings offer potential for STI screening activities for men who engage in sport (21-23). Forty per cent of men (over 16 years) in a recent English survey reported participating in sport at least once a week (24). Football is the most popular team sport in England, with over 16% of 14-25 year olds playing at least once a week (24). Many teams operate within a national league structure which could facilitate widespread implementation of new interventions.

Involving people who are not medically trained to impart information about sexual health, testing and treatment also seems to be well accepted by targeted populations (25-27). However, this approach has not been evaluated as a means of promoting sexual health in sports settings in the UK. We developed two interventions to explore the acceptability and feasibility of football clubs as settings for STI screening (specifically, *Chlamydia trachomatis* and *Neisseria gonorrhoeae*) and the potential role of team captains in increasing uptake of screening in young men. We tested these interventions in the *SPORTSMART* pilot cluster randomised control trial (RCT), to determine preliminary evidence of effectiveness.

## **METHODS**

#### Trial design

We used a cluster RCT design. We allocated two clubs to each of our three trial arms: team-captain-led and poster STI screening promotion (arm 1), sexual health advisor-led and poster STI screening promotion (arm 2), or a poster-only STI screening promotion (control / comparator arm 3).

## **Outcomes**

Primary outcome: proportion of eligible men accepting the offer of screening (intervention uptake) Secondary outcomes: proportion of screened men who tested positive for chlamydia and/or gonorrhoea; health service costs (reported elsewhere).

## Statistical analysis

We reported the primary outcome with a 95% confidence interval based on a robust standard error that acknowledges the clustering of participants by club.

#### Club recruitment

We identified all potentially eligible amateur clubs in appropriate geographical areas from the Amateur Football Combination London listings available on the Internet (28).

## **Eligibility requirements**

We assessed each football club's eligibility by telephone discussion with the club manager or secretary. Clubs were considered eligible if they had: working toilet facilities, private/team changing rooms, and a minimum of two teams with 11 or more men aged at least 18 years old; and at least one home match (match played at the participating club) during the three month study period. We offered each club £1000 as reimbursement of their participation costs.

#### Randomisation

Prior to randomisation, we divided clubs into three pairs. Pairing was based on a description of the club memberships' ethnicity, age, education status, and membership size, as described by early qualitative work (14) and club representatives' reports, and was performed to achieve approximate balance across pairs in these characteristics. The pairs of clubs were then allocated to one of three study arms by the lead study statistician by random permutation. Clubs (and thus participants) were unblinded directly following study arm allocation. It was not feasible that clubs or investigators be blind to the intervention type during implementation or evaluation.

#### Team captain and health adviser recruitment

During the recruitment phase the trial coordinator explained to the club contacts that two of the participating clubs would be randomly allocated to a captain-promoted screening intervention and so all participating clubs needed to have at least one captain willing to promote the screening intervention among two teams in each club.

## **Health advisor selection**

Based on our preclinical qualitative work (14), we recruited a male health advisor to deliver our STI screening promotion. The health advisor was also in the same age group as the football players involved in the intervention, and so the distinguishing difference between the self-selected team captain and the health advisor was that the health advisor was a medical professional from outside the club.

## **Delivery of the interventions**

The trial coordinator emailed the club contacts prior to the match with brief details of the screening event. On the day, the trial coordinator put up posters in all participating clubs and set up the test kit collection boxes in the club changing rooms just prior to the players' arrival. The interventions were delivered according to randomisation during the usual pre or post-match team briefing. Interventions were as follows:

- 1. Captain and poster screening promotion: the team captain delivered a standardised brief screening promotion talk of less than five minutes duration (Figure 2) and then handed each player a test kit and answered any questions from participants.
- 2. Health adviser and poster screening promotion: a sexual health adviser from the study clinic delivered the standardised brief screening promotion talk of less than five minutes duration and then handed each player a test kit and answered any questions from participants.
- 3. Poster only screening promotion (comparator arm): posters were displayed which the men were free to read with kits readily available but there was no verbal information given.

Men who wished to participate completed a sample kit according to the instructions provided and placed their completed kits back into the secure collection box. Alternatively men could take the kit away with them for later completion and post it back to the clinic in a discreet postage-paid package. All clinical follow up, including provision of test results via text (SMS) message was done by clinic staff according to routine standards of care.

## Process Evaluation and additional data collection

Captains and the sexual health advisor completed a 'report-back' form directly after each intervention. Information gathered included: number of men in the changing room and exposed to the intervention, and their views of implementing the intervention. In addition, the trial coordinator took field notes to describe the circumstances of each intervention (including weather, match outcome, timing of intervention) to assess fidelity of the interventions in practice.

Resource use data were collected prospectively for use in health economics analyses (reported elsewhere).

Participants (players) were invited to take part in a telephone semi-structured interview to explore their views of the interventions within a month of participating in the initial screening event (reported elsewhere).

Two weeks after the intervention was completed, all (playing and non-playing) club members aged at least 18 years were invited to take part in a brief, self-administered, anonymous, pen-and-paper survey questionnaire to assess club members' sexual risk behaviour and previous STI testing history to inform estimates of public health impact of offering screening in these settings (reported elsewhere).

#### Sample size

We aimed to recruit 200 men to estimate the overall acceptance of screening rate with acceptable precision considering a wide range of possible rates due to the lack of directly relevant evidence from previous studies. Specifically this sample size allows us to estimate the rate within 7% if the rate is 50% (i.e. a 95% confidence interval of 43-57%) or within 5% if it is either higher or lower (85 or 15%), assuming minimal variability between clubs.

#### Consent

Club managers gave consent for the club's involvement in the study. Signed informed consent was obtained from captains before the intervention. Football team members opted in to screening by completing the kit offered but could opt out of the intervention at any time.

Ethical approval for this study was given by the National Research Ethics Service, study 13/SC/0029.

#### **RESULTS**

## Recruitment

Recruitment was conducted between October and December 2012. Clubs were contacted by the trial coordinator via email and/or telephone to assess interest and eligibility. Five of the 18 clubs initially identified had invalid contact details. Of the remaining 13 clubs, five did not respond and eight (62%) indicated that they were willing to participate. Six were chosen based on the willingness of a club representative to meet with the study coordinator and fully discuss the study objectives; the remaining two clubs were placed on a reserve list (Figure 1).

## Acceptability of screening and STI positivity

The interventions were implemented between February and April 2013. Across the three arms 153 men in six clubs participated in the trial and 90 (59%, 95% confidence interval 35-79%) accepted the offer of screening (Table 1). Acceptance rates varied considerably by club, (Table 1), but the aggregate rates were broadly comparable across the arms: captain-led: 28/56 (50%); health professional-led: 31/46 (67%); control: 31/51 (61%). The variability within arms was greater than the variability between arms. The majority of test kits were completed within the clubs and only one was returned by mail. There were no positive tests for chlamydia or gonorrhoea from any of the study arms.

Study arm	Club	Players in changing room	Completed kits returned	% Return
Health professional-led	1a	24	10	42
Health professional-led	1b	22	21	95
Captain-led	2a	26	10	38
Captain-led	2b	30	18	60
Control	3a	24	20	83
Control	3b	27	11	41
Total	ALL	153	90	59

Table 1: Screening kit uptake among participating clubs

## **Process evaluation**

The Amateur Football Combination club listings were a useful initial resource to identify clubs but contact details for individual clubs were often incorrect and some club websites contained out of date contact information. We do not know whether the reason five clubs did not respond was because of a lack of interest in the study or our failure to establish an appropriate means of communication.

A number of cancelled and rescheduled matches during the limited time in the football season meant that we were unable to deliver the interventions to as many players as planned. Evaluation of field notes and report-back forms from captains and the sexual health adviser confirmed that the interventions were delivered in a standardised way across all study arms and captains felt comfortable delivering the short intervention. However, the poster comparator arm was unintentionally "enhanced" by some captains, who actively publicised the availability of STI screening at the club prior to the day by including details of the research in their weekly team information email and encouraging players to participate. There were no adverse effects from this research.

#### **DISCUSSION**

To our knowledge, this is the first UK trial of STI screening which targets young men in the football clubs in which they play. The design enabled us to report accurate measures of uptake as, unlike many published community and non-healthcare-based screening evaluations, we measured the number of men to whom the interventions were offered. Urine-based STI screening was acceptable irrespective of how it was offered. The additional support of team captains and sexual health advisers in the form of a short verbal explanation of the rationale and process for STI screening, followed by handing a kit directly to each man, did not result in greater uptake than simply making the tests kits available on the day, supported by an explanatory poster.

Although implementation of the interventions was straightforward, the poster-only arm was unintentionally promoted by some team captains who encouraged men to participate in the research via their regular team information emails. We were dependent on club fixtures and subject to last-minute match cancellations which meant that we were unable to deliver the interventions to as many players as planned and we did not achieve our intended sample size. The interventions began late in the match season and although we were confident that extending the recruitment phase would have enabled us to reach our intended sample size, this was unfeasible as no further matches were scheduled until after the four month match break. We found a greater than anticipated variability between clubs in the acceptability of screening, which limited our ability to estimate acceptability under any single intervention and reduced precision in our estimate of overall acceptability.

Although many different forms of "outreach" screening have been described, very few focus exclusively on men, despite research indicating that male patterns of sexual health care access differ from those of women (10, 15, 30). A recent systematic review which included 25 chlamydia screening outreach screening strategies for men and women found a median participation rate of 53% with close to 80% of participants tested (30). The highest uptake of testing (85%) was reported in one of the two studies offering chlamydia screening in Australian Football League clubs (21-23), considerably higher than in our study. However, the Australian studies were set in rural areas with few alternative opportunities for STI screening, unlike our London urban areas which all had multiple different STI screening venues within easy reach. Only one of the included studies (young people attending a leisure centre), was conducted in the UK and uptake in this study was just under 50% (30). Other studies of chlamydia screening promotion have found varying uptake of screening within similar venues, but unlike our trial, this was attributed to differences in the way researchers invited potential participants to engage in the study (10).

More young men play football at least once a week than any other sport (24), and so amateur football clubs could be promising settings for STI screening initiatives. A recent random probability sample survey of young UK men suggests that men who do and do not play football are at similar risk of STIs (11). The same survey also reported that just over half of men who play football at least once a month would find the venue in which they play an acceptable setting to access self-testing kits (11), reflected in the uptake of testing within this pilot study.

Our approach appears to be broadly acceptable and feasible to young football players, team captains and football clubs. However, several clubs were uncontactable and others did not respond. Although the poster-only arm was unintentionally enhanced due to the enthusiasm of the captains in this arm, their strategy for enhancement required minimal effort at no additional cost. Should this type of screening be implemented more widely, we would expect captains to forewarn their players of the screening activity even if they had no further role in promotion of screening.

We did not detect any new *Chlamydia trachomatis* or *Neisseria gonorrhoeae* infections but this was not unexpected given the estimated population prevalence (29). Adopting a male-focussed approach to screening may have been an important factor in high uptake and factors related to the role of setting and collective screening within groups of men who know each other deserve further study. Although we have developed a simple, feasible, and acceptable approach to male STI screening and operationalised it within football clubs, given men's reported preference for traditional health care settings (11, 14), a clearer view of the public health benefits of this approach is needed before we can be certain of its wider impact.

#### **KEY MESSAGES:**

- Compared with other community based screening approaches, uptake to the SPORTSMART intervention was high.
- Acceptance rates were highly variable between clubs, but were broadly comparable irrespective of intervention type.
- Adopting a male-focussed approach to screening may have been an important factor in high uptake; the impact of social group setting on screening uptake warrants further investigation.

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## **COMPETING INTERESTS**

We declare we have no conflicts of interest.

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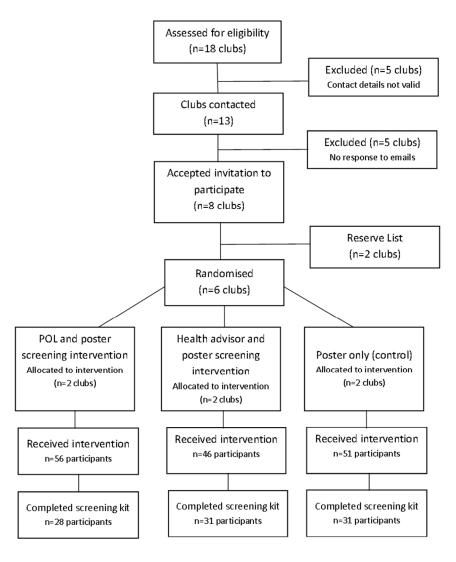


Figure 1: Participant flow in the SPORTSMART trial

Figure 1: Participant flow in the SPORTSMART trial 248x314mm (96 x 96 DPI)

Topic	Message
Health promotion message	Chlamydia and Gonorrhoea are common and often present without any sign that anything is wrong (asymptomatic)
Screening information	Confidential; right to refuse; how contacted with results
Test kit instructions	Step-by-step instructions
Further research participation	Invitation to follow-up qualitative interview

Figure 2: Screening promotion content

Figure 2: Screening promotion content

