

BMJ Open

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Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2015-009774
Article Type:	Research
Date Submitted by the Author:	19-Aug-2015
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Primary Subject Heading:	Infectious diseases
Secondary Subject Heading:	Infectious diseases, Public health, Epidemiology, HIV/AIDS
Keywords:	HIV & AIDS < INFECTIOUS DISEASES, Public health < INFECTIOUS DISEASES, SEXUAL MEDICINE

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Association between treatment for sexually transmitted infections and lower condom use among female sex workers in southern India

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Word counts: 3309 (main text); 250 (abstract)

Key words : Female sex workers, HIV, condom use, STI treatment, periodic presumptive treatment

ABSTRACT

Background: Treatment for sexually transmitted infections (STIs) is often used in HIV prevention programs targeted at female sex workers (FSWs). In the case of the *Avahan* program in India, both periodic presumptive treatment (PPT) and STI syndromic management were used among FSWs. In this study, we assessed whether having received a grey packet containing treatment for both gonorrhoea and chlamydia was associated with condom use among FSWs in southern India.

Methods: This cross-sectional study was conducted in 2006-2007 among 1378 FSWs in five Indian districts. Data were collected through face-to-face interviews. Poisson regression was used to model the association between the number of grey packets received in the last 3-12 months and consistent condom use (CCU) with new or occasional clients, and with the most recent repeat client.

Results: Reported CCU was lowest among FSWs who had received ≥ 3 grey packets in the last 3- 12 months with their new or occasional clients [Adjusted prevalence ratio (APR): 0.70, 95% Confidence interval (95%CI): 0.57-0.84] and with the most recent repeat client (APR 0.63, 95%CI: 0.51-0.78). Tests for trends showed that CCU with both types of clients decreased with the number of grey packets received ($p < 0.001$).

Conclusion: As we could not distinguish grey packets used for PPT from those given for syndromic management, these results could be either due to a perception of protection

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3 conferred by PPT or by the fact that inconsistent condom users are more at risk for STIs.
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6 Further research on the potential disinhibiting effect of PPT is warranted.
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9 10 **ARTICLE SUMMARY**

11 12 **Strengths and limitations of the study**

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17 • This study is part of the evaluation of Avahan, an HIV prevention program
18 targeted at high risk groups, notably female sex workers, in India.
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23 • In this study, the use of treatment for gonococcal and chlamydial infection, in the
24 context of both periodic presumptive treatment and syndromic management of
25 female sex workers, was associated with lower consistent condom use.
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31 • The strengths of this study include its large sample size across five Indian districts
32 and the fact that the hypothesis that inappropriate counselling in clinical settings
33 may lead to decrease in condom use is based on the results of a previous
34 qualitative study conducted in the same population.
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39 • The main limitation is that it was impossible to determine if the treatment was
40 given presumptively or in the context of syndromic management.
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47 • This association that we observed could thus be due to a perception of
48 protection conferred by the treatment or because inconsistent condom users are
49 more at risk for STIs.
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BACKGROUND

Sexually transmitted infections (STIs) are considered to increase the risk of human immunodeficiency virus (HIV) transmission, since both infectiousness among HIV infected people and susceptibility for HIV acquisition among those uninfected are increased by STIs. There has thus been interest in treating STIs as a way to prevent HIV acquisition(1-4). In resource-limited settings, where sophisticated laboratory are not regularly accessible, STIs are often treated presumptively or on the basis of symptom-based algorithms. Unfortunately among women, the sensitivity and specificity of syndromic case management tend to be very low when the vaginal discharge syndrome is used as an indication for treating gonorrhoea and chlamydia, with the latter infections sometimes not even associated with symptoms of vaginal discharge(5). Moreover, gonorrhoea and chlamydia are often characterized by an absence of symptoms, especially among women(5,6). In settings where STI prevalence is high and concentrated in certain core groups, it is assumed that periodic presumptive treatment (PPT) can be effective as an HIV prevention strategy(3,7-9). However, this strategy has to be part of a more complete program to have long-term sustainability. The program has to include communication for behavioural change with regard to risky sexual behaviour, in particular condom use, as well as structural components and clinical services other than PPT(10,11).

Avahan, the India AIDS initiative of the Bill & Melinda Gates Foundation implemented since 2003, is a large-scale HIV prevention program whose main objective was to reduce

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3 HIV prevalence among high-risk groups such as female sex workers (FSWs), men who
4 have sex with men (MSM), people who inject drugs (PWID) and clients of FSWs in the six
5 states of India with the highest HIV prevalence(12,13). The intervention, that has been
6 described in more detail elsewhere(12), includes behavioural change communication
7 with the promotion of condom use using peer educators, free distribution of
8 commodities (condoms, clean syringes for PWID), community development,
9 interventions against stigma and discrimination, and STI care. The latter used an
10 “essential service package” for FSWs that was offered exclusively at *Avahan* FSW-
11 dedicated STI clinics and included PPT for gonorrhoea and chlamydia (recommended
12 quarterly), syndromic case management of women coming to the clinic with STI
13 symptoms and serological testing, followed by treatment, when appropriate, for syphilis
14 twice a year. The target of the strategy was to attain one clinic visit per FSW every 3
15 months(14). Anecdotally, program implementers observed that in their communication
16 with patients, physicians were not always very clear about the STIs for which the
17 treatment was protective, which could have led some women to think that the
18 treatment given may protect directly against HIV. Such beliefs were also observed in a
19 qualitative study carried out among FSWs in Guntur district, state of Andhra
20 Pradesh(15). Although a few previous studies did not show a decrease in condom use
21 following the implementation of PPT among FSWs(6,8), data on this issue remain sparse
22 and a concern subsists about a disinhibiting effect of STI treatment in relation to
23 condom use. In an order to constantly improve prevention programs, the objective of
24 this secondary data analysis was to determine if an association could be found between
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3 the prescription of STI treatment and condom use and more specifically, if the
4 disinhibiting hypothesis could be plausible in the context of FSWs with their clients, in
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6 five districts of south India.
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10 11 **METHODS**

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13 Under the CHARME-India project (led by the Centre hospitalier *affilié* universitaire de
14 Québec in partnership with Canadian, British and Indian institutions) whose aim was to
15 evaluate the impact of the *Avahan* program, we conducted detailed behavioural cross-
16 sectional studies among FSWs in five districts of south India between February 2006 and
17 December 2007. Of the 1442 FSWs invited, 1378 (95.6%) participated in the study.
18
19 Three of the study districts were in the state of Karnataka [Bangalore (n=369), Belgaum
20 and (n=208) Bellary (n=198) and], whereas the two other districts were Guntur in the
21 state of Andhra Pradesh (n=208) and Mumbai in the state of Maharashtra (n=395). The
22 interviews were conducted face-to-face by trained interviewers.
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38 Two sampling procedures were used for the selection of clusters. For fixed sex work
39 sites, such as home-based, brothel-based and lodge-based sites, a conventional cluster
40 sampling was used. For street-based and other public place-based sex work sites, time-
41 location cluster (TLC) sampling was used. Normalized weights were calculated for the
42 complex sampling design. Within selected clusters, the respondents were selected
43 randomly. District-wide mapping of the sites where FSWs could be found was used as
44 well as information about hours of operation for the TLC sampling. We also
45 approximated the possible number of respondents at different times of the day and of
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3 the week. Site maps were then used by the research teams for the sampling frame
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5 development. Sampling methods were the same as those reported by Saidel *et al*(16).
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9 Data from face-to-face interviews with FSWs were collected about their sexual activity
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11 with two types of commercial partners: new or occasional clients and the most recent
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13 repeat client. The two categories of partners were not mutually exclusive, since every
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15 FSW having a most recent repeat client also had new or occasional clients, but not
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17 necessarily the opposite.
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20 21 22 **Ethical approval**

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24 The overall study was approved by the ethics committees of the Centre hospitalier
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26 *affilié* universitaire de Québec (Canada) and of the University of Manitoba. The project
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28 has also been approved by the ethics committees of the implementing partners in each
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30 state.
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35 36 37 **Dependent variable**

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39 The dependent variable, consistent condom use (CCU), with new or occasional clients
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41 (clients who are not well known by the FSW and who visited her only once or at most a
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43 few times) and with the most recent repeat client (clients with whom FSWs are
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45 familiar), was obtained through the survey question: “In general, how often is a condom
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47 used when you have sex with ‘type of partner’? “. Interviewers were instructed to
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49 explain the meaning of “in general” as the current sex work practice of the participants.
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56 Possible answers to this question were: never (0%), sometimes (<50%), frequently
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(≥50%) or always (100%). We considered FSWs were using condoms consistently with their partners if they answered “always” and inconsistently if they answered “never”, “sometimes” or “frequently”, in order to create a dichotomous variable.

Independent variables

To determine the relationship between condom use and treatment for STIs, we assessed whether the variable “number of grey packets received in the last three to 12 months” was associated with CCU among FSWs with their new or occasional clients and with their most recent repeat client, while controlling for variables affecting condom use. The grey packets were used for presumptive treatment of asymptomatic chlamydial and gonococcal infections and contained a single dose of cefixime 400 mg and azithromycin 1000 mg. In the case of syndromic management, the grey packets were mostly used in combination with the green packet that was designed to treat vaginitis agents. Unfortunately, the questionnaire did not address the issue on the reason why the grey packets were taken (PPT or because of vaginal discharge). An analysis of the data of the *Avahan* computerized information system for years 2006 and 2007 for the three Karnataka districts (data were not available for Mumbai and Guntur) showed that among the 25,530 grey packets administered to FSWs, 32.7% were used for PPT (*Avahan* program, unpublished data).

The time frame used (three to 12 months) was wide because of inter-district variations in the start dates of the implementation of the STI essential package for FSWs. In all districts except Bangalore, the program had started 12 months or more prior to data

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3 collection. In Bangalore, it had only started three months before the interviews were
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5 conducted. The treatment variable was divided into four categories, which were zero,
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7 one, two or three or more grey packets.
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11 We determined, based on the literature, a set of socio-demographic, sex-work related
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13 and intervention exposure factors that may affect condom use(17-22). Each model was
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15 adjusted for those variables. Socio-demographic factors included district, age, marital
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17 status (currently married, divorced/separated/widowed, never married or devadasi, a
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19 particular form of sex work where women are dedicated to gods and goddesses through
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21 marriage, who practice traditional, caste-based sex work(23,24)), literacy and age at first
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23 sex. Sex-work related factors included age at first sex work, main place of solicitation of
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25 clients (brothel, home, public places or rented room/lodge or other), main place of
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27 entertaining (with the same categories as main place of solicitation), having sex work as
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29 sole income, if the FSW is usually under influence of alcohol, if the partner is usually
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31 under influence of alcohol when having sex with the FSW and if FSW solicits her clients
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33 independently or through a middleman or a pimp. Intervention exposure variables other
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35 than the number of grey packets received, included the number of times contacted by
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37 intervention staff in the last month, the number of condom demonstrations seen in the
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39 past month and the time since first contacted by intervention staff.
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49 50 **Statistical analysis**

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52 Statistical analysis was carried out using SAS version 9.3 (SAS Institute, Cary, NC).
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54 Poisson regression was used for univariate and multivariate analyses(25, 26) to
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determine the association between condom use and the number of grey packets received in the last three to 12 months. Prevalence ratios (PRs) and adjusted prevalence ratios (APRs), with 95% confidence intervals [95% CIs], were generated with Poisson regression. Continuous variables were categorized. One model was created for each type of partner in the multivariable analysis. Variables from the univariate analysis were initially included in the multivariate model based on a significance level of $p < 0.10$. An iterative process was then used to keep only the variables that were found to be confounding in the model (e.g. that changes the APR of the association between receiving grey packets and condom use by $\geq 10\%$). A test for trend was used to evaluate the dose-response relationship between the number of grey packets received and condom use. All p-values shown are two-sided.

RESULTS

Socio-demographic, sex-work related and intervention exposure factors were measured among all 1378 FSWs with new or occasional clients, among whom, 938 (68.7%) had had a repeat client. Tables 1 and 2 show sample characteristics and univariate associations between each factor and consistent condom use with the two types of partner.

Table 1: Sample characteristics and univariate associations between these characteristics and consistent condom use by FSWs with new or occasional clients in five districts of south India^{1,2,3,4}

	N (%) (n=1378)	% CCU	Prevalence ratio (95% CI)	p-value
SOCIO-DEMOGRAPHIC FACTORS				
District				0.024
Bangalore	369 (26.8)	63.7	0.97 (0.83-1.14)	

1					
2					
3	Bellary	198 (14.4)	70.2	1.11 (0.96-1.29)	
4	Guntur	208 (15.1)	79.8	1.20 (1.05-1.37)	
5	Belgaum	208 (15.1)	75.0	1.07 (0.92-1.23)	
6	Mumbai	395 (28.7)	68.6	Ref	
7					
8	Age				0.175
9	<25	296 (21.5)	74.0	1.07 (0.97-1.18)	
10	25+	1082 (78.5)	69.1	Ref	
11					
12	Marital status				0.004
13	Devadasi	156 (11.3)	79.5	1.18 (1.05-1.32)	
14	Never married	143 (10.4)	67.1	0.88 (0.73-1.06)	
15	Divorced/Separated/Widowed	651 (47.2)	68.8	1.00 (0.89-1.13)	
16	Currently married	428 (31.0)	69.9	Ref	
17					
18	Literate				0.107
19	Yes	403 (29.2)	73.2	1.09 (0.98-1.21)	
20	No	975 (70.8)	68.9	Ref	
21					
22	Age at first sex				0.562
23	<15	470 (34.1)	67.9	0.96 (0.82-1.11)	
24	15+	908 (65.9)	71.3	Ref	
25					
26					
27	SEX-WORK RELATED FACTORS				
28	Age at first sex work				0.004
29	<22	587 (42.6)	75.1	1.14 (1.04-1.24)	
30	22+	791 (57.4)	66.5	Ref	
31					
32	Main place of solicitation				0.411
33	Brothel	315 (22.9)	68.3	1.06 (0.94-1.19)	
34	Home	318 (23.1)	74.8	1.09 (0.97-1.22)	
35	Rented room/lodge or other	82 (5.6)	72.0	1.10 (0.91-1.34)	
36	Public places	661 (48.0)	68.5	Ref	
37					
38	Main place of entertaining				0.067
39	Brothel	349 (25.3)	78.2	1.17 (0.99-1.39)	
40	Home	394 (28.6)	66.8	1.11 (0.94-1.31)	
41	Rented room/lodge or other	523 (38.0)	68.5	1.02 (0.86-1.21)	
42	Public places	111 (8.1)	64.9	Ref	
43					
44	Sex work sole income				0.187
45	Yes	476 (34.5)	70.3	1.06 (0.97-1.16)	
46	No	898 (65.2)	69.8	Ref	
47					
48	FSW usually under influence of alcohol with partner				0.517
49	Yes	542 (39.3)	70.7	1.03 (0.94-1.14)	
50	No	834 (60.5)	70.0	Ref	
51					
52	Partner usually under influence of alcohol				0.063
53	Yes	1189 (86.3)	75.8	0.86 (0.74-1.01)	
54	No	186 (13.5)	69.3	Ref	
55					
56	Solicit independently				0.046
57	Yes	815 (59.1)	66.6	0.91 (0.83-1.00)	
58	No	560 (40.6)	75.4	Ref	
59					
60					

INTERVENTION EXPOSURE

Number of times contacted by staff last month				<0.001
<2	393 (28.5)	60.3	Ref	
2+	981 (71.2)	74.3	1.26 (1.10-1.44)	
Number of condom demos seen past month				0.002
0	257 (18.7)	57.2	Ref	
1	303 (22.0)	68.7	1.26 (1.02-1.56)	
2	363 (26.34)	76.6	1.44 (1.18-1.76)	
3+	397 (28.8)	76.8	1.36 (1.10-1.67)	
Test for trend				0.077
Duration since first contacted by intervention staff				0.001
Has not been contacted	229 (16.6)	54.1	Ref	
<1 (greater than zero)	284 (20.6)	68.0	1.25 (1.01-1.54)	
1 year	284 (20.6)	72.9	1.35 (1.09-1.66)	
2-3 years	360 (26.1)	74.7	1.44 (1.18-1.74)	
4 years +	219 (15.9)	78.5	1.46 (1.19-1.79)	
Test for trend				0.039
Treatment of STIs: Number of grey packet received in the last 3 to 12 months				0.259
0	668 (48.5)	68.7	Ref	
1	129 (9.4)	74.4	1.02 (0.88-1.18)	
2	254 (18.4)	74.4	1.10 (0.98-1.23)	
3+	326 (23.7)	68.1	0.88 (0.73-1.07)	
Test for trend				0.259

¹ Consistent condom use is defined as reporting always using condoms.

² Due to missing values, the total N for each variable may be different from 1378 (total of FSW with a new or occasional client). The small number of missing values do not significantly affect the results.

³ Prevalence ratios are presented with a 95% confidence interval.

⁴ CCU is defined as consistent condom use

Table 2: Sample characteristics and univariate associations between these characteristics and consistent condom use by FSWs with the most recent repeat client in five districts of south India^{1,2,3,4}

	N (%) (n=1378)	% CCU	Prevalence ratio (95% CI)	p-value
SOCIO-DEMOGRAPHIC FACTORS				
District				<0.001
Bangalore	221 (23.6)	64.7	1.13 (0.73-1.75)	

1					
2					
3	Bellary	95 (10.1)	67.3	1.56 (1.30-1.87)	
4	Guntur	181 (19.3)	85.6	1.74 (1.49-2.03)	
5	Belgaum	117 (12.5)	53.0	1.06 (0.83-1.36)	
6	Mumbai	324 (34.5)	51.5	Ref	
7					
8	Age				0.045
9	<25	199 (21.2)	71.3	1.21 (1.00-1.46)	
10	25+	739 (78.8)	60.8	Ref	
11					
12	Marital status				0.100
13	Devadasi	90 (9.5)	68.9	1.19 (0.99-1.42)	
14	Never married	115 (12.3)	66.1	0.94 (0.74-1.21)	
15	Divorced/Separated/Widowed	450 (48.0)	61.6	0.94 (0.73-1.20)	
16	Currently married	283 (30.1)	62.1	Ref	
17					
18	Literate				0.958
19	Yes	307 (32.7)	64.5	1.01 (0.81-1.24)	
20	No	631 (67.3)	62.3	Ref	
21					
22	Age at first sex				0.938
23	<15	311 (33.1)	61.4	0.99 (0.86-1.15)	
24	15+	627 (66.8)	63.8	Ref	
25					
26	SEX-WORK RELATED FACTORS				
27					
28	Age at first sex work				0.196
29	<22	418 (44.6)	66.8	1.15 (0.93-1.43)	
30	22+	520 (55.4)	60.0	Ref	
31					
32	Main place of solicitation				0.084
33	Brothel	210 (22.4)	67.1	1.24 (0.98-1.57)	
34	Home	207 (22.1)	69.6	1.34 (1.06-1.68)	
35	Rented room/lodge or other	60 (6.4)	70.0	1.33 (0.99-1.79)	
36	Public places	459 (48.9)	57.1	Ref	
37					
38	Main place of entertaining				0.192
39	Brothel	249 (26.5)	61.5	0.92 (0.76-1.11)	
40	Home	252 (26.9)	69.4	0.99 (0.81-1.20)	
41	Rented room/lodge or other	358 (38.2)	58.4	0.75 (0.56-1.01)	
42	Public places	78 (8.3)	68.0	Ref	
43					
44	Sex work sole income				0.013
45	Yes	319 (34.0)	67.4	1.29 (1.06-1.56)	
46	No	616 (65.7)	60.7	Ref	
47					
48	FSW usually under influence of alcohol with partner				0.007
49	Yes	378 (40.3)	55.0	0.79 (0.67-0.94)	
50	No	559 (59.6)	68.3	Ref	
51					
52	Partner usually under influence of alcohol				0.047
53	Yes	603 (64.3)	58.0	0.85 (0.72-1.00)	
54	No	334 (35.6)	72.2	Ref	
55					
56	Solicit independently				0.150
57	Yes	510 (54.4)	57.8	0.85 (0.68-1.06)	
58	No	427 (45.5)	69.1	Ref	
59					
60					

INTERVENTION EXPOSURE

Number of times contacted by staff last month				0.525
<2	238 (25.4)	57.1	Ref	
2+	697 (74.3)	65.3	1.08 (0.86-1.36)	
Number of condom demos seen past month				0.041
0	151 (16.1)	52.3	Ref	
1	198 (21.1)	62.1	1.09 (0.84-1.41)	
2	258 (27.5)	70.0	1.23 (0.97-1.57)	
3+	289 (30.8)	65.7	0.98 (0.65-1.47)	
Test for trend				0.222
Duration since first contacted by intervention staff				0.004
Has not been contacted	132 (14.1)	50.0	Ref	
<1 (greater than zero)	180 (19.2)	65.0	0.94 (0.55-1.60)	
1 year	169 (18.0)	65.7	1.39 (0.98-1.71)	
2-3 years	270 (28.8)	68.9	1.43 (1.12-1.83)	
4 years +	185 (19.7)	58.9	1.09 (0.83-1.44)	
Test for trend				0.017
Treatment of STIs: Number of grey packet received in the last 3 to 12 months				0.270
0	447 (47.7)	63.3	Ref	
1	80 (8.5)	71.3	1.08 (0.91-1.29)	
2	174 (18.6)	60.3	0.80 (0.56-1.13)	
3+	237 (25.3)	61.6	0.82 (0.64-1.05)	
Test for trend				0.270

¹ Consistent condom use is defined as reporting always using condoms.

² Due to missing values, the total N for each variable may be different from 938 (total of FSW with a most recent repeat client). The small number missing values does not significantly affect the results.

³ Prevalence ratios are presented with a 95% confidence interval.

⁴ CCU is defined as consistent condom use

The majority of FSWs (78.5%) were older than 25 years and were illiterate (70.8%).

Seventy percent reported using condoms consistently with their new or occasional clients whereas 591 (63.0%) of FSWs who reported repeat clients, reported consistent condom use with their most recent one. Less than half (48.5%) FSWs had not received a grey packet in the last three to 12 months, while 129 (9.4%) had received one

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3 treatment, 254 (18.4%) had received two treatments and 326 (23.7%) had received 3
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5 treatments or more.
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9 In univariate analysis (tables 1 and 2), CCU was higher among FSWs who had seen
10 condom demonstrations in the last month in comparison to those who had not seen
11 any. CCU was at its highest level for 2 condom demonstrations seen in the last month
12 for both FSWs with new or occasional clients (PR 1.44, $p<0.001$) as well as for FSWs with
13 a most recent repeat client (PR 1.23, $p=0.095$). CCU was also higher among FSWs who
14 had been contacted by intervention staff in comparison to those who had not been
15 contacted. CCU increased when time since first contacted by intervention staff
16 increased and was at its highest level at 4 years and more for new and occasional clients
17 (PR 1.46, $p<0.001$), and was at its highest level at 2 or 3 years since first contacted
18 for most recent repeat client (PR 1.43, $p=0.004$). CCU with new and occasional clients
19 was higher among FSWs who had two or more contacts with intervention staff in the
20 last month for (PR 1.26, $p<0.001$), but results were not significant for FSWs with the
21 most recent repeat client. In univariate analysis, no significant association was found
22 between CCU and the number of grey packets received in the last three to 12 months.
23
24 For the socio-demographic factors, district was associated with consistent condom use
25 with both types of partner (new/occasional clients $p=0.024$ and most recent repeat
26 client $p<0.001$). Age was only significant for FSWs with a most recent repeat client (PR
27 1.21, $p=0.045$). For sex-work related factors, alcohol intake by the FSW with clients was
28 only significantly associated with CCU with the most recent repeat client (PR 0.79
29 $p=0.007$), but was significant for both type in the case for alcohol intake by the client
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(new/occasional clients: PR 0.85, p=0.063 and most recent repeat client: PR 0.85, p=0.047).

In multivariate analysis (table 3), final models were adjusted for the district, the number of condom demonstrations seen in the past month and the time since first contacted by intervention staff.

Table 3: Multivariate associations between these characteristics and consistent condom use by FSWs with new or occasional clients and with a most recent repeat client in five districts of south India^{1,2,3}

	Consistent condom use with new or occasional clients		Consistent condom use with most recent repeat client	
	Adjusted prevalence ratio (95% CI)	p-value	Adjusted prevalence ratio (95% CI)	P-value
Number of grey packets received in the last 3 to 12 months (versus 0)				
1	0.92 (0.80-1.06)	0.258	0.90 (0.75-1.09)	0.276
2	0.90 (0.79-1.02)	0.089	0.63 (0.47-0.85)	0.003
3	0.70 (0.57-0.84)	<0.001	0.63 (0.51-0.78)	<0.001
Test for trend		<0.001		<0.001
District				
Bangalore	1.14 (0.95-1.36)	0.165	1.51 (1.17-1.95)	0.002
Bellary	1.23 (1.04-1.45)	0.015	1.93 (1.48-2.52)	<0.001
Guntur	1.32 (1.14-1.53)	<0.001	1.85 (1.58-2.18)	<0.001
Belgaum	1.27 (1.08-1.50)	0.004	1.24 (0.93-1.64)	0.142
Mumbai	Ref		Ref	
Number of condom demos seen in the past month (versus 0)				
1	1.18 (0.69-2.02)	0.545	0.88 (0.58-1.32)	0.531
2	1.34 (0.79-2.29)	0.278	0.94 (0.63-1.40)	0.750
3+	1.36 (0.80-2.32)	0.253	0.87 (0.56-1.36)	0.549
Test for trend		0.025		0.834
Duration since first contacted by intervention staff (versus never contacted)				
<1 year	1.03 (0.59-1.80)	0.911	1.13 (0.65-1.97)	0.664
1	1.15 (0.64-2.05)	0.646	1.70 (1.07-2.70)	0.024
2	1.21 (0.69-2.12)	0.502	1.96 (1.22-3.14)	0.006
3+	1.32 (0.76-2.27)	0.325	1.62 (1.04-2.53)	0.034
Test for trend		<0.001		0.033

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¹Consistent condom use is defined as reporting always using condoms.

²Models were adjusted for variables that were significantly associated with the main outcome, CCU, on a P<0.10 significance level in univariate analysis and were found to be confounders of the association between CCU and PPT. For consistent condom use with new or occasional clients and for the most recent repeat client, final models were adjusted for district, the number of condom demos seen past month and the duration since first contacted by intervention staff.

³Adjusted prevalence ratios are presented with a 95% confidence interval.

Tests for trend were carried out to evaluate the dose-relationship between CCU and continuous variables. For the variable number of grey packets received in the last 3 to 12 months, tests for trends were significant for both new or occasional clients ($p<0.001$) and most recent repeat client ($p<0.001$). Results show that CCU fell when the number of grey packets received increased. The lowest CCU was observed when FSWs received 3 grey packets or more, both with new or occasional clients (APR 0.70, 95% CI 0.57-0.84, $p<0.001$) and most recent repeat client (APR 0.63, 95% CI 0.51-0.78, $p<0.001$). No significant association was found between receiving one treatment and CCU with new or occasional clients (APR 0.92, 95% CI 0.80-1.06, $p=0.258$) and with the most recent repeat client (APR 0.90, 95% CI 0.75-1.09, $p=0.276$).

DISCUSSION:

Results from this study show an association between the use of grey packets and lower levels of consistent condom use among FSWs in the context of the *Avahan* intervention in India. After adjusting for confounding factors, a dose-response relationship was found between the number of grey packets received and CCU with new and occasional clients, and with the most recent repeat client. However, the results were only significant when FSWs had received two or more grey packets in the last three to 12 months.

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There are several explanations possible for this association. Due to the cross-sectional nature of the study and the way the questions were asked, we could not make sure if condom use was already inconsistent before the FSW took the treatment or if it became inconsistent after taking the treatment.

On one hand, if condom use was already inconsistent, the explanation for the association could be two-fold: firstly, women who did not use condoms consistently attended the clinic more often than others as a compensatory action and were thus more likely to receive grey packets for PPT; secondly, FSWs with a higher burden of cervicitis due to possible inconsistent condom use were more likely to present with symptoms of vaginal discharge and receive grey packets in the context of syndromic management.

On the other hand, given the relatively low prevalence of gonorrhoea and chlamydia (3.5% and 6.5%, respectively) among FSWs in prevalence studies conducted in the context of Avahan(27), it is likely that the vast majority of cases of vaginal discharge consulting at the clinics did not have cervicitis but rather vaginitis, a condition less clearly related to inconsistent condom use. In addition, the way the question was asked about condom use refers to recent use whereas the question on grey packets covered a three to twelve-month period. It is thus likely that in many instances, inconsistent condom use came after treatment. This plausible hypothesis, thus suggests that a possible disinhibiting effect of receiving a STI treatment would lead to more unsafe sex, in the context where appropriate information is not always conveyed to the patients.

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3 Furthermore, the importance of good communication between physicians and patients
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5 has not been extensively studied in this type of context. However, good communication
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7 has been shown to have an important impact on various patient health outcomes,
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9 adherence to treatment and patient satisfaction in other settings(28-31). In our study, it
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11 is possible that poor communication about the treatment led to a false feeling of
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13 security and disinhibition, which resulted in reduced condom use. Thus, there is a need
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15 to improve communication about the treatment and about the need for continued and
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17 consistent condom use. Such a false feeling of security was revealed in a qualitative
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19 study carried out in Guntur district in conjunction with the quantitative study used in
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21 the present analysis. Here is what some of the interviewed FSWs said:(15)
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29 *“It is said that sex workers get AIDS. It appears as sores and itching develops*
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31 *near the vagina when one has AIDS. It cannot be cured with medicines. The*
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33 *organization gives medicines to prevent such things from happening”*
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37 *“To have sex without a condom and to avoid AIDS, one should wash thoroughly*
38
39 *with hot water and use good medicines”*
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44 On the other hand, almost one third of the study population in our study were illiterate
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46 (29.2%) and a lot of them had wrong beliefs about HIV and treatments of STIs in general,
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48 as also noted in the citations above. This could have contributed to a wrong
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50 understanding of the effect of the treatment, even if the physicians were giving clear
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52 explanations.
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3 Furthermore, risk compensation can be observed with those types of interventions(32).
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5 It has been observed in other contexts, for example, in male circumcision
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7 interventions(33,34). In a study taking place in rural areas of South Africa, condom and
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9 STI knowledge was found to have an impact on condom use. As the community had
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11 wrong beliefs about circumcision and its protective effect, lower condom use was
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13 observed among circumcised men(33). A rise in HIV incidence among MSM was also
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15 observed in many developed countries, as a consequence of an increase in condomless
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17 sex, following the availability of highly active antiretroviral therapy(35). Few studies
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19 were available regarding disinhibition after PPT. However, the few studies that have
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21 examined trends in condom use following implementation of PPT programs did not
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23 report any evidence of risk(6,8)
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32 Unfortunately, it was impossible to determine if the treatment was given presumptively
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34 or not with our data. This is the main limitation of the present study. Consequently,
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36 further studies would be needed to examine if PPT could lead to inconsistent condom
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38 use. The present study also has other limitations. All data were self-reported and could
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40 therefore be susceptible to a social desirability bias since many questions were socially
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42 sensitive. In addition, many FSWs are mobile and difficult to reach and so this study may
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44 not represent all types of FSWs.
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51 In conclusion, the results of our study suggest an association between receiving a STI
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53 treatment and inconsistent condom use. Although the directionality of the association
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55 cannot be fully determined with our data, this observation underlines the importance of
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3 both improving messaging about the effect of the treatment and also of implementing a
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5 broad range of strategies to reduce risky sexual behavior. Further studies are needed to
6
7 clarify the relationship between the use of STI treatments and condom use, especially
8
9 regarding the effect of PPT on condom use.
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12 13 14 **ACKNOWLEDGMENTS**

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16
17 We thank Eric Demers for support in the data analysis. We are grateful to all the
18
19 interviewers involved in this study and above all, for the time and contribution of all
20
21 participants. This study was funded by the Bill & Melinda Gates Foundation (grant #
22
23 OPP33978). The views expressed herein are those of the authors and do not necessarily
24
25 reflect the official policy or position of the Bill & Melinda Gates Foundation.
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30 31 **CONTRIBUTORSHIP STATEMENT**

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33 Marianne Legendre-Dugal analysed the data and co-drafted the manuscript with Michel
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39 Janet Bradley, Subramanian Potty Rajaram and Catherine M. Lowndes were responsible
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47 and James Blanchard contributed to the study design.
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51 Michel Alary was the principal investigator responsible for the conception of the study
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53 and co-drafted the manuscript with Marianne Legendre-Dugal.
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3 All the authors contributed to the interpretation of data, revised critically the
4 manuscript for important intellectual content and agree to be accountable for all
5 aspects of the work.
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11 Competing interests: Dr. Alary reports grants from Bill & Melinda Gates Foundation
12 during the conduct of the study.
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16 17 **DATA SHARING STATEMENT**

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28 29 **LICENSE TRANSFER STATEMENT**

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Association between treatment for gonorrhoea and chlamydia and lower condom use in a cross-sectional study of female sex workers in southern India

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2015-009774.R1
Article Type:	Research
Date Submitted by the Author:	12-Feb-2016
Complete List of Authors:	Legendre-Dugal, Marianne; Université Laval, Médecine social et préventive Bradley, Janet; University of Manitoba, Rajaram, S; Karnataka Health Promotion Trust, CHARME-India Lowndes, Catherine; Public Health England, HIV & STI Department B.M., Ramesh; Karnataka Health Promotion Trust, Washington, Reynold; Karnataka Health Promotion Trust, Moses, Stephen; University of Manitoba, Department of Community Health Sciences; Karnataka Health Promotion Trust, Blanchard, James; University of Manitoba, Department of Community Health Sciences Alary, Michel; Centre de recherche du CHU de Québec,
Primary Subject Heading:	Infectious diseases
Secondary Subject Heading:	Infectious diseases, Public health, Epidemiology, HIV/AIDS
Keywords:	HIV & AIDS < INFECTIOUS DISEASES, Public health < INFECTIOUS DISEASES, SEXUAL MEDICINE

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Association between treatment for gonorrhoea and chlamydia and lower condom use in a cross-sectional study of female sex workers in southern India

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Word counts: 3595 (main text); 294 (abstract)

Key words: Female sex workers, HIV, condom use, STI treatment, periodic presumptive treatment

ABSTRACT

Objectives: To assess whether having received grey packets containing treatment for both gonorrhoea and chlamydia was associated with condom use among female sex workers (FSWs) in five districts of southern India covered by the *Avahan* program where both periodic presumptive treatment (PPT) and syndromic management were used to control these sexually transmitted infections (STIs) among FSWs.

Setting: Cross-sectional study of FSWs recruited in the field in five districts of southern India (Bangalore, Belgaum, Bellary, Guntur and Mumbai) in 2006-2007.

Participants: 1378 self-identified FSWs out of 1442 approached to participate in the study (participation rate: 95.6%). The only exclusion criterion was to be aged < 18 years.

Primary and secondary outcome measures: Consistent condom use (CCU) with new or occasional clients, and with the most recent repeat client as assessed using a questionnaire administered through face-to-face interviews.

Results: Using Poisson regression to model the association between the number of grey packets received in the last 3-12 months and reported CCU, adjusting for factors associated with condom use and other potential confounders in our data, CCU was lowest among FSWs who had received ≥ 3 grey packets in the last 3-12 months with their new or occasional clients [Adjusted prevalence ratio (APR): 0.70, 95% Confidence interval (95%CI): 0.57-0.84, p-value<0.001] and with the most recent repeat client (APR

0.63, 95%CI: 0.51-0.78, p-value<0.001). Tests for trends showed that CCU with both types of clients decreased with the number of grey packets received (p<0.001).

Conclusions: As we could not distinguish grey packets used for PPT from those given for syndromic management, these results could be either due to a perception of protection conferred by PPT or by the fact that inconsistent condom users are more at risk for STIs. Further research on the potential disinhibiting effect of PPT is warranted.

ARTICLE SUMMARY

Strengths and limitations of the study

- This study is part of the evaluation of *Avahan*, an HIV prevention program targeted at high risk groups, notably female sex workers, in India.
- In this study, the use of treatment for gonococcal and chlamydial infection, in the context of both periodic presumptive treatment and syndromic management of female sex workers, was associated with lower consistent condom use.
- The strengths of this study include its large sample size across five Indian districts and the fact that the hypothesis that inappropriate counselling in clinical settings may lead to decrease in condom use is based on the results of a previous qualitative study conducted in the same population.
- The main limitation is that it was impossible to determine if the treatment was given presumptively or in the context of syndromic management.

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- This association that we observed could thus be due to a perception of protection conferred by the treatment or because inconsistent condom users are more at risk for STIs.

For peer review only

BACKGROUND

Sexually transmitted infections (STIs) are considered to increase the risk of human immunodeficiency virus (HIV) transmission, since both infectiousness among HIV infected people and susceptibility for HIV acquisition among those uninfected are increased by STIs. There has thus been interest in treating STIs as a way to prevent HIV acquisition(1-4). In resource-limited settings, where sophisticated laboratories are not regularly accessible, STIs are often treated presumptively or on the basis of symptom-based algorithms. Unfortunately among women, the sensitivity and specificity of syndromic case management tend to be very low when the vaginal discharge syndrome is used as an indication for treating gonorrhoea and chlamydia, with the latter infections sometimes not even associated with symptoms of vaginal discharge(5). Moreover, gonorrhoea and chlamydia are often characterized by an absence of symptoms, especially among women(5, 6). In settings where STI prevalence is high and concentrated in certain core groups, it is assumed that periodic presumptive treatment (PPT) can be effective as an HIV prevention strategy(3, 7-9). However, this strategy has to be part of a more complete program to have long-term sustainability. The program has to include communication for behavioural change with regard to risky sexual behaviour, in particular condom use, as well as structural components and clinical services other than PPT(10, 11).

Avahan, the India AIDS initiative of the Bill & Melinda Gates Foundation implemented since 2003, is a large-scale HIV prevention program whose main objective was to reduce

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3 HIV prevalence among high-risk groups such as female sex workers (FSWs), men who
4 have sex with men (MSM), people who inject drugs (PWID) and clients of FSWs in the six
5 states of India with the highest HIV prevalence(12, 13). The intervention, that has been
6 described in more detail elsewhere(12), includes behavioural change communication
7 with the promotion of condom use using peer educators, free distribution of
8 commodities (condoms, clean syringes for PWID), community development,
9 interventions against stigma and discrimination, and STI care. The latter used an
10 “essential service package” for FSWs that was offered exclusively at *Avahan* FSW-
11 dedicated STI clinics and included PPT for gonorrhoea and chlamydia (recommended
12 quarterly), syndromic case management of women coming to the clinic with STI
13 symptoms and serological testing, followed by treatment, when appropriate, for syphilis
14 twice a year. The target of the strategy was to attain one clinic visit per FSW every 3
15 months(14). Anecdotally, program implementers observed that in their communication
16 with patients, physicians were not always very clear about the STIs for which the
17 treatment was protective and did not give enough adequate information adapted to
18 FSWs’ understanding, which could have led some women to think that the treatment
19 given may protect directly against HIV or other STIs than those for which treatment was
20 given. Such beliefs were also observed in a qualitative study carried out among FSWs in
21 Guntur district, state of Andhra Pradesh(15). Although a few previous studies did not
22 show a decrease in condom use following the implementation of PPT among FSWs(6, 8),
23 data on this issue remain sparse and a concern subsists about a disinhibiting effect of STI
24 treatment in relation to condom use. In an order to constantly improve prevention
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3 programs, the objective of this secondary data analysis was to determine if an
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5 association could be found between the prescription of STI treatment and condom use
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7 and more specifically, if the disinhibiting hypothesis could be plausible in the context of
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9 FSWs with their clients, in five districts of south India.
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12 13 14 **METHODS**

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16 Under the CHARME-India project (led by the Centre hospitalier *affilié* universitaire de
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18 Québec in partnership with Canadian, British and Indian institutions) whose aim was to
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20 evaluate the impact of the *Avahan* program, we conducted detailed behavioural cross-
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22 sectional studies among FSWs in five districts of south India between February 2006 and
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24 December 2007. Of the 1442 FSWs invited, 1378 (95.6%) participated in the study.
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26 Three of the study districts were in the state of Karnataka [Bangalore (n=369), Belgaum
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28 and (n=208) Bellary (n=198)], whereas the two other districts were Guntur in the state
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30 of Andhra Pradesh (n=208) and Mumbai in the state of Maharashtra (n=395). The
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32 interviews were conducted face-to-face by trained interviewers.
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40 Two sampling procedures were used for the selection of clusters. For fixed sex work
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42 sites, such as home-based, brothel-based and lodge-based sites, a conventional cluster
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44 sampling was used. For street-based and other public place-based sex work sites, time-
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46 location cluster (TLC) sampling was used. Normalized weights were calculated for the
47
48 complex sampling design. Within selected clusters, the respondents were selected
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50 randomly. District-wide mapping of the sites where FSWs could be found was used as
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52 well as information about hours of operation for the TLC sampling. We also
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3 approximated the possible number of respondents at different times of the day and of
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6 the week. Site maps were then used by the research teams for the sampling frame
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9 development. Sampling methods were the same as those reported by Saidel *et al*(16).

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11 Data from face-to-face interviews with FSWs were collected about their sexual activity
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13 with two types of commercial partners: new or occasional clients and the most recent
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15 repeat client. The two categories of partners were not mutually exclusive, since every
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17 FSW having a most recent repeat client also had new or occasional clients, but not
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19 necessarily the opposite.
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24 25 **Ethical considerations**

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28 Participation in the study was on a voluntary basis. The interviews were conducted
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30 anonymously, with no names or personal identifiers recorded on the questionnaire.
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32 Witnessed verbal consent was obtained from each participant prior to the
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34 administration of the questionnaire. This means that a witness independent to the study
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36 confirmed in writing that the subject had provided verbal consent. This procedure was
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38 preferred to written consent to ensure FSWs anonymity as sex work is illegal in India.
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40 The study and its procedures were approved by the ethics committees of the Centre
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42 hospitalier *affilié* universitaire de Québec (Canada) and of the University of Manitoba.
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44 The project was also approved by the ethics committees of the implementing partners
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Dependent variable

The dependent variable, consistent condom use (CCU), with new or occasional clients (clients who are not well known by the FSW and who visited her only once or at most a few times) and with the most recent repeat client (clients with whom FSWs are familiar), was obtained through the survey question: "In general, how often is a condom used when you have sex with 'type of partner'? ". Interviewers were instructed to explain the meaning of "in general" as the current sex work practice of the participants. There was however no time frame specified. Possible answers to this question were: never (0%), sometimes (<50%), frequently (≥50%) or always (100%). We considered FSWs were using condoms consistently with their partners if they answered "always" and inconsistently if they answered "never", "sometimes" or "frequently", in order to create a dichotomous variable.

Independent variables

To determine the relationship between condom use and treatment for STIs, we assessed whether the variable "number of grey packets received in the last three to 12 months" was associated with CCU among FSWs with their new or occasional clients and with their most recent repeat client, while controlling for variables affecting condom use. The grey packets were used for presumptive treatment of asymptomatic chlamydial and gonococcal infections and contained a single dose of cefixime 400 mg and azithromycin 1000 mg. In the case of syndromic management, the grey packets were mostly used in combination with the green packet that was designed to treat vaginitis agents. As the

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grey packets contained a single dose treatment, they were taken on site, in front of the health care worker, thus ensuring that the treatment was actually taken. Unfortunately, the questionnaire used in the interviews did not address the issue on the reason why the grey packets were taken (PPT or because of vaginal discharge). An analysis of the data of the *Avahan* computerized information system for years 2006 and 2007 for the three Karnataka districts (data were not available for Mumbai and Guntur) showed that among the 25,530 grey packets administered to FSWs, 32.7% were used for PPT (*Avahan* program, unpublished data).

The time frame used (three to 12 months) was wide because of inter-district variations in the start dates of the implementation of the STI essential package for FSWs. In all districts except Bangalore, the program had started 12 months or more prior to data collection. In Bangalore, it had only started three months before the interviews were conducted. The treatment variable was divided into four categories, which were zero, one, two or three or more grey packets.

We determined, based on the literature, a set of socio-demographic, sex-work related and intervention exposure factors that may affect condom use(17-22). Each model was adjusted for those variables. Socio-demographic factors included district, age, marital status (currently married, divorced/separated/widowed, never married or devadasi, a particular form of sex work where women are dedicated to gods and goddesses through marriage, who practice traditional, caste-based sex work(23, 24)), literacy and age at first sex. Sex work related factors included age at first sex work, main place of

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3 solicitation of clients (brothel, home, public places or rented room/lodge or other), main
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5 place of entertaining (with the same categories as main place of solicitation), having sex
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7 work as sole income, if the FSW is usually under influence of alcohol when having sex
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9 with a client, if the partner is usually under influence of alcohol when having sex with
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11 the FSW and if FSW solicits her clients independently or through a middleman or a pimp.
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13 Intervention exposure variables other than the number of grey packets received,
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15 included the number of times contacted by intervention staff in the last month, the
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17 number of condom demonstrations seen in the past month and the time since first
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19 contacted by intervention staff.
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25 26 27 **Statistical analysis**

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30 Statistical analysis was carried out using SAS version 9.3 (SAS Institute, Cary, NC).
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32 Weighted Poisson regression taking into account the cluster sampling was used for
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34 univariate and multivariate analyses(25, 26) to determine the association between
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36 condom use and the number of grey packets received in the last three to 12 months.
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38 Prevalence ratios (PRs) and adjusted prevalence ratios (APRs), with 95% confidence
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40 intervals [95% CIs], were generated with Poisson regression. Continuous variables were
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42 categorized. One model was created for each type of partner in the multivariable
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44 analysis. Variables from the univariate analysis were initially included in the multivariate
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46 model based on a significance level of $p < 0.10$. An iterative process was then used to
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48 keep only the variables that were found to be confounding in the model (e.g. that
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50 changes the APR of the association between receiving grey packets and condom use by
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≥10%). A test for trend was used to evaluate the dose-response relationship between the number of grey packets received and condom use. All p-values shown are two-sided.

RESULTS

Socio-demographic, sex-work related and intervention exposure factors were measured among all 1378 FSWs with new or occasional clients, among whom, 938 (68.7%) had had a repeat client. Tables 1 and 2 show the characteristics of the participants and univariate associations between each factor and consistent condom use with the two types of partner.

Table 1: Sample characteristics and univariate associations between these characteristics and consistent condom use by FSWs with new or occasional clients in five districts of south India^{1,2,3,4}

	N (%) (n=1378)	% CCU	Prevalence ratio (95% CI)	p-value
SOCIO-DEMOGRAPHIC FACTORS				
District				0.024
Bangalore	369 (26.8)	63.7	0.97 (0.83-1.14)	
Bellary	198 (14.4)	70.2	1.11 (0.96-1.29)	
Guntur	208 (15.1)	79.8	1.20 (1.05-1.37)	
Belgaum	208 (15.1)	75.0	1.07 (0.92-1.23)	
Mumbai	395 (28.7)	68.6	Ref	
Age				0.175
<25	296 (21.5)	74.0	1.07 (0.97-1.18)	
25+	1082 (78.5)	69.1	Ref	
Marital status				0.004
Devadasi	156 (11.3)	79.5	1.18 (1.05-1.32)	
Never married	143 (10.4)	67.1	0.88 (0.73-1.06)	
Divorced/Separated/Widowed	651 (47.2)	68.8	1.00 (0.89-1.13)	
Currently married	428 (31.0)	69.9	Ref	
Literate				0.107
Yes	403 (29.2)	73.2	1.09 (0.98-1.21)	
No	975 (70.8)	68.9	Ref	
Age at first sex				0.562
<15	470 (34.1)	67.9	0.96 (0.82-1.11)	
15+	908 (65.9)	71.3	Ref	

SEX-WORK RELATED FACTORS**Age at first sex work** **0.004**

<22 587 (42.6) 75.1 1.14 (1.04-1.24)

22+ 791 (57.4) 66.5 Ref

Main place of solicitation **0.411**

Brothel 315 (22.9) 68.3 1.06 (0.94-1.19)

Home 318 (23.1) 74.8 1.09 (0.97-1.22)

Rented room/lodge or other 82 (5.6) 72.0 1.10 (0.91-1.34)

Public places 661 (48.0) 68.5 Ref

Main place of entertaining **0.067**

Brothel 349 (25.3) 78.2 1.17 (0.99-1.39)

Home 394 (28.6) 66.8 1.11 (0.94-1.31)

Rented room/lodge or other 523 (38.0) 68.5 1.02 (0.86-1.21)

Public places 111 (8.1) 64.9 Ref

Sex work sole income **0.187**

Yes 476 (34.5) 70.3 1.06 (0.97-1.16)

No 898 (65.2) 69.8 Ref

FSW usually under influence of alcohol with partner **0.517**

Yes 542 (39.3) 70.7 1.03 (0.94-1.14)

No 834 (60.5) 70.0 Ref

Partner usually under influence of alcohol **0.063**

Yes 1189 (86.3) 75.8 0.86 (0.74-1.01)

No 186 (13.5) 69.3 Ref

Solicit independently **0.046**

Yes 815 (59.1) 66.6 0.91 (0.83-1.00)

No 560 (40.6) 75.4 Ref

INTERVENTION EXPOSURE**Number of times contacted by staff last month** **<0.001**

<2 393 (28.5) 60.3 Ref

2+ 981 (71.2) 74.3 1.26 (1.10-1.44)

Number of condom demos seen past month **0.002**

0 257 (18.7) 57.2 Ref

1 303 (22.0) 68.7 1.26 (1.02-1.56)

2 363 (26.34) 76.6 1.44 (1.18-1.76)

3+ 397 (28.8) 76.8 1.36 (1.10-1.67)

Test for trend **0.077****Duration since first contacted by intervention staff** **0.001**

Has not been contacted 229 (16.6) 54.1 Ref

<1 (greater than zero) 284 (20.6) 68.0 1.25 (1.01-1.54)

1 year 284 (20.6) 72.9 1.35 (1.09-1.66)

2-3 years 360 (26.1) 74.7 1.44 (1.18-1.74)

4 years + 219 (15.9) 78.5 1.46 (1.19-1.79)

Test for trend **0.039****Treatment of STIs: Number of grey packets received in the last** **0.259**

3 to 12 months

0	668 (48.5)	68.7	Ref
1	129 (9.4)	74.4	1.02 (0.88-1.18)
2	254 (18.4)	74.4	1.10 (0.98-1.23)
3+	326 (23.7)	68.1	0.88 (0.73-1.07)

Test for trend**0.259**¹ Consistent condom use is defined as reporting always using condoms.² Due to missing values, the total N for each variable may be different from 1378 (total of FSW with a new or occasional client). The small number of missing values does not significantly affect the results.³ Prevalence ratios are presented with a 95% confidence interval.⁴ CCU is defined as consistent condom use

Table 2: Sample characteristics and univariate associations between these characteristics and consistent condom use by FSWs with the most recent repeat client in five districts of south India^{1,2,3,4}

	N (%) (n=1378)	% CCU	Prevalence ratio (95% CI)	p-value
SOCIO-DEMOGRAPHIC FACTORS				
District				<0.001
Bangalore	221 (23.6)	64.7	1.13 (0.73-1.75)	
Bellary	95 (10.1)	67.3	1.56 (1.30-1.87)	
Guntur	181 (19.3)	85.6	1.74 (1.49-2.03)	
Belgaum	117 (12.5)	53.0	1.06 (0.83-1.36)	
Mumbai	324 (34.5)	51.5	Ref	
Age				0.045
<25	199 (21.2)	71.3	1.21 (1.00-1.46)	
25+	739 (78.8)	60.8	Ref	
Marital status				0.100
Devadasi	90 (9.5)	68.9	1.19 (0.99-1.42)	
Never married	115 (12.3)	66.1	0.94 (0.74-1.21)	
Divorced/Separated/Widowed	450 (48.0)	61.6	0.94 (0.73-1.20)	
Currently married	283 (30.1)	62.1	Ref	
Literate				0.958
Yes	307 (32.7)	64.5	1.01 (0.81-1.24)	
No	631 (67.3)	62.3	Ref	
Age at first sex				0.938
<15	311 (33.1)	61.4	0.99 (0.86-1.15)	
15+	627 (66.8)	63.8	Ref	
SEX-WORK RELATED FACTORS				
Age at first sex work				0.196
<22	418 (44.6)	66.8	1.15 (0.93-1.43)	
22+	520 (55.4)	60.0	Ref	
Main place of solicitation				0.084

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3	Brothel	210 (22.4)	67.1	1.24 (0.98-1.57)	
4	Home	207 (22.1)	69.6	1.34 (1.06-1.68)	
5	Rented room/lodge or other	60 (6.4)	70.0	1.33 (0.99-1.79)	
6	Public places	459 (48.9)	57.1	Ref	
7					
8	Main place of entertaining				0.192
9	Brothel	249 (26.5)	61.5	0.92 (0.76-1.11)	
10	Home	252 (26.9)	69.4	0.99 (0.81-1.20)	
11	Rented room/lodge or other	358 (38.2)	58.4	0.75 (0.56-1.01)	
12	Public places	78 (8.3)	68.0	Ref	
13					
14	Sex work sole income				0.013
15	Yes	319 (34.0)	67.4	1.29 (1.06-1.56)	
16	No	616 (65.7)	60.7	Ref	
17					
18	FSW usually under influence of alcohol with partner				0.007
19	Yes	378 (40.3)	55.0	0.79 (0.67-0.94)	
20	No	559 (59.6)	68.3	Ref	
21					
22	Partner usually under influence of alcohol				0.047
23	Yes	603 (64.3)	58.0	0.85 (0.72-1.00)	
24	No	334 (35.6)	72.2	Ref	
25					
26	Solicit independently				0.150
27	Yes	510 (54.4)	57.8	0.85 (0.68-1.06)	
28	No	427 (45.5)	69.1	Ref	
29					
30	INTERVENTION EXPOSURE				
31	Number of times contacted by staff last month				0.525
32	<2	238 (25.4)	57.1	Ref	
33	2+	697 (74.3)	65.3	1.08 (0.86-1.36)	
34					
35	Number of condom demos seen past month				0.041
36	0	151 (16.1)	52.3	Ref	
37	1	198 (21.1)	62.1	1.09 (0.84-1.41)	
38	2	258 (27.5)	70.0	1.23 (0.97-1.57)	
39	3+	289 (30.8)	65.7	0.98 (0.65-1.47)	
40					
41	Test for trend				0.222
42	Duration since first contacted by intervention staff				0.004
43	Has not been contacted	132 (14.1)	50.0	Ref	
44	<1 (greater than zero)	180 (19.2)	65.0	0.94 (0.55-1.60)	
45	1 year	169 (18.0)	65.7	1.39 (0.98-1.71)	
46	2-3 years	270 (28.8)	68.9	1.43 (1.12-1.83)	
47	4 years +	185 (19.7)	58.9	1.09 (0.83-1.44)	
48					
49	Test for trend				0.017
50	Treatment of STIs: Number of grey packets received in the last				0.270
51	3 to 12 months				
52	0	447 (47.7)	63.3	Ref	
53	1	80 (8.5)	71.3	1.08 (0.91-1.29)	
54	2	174 (18.6)	60.3	0.80 (0.56-1.13)	
55	3+	237 (25.3)	61.6	0.82 (0.64-1.05)	
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Test for trend**0.270**

¹ Consistent condom use is defined as reporting always using condoms.

² Due to missing values, the total N for each variable may be different from 938 (total of FSW with a most recent repeat client). The small number of missing values does not significantly affect the results.

³ Prevalence ratios are presented with a 95% confidence interval.

⁴ CCU is defined as consistent condom use

The majority of FSWs (78.5%) were older than 25 years and were illiterate (70.8%). Seventy percent reported using condoms consistently with their new or occasional clients whereas 591 (63.0%) of FSWs who reported repeat clients, reported consistent condom use with their most recent one. Less than half (48.5%) FSWs had not received a grey packet in the last three to 12 months, while 129 (9.4%) had received one treatment, 254 (18.4%) had received two treatments and 326 (23.7%) had received 3 treatments or more.

In univariate analysis (tables 1 and 2), CCU was higher among FSWs who had seen condom demonstrations in the last month in comparison to those who had not seen any. CCU was at its highest level for 2 condom demonstrations seen in the last month for both FSWs with new or occasional clients (PR 1.44, $p<0.001$) as well as for FSWs with a most recent repeat client (PR 1.23, $p=0.095$). CCU was also higher among FSWs who had been contacted by intervention staff in comparison to those who had not been contacted. CCU increased when time since first contacted by intervention staff increased and was at its highest level at 4 years and more for new and occasional clients (PR 1.46, $p<0.001$), and was at its highest level at 2 or 3 years since first contacted for most recent repeat client (PR 1.43, $p=0.004$). CCU with new and occasional clients was higher among FSWs who had two or more contacts with intervention staff in the

last month for (PR 1.26, $p < 0.001$), but results were not significant for FSWs with the most recent repeat client. In univariate analysis, no significant association was found between CCU and the number of grey packets received in the last three to 12 months. For the socio-demographic factors, district was associated with consistent condom use with both types of partner (new/occasional clients $p = 0.024$ and most recent repeat client $p < 0.001$). Age was only significant for FSWs with a most recent repeat client (PR 1.21, $p = 0.045$). For sex-work related factors, alcohol intake by the FSW with clients was only significantly associated with CCU with the most recent repeat client (PR 0.79 $p = 0.007$), but was significant for both type in the case for alcohol intake by the client (new/occasional clients: PR 0.85, $p = 0.063$ and most recent repeat client: PR 0.85, $p = 0.047$).

In multivariate analysis (table 3), final models were adjusted for the district, the number of condom demonstrations seen in the past month and the time since first contacted by intervention staff.

Table 3: Multivariate associations between these characteristics and consistent condom use by FSWs with new or occasional clients and with a most recent repeat client in five districts of south India^{1,2,3}

	Consistent condom use with new or occasional clients		Consistent condom use with most recent repeat client	
	Adjusted prevalence ratio (95% CI)	p-value	Adjusted prevalence ratio (95% CI)	P-value
Number of grey packets received in the last 3 to 12 months (versus 0)				
1	0.92 (0.80-1.06)	0.258	0.90 (0.75-1.09)	0.276
2	0.90 (0.79-1.02)	0.089	0.63 (0.47-0.85)	0.003
3	0.70 (0.57-0.84)	<0.001	0.63 (0.51-0.78)	<0.001

Test for trend		<0.001		<0.001
District				
Bangalore	1.14 (0.95-1.36)	0.165	1.51 (1.17-1.95)	0.002
Bellary	1.23 (1.04-1.45)	0.015	1.93 (1.48-2.52)	<0.001
Guntur	1.32 (1.14-1.53)	<0.001	1.85 (1.58-2.18)	<0.001
Belgaum	1.27 (1.08-1.50)	0.004	1.24 (0.93-1.64)	0.142
Mumbai	Ref		Ref	
Number of condom demos seen in the past month (versus 0)				
1	1.18 (0.69-2.02)	0.545	0.88 (0.58-1.32)	0.531
2	1.34 (0.79-2.29)	0.278	0.94 (0.63-1.40)	0.750
3+	1.36 (0.80-2.32)	0.253	0.87 (0.56-1.36)	0.549
Test for trend		0.025		0.834
Duration since first contacted by intervention staff (versus never contacted)				
<1 year	1.03 (0.59-1.80)	0.911	1.13 (0.65-1.97)	0.664
1	1.15 (0.64-2.05)	0.646	1.70 (1.07-2.70)	0.024
2	1.21 (0.69-2.12)	0.502	1.96 (1.22-3.14)	0.006
3+	1.32 (0.76-2.27)	0.325	1.62 (1.04-2.53)	0.034
Test for trend		<0.001		0.033

¹ Consistent condom use is defined as reporting always using condoms.

² Models were adjusted for variables that were significantly associated with the main outcome, CCU, on a P<0.10 significance level in univariate analysis and were found to be confounders of the association between CCU and PPT. For consistent condom use with new or occasional clients and for the most recent repeat client, final models were adjusted for district, the number of condom demos seen past month and the duration since first contacted by intervention staff.

³ Adjusted prevalence ratios are presented with a 95% confidence interval.

Tests for trend were carried out to evaluate the dose-relationship between CCU and continuous variables. For the variable number of grey packets received in the last 3 to 12 months, tests for trends were significant for both new or occasional clients ($p<0.001$) and most recent repeat client ($p<0.001$). Results show that CCU fell when the number of grey packets received increased. The lowest CCU was observed when FSWs received 3 grey packets or more, both with new or occasional clients (APR 0.70, 95% CI 0.57-0.84, $p<0.001$) and most recent repeat client (APR 0.63, 95% CI 0.51-0.78, $p<0.001$). No significant association was found between receiving one treatment and CCU with new

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3 or occasional clients (APR 0.92, 95% CI 0.80-1.06, p=0.258) and with the most recent
4
5 repeat client (APR 0.90, 95% CI 0.75-1.09, p=0.276).
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8 9 **DISCUSSION:**

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12 Results from this study show an association between the use of grey packets and lower
13
14 levels of consistent condom use among FSWs in the context of the *Avahan* intervention
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16 in India. After adjusting for confounding factors, a dose-response relationship was found
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18 between the number of grey packets received and CCU with new and occasional clients,
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20 and with the most recent repeat client. However, the results were only significant when
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22 FSWs had received two or more grey packets in the last three to 12 months.
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29 There are several explanations possible for this association. Due to the cross-sectional
30
31 nature of the study and the way the questions were asked, we could not make sure if
32
33 condom use was already inconsistent before the FSW took the treatment or if it became
34
35 inconsistent after taking the treatment.
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40 On one hand, if condom use was already inconsistent, the explanation for the
41
42 association could be two-fold: firstly, women who did not use condoms consistently
43
44 attended the clinic more often than others as a compensatory action and were thus
45
46 more likely to receive grey packets for PPT; secondly, FSWs with a higher burden of
47
48 cervicitis due to possible inconsistent condom use were more likely to present with
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50 symptoms of vaginal discharge and receive grey packets in the context of syndromic
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52 management.
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4 On the other hand, given the relatively low prevalence of gonorrhoea and chlamydia
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6 (3.5% and 6.5%, respectively) among FSWs in prevalence studies conducted in the
7
8 context of *Avahan*(27), it is likely that the vast majority of cases of vaginal discharge
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10 consulting at the clinics did not have cervicitis but rather vaginitis, a condition less
11
12 clearly related to inconsistent condom use. In addition, the way the question was asked
13
14 about condom use refers to recent use whereas the question on grey packets covered a
15
16 three to twelve-month period. It is thus likely that in many instances, inconsistent
17
18 condom use came after treatment. This plausible hypothesis thus suggests that a
19
20 possible disinhibiting effect of receiving a STI treatment would lead to more unsafe sex,
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22 in the context where appropriate information is not always conveyed to the patients.
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24 Furthermore, the importance of good communication between physicians and patients
25
26 has not been extensively studied in this type of context. However, good communication
27
28 has been shown to have an important impact on various patient health outcomes,
29
30 adherence to treatment and patient satisfaction in other settings(28-31). In our study, it
31
32 is possible that the lack of adequate information and poor communication about the
33
34 treatment led to a false feeling of security and disinhibition, which resulted in reduced
35
36 condom use. Thus, there is a need to improve communication about the treatment and
37
38 about the need for continued and consistent condom use. Such a false feeling of
39
40 security was revealed in a qualitative study carried out in Guntur district in conjunction
41
42 with the quantitative study used in the present analysis. Here is what some of the
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44 interviewed FSWs said:(15)
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3 *“It is said that sex workers get AIDS. It appears as sores and itching develops*
4 *near the vagina when one has AIDS. It cannot be cured with medicines. The*
5 *organization gives medicines to prevent such things from happening”*
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11 *“To have sex without a condom and to avoid AIDS, one should wash thoroughly*
12 *with hot water and use good medicines”*
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18 On the other hand, almost one third of the study population in our study were illiterate
19 (29.2%) and a lot of them had wrong beliefs about HIV and treatments of STIs in general,
20 as also noted in the citations above. This could have contributed to a wrong
21 understanding of the effect of the treatment, even if the physicians were giving clear
22 explanations.
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31 Furthermore, risk compensation can be observed with those types of interventions(32).
32 It has been observed in other contexts, for example, in male circumcision
33 interventions(33, 34). In a study taking place in rural areas of South Africa, condom and
34 STI knowledge was found to have an impact on condom use. As the community had
35 wrong beliefs about circumcision and its protective effect, lower condom use was
36 observed among circumcised men(33). A rise in HIV incidence among MSM was also
37 observed in many developed countries, as a consequence of an increase in condomless
38 sex, following the availability of highly active antiretroviral therapy(35). Few studies
39 were available regarding disinhibition after PPT. However, the few studies that have
40 examined trends in condom use following implementation of PPT programs did not
41 report any evidence of increased risk-taking(6, 8).
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3 Unfortunately, it was impossible to determine if the treatment was given presumptively
4 or not with our data. This is the main limitation of the present study. Consequently,
5
6 further studies would be needed to examine if PPT could lead to inconsistent condom
7
8 use. The present study also has other limitations. All data were self-reported and could
9
10 therefore be susceptible to a social desirability bias since many questions were socially
11
12 sensitive. In addition, many FSWs are mobile and difficult to reach and so this study may
13
14 not represent all types of FSWs.
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22 The condom use levels in our study were moderately high, which is in line with the
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24 results of the first round of the integrated biological and behavioural assessment (IBBA)
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26 surveys that were conducted in the same period than our study (16). CCU with clients in
27
28 general was 65.2% in IBBA round 1. Several years after the implementation of the
29
30 *Avahan* program, in IBBA round 2 conducted in 2009, CCU reached 84.0%(36). In
31
32 general terms, the strength of the *Avahan* program was mostly in the behavioural and
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34 community components, as regular coverage of FSWs by these components of the
35
36 intervention was a lot higher than regular clinical coverage(37). Nevertheless, most
37
38 reports suggest that *Avahan* had major impact on the HIV epidemic among both
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40 FSWs(27, 36, 38) and the general population(39) in the states of south India covered by
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42 the intervention.
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51 In conclusion, the results of our study suggest an association between receiving a STI
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53 treatment and inconsistent condom use in the early days of the *Avahan* program in
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55 India. Although the directionality of the association cannot be fully determined with our
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3 data, this observation underlines the importance of both improving counselling about
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5 the effect of STI treatment in clinical settings and implementing a broad range of
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7 strategies for HIV prevention among FSWs. Such strategies, implemented within a
8
9 combination framework, could notably include regular HIV testing followed by pre-
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11 exposure prophylaxis for HIV-negative FSWs and immediate treatment (often called
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13 treatment as prevention) for those found infected(40). Finally, further studies are
14
15 needed to clarify the relationship between the use of STI treatments and condom use,
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17 especially regarding the effect of PPT on condom use.
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24 **ACKNOWLEDGMENTS**

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26
27 We thank Eric Demers for support in the data analysis. We are grateful to all the
28
29 interviewers involved in this study and above all, for the time and contribution of all
30
31 participants. This study was funded by the Bill & Melinda Gates Foundation (grant #
32
33 OPP33978). The views expressed herein are those of the authors and do not necessarily
34
35 reflect the official policy or position of the Bill & Melinda Gates Foundation.
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41 **CONTRIBUTORSHIP STATEMENT**

42
43 Marianne Legendre-Dugal analysed the data and co-drafted the manuscript with Michel
44
45 Alary.
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47

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49 Janet Bradley, Subramanian Potty Rajaram and Catherine M. Lowndes were responsible
50
51 for the data collection in the field
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3 Catherine M. Lowndes, Banadakoppa M. Ramesh, Reynold Washington, Stephen Moses
4
5 and James Blanchard contributed to the study design.
6
7

8
9 Michel Alary was the principal investigator responsible for the conception of the study
10
11 and co-drafted the manuscript with Marianne Legendre-Dugal.
12
13

14
15 All the authors contributed to the interpretation of data, revised critically the
16
17 manuscript for important intellectual content and agree to be accountable for all
18
19 aspects of the work.
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21

22
23 Competing interests: Dr. Alary reports grants from the Bill & Melinda Gates Foundation
24
25 during the conduct of the study.
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28 29 **DATA SHARING STATEMENT**

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31 No additional data available
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34 35 **LICENSE TRANSFER STATEMENT**

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38
39 on behalf of all authors, an exclusive licence (or non-exclusive for government
40
41 employees) on a worldwide basis to the BMJ Publishing Group Ltd and its Licensees to
42
43 permit this article (if accepted) to be published in Sexually Transmitted Infections and
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45 any other BMJ PGL products to exploit all subsidiary rights, as set out in our licence
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STROBE Statement—Checklist of items that should be included in reports of *cross-sectional studies*

	Item No	Recommendation
Title and abstract	1	<p><i>a)</i> Indicate the study's design with a commonly used term in the title or the abstract</p> <p>Revised title: Association between treatment for gonorrhoea and chlamydia and lower condom use in a cross-sectional study of female sex workers in southern India</p> <hr/> <p><i>b)</i> Provide in the abstract an informative and balanced summary of what was done and what was found: see page all page 2 and page 3 (2 top lines)</p>
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported: see all of pages 4 and 5
Objectives	3	State specific objectives, including any prespecified hypotheses: see top of page 6 (the 4 lines before the methods section)
Methods		
Study design	4	Present key elements of study design early in the paper: see page 6, 1st paragraph of the methods section, lines 1 to 5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection: see page 6, the whole first paragraph of the methods section.
Participants	6	<i>(a)</i> Give the eligibility criteria, and the sources and methods of selection of participants: see the paragraph starting at the bottom of page 6 and ending at the top of page 7 providing explicitly the sources and methods for selecting the participants, whereas their eligibility criteria are implicitly provided by mentioning all the types of sex work-sites from which the participating FSWs were recruited
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable: see the sections on the dependent variable and on the independent variables, pages 8, 9 and top of page 10
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group: the source (face-to-face interviews) is presented in the paragraph just above the Ethical considerations on page 7 whereas the exact wording of the questions relating to the dependent variable is presented in the 1st paragraph of page 8 and that concerning the main independent variable is presented in the first 2 lines of the 2nd paragraph of page 8
Bias	9	Describe any efforts to address potential sources of bias: the method used to get a representative sample is described at the bottom of page 7 and top of page 8; control of confounding was carried out through the use of a multivariate analysis (see section on statistical analyses, bottom of page 10 and top of page 11)
Study size	10	Explain how the study size was arrived at: this is not explained as we are in the context of secondary data analyses (we used data already collected for other purposes) as clearly stated on the first line of page 6
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why: the subsections of the methods on

the dependent variable, the independent variables and the statistical analysis (pages 8 to 11) provide these explanations		
Statistical methods	12	<p>(a) Describe all statistical methods, including those used to control for confounding: see the sub-section on statistical analyses, pages 10-11</p> <p>(b) Describe any methods used to examine subgroups and interactions: not applicable</p> <p>(c) Explain how missing data were addressed: very few missing data (see categories in tables 1 and 2 that add up to or very close to the sample size of 1378 for table 1 and 938 for table 2 (there is a mistake in the N column of table 2 where one should read at the top 938 and not 1378: see first 3 lines of the results section on page 11 for the explanations of these 2 different sample sizes); given this very small number of missing data, nothing special was done to address the missing data problem since it was not existing: this is specified in a footnote to each of the 3 tables</p> <p>(d) If applicable, describe analytical methods taking account of sampling strategy: All the analyses used the weights related to the sampling design (see lines 4 and 5 of the last paragraph of page 6) and the cluster sampling; however, this is not clearly explained in the statistical analysis section where the second sentence of this section on page 10 should be reworded as follows: “Weighted Poisson regression taking into account the cluster sampling was used....”. You could make this small correction yourself or re-open the submission system so as we can submit a revised version.</p> <p>(e) Describe any sensitivity analyses: not applicable</p>
Results		
Participants	13*	<p>(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed: very few women did not accept to participate (see 5th line of the 1st paragraph of the methods section on page 6) and there was only one stage of selection</p> <p>(b) Give reasons for non-participation at each stage: no reason provided and this information is not easily available as this paper is about a secondary data analysis as mentioned above; however, it is somewhat irrelevant given the very high participation rate</p> <p>(c) Consider use of a flow diagram: not applicable as there was only one stage</p>
Descriptive data	14*	<p>(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders: see tables 1 and 2</p> <p>(b) Indicate number of participants with missing data for each variable of interest: very few missing data as indicated in footnotes to all 3 tables</p>
Outcome data	15*	Report numbers of outcome events or summary measures: see first paragraph of page 15 where the frequencies of the outcome and of the main independent variables
Main results	16	<p>(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval): see tables 1 and 2. Make clear which confounders were adjusted for and why they were included: see table 3 and the paragraph just above; the strategy to selection the confounders to keep in the final model is explained in the statistical analysis section at the bottom of page 10</p> <p>(b) Report category boundaries when continuous variables were categorized: see all tables</p>

		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period: not relevant in the context of this paper
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses: no other analysis was carried out
Discussion		
Key results	18	Summarise key results with reference to study objectives: see the 1st paragraph of the discussion section, page 18
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision: the main limitations are presented in the 1st paragraph of page 21 . Discuss both direction and magnitude of any potential bias: beside the bias due to possible non-differential misclassification of the self-reported data (universally known as reducing the strength of the associations observed and not needing more discussion once this acknowledged as we did in the 1st paragraph of page 21), the main issue in this paper is not so much about bias but about the directionality of the association given the cross-sectional nature of the data: this is discussed with lots of details from the 2nd paragraph of the discussion (page 18) till page 20
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence: see the 1st half of the conclusion paragraph, bottom of page 21 and top of page 22
Generalisability	21	Discuss the generalisability (external validity) of the study results: our conclusions are setting specific, but we discussed the issue of risk compensation related to the main association studied with regards to findings on this issue in studies conducted in other settings in the last paragraph of page 20
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based: see the acknowledgements section on page 22

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.