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LIFETIME PREVALENCE AND INCIDENCE OF INDUCED ABORTION AND CORRELATES IN A CLUSTER-RANDOM SAMPLE OF FEMALE SEX WORKERS IN MOMBASA, KENYA

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Keywords:	SEXUAL MEDICINE, PUBLIC HEALTH, EPIDEMIOLOGY

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LIFETIME PREVALENCE AND INCIDENCE OF INDUCED ABORTION AND CORRELATES IN A CLUSTER-RANDOM SAMPLE OF FEMALE SEX WORKERS IN MOMBASA, KENYA

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STRUCTURED ABSTRACT

Introduction

Prevalence of lifetime induced abortion in female sex workers (FSWs) in Kenya was previously estimated between 43 and 86%. Our secondary objective aimed to assess lifetime prevalence and correlates, and incidence and predictors of induced abortions among FSWs in Kenya.

Methods

Data was collected as part of the WHISPER or SHOUT cluster-randomized trial in Mombasa, assessing effectiveness of an SMS-intervention to reduce incidence of unintended pregnancy. Eligible participants were current FSWs, 16-34 years and not pregnant or planning pregnancy. Baseline data on self-reported lifetime abortion, correlates and predictors were collected between September 2016 and May 2017. Abortion incidence was measured at six- and twelve-months follow-up. A multivariable logistic regression model was used to assess correlates of lifetime abortion and discrete-time survival analysis was used to assess predictors of abortions during follow-up.

Results

Among 866 eligible participants with available data on outcome and exposure variables, lifetime abortion prevalence was 11.9%, while lifetime unintended pregnancy prevalence was 51.2%. Correlates of lifetime abortions were currently not using a highly effective contraceptive (AOR=1.76 [95%CI=1.11-2.79] p=0.017) and having ever experienced intimate partner violence (IPV) (AOR=2.61 [95%CI=1.35-5.06] p=0.005). Incidence of unintended pregnancy and induced abortion were 15.5 and 3.9 per 100 women-years, respectively. No statistically significant associations were found between hazard of abortion and age, sex work duration, partner status, contraceptive use and IPV experience.

Conclusion

Although experience of unintended pregnancy remains high, lifetime prevalence of abortion may have decreased among FSW in Kenya. Addressing IPV could further decrease induced abortions in this population.

KEYWORDS

Sex Work, induced abortion, unintended pregnancy, contraception, cluster-random sample, Kenya

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ARTICLE SUMMARY

Strengths and limitations

- This study presents incidence of abortion in a cluster-randomised cohort of FSWs.
- It is the first to analyse predictors of abortions in FSWs, rather than correlates of past abortions only.
- This paper explores a secondary research question, and the study was not originally powered to assess the predictors of abortions during follow-up.
- The sensitive topic of abortions and SRH in general, might have resulted in a social desirability bias.

75 INTRODUCTION

76 Research findings show that about 5% of Kenya's urban female reproductive population
77 could be involved in sex work.[1] Female sex workers (FSWs) experience higher than
78 average rates of HIV, other sexually transmitted infections (STIs) and unintended
79 pregnancy.[2–5]
80 Unintended pregnancies often have negative consequences for FSWs, including financial
81 adversity, social stigma and induced abortion.[4] In countries where abortion is illegal or
82 difficult to access, women frequently resort to unsafe practices, risking severe medical
83 complications.[6]
84 Reported prevalence of lifetime abortion among FSWs in low- and middle-income countries
85 (LMICs) varies from 24% in Laos in 2012 to 86% in 2000/01 in Central and Western
86 Kenya.[7–16] Many of these abortions are unsafe or sought in the informal sector.[8,11,16]
87 In Mombasa, lifetime abortion among FSWs was estimated at 43% in 2008.[17]
88 In 2010, Kenya liberalized its abortion law, making abortion legal when “there is need for
89 emergency treatment, or the life or health of the mother is in danger”.[18] In practice, older
90 laws criminalizing abortion remain in place, creating ambiguity among health professionals
91 with lawsuits remaining a threat.[19] Moreover, social, cultural and religious beliefs
92 condemning pregnancy termination, misconceptions about the illegality and costs of the
93 procedure, still hamper access to safe services for women.[4,19]
94 Previous articles recognized the need for longitudinal data about abortions in FSWs.[8,14]
95 Identifying predictors for induced abortions will help inform future policies to improve care
96 around abortions for FSWs.
97 This secondary data analysis aimed to examine lifetime prevalence and correlates, and
98 incidence and predictors of induced abortions in a cluster-random sample of FSWs in
99 Mombasa, Kenya.

1
2
3 100 **MATERIAL AND METHODS**

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5 101 **Study design**

6 102 This study analysed data collected in the WHISPER or SHOUT trial. A detailed description
7
8 103 of the study protocol can be found elsewhere.[20] In summary, the study was a two-arm
9
10 104 cluster-randomized controlled trial assessing the effectiveness of two SMS-based
11
12 105 interventions targeting sexual and reproductive health (SRH) and nutrition in FSWs in
13
14 106 Mombasa, Kenya. The primary aim of the SRH intervention was to reduce the incidence of
15
16 107 unintended pregnancy among FSWs.
17
18 108 The study was conducted in two sub-counties in Mombasa, Kisauni and Changamwe,
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20 109 between September 2016 and July 2018. Ninety-three venues were randomly sampled with
21
22 110 a probability proportional to FSW population size at the venue (Figure 1). Trained community
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24 111 mobilisers and peer educators recruited FSWs from the venues until the required sample
25
26 112 size of 860 FSWs was achieved. Sex-work venues were randomized to either the SRH or
27
28 113 nutrition intervention group after the cluster was fully enrolled and baseline data obtained.
29
30 114 The study was approved by the Kenyatta National Hospital and University of Nairobi Ethics
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32 115 and Research Committee, Kenya (KNH-UoN ERC—KNH-ERC/RR/493) and the Monash
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34 116 University Human Research Ethics Committee, Australia (MUHREC—CF16/1552—
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36 117 2016000812).

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40 119 **Study participants and procedures**

41 120 Women were eligible for the study if they were aged 16-34 years; self-reported to have
42
43 121 engaged in paid sex work in the last 6 months; were not pregnant or planning pregnancy
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45 122 within the next 12 months; resided within the study area; and were able to read text
46
47 123 messages in basic English. Study-specific community mobilizers visited the selected clusters
48
49 124 to recruit FSWs and conducted pre-screening interviews. Eligible FSWs were referred to the
50
51 125 nearest study clinic for a clinical assessment, including a urine pregnancy test, and STI and
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53 126 HIV testing. Enrolled participants then completed a structured questionnaire administered in
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55 127 Swahili by trained research assistants, who had previously participated in research with
56
57 128 FSWs. The questionnaire captured detailed sociodemographic, sexual and reproductive
58
59 129 health information. Follow-up visits were scheduled at 6 and 12 months after enrolment.
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61 130 Procedures at follow-up visits were similar to those done at enrolment.
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63 131 Participants received two to three SMS messages per week for 12 months. The messages
64
65 132 consisted of stand-alone push messages, role model stories and on-demand messages,
66
67 133 accessed using assigned codes. Participants only received and accessed messages on their
68
69 134 phones from their assigned intervention.

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71 135
72
73 136 **Outcomes**

Lifetime prevalence of induced abortion was assessed at baseline with the question 'How many times have you ever had an induced abortion?'. Induced abortions were assessed during follow-up, by asking participants if they had been pregnant since their last visit. The outcome of each reported pregnancy was then assessed, and in the case of an induced abortion, the location was documented. Formal sector abortions were those taking place at a government or private hospital/clinic, a private doctor/GP or an FP clinic. Informal sector abortions were defined as those taking place at home, a pharmacy or traditional healer.[21] Pregnancies during follow-up were confirmed with a urine pregnancy test at the study clinic, or self-reported by the participant when occurring between study visits. Pregnancy intention for all reported pregnancies was assessed using the London Measure of Unintended Pregnancy (LMUP), a six-item scale. A pregnancy scoring less than 10 out of 12 on the LMUP was defined as unintended.[22]

All correlates of lifetime induced abortions and predictors of incident induced abortions were self-reported at baseline. Use of a highly effective contraceptive method was defined as use of contraceptive implants, IUD, injection, oral contraceptive pill and sterilization. High knowledge on FP was defined as answering five out of six true-false statements on FP correctly. Having a positive attitude on FP was defined as agreeing with at least three out of four positive attitude statements. Self-efficacy in FP was defined as high when agreeing with two statements on this topic. Household socio-economic status tertiles were generated using principal component analysis, based on 12 household assets. Prevalence of intimate partner violence (IPV) was assessed by asking if the participant had ever been pushed, slapped, hit or kicked by a partner, or had been physically forced to have sex, agreed to sex out of fear of the consequences or forced to do something sexual that she perceived as degrading or humiliating. For each item, it was also assessed if this happened in the previous 12 months.

Statistical analysis

Statistical analysis was performed using Stata software version 14 (StataCorp, College Station, TX, USA). Covariates for the multivariate models were determined on the basis of a review of literature or theoretical assumptions by the co-authors. Correlates of lifetime abortion were identified using weighted multivariable logistic regression. Associations were considered statistically significant at the 5% level. The outcome incident abortion was interval-censored (measured at 6-monthly intervals). Therefore, a discrete-time survival analysis was performed using generalized linear mixed (GLM) modelling with complementary log-log link function and binomial distribution, a method that produces estimated hazard ratios. Abortions during follow-up were analysed for all participants who attended at least one follow-up visit. All outcomes presented here are cluster-adjusted, based on inverse probability sample means to account for sampling bias.

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175 **Patient and public involvement**
176 Patients or the public were not directly involved in the design, or conduct, or reporting, or
177 dissemination plans of our research.

For peer review only

RESULTS

During the recruitment period of 14 September 2016 to 16 May 2017, 882 women were enrolled in the study. Follow-up continued until 31 July 2018. A sub-sample of 866 women (98.2%) was analysed for this paper (Figure 1).

Mean age was 25.5 years (SD=4.7) (Table 1). The majority of women (n=765, 88.7%) had at least completed primary education and 306 (34.9%) had completed secondary education. Just over half of the participants (n=484, 56.6%) reported to have a current husband or boyfriend, but 812 (94.0%) reported not to live with a partner. Mean duration of employment in sex work was 4.7 years (SD=3.5). Among women currently reporting a husband or boyfriend, 344/483 (70.8%) had not disclosed their employment in sex work to their partners. 605/861 women (68.9%) worked fulltime in sex work and 508/863 (59.8%) earned more than 2000 Ksh (about USD \$20) per week from sex work. The majority of women (n=666, 76.1%) had ever been pregnant, and 451 (51.2%) ever had an unintended pregnancy. 103/866 (11.9%) reported to have had at least one induced abortion in their lifetime. Among women who had an induced abortion, 58/102 (57.1%) went to a private hospital or clinic for the most recent abortion. 29/102 (29.1%) women had their most recent abortion in the informal sector, like home, a pharmacy or traditional healer. At baseline, 463 women (54.4%) reported to use a highly effective contraceptive method. Three-quarters of FSW (650/866; 75.0%) ever experienced IPV and 525/866 (60.1%) experienced IPV in the past 12 months the before the baseline questionnaire was conducted.

Table 1. Socio-demographic characteristics, reproductive history, contraceptive use and intimate partner violence at baseline of female sex workers in Mombasa, Kenya (n=866, unless stated otherwise)

Characteristic	n	Cluster-adjusted mean (SD) or proportion in % (95% CI) ^a
Mean age, in years		25.5 (4.7)
Highest level of education		
None or some primary	101	11.2 (9.2-13.6)
Completed primary or some secondary	459	53.8 (50.1-57.6)
Completed secondary or some tertiary	306	34.9 (31.3-38.7)
Religion (n=864)		
Protestant	389	44.8 (41.4-48.2)
Catholic	304	36.0 (32.3-39.8)
Muslim	171	19.2 (15.6-23.4)
Electricity available in household (n=863) ^b	660	76.4 (73.0-79.5)
Duration of sex work, in years		4.7 (3.5)

Fulltime FSW (n=861) ^c	605	68.9 (64.0-73.5)
Weekly income from sex work (n=861)		
≤1000 Ksh	144	16.2 (13.2-19.8)
1001-2000 Ksh	211	24.0 (21.0-27.3)
≥2001 Ksh ^d	508	59.8 (55.1-64.3)
Sex work venue		
Bar with lodging	388	43.8 (37.7-50.2)
Bar without lodging	147	17.2 (13.7-21.3)
Lodging/guesthouse	138	15.1 (10.9-20.5)
Street/beach	86	11.2 (7.8-15.7)
Other ^e	107	12.7 (9.1-17.5)
Marital status		
Married/cohabiting	54	6.0 (4.5-8.0)
Single (not cohabiting)	627	73.0 (69.6-76.2)
Separated/divorced/widowed	185	21.0 (18.0-24.3)
Currently has husband/boyfriend	484	56.6 (52.5-60.7)
Disclosure of sex work to husband/boyfriend (n=483) ^f		
Yes	136	28.7 (24.4-33.3)
No	344	70.8 (66.0-75.1)
Don't know	3	0.6 (0.2-1.7)
Ever had a pregnancy	666	76.1 (72.3-79.5)
Has a living child	622	71.2 (67.1-75.0)
Ever had an unintended pregnancy (N=864) ^g	451	51.2 (47.4-54.9)
Ever had an induced abortion	103	11.9 (10.0-14.2)
Location of most recent induced abortion (N=102)		
Government hospital	2	1.8 (0.4-6.9)
FP clinic, like Marie Stopes	9	8.3 (4.4-15.0)
Private hospital/clinic	58	57.1 (46.5-67.2)
Private doctor GP	4	3.7 (1.4-9.6)
Pharmacy	9	8.9 (4.6-16.8)
Traditional healer	4	3.8 (1.4-10.0)
Home	16	16.4 (9.0-27.8)
Uses a highly effective contraceptive method ^h	473	54.4 (49.5-59.2)
Ever experienced IPV ⁱ	650	75.0 (71.1-78.5)
Experienced IPV in past 12 months ^j	525	60.1 (55.5-64.6)

^a Inverse probability-weighted percentages. ^b Availability of electricity in the household is presented here as a proxy for household SES. ^c Fulltime work as FSW is characterized as having no other sources of income in the last 6 months. ^d 1000 Kenyan Shilling (Ksh) is about USD \$10. ^e Brothel, strip club, casino, massage parlors, parks or home. ^f Among participants with a husband or boyfriend. ^g Assessed using the London Measure of Unintended Pregnancy (LMUP) ^h Highly effective is defined as use of contraceptive implants, IUD, injection, oral contraceptive pill and sterilization. ⁱ IPV= intimate partner violence. ^j Before baseline.

Women currently not using a highly effective contraceptive (AOR=1.76 [95%CI=1.11-2.79] p=0.017) and women who ever experienced IPV (AOR=2.61 [95%CI=1.35-5.06] p=0.005) were significantly more likely to report a history of induced abortion, when controlled for

potential confounders (Table 2). Longer duration of sex work showed a borderline positive association with history of abortion (AOR=1.08 [95%CI=1.00-1.16] p=0.053). Although higher age was significantly associated with a history of abortion in bivariate analysis, after adjusting for confounding factors this association was no longer seen.

Table 2. Correlates of participants with a history of induced abortion, and cluster-adjusted bi- and multivariable logistic regression analysis on history of induced abortion (n=866)

Characteristic	Ever had an induced abortion (n=103); n/N (cluster-adjusted proportion in %) ^a	Crude Odds Ratio (OR)		Adjusted OR	
		OR (95% CI) ^b	p-value	OR (95% CI) ^b	p-value
Age (in years)	27.0 (4.9) ^c	1.08 (1.03-1.14)	0.001	1.04 (0.97-1.11)	0.280
Highest level of education					
None or some primary	14/101 (13.5)	Ref.		Ref.	
Completed primary or some secondary	57/459 (12.4)	0.90 (0.47-1.72)	0.749	0.96 (0.48-1.99)	0.895
Completed secondary or some tertiary	32/306 (10.7)	0.77 (0.40-1.47)	0.423	0.83 (0.40-1.84)	0.620
SES-tertile ^e					
Poorest	39/290 (13.4)	Ref.		Ref.	
Middle	33/287 (10.9)	0.79 (0.46-1.35)	0.386	0.89 (0.50-1.59)	0.697
Richest	31/289 (11.4)	0.83 (0.47-1.46)	0.510	0.83 (0.46-1.50)	0.674
Mean duration of sex work (in years)	6.1 (3.4) ^c	1.12 (1.07-1.17)	<0.001	1.08 (1.00-1.16)	0.053
Highly effective contraceptive use ^d					
Yes	51/473 (10.6)	Ref.		Ref.	
No	52/393 (13.5)	1.32 (0.88-1.97)	0.173	1.76 (1.11-2.79)	0.017
High FP knowledge score					
No	60/562 (10.5)	Ref.		Ref.	
Yes	43/304 (14.5)	1.44 (0.95-2.19)	0.084	1.34 (0.85-2.10)	0.200
Positive attitude to FP use					
No	43/354 (12.4)	Ref.		Ref.	
Yes	60/512 (11.6)	0.93 (0.60-1.44)	0.743	0.90 (0.56-1.45)	0.661
High FP-specific self-efficacy					
No	24/237 (10.1)	Ref.		Ref.	
Yes	79/629 (12.6)	1.28 (0.76-2.17)	0.345	1.23 (0.72-2.10)	0.454
Ever experienced intimate partner violence					
No	12/216 (5.2)	Ref.		Ref.	
Yes	91/650 (14.1)	2.98 (1.55-5.74)	0.001	2.61 (1.35-5.06)	0.005

^a Inverse probability-weighted percentages. ^b Standard errors are corrected by cluster sandwich variance estimation. ^c Mean (SD) of women who ever had an induced abortion. ^d Highly effective is defined as use of contraceptive implants, IUD, injection, oral contraceptive pill and sterilization. ^e SES = Socio-economic status.

During the study follow-up, 773 women attended at least one follow-up visit (Figure 1). A total of 131 participants became pregnant, with a total of 145 pregnancies among these women (Figure 2). Of these pregnancies, 122/145 were unintended according to the LMUP.

Among 145 pregnancies, 31 ended in induced abortion, among 29 women and across 789 women-years at risk. Overall incidence rate was 3.9 induced abortions per 100 women-years of observation. Out of 31 abortions, 19 took place in the formal sector and 12 in an informal setting.

The GLM modelling of abortion incidence showed that women experiencing IPV in the past year (HR=1.93 [95%CI=0.86-4.34] p=0.122) and women not using a highly effective contraceptive (HR=1.51 [95%CI=0.66-3.49] p=0.332) exhibited a higher hazard of abortion, independent of other factors, although these results were not significant (Table 3). We did not find a relation between age, mean duration of sex work, currently having a husband or boyfriend and the intervention under study and hazard of induced abortion.

Table 3. Baseline predictors of incident abortion in FSWs among Mombasa, Kenya (N=773) ^a				
Baseline predictors of incident abortions	Unadjusted ^b		Adjusted HR ^c	
	HR (95% CI) ^d	p-value	HR (95% CI) ^d	p-value
Age (in years)	0.96 (0.89-1.04)	0.315	1.00 (0.91-1.09)	0.918
Mean duration of sex work (in years)	0.93 (0.82-1.05)	0.234	0.92 (0.79-1.09)	0.336
Currently has husband/boyfriend	0.83 (0.40-1.73)	0.622	0.80 (0.39-1.64)	0.537
Not using highly effective contraceptive ^e	1.50 (0.69-3.23)	0.310	1.51 (0.66-3.49)	0.332
Experienced IPV in last 12 months	1.67 (0.74-3.79)	0.216	1.93 (0.86-4.34)	0.122

^a Discrete-time survival analysis including the first induced abortion per women. Generalized linear mixed model with complementary log-log link, binomial distribution, offset for log time between visits and random intercept for participants. ^b HR = Hazard Ratio. ^c All adjusted Hazard Ratios are also adjusted for the intervention. The intervention had no detectable effect on the outcome of incident abortions. ^d Cluster robust standard errors for sex-work venue clustering. ^e Highly effective is defined as use of contraceptive implants, IUD, injection, oral contraceptive pill and sterilization.

DISCUSSION

This study adds to the current knowledge of abortion practices in FSWs. Lifetime induced abortion prevalence in this population was 11.9%. This seems considerably lower than previous figures of lifetime abortion of 86% in 2004 in central and western Kenya among FSWs of a similar age, and 43% in 2008 in Mombasa among FSWs who were on average 2 years older.[7,17] In the former study, it was not specified if these abortions also included spontaneous abortions, which might have overestimated the prevalence of abortions. However, despite the sociodemographic and methodological differences between the studies, the size of the difference is suggestive of an actual reduction in abortions in this population. The prevalence of abortions found here is also lower than reports from other LMICs ranging between 24% and 64% in Laos and Cote d'Ivoire, respectively.[8–16] A possible explanation for this lower prevalence is the relatively high use of highly effective contraceptives of 54% in our cohort, compared to similar studies from LMICs. [8,12,14–16] The findings are furthermore consistent with a lower-than-expected HIV prevalence and unintended pregnancy incidence in our cohort and could be a result of peer-mediated interventions implemented over the past years in the Mombasa area.[23,24] These have mostly targeted prevention of HIV and STIs, but likely have had a lowering effect on unintended pregnancies and induced abortions as well.[20,23] Furthermore, this study, in contrast to above referenced studies, attempted to draw a representative sample of a FSW population from community settings, whereas other studies used non-probability sampling methods, which might have overestimated past abortions. Despite the lower-than-expected unintended pregnancy incidence, still 51% of FSWs in our cohort reported an unintended pregnancy in their lifetime. The gap between lifetime unintended pregnancies and lifetime induced abortions could indicate a high unmet need for induced abortion among FSWs, for example due to ongoing or increasing difficulties in accessing SRH or abortion services for this group or increasing sociocultural barriers to abortion. The present study is one of the few studies to report incidence of abortion among FSWs and to our knowledge, the first to analyse predictors of abortions in FSWs, rather than correlates of past abortions only. Incidence of induced abortion in our cohort was 3.9 per 100 women-years. Compared to other studies from LMICs, this is similar to two studies reporting abortion incidence rates of 3.1 and 3.0 per 100 women-years and lower than a third study reporting 7.4 induced abortions per 100 women-years among FSWs.[25] The intervention under study had no measurable effect on unintended pregnancy incidence and is therefore unlikely to have affected incidence of induced abortions.[24] Informal sector abortions were common in this cohort, with 30% of women having had their most recent abortion in the informal sector, and 39% of the reported abortions during follow-

up happening in the informal sector. These informal sector abortions, put women at higher risk of complications due to unsafe practices and this denotes a need for information on safer alternatives, like the Marie Stopes clinics.[21]

Multiple studies have found both age and duration of sex work to be correlated to past abortions. Commonly higher age [8,11,15] and longer duration [9,12] of sex work were associated with higher lifetime abortion prevalence. One study found that younger age was associated with past abortions.[10] In our cohort, although FSWs with a past abortion in our cohort were older in the crude analysis, after adjusting for other correlates, this difference was no longer significant. The association with longer duration of sex work remained borderline significant in multivariate analysis. We did not find a relation between age and mean duration of sex work and having an induced abortion during follow-up. This might suggest that the association between past abortions and higher age and longer duration of sex work is caused by cumulative exposure to high risk of pregnancies and abortion. We found a positive association between currently not using a highly effective contraceptive and having a past abortion. No difference was found in FP-specific self-efficacy or knowledge, or attitude towards FP among women with and without a past abortion. The found association could indicate significant barriers to uptake or continuation of a highly effective contraceptive method post abortion, as has previously been acknowledged by a study in Kenya.[26]

In our cohort, experience of IPV was high and the odds of having had a past abortion were more than 2.5-times as high for women who experienced IPV in the past, consistent with findings from other studies.[14,15] Our study also showed a positive association between experience of IPV in the past twelve months and abortions during follow-up, but this was not significant. Experience of (intimate partner) violence has been shown to have a negative effect on the reproductive health of FSWs, with greater risks of adverse pregnancy outcomes and forced termination of pregnancy.[27,28] Addressing the problem of IPV in this population could further lower induced abortions.

Limitations

Some limitations should be considered when interpreting the findings from this study. The sensitive topic of abortions and SRH in general, might have resulted in a social desirability bias. To minimize this, peer-educators and research assistants had previous experience working with the target population and received additional training. Attrition bias might have occurred due to loss to follow-up of pregnant participants, as has been recognized by anecdotal evidence.[24] This might have resulted in an underestimation of abortions in our study. A further limitation is that this paper explores a secondary research question, and the study was not originally powered to assess the predictors of abortions during follow-up.

Unknown timing of the past abortions in relation to studied correlates, restrict judgement of temporality of the studied associations. Lastly, measurements of abortions stopped when the intervention stopped, so the actual number of abortions during follow-up might in fact be higher than captured in the study.

Suggestions for further research

Future research is needed to explore the trend in abortion incidence among FSWs in Kenya. In order to improve care, we need to better understand current abortion practices, the decision-making process around terminating unintended pregnancies, how uptake of highly effective contraceptives can be increased post-abortion, as well as the relationship between experience of IPV and induced abortions.

CONCLUSIONS

In conclusion, the prevalence of lifetime induced abortions in a random cohort of FSWs in Mombasa, was 11.9% and incidence was 3.9 per 100 women-years, whereas prevalence and incidence of unintended pregnancies were higher at 51% and 15.5 per 100 women-years, respectively. A history of induced abortion was positively associated with not using a highly contraceptive method at baseline and having experienced IPV in the past. This was, to our knowledge the first study attempting to identify predictors of abortions in FSWs, however the study did not find a significant association with the studied predictors of abortions.

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TRIAL REGISTRATION

The trial was registered in the Australian New Zealand Clinical Trials Registry, ACTRN12616000852459.

AUTHOR CONTRIBUTORSHIP

SL was the Principal Investigator on the study. SL, FHA, PG, MSCL, PAA, MH, WJ, MS, KL, MT and MFC contributed to the study design. CG and GM coordinated the trial and undertook data acquisition in Kenya under the supervision of PG. AMS and SL conceptualized the manuscript. AMS and PAA conducted the statistical analyses. AMS and CG wrote the first draft of the manuscript. All authors contributed to data interpretation, provided critical input, and approved the final version of the manuscript.

DECLARATION OF INTERESTS

The authors have no conflicts of interest.

PATIENT AND PUBLIC INVOLVEMENT

Patients or the public were not directly involved in the design, or conduct, or reporting, or dissemination plans of our research.

DATA AVAILABILITY STATEMENT

The original data are not available in a public repository. The corresponding author is to be contacted for the consideration of any data requests.

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3 368 **FIGURE CAPTIONS**

4 369 **Figure 1:** Eligibility flow diagram for the WHISPER or SHOUT study as per Consort 2010
5 statement: extension to cluster randomized trials.[29]
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8 371 **Figure 2:** Overview of pregnancy outcomes during the 12-month follow-up. N=773
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For peer review only

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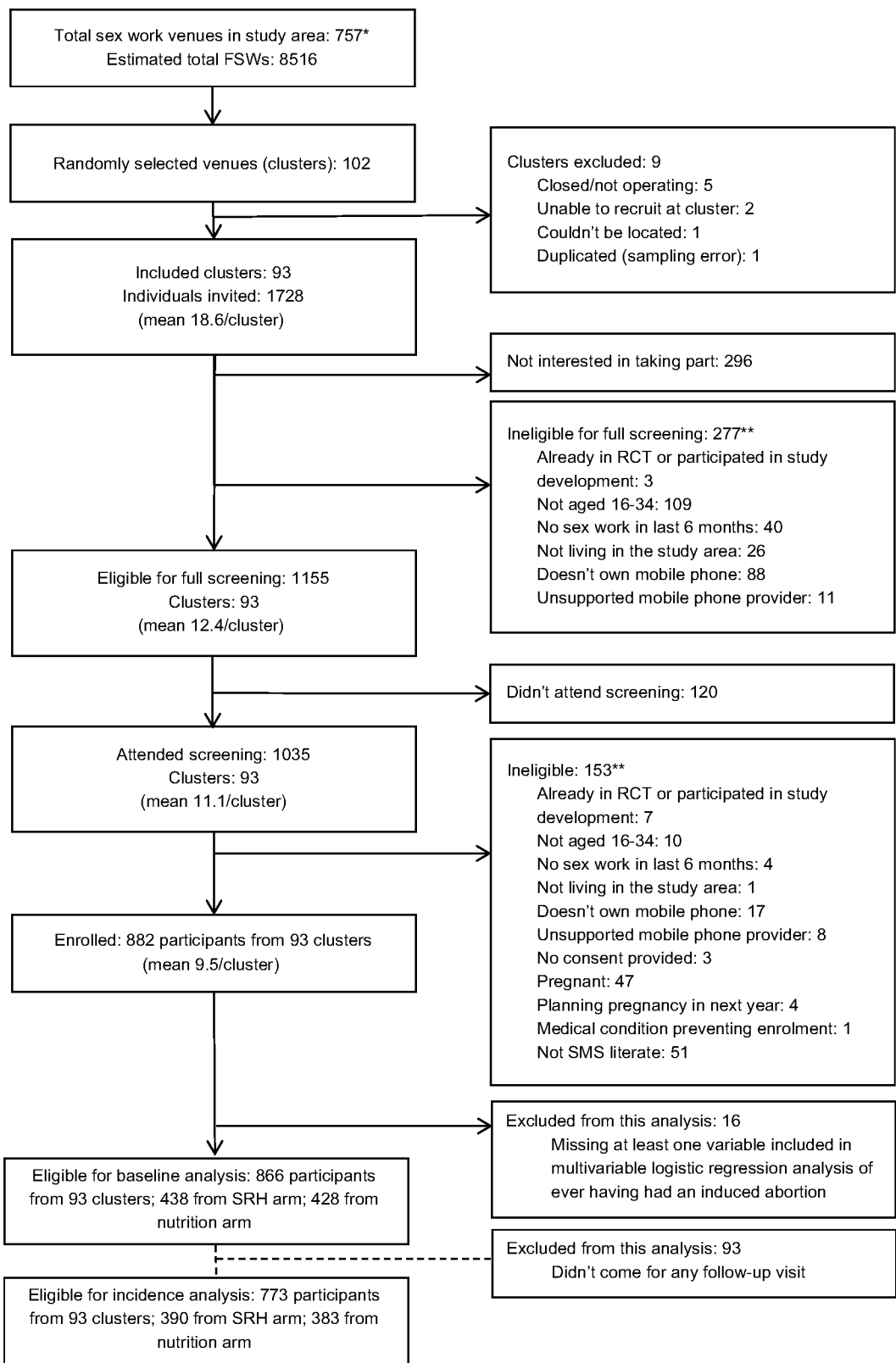
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Figure 1: Eligibility flow diagram for the WHISPER or SHOUT study as per Consort 2010 statement: extension to cluster randomized trials.[29]



*Total hotspots and number per hotspot in study area enumerated by Cheuk et al.[30]

**One reason for ineligibility reported per participant and criteria determined in the order shown.

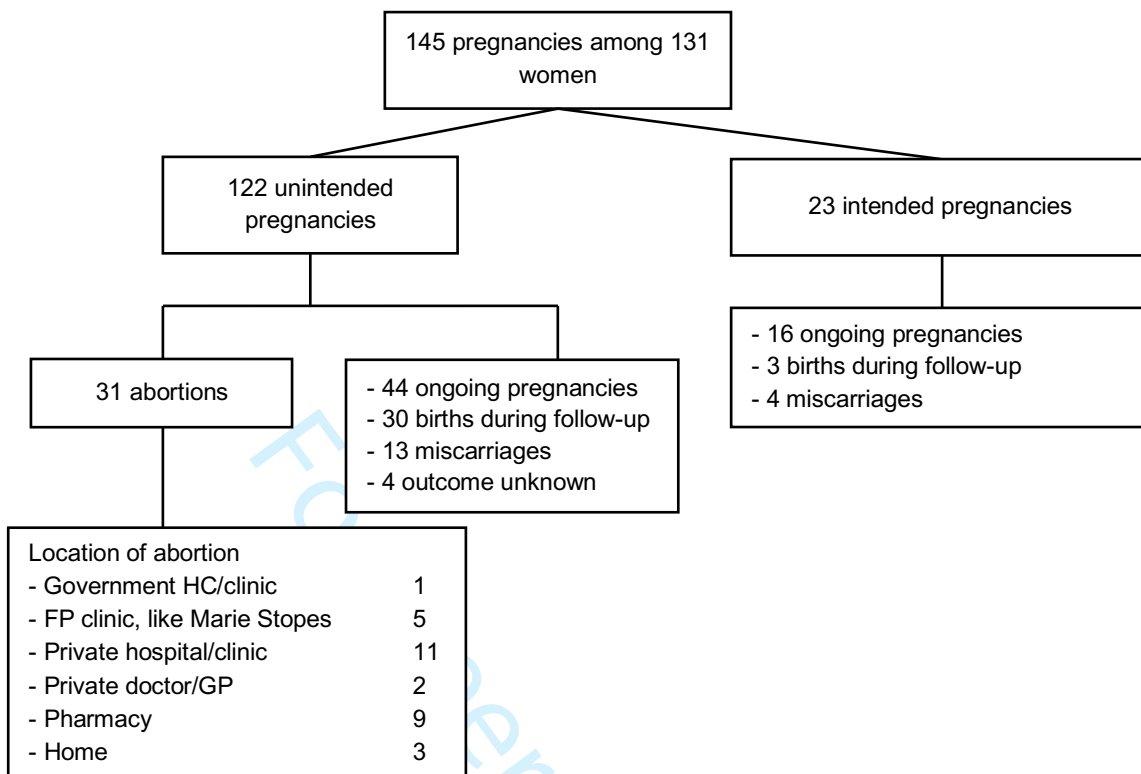
Figure 2: Overview of pregnancy outcomes during the 12-month follow-up. N=773

Table 1: CONSORT 2010 checklist of information to include when reporting a cluster randomised trial :

Protocol paper[1] and primary outcome paper[2]:

1 Ampt FH, Mudogo C, Gichangi P, *et al.* WHISPER or SHOUT study: Protocol of a cluster-randomised controlled trial assessing mHealth sexual reproductive health and nutrition interventions among female sex workers in Mombasa, Kenya. *BMJ Open* 2017;**7**. doi:10.1136/bmjopen-2017-017388

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Section/Topic	Item No	Standard Checklist item	Extension for cluster designs	Page No *
Title and abstract				
	1a	Identification as a randomised trial in the title	Identification as a cluster randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts) ^{1,2}	See table 2	2
Introduction				
Background and objectives	2a	Scientific background and explanation of rationale	Rationale for using a cluster design	5 (and reference to protocol paper[1])
	2b	Specific objectives or hypotheses	Whether objectives pertain to the the cluster level, the individual participant level or both	4 (and reference to protocol paper[1])
Methods				
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Definition of cluster and description of how the design features apply to the clusters	5 (and reference to protocol paper[1])
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons		N/A

Participants	4a	Eligibility criteria for participants	Eligibility criteria for clusters	5 (and reference to protocol paper[1])
	4b	Settings and locations where the data were collected		5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Whether interventions pertain to the cluster level, the individual participant level or both	5 (and reference to protocol paper[1])
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Whether outcome measures pertain to the cluster level, the individual participant level or both	4, 6 (and reference to protocol paper[1])
	6b	Any changes to trial outcomes after the trial commenced, with reasons		N/A
Sample size	7a	How sample size was determined	Method of calculation, number of clusters(s) (and whether equal or unequal cluster sizes are assumed), cluster size, a coefficient of intracluster correlation (ICC or k), and an indication of its uncertainty	Reference to protocol paper[1]
	7b	When applicable, explanation of any interim analyses and stopping guidelines		N/A
Randomisation:				
Sequence generation	8a	Method used to generate the random allocation sequence		5 (and reference to protocol paper[1])
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Details of stratification or matching if used	Reference to protocol paper[1]

Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Specification that allocation was based on clusters rather than individuals and whether allocation concealment (if any) was at the cluster level, the individual participant level or both	Reference to protocol paper[1]
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Replace by 10a, 10b and 10c	5 (and reference to protocol paper[1])
	10a		Who generated the random allocation sequence, who enrolled clusters, and who assigned clusters to interventions	5 (and reference to protocol paper[1])
	10b		Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete enumeration, random sampling)	5
	10c		From whom consent was sought (representatives of the cluster, or individual cluster members, or both), and whether consent was sought before or after randomisation	5
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how		Reference to protocol paper[1]
	11b	If relevant, description of the similarity of interventions		5 (and reference to protocol paper[1])
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	How clustering was taken into account	6

	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	6
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	For each group, the numbers of clusters that were randomly assigned, received intended treatment, and were analysed for the primary outcome Figure 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	For each group, losses and exclusions for both clusters and individual cluster members Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	8
	14b	Why the trial ended or was stopped	5, 8
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Baseline characteristics for the individual and cluster levels as applicable for each group 8, 9
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	For each group, number of clusters included in each analysis Figure 1, Table 1, 2 and 3
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Results at the individual or cluster level as applicable and a coefficient of intracluster correlation (ICC or k) for each primary outcome Table 2 and 3
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Table 2 and 3
Ancillary analyses	18	Results of any other analyses performed,	Table 2 and 3

		including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms ³)	Reference to primary outcome paper[2]
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	13, 14
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Generalisability to clusters and/or individual participants (as relevant) 12, 13
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	12, 13
Other information			
Registration	23	Registration number and name of trial registry	15
Protocol	24	Where the full trial protocol can be accessed, if available	Reference to protocol paper[1] (page 5)
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	2

* Note: page numbers optional depending on journal requirements

Table 2: Extension of CONSORT for abstracts^{1,2} to reports of cluster randomised trials

Item	Standard Checklist item	Extension for cluster trials
Title	Identification of study as randomised	Identification of study as cluster randomised
Trial design	Description of the trial design (e.g. parallel, cluster, non-inferiority)	
Methods		
Participants	Eligibility criteria for participants and the settings where the data were collected	Eligibility criteria for clusters
Interventions	Interventions intended for each group	
Objective	Specific objective or hypothesis	Whether objective or hypothesis pertains to the cluster level, the individual participant level or both
Outcome	Clearly defined primary outcome for this report	Whether the primary outcome pertains to the cluster level, the individual participant level or both
Randomization	How participants were allocated to interventions	How clusters were allocated to interventions
Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment	
Results		
Numbers randomized	Number of participants randomized to each group	Number of clusters randomized to each group
Recruitment	Trial status ¹	
Numbers analysed	Number of participants analysed in each group	Number of clusters analysed in each group
Outcome	For the primary outcome, a result for each group and the estimated effect size and its precision	Results at the cluster or individual participant level as applicable for each primary outcome
Harms	Important adverse events or side effects	
Conclusions	General interpretation of the results	
Trial registration	Registration number and name of trial register	
Funding	Source of funding	

¹ Relevant to Conference Abstracts

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ASSESSMENT OF THE LIFETIME PREVALENCE AND INCIDENCE OF INDUCED ABORTION AND CORRELATES AMONG FEMALE SEX WORKERS IN MOMBASA, KENYA: A SECONDARY COHORT ANALYSIS

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Primary Subject Heading:	Sexual health
Secondary Subject Heading:	Sexual health, Public health
Keywords:	SEXUAL MEDICINE, PUBLIC HEALTH, EPIDEMIOLOGY

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ASSESSMENT OF THE LIFETIME PREVALENCE AND INCIDENCE OF INDUCED ABORTION AND CORRELATES AMONG FEMALE SEX WORKERS IN MOMBASA, KENYA: A SECONDARY COHORT ANALYSIS

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STRUCTURED ABSTRACT

Introduction

Prevalence of lifetime induced abortion in female sex workers (FSWs) in Kenya was previously estimated between 43 and 86%. Our analysis aimed at assessing lifetime prevalence and correlates, and incidence and predictors of induced abortions among FSWs in Kenya.

Methods

This is a secondary prospective cohort analysis using data collected as part of the WHISPER or SHOUT cluster-randomized trial in Mombasa (Australian New Zealand Clinical Trials Registry number: ACTRN12616000852459), assessing effectiveness of an SMS-intervention to reduce incidence of unintended pregnancy. Eligible participants were current FSWs, 16-34 years and not pregnant or planning pregnancy. Baseline data on self-reported lifetime abortion, correlates and predictors were collected between September 2016 and May 2017. Abortion incidence was measured at six- and twelve-months follow-up. A multivariable logistic regression model was used to assess correlates of lifetime abortion and discrete-time survival analysis was used to assess predictors of abortions during follow-up.

Results

Among 866 eligible participants, lifetime abortion prevalence was 11.9%, while lifetime unintended pregnancy prevalence was 51.2%. Correlates of lifetime abortions were currently not using a highly effective contraceptive (AOR=1.76 [95%CI=1.11-2.79] $p=0.017$) and having ever experienced intimate partner violence (IPV) (AOR=2.61 [95%CI=1.35-5.06] $p=0.005$). Incidence of unintended pregnancy and induced abortion were 15.5 and 3.9 per 100 women-years, respectively. No statistically significant associations were found between hazard of abortion and age, sex work duration, partner status, contraceptive use and IPV experience.

Conclusion

Although experience of unintended pregnancy remains high, lifetime prevalence of abortion may have decreased among FSW in Kenya. Addressing IPV could further decrease induced abortions in this population.

KEYWORDS

Sex Work, induced abortion, unintended pregnancy, contraception, cluster-random sample, Kenya

FUNDING STATEMENT

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ARTICLE SUMMARY

Strengths and limitations

- This study presents incidence of abortion in a cluster-randomised cohort of FSWs.
- It is the first to analyse predictors of abortions in FSWs, rather than correlates of past abortions only.
- This paper explores a secondary research question, and the study was not originally powered to assess the predictors of abortions during follow-up.
- The sensitive topic of abortions and SRH in general, might have resulted in a social desirability bias.

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INTRODUCTION

Research findings show that about 5% of Kenya’s urban female reproductive population could be involved in sex work.[1] Female sex workers (FSWs) experience higher than average rates of HIV, other sexually transmitted infections (STIs) and unintended pregnancy.[2–5]

Unintended pregnancies often have negative consequences for FSWs, including financial adversity, social stigma and induced abortion.[4] In countries where abortion is illegal or difficult to access, women frequently resort to unsafe practices, risking severe medical complications.[6]

Reported prevalence of lifetime abortion among FSWs in low- and middle-income countries (LMICs) varies from 24% in Laos in 2012 to 86% in 2000/01 in Central and Western Kenya.[7–16] Many of these abortions are unsafe or sought in the informal sector.[8,11,16]

In Mombasa, lifetime abortion among FSWs was estimated at 43% in 2008.[17]

In 2010, Kenya liberalized its abortion law, making abortion legal when “there is need for emergency treatment, or the life or health of the mother is in danger”.[18] In practice, older laws criminalizing abortion remain in place, creating ambiguity among health professionals with lawsuits remaining a threat.[19] Moreover, social, cultural and religious beliefs condemning pregnancy termination, misconceptions about the illegality and costs of the procedure, still hamper access to safe services for women.[4,19]

A national study in 2012 estimated an induced abortion rate of 48 per 1,000 women among women aged 15-49, based on data of women who sought care for abortion complications.[20] It showed a diverse sociodemographic and economic background among these women in terms of educational level, employment status, marital status and religion.

Incidence of induced abortions among FSWs has not been studied in Kenya and studies analysing correlates of induced abortions elsewhere have been cross-sectional and report correlates of lifetime abortions, precluding attribution of causality.[8–15,21] Examining incidence of abortions and identifying predictors will help inform future policies to improve care around abortions for FSWs and the need for longitudinal data about abortions in FSWs has therefore been recognised.[8,14]

This secondary data analysis aimed to examine lifetime prevalence and correlates, and incidence and predictors of induced abortions in a cluster-random sample of FSWs in Mombasa, Kenya.

MATERIAL AND METHODS

Study design

This is a secondary prospective cohort analysis using data collected as part of the WHISPER or SHOUT cluster-randomized trial in Mombasa. A detailed description of the study protocol can be found elsewhere.[22] In summary, the study was a two-arm cluster-randomized controlled trial assessing the effectiveness of two SMS-based interventions targeting sexual and reproductive health (SRH) and nutrition in FSWs in Mombasa, Kenya. The study was conducted in two sub-counties in Mombasa, Kisauni and Changamwe, between September 2016 and July 2018. Ninety-three venues were randomly sampled with a probability proportional to FSW population size at the venue (Figure 1). Trained community mobilisers and peer educators recruited FSWs from the venues until the required sample size of 860 FSWs was achieved. This study uses baseline and follow-up data from the trial. During the recruitment period of 14 September 2016 to 16 May 2017, 882 women were enrolled in the study. Follow-up continued until 31 July 2018. A sub-sample of 866 women (98.2%) was analysed for this secondary analysis (Figure 1).

Study participants and procedures

Women were eligible for the study if they were aged 16-34 years; self-reported to have engaged in paid sex work in the last 6 months; were reportedly not pregnant or planning pregnancy within the next 12 months; resided within the study area; and were able to read text messages in basic English. Study-specific community mobilizers visited the selected clusters to recruit FSWs and conducted pre-screening interviews identifying women who self-reported to be sex workers. Potentially eligible FSWs were referred to the nearest study clinic for a clinical assessment, including a urine pregnancy test, and STI and HIV testing. Enrolled participants then completed a structured questionnaire administered in Swahili by trained research assistants, who had previously participated in research with FSWs. The questionnaire captured detailed sociodemographic, sexual and reproductive health information. Follow-up visits were scheduled at 6 and 12 months after enrolment. Procedures at follow-up visits were similar to those done at enrolment. Participants received two to three SMS messages per week for 12 months. The messages consisted of stand-alone push messages, role model stories and on-demand messages, accessed using assigned codes. Participants only received and accessed messages on their phones from their assigned intervention.

Outcomes and correlates

Lifetime prevalence of induced abortion was assessed at baseline with the question 'How many times have you ever had an induced abortion?'. Induced abortions were assessed

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3 146 during follow-up, by asking participants if they had been pregnant since their last visit. The
4 147 outcome of each reported pregnancy was then assessed, and in the case of an induced
5 148 abortion, the location was documented. Formal sector abortions were those taking place at a
6 149 government or private hospital/clinic, a private doctor/General Practitioner (GP) or a Family
7 150 Planning (FP) clinic. Informal sector abortions were defined as those taking place at home, a
8 151 pharmacy or traditional healer.[23]
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10 152 Pregnancies during follow-up were confirmed with a urine pregnancy test at the study clinic,
11 153 or self-reported by the participant when occurring between study visits. Pregnancy intention
12 154 for all reported pregnancies was assessed using the London Measure of Unintended
13 155 Pregnancy (LMUP), a six-item scale. A pregnancy scoring less than 10 out of 12 on the
14 156 LMUP was defined as unintended.[24]
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16 157 All correlates of lifetime induced abortions and predictors of incident induced abortions were
17 158 self-reported at baseline. Use of a highly effective contraceptive method was defined as use
18 159 of contraceptive implants, IUD, injection, oral contraceptive pill and sterilization. High
19 160 knowledge on FP was defined as answering five out of six true-false statements on FP
20 161 correctly. Having a positive attitude on FP was defined as agreeing with at least three out of
21 162 four positive attitude statements. Self-efficacy in FP was defined as high when agreeing with
22 163 two statements on this topic. Household socio-economic status tertiles were generated using
23 164 principal component analysis, based on 12 household assets.[25] Prevalence of intimate
24 165 partner violence (IPV) was assessed by asking if the participant had ever been pushed,
25 166 slapped, hit or kicked by a partner, or had been physically forced to have sex, agreed to sex
26 167 out of fear of the consequences or forced to do something sexual that she perceived as
27 168 degrading or humiliating. For each item, it was also assessed if this happened in the
28 169 previous 12 months.
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43 171 **Statistical analysis**

44 172 Statistical analysis was performed using Stata software version 14 (StataCorp, College
45 173 Station, TX, USA). Distributions of socio-demographic characteristics, reproductive history,
46 174 contraceptive use and intimate partner violence at baseline were explored with means and
47 175 standard deviations for continuous variables and proportions for categorical variables.
48
49 176 Covariates age, education level, SES-tertile, duration of sex work, having a
50 177 husband/boyfriend, use of highly effective contraceptives and experience of IPV, were
51 178 included in the multivariate models on the basis of a review of literature.[8–15,21] Covariates
52 179 high FP knowledge, positive attitude to FP and high FP specific self-efficacy were included
53 180 in the multivariate models on the basis of theoretical assumptions by the co-authors. It was
54 181 hypothesised that these characteristics would be positively associated with contraceptive
55 182 use and would protect against experiencing an induced abortion. Correlates of lifetime
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abortion were identified using weighted multivariable logistic regression. Associations were considered statistically significant at the 5% level. The outcome incident abortion was interval-censored (measured at 6-monthly intervals). Therefore, a discrete-time survival analysis was performed using generalized linear mixed (GLM) modelling with complementary log-log link function and binomial distribution, a method that produces estimated hazard ratios. Abortions during follow-up were analysed for all participants who attended at least one follow-up visit. All outcomes presented here are cluster-adjusted, based on inverse probability sample means to account for sampling bias.

Ethical consideration

All study participants provided written informed consent. The study was approved by the Kenyatta National Hospital and University of Nairobi Ethics and Research Committee, Kenya (KNH-UoN ERC—KNH-ERC/RR/493) and the Monash University Human Research Ethics Committee, Australia (MUHREC—CF16/1552—2016000812).

Patient and public involvement

Patients or the public were not directly involved in the design, or conduct, or reporting, or dissemination plans of our research.

RESULTS

Mean age was 25.5 years (SD=4.7) (Table 1). The majority of women (n=765, 88.7%) had at least completed primary education and 306 (34.9%) had completed secondary education. Just over half of the participants (n=484, 56.6%) reported to have a current husband or boyfriend, but 812 (94.0%) reported not to live with a partner. Mean duration of employment in sex work was 4.7 years (SD=3.5). Among women currently reporting a husband or boyfriend, 344/483 (70.8%) had not disclosed their employment in sex work to their partners. 605/861 women (68.9%) worked fulltime in sex work and 508/863 (59.8%) earned more than 2000 Ksh (about USD \$20) per week from sex work. The majority of women (n=666, 76.1%) had ever been pregnant, and 451 (51.2%) ever had an unintended pregnancy. 103/866 (11.9%) reported to have had at least one induced abortion in their lifetime. Among women who had an induced abortion, 58/102 (57.1%) went to a private hospital or clinic for the most recent abortion. 29/102 (29.1%) women had their most recent abortion in the informal sector, like home, a pharmacy or traditional healer. At baseline, 463 women (54.4%) reported to use a highly effective contraceptive method. Three-quarters of FSW (650/866; 75.0%) ever experienced IPV and 525/866 (60.1%) experienced IPV in the past 12 months the before the baseline questionnaire was conducted.

Table 1. Socio-demographic characteristics, reproductive history, contraceptive use and intimate partner violence at baseline of female sex workers in Mombasa, Kenya (n=866, unless stated otherwise)

Characteristic	n	Cluster-adjusted mean (SD) or proportion in % (95% CI) ^a
Mean age, in years		25.5 (4.7)
Highest level of education		
None or some primary	101	11.2 (9.2-13.6)
Completed primary or some secondary	459	53.8 (50.1-57.6)
Completed secondary or some tertiary	306	34.9 (31.3-38.7)
Religion (n=864)		
Protestant	389	44.8 (41.4-48.2)
Catholic	304	36.0 (32.3-39.8)
Muslim	171	19.2 (15.6-23.4)
Electricity available in household (n=863) ^b	660	76.4 (73.0-79.5)
Duration of sex work, in years		4.7 (3.5)
Fulltime FSW (n=861) ^c	605	68.9 (64.0-73.5)
Weekly income from sex work (n=861)		
≤1000 Ksh	144	16.2 (13.2-19.8)
1001-2000 Ksh	211	24.0 (21.0-27.3)

≥2001 Ksh ^d	508	59.8 (55.1-64.3)
Sex work venue		
Bar with lodging	388	43.8 (37.7-50.2)
Bar without lodging	147	17.2 (13.7-21.3)
Lodging/guesthouse	138	15.1 (10.9-20.5)
Street/beach	86	11.2 (7.8-15.7)
Other ^e	107	12.7 (9.1-17.5)
Marital status		
Married/cohabiting	54	6.0 (4.5-8.0)
Single (not cohabiting)	627	73.0 (69.6-76.2)
Separated/divorced/widowed	185	21.0 (18.0-24.3)
Currently has husband/boyfriend	484	56.6 (52.5-60.7)
Disclosure of sex work to husband/boyfriend (n=483) ^f		
Yes	136	28.7 (24.4-33.3)
No	344	70.8 (66.0-75.1)
Don't know	3	0.6 (0.2-1.7)
Ever had a pregnancy	666	76.1 (72.3-79.5)
Has a living child	622	71.2 (67.1-75.0)
Ever had an unintended pregnancy (N=864) ^g	451	51.2 (47.4-54.9)
Ever had an induced abortion	103	11.9 (10.0-14.2)
Location of most recent induced abortion (N=102)		
Government hospital	2	1.8 (0.4-6.9)
FP clinic, like Marie Stopes	9	8.3 (4.4-15.0)
Private hospital/clinic	58	57.1 (46.5-67.2)
Private doctor GP	4	3.7 (1.4-9.6)
Pharmacy	9	8.9 (4.6-16.8)
Traditional healer	4	3.8 (1.4-10.0)
Home	16	16.4 (9.0-27.8)
Uses a highly effective contraceptive method ^h	473	54.4 (49.5-59.2)
Ever experienced IPV ⁱ	650	75.0 (71.1-78.5)
Experienced IPV in past 12 months ^j	525	60.1 (55.5-64.6)

^a Inverse probability-weighted percentages. ^b Availability of electricity in the household is presented here as a proxy for household SES. ^c Fulltime work as FSW is characterized as having no other sources of income in the last 6 months. ^d 1000 Kenyan Shilling (Ksh) is about USD \$10. ^e Brothel, strip club, casino, massage parlors, parks or home. ^f Among participants with a husband or boyfriend. ^g Assessed using the London Measure of Unintended Pregnancy (LMUP) ^h Highly effective is defined as use of contraceptive implants, IUD, injection, oral contraceptive pill and sterilization. ⁱ IPV= intimate partner violence. ^j Before baseline.

Women currently not using a highly effective contraceptive (AOR=1.76 [95%CI=1.11-2.79] p=0.017) and women who ever experienced IPV (AOR=2.61 [95%CI=1.35-5.06] p=0.005) were significantly more likely to report a history of induced abortion, when controlled for potential confounders (Table 2). Longer duration of sex work showed a borderline positive association with history of abortion (AOR=1.08 [95%CI=1.00-1.16] p=0.053). Although

higher age was significantly associated with a history of abortion in bivariate analysis, after adjusting for confounding factors this association was no longer seen.

Table 2. Correlates of participants with a history of induced abortion, and cluster-adjusted bi- and multivariable logistic regression analysis on history of induced abortion (n=866)

Characteristic		Crude Odds Ratio (OR)		Adjusted OR	
	Ever had an induced abortion (n=103); n/N (cluster-adjusted proportion in %) ^a	OR (95% CI) ^b	p-value	OR (95% CI) ^b	p-value
Age (in years)	27.0 (4.9) ^c	1.08 (1.03-1.14)	0.001	1.04 (0.97-1.11)	0.280
Highest level of education					
None or some primary	14/101 (13.5)	Ref.		Ref.	
Completed primary or some secondary	57/459 (12.4)	0.90 (0.47-1.72)	0.749	0.96 (0.48-1.99)	0.895
Completed secondary or some tertiary	32/306 (10.7)	0.77 (0.40-1.47)	0.423	0.83 (0.40-1.84)	0.620
SES-tertile ^e					
Poorest	39/290 (13.4)	Ref.		Ref.	
Middle	33/287 (10.9)	0.79 (0.46-1.35)	0.386	0.89 (0.50-1.59)	0.697
Richest	31/289 (11.4)	0.83 (0.47-1.46)	0.510	0.83 (0.46-1.50)	0.674
Mean duration of sex work (in years)	6.1 (3.4) ^c	1.12 (1.07-1.17)	<0.001	1.08 (1.00-1.16)	0.053
Highly effective contraceptive use ^d					
Yes	51/473 (10.6)	Ref.		Ref.	
No	52/393 (13.5)	1.32 (0.88-1.97)	0.173	1.76 (1.11-2.79)	0.017
High FP knowledge score					
No	60/562 (10.5)	Ref.		Ref.	
Yes	43/304 (14.5)	1.44 (0.95-2.19)	0.084	1.34 (0.85-2.10)	0.200
Positive attitude to FP use					
No	43/354 (12.4)	Ref.		Ref.	
Yes	60/512 (11.6)	0.93 (0.60-1.44)	0.743	0.90 (0.56-1.45)	0.661
High FP-specific self-efficacy					
No	24/237 (10.1)	Ref.		Ref.	
Yes	79/629 (12.6)	1.28 (0.76-2.17)	0.345	1.23 (0.72-2.10)	0.454
Ever experienced intimate partner violence					
No	12/216 (5.2)	Ref.		Ref.	
Yes	91/650 (14.1)	2.98 (1.55-5.74)	0.001	2.61 (1.35-5.06)	0.005

^a Inverse probability-weighted percentages. ^b Standard errors are corrected by cluster sandwich variance estimation. ^c Mean (SD) of women who ever had an induced abortion. ^d Highly effective is defined as use of contraceptive implants, IUD, injection, oral contraceptive pill and sterilization. ^e SES = Socio-economic status.

During the study follow-up, 773 women attended at least one follow-up visit (Figure 1). Total follow-up time was 9,468 months, with an average of 12.2 months per woman (data not shown). A total of 131 participants became pregnant, with a total of 145 pregnancies among these women (Figure 2). Of these pregnancies, 122/145 were unintended according to the LMUP. Among 145 pregnancies, 31 ended in induced abortion, among 29 women and

across 789 women-years at risk. Overall incidence rate was 3.9 induced abortions per 100 women-years of observation. Out of 31 abortions, 19 took place in the formal sector and 12 in an informal setting.

The GLM modelling of abortion incidence showed that women experiencing IPV in the past year (HR=1.93 [95%CI=0.86-4.34] p=0.122) and women not using a highly effective contraceptive (HR=1.51 [95%CI=0.66-3.49] p=0.332) exhibited a higher hazard of abortion, independent of other factors, although these results were not significant (Table 3). We did not find a relation between age, mean duration of sex work, currently having a husband or boyfriend and the intervention under study and hazard of induced abortion.

Table 3. Baseline predictors of incident abortion in FSWs among Mombasa, Kenya (N=773)^a

Baseline predictors of incident abortions	Unadjusted ^b		Adjusted HR ^c	
	HR (95% CI) ^d	p-value	HR (95% CI) ^d	p-value
Age (in years)	0.96 (0.89-1.04)	0.315	1.00 (0.91-1.09)	0.918
Mean duration of sex work (in years)	0.93 (0.82-1.05)	0.234	0.92 (0.79-1.09)	0.336
Currently has husband/boyfriend	0.83 (0.40-1.73)	0.622	0.80 (0.39-1.64)	0.537
Not using highly effective contraceptive ^e	1.50 (0.69-3.23)	0.310	1.51 (0.66-3.49)	0.332
Experienced IPV in last 12 months	1.67 (0.74-3.79)	0.216	1.93 (0.86-4.34)	0.122

^a Discrete-time survival analysis including the first induced abortion per women. Generalized linear mixed model with complementary log-log link, binomial distribution, offset for log time between visits and random intercept for participants. ^b HR = Hazard Ratio. ^c All adjusted Hazard Ratios are also adjusted for the intervention. The intervention had no detectable effect on the outcome of incident abortions. ^d Cluster robust standard errors for sex-work venue clustering. ^e Highly effective is defined as use of contraceptive implants, IUD, injection, oral contraceptive pill and sterilization.

DISCUSSION

This study adds to the current knowledge of abortion practices in FSWs. Lifetime induced abortion prevalence in this population was 11.9%. This seems considerably lower than previous figures of lifetime abortion of 86% in 2004 in central and western Kenya among FSWs of a similar age, and 43% in 2008 in Mombasa among FSWs who were on average 2 years older.[7,17] In the former study, it was not specified if these abortions also included spontaneous abortions, which might have overestimated the prevalence of abortions. However, despite the sociodemographic and methodological differences between the studies, the size of the difference is suggestive of an actual lower rate in abortions in this population. The prevalence of abortions found here is also lower than reports from other LMICs ranging between 24% and 64% in Laos and Cote d'Ivoire, respectively.[8–16] A possible explanation for this lower prevalence is the relatively high use of highly effective contraceptives of 54% in our cohort, compared to similar studies from LMICs. [8,12,14–16] The findings are furthermore consistent with a lower-than-expected HIV prevalence and unintended pregnancy incidence in our cohort and could be a result of peer-mediated interventions implemented over the past years in the Mombasa area.[26,27] These have mostly targeted prevention of HIV and STIs, but likely have had a lowering effect on unintended pregnancies and induced abortions as well.[22,26] Furthermore, this study, in contrast to above referenced studies, attempted to draw a representative sample of a FSW population from community settings, whereas other studies used non-probability sampling methods, which might have overestimated past abortions. Despite the lower-than-expected unintended pregnancy incidence, still 51% of FSWs in our cohort reported an unintended pregnancy in their lifetime. The gap between lifetime unintended pregnancies and lifetime induced abortions could indicate that many women decide to keep a child from unintended pregnancies, which could be supported by the fact that between 70-80% of young FSW in Mombasa have reported one or more children.[4,27] It may also indicate a high unmet need for induced abortion services among FSWs, for example due to ongoing or increasing difficulties in accessing SRH or abortion services for this group or increasing sociocultural barriers to abortion. Barriers to accessing other SRH services such as long-acting reversible contraceptives has previously been reported for this population.[28] The present study is one of the few studies to report incidence of abortion among FSWs and to our knowledge, the first to analyse predictors of abortions in FSWs, rather than correlates of past abortions only. Incidence of induced abortion in our cohort was 3.9 per 100 women-years. Compared to other studies from LMICs, this is similar to two studies reporting abortion incidence rates of 3.1 and 3.0 per 100 women-years and lower than a third study reporting 7.4 induced abortions per 100 women-years among FSWs.[29] The intervention

under study had no measurable effect on unintended pregnancy incidence and is therefore unlikely to have affected incidence of induced abortions.[27]

Informal sector abortions were common in this cohort, with 29% of women having had their most recent abortion in the informal sector, and 39% of the reported abortions during follow-up happening in the informal sector. These informal sector abortions, put women at higher risk of complications due to unsafe practices and this denotes a need for information on safer alternatives, like the Marie Stopes clinics.[23]

Multiple studies have found both age and duration of sex work to be correlated to past abortions. Commonly higher age [8,11,15] and longer duration [9,12] of sex work were associated with higher lifetime abortion prevalence. One study found that younger age was associated with past abortions.[10] In our cohort, although FSWs with a past abortion in our cohort were older in the crude analysis, after adjusting for other correlates, this difference was no longer significant. The association with longer duration of sex work remained borderline significant in multivariate analysis. We did not find a relation between age and mean duration of sex work and having an induced abortion during follow-up. This might suggest that the association between past abortions and higher age and longer duration of sex work is caused by cumulative exposure to high risk of pregnancies and abortion. We found a positive association between currently not using a highly effective contraceptive and having a past abortion. No difference was found in FP-specific self-efficacy or knowledge, or attitude towards FP among women with and without a past abortion. The found association could indicate significant barriers to uptake or continuation of a highly effective contraceptive method post abortion, as has previously been acknowledged by a study in Kenya.[30]

In our cohort, experience of IPV was high and the odds of having had a past abortion were more than 2.5-times as high for women who experienced IPV in the past, consistent with findings from other studies.[14,15] Our study also showed a positive association between experience of IPV in the past twelve months and abortions during follow-up, but this was not significant. Experience of (intimate partner) violence has been shown to have a negative effect on the reproductive health of FSWs, with greater risks of adverse pregnancy outcomes and forced termination of pregnancy.[31,32] Addressing the problem of IPV in this population could further lower induced abortions.

Limitations

Some limitations should be considered when interpreting the findings from this study. The sensitive topic of abortions and SRH in general, might have resulted in a social desirability bias. To minimize this, peer-educators and research assistants had previous experience working with the target population and received additional training. Attrition bias might have

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occurred due to loss to follow-up of pregnant participants, as has been recognized by anecdotal evidence.[27] This might have resulted in an underestimation of abortions in our study. A further limitation is that this paper explores a secondary research question, and the study was not originally powered to assess the predictors of abortions during follow-up. Unknown timing of the past abortions in relation to studied correlates, restrict judgement of temporality of the studied associations. Lastly, measurements of abortions stopped when the intervention stopped, so the actual number of abortions during follow-up might in fact be higher than captured in the study.

Suggestions for further research

Future research is needed to explore the trend in abortion incidence among FSWs in Kenya. In order to improve care, we need to better understand current abortion practices, the decision-making process around terminating unintended pregnancies, how uptake of highly effective contraceptives can be increased post-abortion, as well as the relationship between experience of IPV and induced abortions.

CONCLUSIONS

In conclusion, the prevalence of lifetime induced abortions in a random cohort of FSWs in Mombasa, was 11.9% and incidence was 3.9 per 100 women-years, whereas prevalence and incidence of unintended pregnancies were higher at 51% and 15.5 per 100 women-years, respectively. A history of induced abortion was positively associated with not using a highly contraceptive method at baseline and having experienced IPV in the past. The study did not find a significant association with the studied predictors of abortions.

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TRIAL REGISTRATION

The trial was registered in the Australian New Zealand Clinical Trials Registry, ACTRN12616000852459.

AUTHOR CONTRIBUTORSHIP

SL was the Principal Investigator on the study. SL, FHA, PG, MSCL, PAA, MH, WJ, MS, KL, MT and MFC contributed to the study design. CG and GM coordinated the trial and undertook data acquisition in Kenya under the supervision of PG. AMS and SL conceptualized the manuscript. AMS and PAA conducted the statistical analyses. AMS and CG wrote the first draft of the manuscript. All authors contributed to data interpretation, provided critical input, and approved the final version of the manuscript.

DECLARATION OF INTERESTS

The authors have no conflicts of interest.

DATA AVAILABILITY STATEMENT

The original data are not available in a public repository. The corresponding author is to be contacted for the consideration of any data requests.

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FIGURE CAPTIONS

Figure 1: Eligibility flow diagram for the WHISPER or SHOUT study as per Consort 2010 statement: extension to cluster randomized trials.[33]

Figure 2: Overview of pregnancy outcomes during the 12-month follow-up. N=773

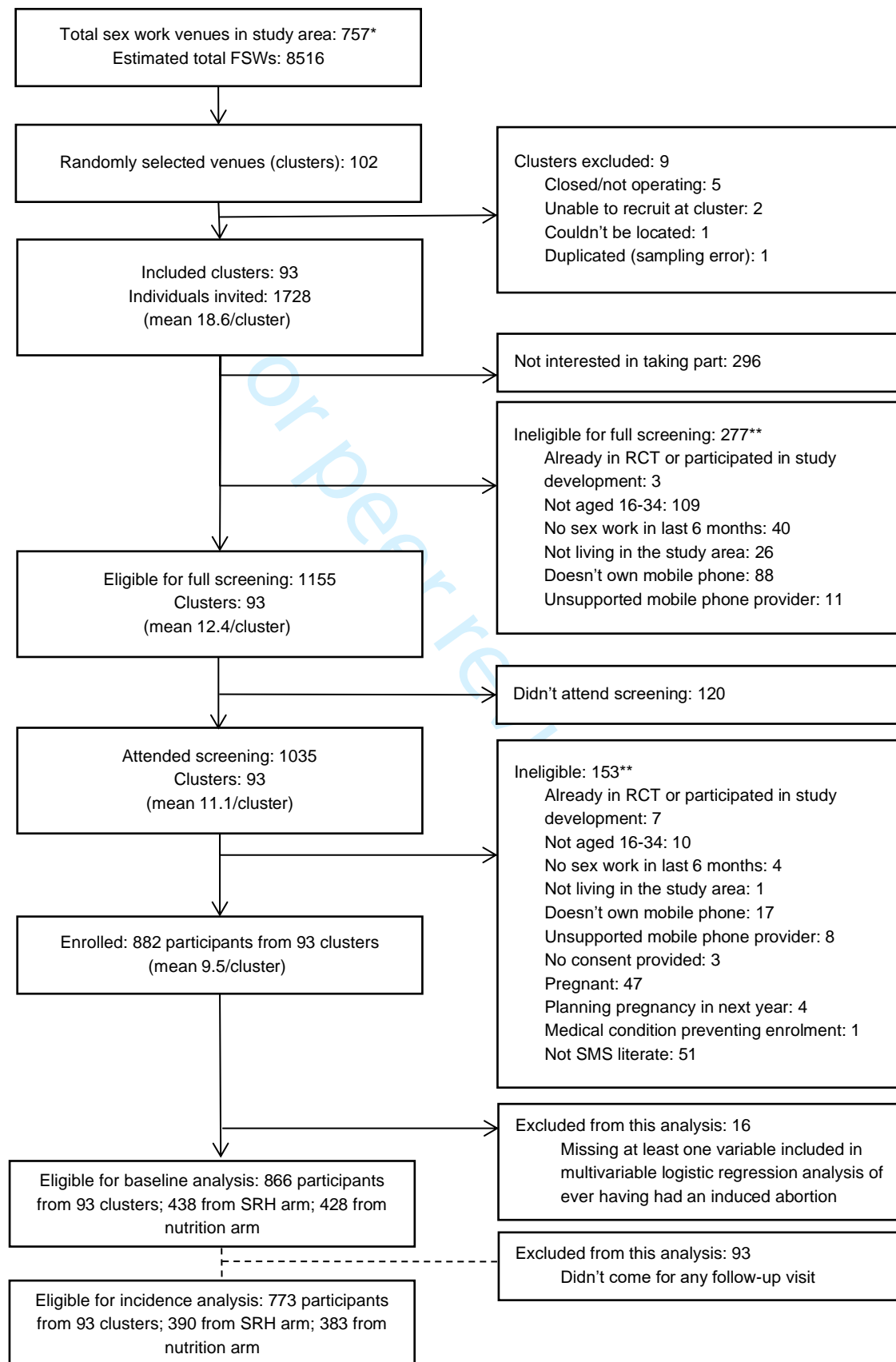
For peer review only

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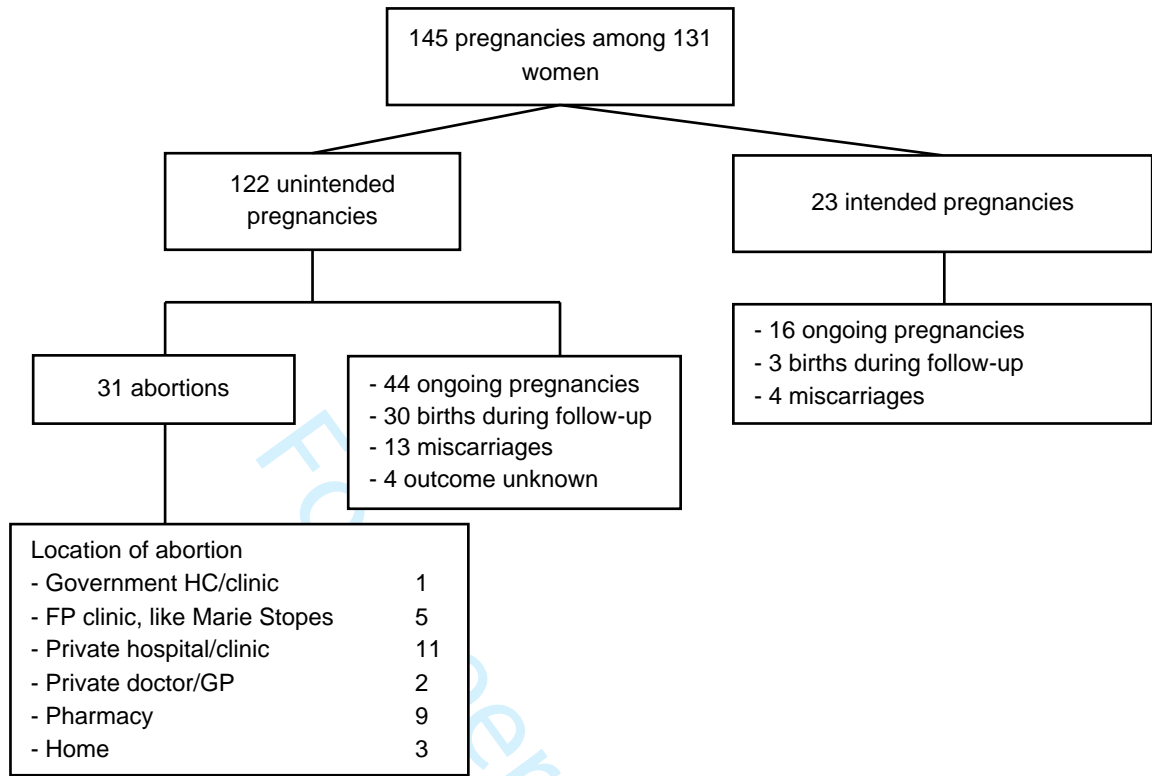
Figure 1: Eligibility flow diagram for the WHISPER or SHOUT study as per Consort 2010 statement: extension to cluster randomized trials.[33]



*Total hotspots and number per hotspot in study area enumerated by Cheuk et al.[34]

**One reason for ineligibility reported per participant and criteria determined in the order shown.

Figure 2: Overview of pregnancy outcomes during the 12-month follow-up. N=773



CONSORT 2010 checklist of information to include when reporting a cluster randomised trial:

Protocol paper[1] and primary outcome paper[2]:

- 1 Ampt FH, Mudogo C, Gichangi P, *et al.* WHISPER or SHOUT study: Protocol of a cluster-randomised controlled trial assessing mHealth sexual reproductive health and nutrition interventions among female sex workers in Mombasa, Kenya. *BMJ Open* 2017;**7**. doi:10.1136/bmjopen-2017-017388
- 2 Ampt FH, Lim MSC, Agius PA, *et al.* Effect of a mobile phone intervention for female sex workers on unintended pregnancy in Kenya (WHISPER or SHOUT): a cluster-randomised controlled trial. *Lancet Glob Heal* 2020;**8**:e1534–45. doi:10.1016/S2214-109X(20)30389-2

Section/Topic	Item No	Standard Checklist item	Extension for cluster designs	Page No *
Title and abstract				
	1a	Identification as a randomised trial in the title	Identification as a cluster randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts) ^{1,2}	See table 2	2
Introduction				
Background and objectives	2a	Scientific background and explanation of rationale	Rationale for using a cluster design	5 (and reference to protocol paper[1])
	2b	Specific objectives or hypotheses	Whether objectives pertain to the the cluster level, the individual participant level or both	4 (and reference to protocol paper[1])
Methods				
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Definition of cluster and description of how the design features apply to the clusters	5 (and reference to protocol paper[1])
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons		N/A

Participants	4a	Eligibility criteria for participants	Eligibility criteria for clusters	5 (and reference to protocol paper[1])
	4b	Settings and locations where the data were collected		5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Whether interventions pertain to the cluster level, the individual participant level or both	5 (and reference to protocol paper[1])
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Whether outcome measures pertain to the cluster level, the individual participant level or both	4, 6 (and reference to protocol paper[1])
	6b	Any changes to trial outcomes after the trial commenced, with reasons		N/A
Sample size	7a	How sample size was determined	Method of calculation, number of clusters(s) (and whether equal or unequal cluster sizes are assumed), cluster size, a coefficient of intracluster correlation (ICC or <i>k</i>), and an indication of its uncertainty	Reference to protocol paper[1]
	7b	When applicable, explanation of any interim analyses and stopping guidelines		N/A
Randomisation:				
Sequence generation	8a	Method used to generate the random allocation sequence		5 (and reference to protocol paper[1])
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Details of stratification or matching if used	Reference to protocol paper[1]

Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Specification that allocation was based on clusters rather than individuals and whether allocation concealment (if any) was at the cluster level, the individual participant level or both	Reference to protocol paper[1]
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Replace by 10a, 10b and 10c	5 (and reference to protocol paper[1])
	10a		Who generated the random allocation sequence, who enrolled clusters, and who assigned clusters to interventions	5 (and reference to protocol paper[1])
	10b		Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete enumeration, random sampling)	5
	10c		From whom consent was sought (representatives of the cluster, or individual cluster members, or both), and whether consent was sought before or after randomisation	5
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how		Reference to protocol paper[1]
	11b	If relevant, description of the similarity of interventions		5 (and reference to protocol paper[1])
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	How clustering was taken into account	6

	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	6
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	For each group, the numbers of clusters that were randomly assigned, received intended treatment, and were analysed for the primary outcome Figure 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	For each group, losses and exclusions for both clusters and individual cluster members Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	8
	14b	Why the trial ended or was stopped	5, 8
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Baseline characteristics for the individual and cluster levels as applicable for each group 8, 9
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	For each group, number of clusters included in each analysis Figure 1, Table 1, 2 and 3
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Results at the individual or cluster level as applicable and a coefficient of intracluster correlation (ICC or k) for each primary outcome Table 2 and 3
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Table 2 and 3
Ancillary analyses	18	Results of any other analyses performed,	Table 2 and 3

		including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms ³)	Reference to primary outcome paper[2]
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	13, 14
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Generalisability to clusters and/or individual participants (as relevant) 12, 13
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	12, 13
Other information			
Registration	23	Registration number and name of trial registry	15
Protocol	24	Where the full trial protocol can be accessed, if available	Reference to protocol paper[1] (page 5)
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	2

* Note: page numbers optional depending on journal requirements

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Table 2: Extension of CONSORT for abstracts^{1,2} to reports of cluster randomised trials

Item	Standard Checklist item	Extension for cluster trials
Title	Identification of study as randomised	Identification of study as cluster randomised
Trial design	Description of the trial design (e.g. parallel, cluster, non-inferiority)	
Methods		
Participants	Eligibility criteria for participants and the settings where the data were collected	Eligibility criteria for clusters
Interventions	Interventions intended for each group	
Objective	Specific objective or hypothesis	Whether objective or hypothesis pertains to the cluster level, the individual participant level or both
Outcome	Clearly defined primary outcome for this report	Whether the primary outcome pertains to the cluster level, the individual participant level or both
Randomization	How participants were allocated to interventions	How clusters were allocated to interventions
Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment	
Results		
Numbers randomized	Number of participants randomized to each group	Number of clusters randomized to each group
Recruitment	Trial status ¹	
Numbers analysed	Number of participants analysed in each group	Number of clusters analysed in each group
Outcome	For the primary outcome, a result for each group and the estimated effect size and its precision	Results at the cluster or individual participant level as applicable for each primary outcome
Harms	Important adverse events or side effects	
Conclusions	General interpretation of the results	
Trial registration	Registration number and name of trial register	
Funding	Source of funding	

¹ Relevant to Conference Abstracts

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ASSESSMENT OF THE LIFETIME PREVALENCE AND INCIDENCE OF INDUCED ABORTION AND CORRELATES AMONG FEMALE SEX WORKERS IN MOMBASA, KENYA: A SECONDARY COHORT ANALYSIS

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Manuscript ID	bmjopen-2021-053218.R2
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**ASSESSMENT OF THE LIFETIME PREVALENCE AND INCIDENCE OF INDUCED
ABORTION AND CORRELATES AMONG FEMALE SEX WORKERS IN
MOMBASA, KENYA: A SECONDARY COHORT ANALYSIS**

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STRUCTURED ABSTRACT

Introduction

Prevalence of lifetime induced abortion in female sex workers (FSWs) in Kenya was previously estimated between 43 and 86%. Our analysis aimed at assessing lifetime prevalence and correlates, and incidence and predictors of induced abortions among FSWs in Kenya.

Methods

This is a secondary prospective cohort analysis using data collected as part of the WHISPER or SHOUT cluster-randomized trial in Mombasa (Australian New Zealand Clinical Trials Registry number: ACTRN12616000852459), assessing effectiveness of an SMS-intervention to reduce incidence of unintended pregnancy. Eligible participants were current FSWs, 16-34 years and not pregnant or planning pregnancy. Baseline data on self-reported lifetime abortion, correlates and predictors were collected between September 2016 and May 2017. Abortion incidence was measured at six- and twelve-months follow-up. A multivariable logistic regression model was used to assess correlates of lifetime abortion and discrete-time survival analysis was used to assess predictors of abortions during follow-up.

Results

Among 866 eligible participants, lifetime abortion prevalence was 11.9%, while lifetime unintended pregnancy prevalence was 51.2%. Correlates of lifetime abortions were currently not using a highly effective contraceptive (AOR=1.76 [95%CI=1.11-2.79] $p=0.017$) and having ever experienced intimate partner violence (IPV) (AOR=2.61 [95%CI=1.35-5.06] $p=0.005$). Incidence of unintended pregnancy and induced abortion were 15.5 and 3.9 per 100 women-years, respectively. No statistically significant associations were found between hazard of abortion and age, sex work duration, partner status, contraceptive use and IPV experience.

Conclusion

Although experience of unintended pregnancy remains high, lifetime prevalence of abortion may have decreased among FSW in Kenya. Addressing IPV could further decrease induced abortions in this population.

KEYWORDS

Sex Work, induced abortion, unintended pregnancy, contraception, cluster-random sample, Kenya

FUNDING STATEMENT

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ARTICLE SUMMARY

Strengths and limitations

- This study presents incidence of abortion in a cluster-randomised cohort of FSWs.
- It is the first to analyse predictors of abortions in FSWs, rather than correlates of past abortions only.
- This paper explores a secondary research question, and the study was not originally powered to assess the predictors of abortions during follow-up.
- The sensitive topic of abortions and SRH in general, might have resulted in a social desirability bias.

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INTRODUCTION

Research findings show that about 5% of Kenya’s urban female reproductive population could be involved in sex work.[1] Female sex workers (FSWs) experience higher than average rates of HIV, other sexually transmitted infections (STIs) and unintended pregnancy.[2–5]

Unintended pregnancies often have negative consequences for FSWs, including financial adversity, social stigma and induced abortion.[4] In countries where abortion is illegal or difficult to access, women frequently resort to unsafe practices, risking severe medical complications.[6]

Reported prevalence of lifetime abortion among FSWs in low- and middle-income countries (LMICs) varies from 24% in Laos in 2012 to 86% in 2000/01 in Central and Western Kenya.[7–16] Many of these abortions are unsafe or sought in the informal sector.[8,11,16]

In Mombasa, lifetime abortion among FSWs was estimated at 43% in 2008.[17]

In 2010, Kenya liberalized its abortion law, making abortion legal when “there is need for emergency treatment, or the life or health of the mother is in danger”.[18] In practice, older laws criminalizing abortion remain in place, creating ambiguity among health professionals with lawsuits remaining a threat.[19] Moreover, social, cultural and religious beliefs condemning pregnancy termination, misconceptions about the illegality and costs of the procedure, still hamper access to safe services for women.[4,19]

A national study in 2012 estimated an induced abortion rate of 48 per 1,000 women among women aged 15-49, based on data of women who sought care for abortion complications.[20] It showed a diverse sociodemographic and economic background among these women in terms of educational level, employment status, marital status and religion.

Incidence of induced abortions among FSWs has not been studied in Kenya and studies analysing correlates of induced abortions elsewhere have been cross-sectional and report correlates of lifetime abortions, precluding attribution of causality.[8–15,21] Examining incidence of abortions and identifying predictors will help inform future policies to improve care around abortions for FSWs and the need for longitudinal data about abortions in FSWs has therefore been recognised.[8,14]

This secondary data analysis aimed to examine lifetime prevalence and correlates, and incidence and predictors of induced abortions in a cluster-random sample of FSWs in Mombasa, Kenya.

MATERIAL AND METHODS

Study design

This is a secondary prospective cohort analysis using data collected as part of the WHISPER or SHOUT cluster-randomized trial in Mombasa. A detailed description of the study protocol can be found elsewhere.[22] In summary, the study was a two-arm cluster-randomized controlled trial assessing the effectiveness of two SMS-based interventions targeting sexual and reproductive health (SRH) and nutrition in FSWs in Mombasa, Kenya. The study was conducted in two sub-counties in Mombasa, Kisauni and Changamwe, between September 2016 and July 2018. Ninety-three venues were randomly sampled with a probability proportional to FSW population size at the venue (Figure 1). Trained community mobilisers and peer educators recruited FSWs from the venues until the required sample size of 860 FSWs was achieved. This study uses baseline and follow-up data from the trial. During the recruitment period of 14 September 2016 to 16 May 2017, 882 women were enrolled in the study. Follow-up continued until 31 July 2018. A sub-sample of 866 women (98.2%) was analysed for this secondary analysis (Figure 1).

Study participants and procedures

Women were eligible for the study if they were aged 16-34 years; self-reported to have engaged in paid sex work in the last 6 months; were reportedly not pregnant or planning pregnancy within the next 12 months; resided within the study area; and were able to read text messages in basic English. Study-specific community mobilizers visited the selected clusters to recruit FSWs and conducted pre-screening interviews identifying women who self-reported to be sex workers. Potentially eligible FSWs were referred to the nearest study clinic for a clinical assessment, including a urine pregnancy test, and STI and HIV testing. Enrolled participants then completed a structured questionnaire administered in Swahili by trained research assistants, who had previously participated in research with FSWs. The questionnaire captured detailed sociodemographic, sexual and reproductive health information. Follow-up visits were scheduled at 6 and 12 months after enrolment. Procedures at follow-up visits were similar to those done at enrolment. Participants received two to three SMS messages per week for 12 months. The messages consisted of stand-alone push messages, role model stories and on-demand messages, accessed using assigned codes. Participants only received and accessed messages on their phones from their assigned intervention.

Outcomes and correlates

Lifetime prevalence of induced abortion was assessed at baseline with the question 'How many times have you ever had an induced abortion?'. Induced abortions were assessed

during follow-up, by asking participants if they had been pregnant since their last visit. The outcome of each reported pregnancy was then assessed, and in the case of an induced abortion, the location was documented. Formal sector abortions were those taking place at a government or private hospital/clinic, a private doctor/General Practitioner (GP) or a Family Planning (FP) clinic. Informal sector abortions were defined as those taking place at home, a pharmacy or traditional healer.[23]

Pregnancies during follow-up were confirmed with a urine pregnancy test at the study clinic, or self-reported by the participant when occurring between study visits. Pregnancy intention for all reported pregnancies was assessed using the London Measure of Unintended Pregnancy (LMUP), a six-item scale. A pregnancy scoring less than 10 out of 12 on the LMUP was defined as unintended.[24]

All correlates of lifetime induced abortions and predictors of incident induced abortions were self-reported at baseline. Use of a highly effective contraceptive method was defined as use of contraceptive implants, IUD, injection, oral contraceptive pill and sterilization. High knowledge on FP was defined as answering five out of six true-false statements on FP correctly. Having a positive attitude on FP was defined as agreeing with at least three out of four positive attitude statements. Self-efficacy in FP was defined as high when agreeing with two statements on this topic. Household socio-economic status tertiles were generated using principal component analysis, based on 12 household assets.[25] Prevalence of intimate partner violence (IPV) was assessed by asking if the participant had ever been pushed, slapped, hit or kicked by a partner, or had been physically forced to have sex, agreed to sex out of fear of the consequences or forced to do something sexual that she perceived as degrading or humiliating. For each item, it was also assessed if this happened in the previous 12 months.

Statistical analysis

Statistical analysis was performed using Stata software version 14 (StataCorp, College Station, TX, USA). Distributions of socio-demographic characteristics, reproductive history, contraceptive use and intimate partner violence at baseline were explored with means and standard deviations for continuous variables and proportions for categorical variables. Covariates age, education level, SES-tertile, duration of sex work, having a husband/boyfriend, use of highly effective contraceptives and experience of IPV, were included in the multivariate models on the basis of a review of literature.[8–15,21] Covariates high FP knowledge, positive attitude to FP and high FP specific self-efficacy were included in the multivariate models on the basis of theoretical assumptions by the co-authors. It was hypothesised that these characteristics would be positively associated with contraceptive use and would protect against experiencing an induced abortion. Correlates of lifetime

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3 183 abortion were identified using weighted multivariable logistic regression. Associations were
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5 184 considered statistically significant at the 5% level. The outcome incident abortion was
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7 185 interval-censored (measured at 6-monthly intervals). Therefore, a discrete-time survival
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9 186 analysis was performed using generalized linear mixed (GLM) modelling with
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11 187 complementary log-log link function and binomial distribution, a method that produces
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13 188 estimated hazard ratios. Abortions during follow-up were analysed for all participants who
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15 189 attended at least one follow-up visit. All outcomes presented here are cluster-adjusted,
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17 190 based on inverse probability sample means to account for sampling bias.
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192 **Ethical consideration**

193 All study participants provided written informed consent. The study was approved by the
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195 Kenyatta National Hospital and University of Nairobi Ethics and Research Committee, Kenya
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197 (KNH-UoN ERC—KNH-ERC/RR/493) and the Monash University Human Research Ethics
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199 Committee, Australia (MUHREC—CF16/1552—2016000812).
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201 **Patient and public involvement**

202 Patients or the public were not directly involved in the design, or conduct, or reporting, or
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204 dissemination plans of our research.
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RESULTS

Mean age was 25.5 years (SD=4.7) (Table 1). The majority of women (n=765, 88.7%) had at least completed primary education and 306 (34.9%) had completed secondary education. Just over half of the participants (n=484, 56.6%) reported to have a current husband or boyfriend, but 812 (94.0%) reported not to live with a partner. Mean duration of employment in sex work was 4.7 years (SD=3.5). Among women currently reporting a husband or boyfriend, 344/483 (70.8%) had not disclosed their employment in sex work to their partners. 605/861 women (68.9%) worked fulltime in sex work and 508/863 (59.8%) earned more than 2000 Ksh (about USD \$20) per week from sex work. The majority of women (n=666, 76.1%) had ever been pregnant, and 451 (51.2%) ever had an unintended pregnancy. 103/866 (11.9%) reported to have had at least one induced abortion in their lifetime. Among women who had an induced abortion, 58/102 (57.1%) went to a private hospital or clinic for the most recent abortion. 29/102 (29.1%) women had their most recent abortion in the informal sector, like home, a pharmacy or traditional healer. At baseline, 463 women (54.4%) reported to use a highly effective contraceptive method. Three-quarters of FSW (650/866; 75.0%) ever experienced IPV and 525/866 (60.1%) experienced IPV in the past 12 months the before the baseline questionnaire was conducted.

Table 1. Socio-demographic characteristics, reproductive history, contraceptive use and intimate partner violence at baseline of female sex workers in Mombasa, Kenya (n=866, unless stated otherwise)		
Characteristic	n	Cluster-adjusted mean (SD) or proportion in % (95% CI) ^a
Mean age, in years		25.5 (4.7)
Highest level of education		
None or some primary	101	11.2 (9.2-13.6)
Completed primary or some secondary	459	53.8 (50.1-57.6)
Completed secondary or some tertiary	306	34.9 (31.3-38.7)
Religion (n=864)		
Protestant	389	44.8 (41.4-48.2)
Catholic	304	36.0 (32.3-39.8)
Muslim	171	19.2 (15.6-23.4)
Electricity available in household (n=863) ^b	660	76.4 (73.0-79.5)
Duration of sex work, in years		4.7 (3.5)
Fulltime FSW (n=861) ^c	605	68.9 (64.0-73.5)
Weekly income from sex work (n=861)		
≤1000 Ksh	144	16.2 (13.2-19.8)
1001-2000 Ksh	211	24.0 (21.0-27.3)

≥2001 Ksh ^d	508	59.8 (55.1-64.3)
Sex work venue		
Bar with lodging	388	43.8 (37.7-50.2)
Bar without lodging	147	17.2 (13.7-21.3)
Lodging/guesthouse	138	15.1 (10.9-20.5)
Street/beach	86	11.2 (7.8-15.7)
Other ^e	107	12.7 (9.1-17.5)
Marital status		
Married/cohabiting	54	6.0 (4.5-8.0)
Single (not cohabiting)	627	73.0 (69.6-76.2)
Separated/divorced/widowed	185	21.0 (18.0-24.3)
Currently has husband/boyfriend	484	56.6 (52.5-60.7)
Disclosure of sex work to husband/boyfriend (n=483) ^f		
Yes	136	28.7 (24.4-33.3)
No	344	70.8 (66.0-75.1)
Don't know	3	0.6 (0.2-1.7)
Ever had a pregnancy	666	76.1 (72.3-79.5)
Has a living child	622	71.2 (67.1-75.0)
Ever had an unintended pregnancy (N=864) ^g	451	51.2 (47.4-54.9)
Ever had an induced abortion	103	11.9 (10.0-14.2)
Location of most recent induced abortion (N=102)		
Government hospital	2	1.8 (0.4-6.9)
FP clinic, like Marie Stopes	9	8.3 (4.4-15.0)
Private hospital/clinic	58	57.1 (46.5-67.2)
Private doctor GP	4	3.7 (1.4-9.6)
Pharmacy	9	8.9 (4.6-16.8)
Traditional healer	4	3.8 (1.4-10.0)
Home	16	16.4 (9.0-27.8)
Uses a highly effective contraceptive method ^h	473	54.4 (49.5-59.2)
Ever experienced IPV ⁱ	650	75.0 (71.1-78.5)
Experienced IPV in past 12 months ^j	525	60.1 (55.5-64.6)

^a Inverse probability-weighted percentages. ^b Availability of electricity in the household is presented here as a proxy for household SES. ^c Fulltime work as FSW is characterized as having no other sources of income in the last 6 months. ^d 1000 Kenyan Shilling (Ksh) is about USD \$10. ^e Brothel, strip club, casino, massage parlors, parks or home. ^f Among participants with a husband or boyfriend. ^g Assessed using the London Measure of Unintended Pregnancy (LMUP) ^h Highly effective is defined as use of contraceptive implants, IUD, injection, oral contraceptive pill and sterilization. ⁱ IPV= intimate partner violence. ^j Before baseline.

Women currently not using a highly effective contraceptive (AOR=1.76 [95%CI=1.11-2.79] p=0.017) and women who ever experienced IPV (AOR=2.61 [95%CI=1.35-5.06] p=0.005) were significantly more likely to report a history of induced abortion, when controlled for potential confounders (Table 2). Longer duration of sex work showed a borderline positive association with history of abortion (AOR=1.08 [95%CI=1.00-1.16] p=0.053). Although

higher age was significantly associated with a history of abortion in bivariate analysis, after adjusting for confounding factors this association was no longer seen.

Table 2. Correlates of participants with a history of induced abortion, and cluster-adjusted bi- and multivariable logistic regression analysis on history of induced abortion (n=866)

Characteristic		Crude Odds Ratio (OR)		Adjusted OR	
	Ever had an induced abortion (n=103); n/N (cluster-adjusted proportion in %) ^a	OR (95% CI) ^b	p-value	OR (95% CI) ^b	p-value
Age (in years)	27.0 (4.9) ^c	1.08 (1.03-1.14)	0.001	1.04 (0.97-1.11)	0.280
Highest level of education					
None or some primary	14/101 (13.5)	Ref.		Ref.	
Completed primary or some secondary	57/459 (12.4)	0.90 (0.47-1.72)	0.749	0.96 (0.48-1.99)	0.895
Completed secondary or some tertiary	32/306 (10.7)	0.77 (0.40-1.47)	0.423	0.83 (0.40-1.84)	0.620
SES-tertile ^e					
Poorest	39/290 (13.4)	Ref.		Ref.	
Middle	33/287 (10.9)	0.79 (0.46-1.35)	0.386	0.89 (0.50-1.59)	0.697
Richest	31/289 (11.4)	0.83 (0.47-1.46)	0.510	0.83 (0.46-1.50)	0.674
Mean duration of sex work (in years)	6.1 (3.4) ^c	1.12 (1.07-1.17)	<0.001	1.08 (1.00-1.16)	0.053
Highly effective contraceptive use ^d					
Yes	51/473 (10.6)	Ref.		Ref.	
No	52/393 (13.5)	1.32 (0.88-1.97)	0.173	1.76 (1.11-2.79)	0.017
High FP knowledge score					
No	60/562 (10.5)	Ref.		Ref.	
Yes	43/304 (14.5)	1.44 (0.95-2.19)	0.084	1.34 (0.85-2.10)	0.200
Positive attitude to FP use					
No	43/354 (12.4)	Ref.		Ref.	
Yes	60/512 (11.6)	0.93 (0.60-1.44)	0.743	0.90 (0.56-1.45)	0.661
High FP-specific self-efficacy					
No	24/237 (10.1)	Ref.		Ref.	
Yes	79/629 (12.6)	1.28 (0.76-2.17)	0.345	1.23 (0.72-2.10)	0.454
Ever experienced intimate partner violence					
No	12/216 (5.2)	Ref.		Ref.	
Yes	91/650 (14.1)	2.98 (1.55-5.74)	0.001	2.61 (1.35-5.06)	0.005

^a Inverse probability-weighted percentages. ^b Standard errors are corrected by cluster sandwich variance estimation. ^c Mean (SD) of women who ever had an induced abortion. ^d Highly effective is defined as use of contraceptive implants, IUD, injection, oral contraceptive pill and sterilization. ^e SES = Socio-economic status.

During the study follow-up, 773 women attended at least one follow-up visit (Figure 1). Total follow-up time was 9,468 months, with an average of 12.2 months per woman (data not shown). A total of 131 participants became pregnant, with a total of 145 pregnancies among these women (Figure 2). Of these pregnancies, 122/145 were unintended according to the LMUP. Among 145 pregnancies, 31 ended in induced abortion, among 29 women and

across 789 women-years at risk. Overall incidence rate was 3.9 induced abortions per 100 women-years of observation. Out of 31 abortions, 19 took place in the formal sector and 12 in an informal setting.

The GLM modelling of abortion incidence showed that women experiencing IPV in the past year (HR=1.93 [95%CI=0.86-4.34] p=0.122) and women not using a highly effective contraceptive (HR=1.51 [95%CI=0.66-3.49] p=0.332) exhibited a higher hazard of abortion, independent of other factors, although these results were not significant (Table 3). We did not find a relation between age, mean duration of sex work, currently having a husband or boyfriend and the intervention under study and hazard of induced abortion.

Table 3. Baseline predictors of incident abortion in FSWs among Mombasa, Kenya (N=773)^a

Baseline predictors of incident abortions	Unadjusted ^b		Adjusted HR ^c	
	HR (95% CI) ^d	p-value	HR (95% CI) ^d	p-value
Age (in years)	0.96 (0.89-1.04)	0.315	1.00 (0.91-1.09)	0.918
Mean duration of sex work (in years)	0.93 (0.82-1.05)	0.234	0.92 (0.79-1.09)	0.336
Currently has husband/boyfriend	0.83 (0.40-1.73)	0.622	0.80 (0.39-1.64)	0.537
Not using highly effective contraceptive ^e	1.50 (0.69-3.23)	0.310	1.51 (0.66-3.49)	0.332
Experienced IPV in last 12 months	1.67 (0.74-3.79)	0.216	1.93 (0.86-4.34)	0.122

^a Discrete-time survival analysis including the first induced abortion per women. Generalized linear mixed model with complementary log-log link, binomial distribution, offset for log time between visits and random intercept for participants. ^b HR = Hazard Ratio. ^c All adjusted Hazard Ratios are also adjusted for the intervention. The intervention had no detectable effect on the outcome of incident abortions. ^d Cluster robust standard errors for sex-work venue clustering. ^e Highly effective is defined as use of contraceptive implants, IUD, injection, oral contraceptive pill and sterilization.

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DISCUSSION

This study adds to the current knowledge of abortion practices in FSWs. Lifetime induced abortion prevalence in this population was 11.9%. This seems considerably lower than previous figures of lifetime abortion of 86% in 2004 in central and western Kenya among FSWs of a similar age, and 43% in 2008 in Mombasa among FSWs who were on average 2 years older.[7,17] In the former study, it was not specified if these abortions also included spontaneous abortions, which might have overestimated the prevalence of abortions. However, despite the sociodemographic and methodological differences between the studies, the size of the difference is suggestive of an actual lower rate in abortions in this population. The prevalence of abortions found here is also lower than reports from other LMICs ranging between 24% and 64% in Laos and Cote d'Ivoire, respectively.[8–16] A possible explanation for this lower prevalence is the relatively high use of highly effective contraceptives of 54% in our cohort, compared to similar studies from LMICs. [8,12,14–16] The findings are furthermore consistent with a lower-than-expected HIV prevalence and unintended pregnancy incidence in our cohort and could be a result of peer-mediated interventions implemented over the past years in the Mombasa area.[26,27] These have mostly targeted prevention of HIV and STIs, but likely have had a lowering effect on unintended pregnancies and induced abortions as well.[22,26] Furthermore, this study, in contrast to above referenced studies, attempted to draw a representative sample of a FSW population from community settings, whereas other studies used non-probability sampling methods, which might have overestimated past abortions. Despite the lower-than-expected unintended pregnancy incidence, still 51% of FSWs in our cohort reported an unintended pregnancy in their lifetime. The gap between lifetime unintended pregnancies and lifetime induced abortions could indicate that many women decide to keep a child from unintended pregnancies, which could be supported by the fact that between 70-80% of young FSW in Mombasa have reported one or more children.[4,27] It may also indicate a high unmet need for induced abortion services among FSWs, for example due to ongoing or increasing difficulties in accessing SRH or abortion services for this group or increasing sociocultural barriers to abortion. Barriers to accessing other SRH services such as long-acting reversible contraceptives has previously been reported for this population.[28] The present study is one of the few studies to report incidence of abortion among FSWs and to our knowledge, the first to analyse predictors of abortions in FSWs, rather than correlates of past abortions only. Incidence of induced abortion in our cohort was 3.9 per 100 women-years. Compared to other studies from LMICs, this is similar to two studies reporting abortion incidence rates of 3.1 and 3.0 per 100 women-years and lower than a third study reporting 7.4 induced abortions per 100 women-years among FSWs.[29] The intervention

under study had no measurable effect on unintended pregnancy incidence and is therefore unlikely to have affected incidence of induced abortions.[27]

Informal sector abortions were common in this cohort, with 29% of women having had their most recent abortion in the informal sector, and 39% of the reported abortions during follow-up happening in the informal sector. These informal sector abortions, put women at higher risk of complications due to unsafe practices and this denotes a need for information on safer alternatives, like the Marie Stopes clinics.[23]

Multiple studies have found both age and duration of sex work to be correlated to past abortions. Commonly higher age [8,11,15] and longer duration [9,12] of sex work were associated with higher lifetime abortion prevalence. One study found that younger age was associated with past abortions.[10] In our cohort, although FSWs with a past abortion in our cohort were older in the crude analysis, after adjusting for other correlates, this difference was no longer significant. The association with longer duration of sex work remained borderline significant in multivariate analysis. We did not find a relation between age and mean duration of sex work and having an induced abortion during follow-up. This might suggest that the association between past abortions and higher age and longer duration of sex work is caused by cumulative exposure to high risk of pregnancies and abortion. We found a positive association between currently not using a highly effective contraceptive and having a past abortion. No difference was found in FP-specific self-efficacy or knowledge, or attitude towards FP among women with and without a past abortion. The found association could indicate significant barriers to uptake or continuation of a highly effective contraceptive method post abortion, as has previously been acknowledged by a study in Kenya.[30]

In our cohort, experience of IPV was high and the odds of having had a past abortion were more than 2.5-times as high for women who experienced IPV in the past, consistent with findings from other studies.[14,15] Our study also showed a positive association between experience of IPV in the past twelve months and abortions during follow-up, but this was not significant. Experience of (intimate partner) violence has been shown to have a negative effect on the reproductive health of FSWs, with greater risks of adverse pregnancy outcomes and forced termination of pregnancy.[31,32] Addressing the problem of IPV in this population could further lower induced abortions.

Limitations

Some limitations should be considered when interpreting the findings from this study. The sensitive topic of abortions and SRH in general, might have resulted in a social desirability bias. To minimize this, peer-educators and research assistants had previous experience working with the target population and received additional training. Attrition bias might have

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occurred due to loss to follow-up of pregnant participants, as has been recognized by anecdotal evidence.[27] This might have resulted in an underestimation of abortions in our study. The robust multi-stage sampling method improved the ability to generalise the findings to the larger sex work population in the Coast region. However, this study was done in a well-researched population, targeted by other peer-mediated interventions in the past two decades, which may limit generalisation to sex worker populations in other settings. A further limitation is that this paper explores a secondary research question, and the study was not originally powered to assess the predictors of abortions during follow-up. Unknown timing of the past abortions in relation to studied correlates, restrict judgement of temporality of the studied associations. Lastly, measurements of abortions stopped when the intervention stopped, so the actual number of abortions during follow-up might in fact be higher than captured in the study.

Suggestions for further research

Future research is needed to explore the trend in abortion incidence among FSWs in Kenya. In order to improve care, we need to better understand current abortion practices, the decision-making process around terminating unintended pregnancies, how uptake of highly effective contraceptives can be increased post-abortion, as well as the relationship between experience of IPV and induced abortions.

CONCLUSIONS

In conclusion, the prevalence of lifetime induced abortions in a random cohort of FSWs in Mombasa, was 11.9% and incidence was 3.9 per 100 women-years, whereas prevalence and incidence of unintended pregnancies were higher at 51% and 15.5 per 100 women-years, respectively. A history of induced abortion was positively associated with not using a highly contraceptive method at baseline and having experienced IPV in the past. The study did not find a significant association with the studied predictors of abortions.

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TRIAL REGISTRATION

The trial was registered in the Australian New Zealand Clinical Trials Registry, ACTRN12616000852459.

AUTHOR CONTRIBUTORSHIP

SL was the Principal Investigator on the study. SL, FHA, PG, MSCL, PAA, MH, WJ, MS, KL, MT and MFC contributed to the study design. CG and GM coordinated the trial and undertook data acquisition in Kenya under the supervision of PG. AMS and SL conceptualized the manuscript. AMS and PAA conducted the statistical analyses. AMS and CG wrote the first draft of the manuscript. All authors contributed to data interpretation, provided critical input, and approved the final version of the manuscript.

DECLARATION OF INTERESTS

The authors have no conflicts of interest.

DATA AVAILABILITY STATEMENT

The original data are not available in a public repository. The corresponding author is to be contacted for the consideration of any data requests.

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FIGURE CAPTIONS

Figure 1: Eligibility flow diagram for the WHISPER or SHOUT study as per Consort 2010 statement: extension to cluster randomized trials.[33,34]

Figure 2: Overview of pregnancy outcomes during the 12-month follow-up. N=773

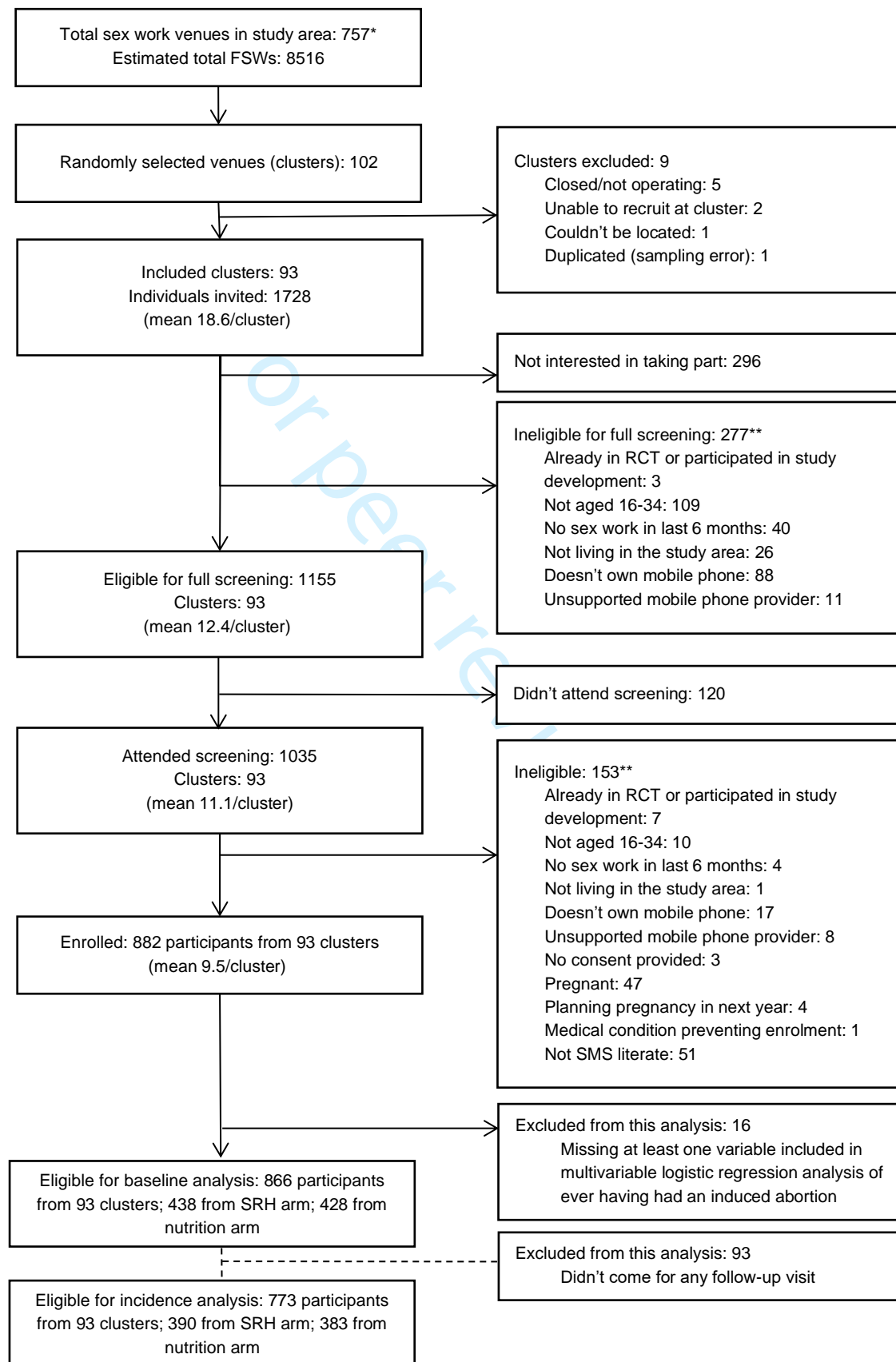
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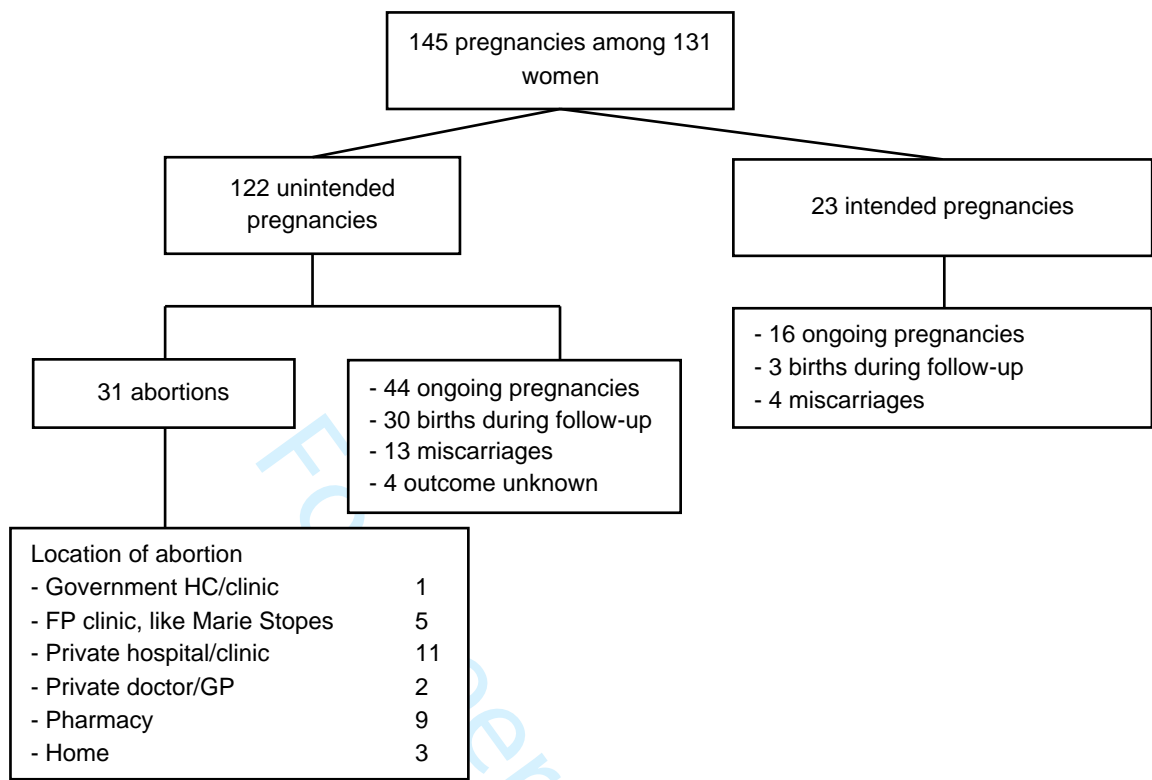
Figure 1: Eligibility flow diagram for the WHISPER or SHOUT study as per Consort 2010 statement: extension to cluster randomized trials.[33]



*Total hotspots and number per hotspot in study area enumerated by Cheuk et al.[34]

**One reason for ineligibility reported per participant and criteria determined in the order shown.

Figure 2: Overview of pregnancy outcomes during the 12-month follow-up. N=773



STROBE Statement—Checklist of items that should be included in reports of *cohort studies*

Protocol paper [1]:

- 1 Ampt FH, Mudogo C, Gichangi P, *et al.* WHISPER or SHOUT study: Protocol of a cluster-randomised controlled trial assessing mHealth sexual reproductive health and nutrition interventions among female sex workers in Mombasa, Kenya. *BMJ Open* 2017;7. doi:10.1136/bmjopen-2017-017388

	Item No	Recommendation	Page No
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	5
Objectives	3	State specific objectives, including any prespecified hypotheses	5
Methods			
Study design	4	Present key elements of study design early in the paper	6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6 + Ref [1] to protocol paper
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up (b) For matched studies, give matching criteria and number of exposed and unexposed	6 + Ref [1] to protocol paper
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	6, 7
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	6, 7
Bias	9	Describe any efforts to address potential sources of bias	Ref [1] to protocol paper
Study size	10	Explain how the study size was arrived at	Ref [1] to protocol paper
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	7, 8
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding (b) Describe any methods used to examine subgroups and interactions (c) Explain how missing data were addressed (d) If applicable, explain how loss to follow-up was addressed (e) Describe any sensitivity analyses	7, 8

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Results			
Participants	13*	(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 (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram	6 + Figure 1
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest (c) Summarise follow-up time (eg, average and total amount)	9, 10, 11 + Table 1
Outcome data	15*	Report numbers of outcome events or summary measures over time	9, 11

1	Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	9-12 + Tables 2 and 3
2			(b) Report category boundaries when continuous variables were categorized	
3			(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
4	Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	12, Table 3
5	Discussion			
6	Key results	18	Summarise key results with reference to study objectives	13
7	Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	14, 15
8	Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	13-15
9	Generalisability	21	Discuss the generalisability (external validity) of the study results	15
10	Other information			
11	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	2-3, 16

*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 <http://www.strobe-statement.org>.