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Summary

Background Female sex workers in low-income and middle-income countries face high risks of unintended pregnancy. We developed a 12-month, multifaceted short messaging service intervention (WHISPER) for female sex workers in Kenya who had the potential to become pregnant, to improve their contraceptive knowledge and behaviours. The aim of this study was to assess the effectiveness of the intervention to reduce the incidence of unintended pregnancy among sex workers in Kenya compared with an equal-attention control group receiving nutrition-focused messages (SHOUT).

Methods Our two-arm, cluster-randomised controlled trial was done in sex-work venues in two subcounties of Mombasa, Kenya (Kisauni and Changamwe). Participants, aged 16–34 years, not pregnant or planning pregnancy, able to read text messages in English, residing in the study area, and who had a personal mobile phone with one of two phone networks, were recruited from 93 randomly selected sex-work venues (clusters). Random cluster allocation (1:1) to the intervention or control group was concealed from participants and researchers until the intervention started. Both groups received text messages in English delivered two to three times per week for 12 months (137 messages in total), as well as additional on-demand messages. Message content in the intervention group focused on promotion of contraception, particularly long-acting reversible contraception and dual method contraceptive use; message content in the control group focused on promotion of nutritional knowledge and practices, including food safety, preparation, and purchasing. The primary endpoint, analysed in all participants who were randomly assigned and attended at least one follow-up visit, compared unintended pregnancy incidence between groups using discrete-time survival analysis at 6 and 12 months. This trial is registered with Australian New Zealand Clinical Trials Registry, ACTRN12616000852459, and is closed to new participants.

Findings Between Sept 14, 2016, and May 16, 2017, 1728 individuals were approached to take part in the study. Of these, 1155 were eligible for full screening, 1035 were screened, and 882 were eligible, enrolled, and randomly assigned (451 participants from 47 venues in the intervention group; 431 participants from 46 venues in the control group). 401 participants from the intervention group and 385 participants from the control group were included in the primary analysis. Incidence of unintended pregnancy was 15·5 per 100 person-years in the intervention group and 14·7 per 100 person-years in the control group (hazard ratio 0·98, 95% CI 0·69–1·39).

Interpretation The intervention had no measurable effect on unintended pregnancy incidence. Mobile health interventions, even when acceptable and rigorously designed, are unlikely to have a sufficient effect on behaviour among female sex workers to change pregnancy incidence when used in isolation.

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Introduction

Female sex workers constitute a large[1] and marginalised population in sub-Saharan Africa, with multiple overlapping sexual and reproductive health needs. High rates of HIV and other sexually transmitted infections have long been recognised in this population and targeted by interventions such as peer education, mobile outreach, and health services tailored to female sex workers.[2] By contrast, unintended pregnancy has received little attention, despite being a high priority for sex workers

with the potential to become pregnant[3] and having multiple adverse health and socioeconomic consequences,[4–6] including increased financial dependence on sex work.[7,8] A systematic review of 3866 studies of female sex workers found only ten in which unintended pregnancy incidence was measured, and the estimated incidence was 27 per 100 woman-years.[9] Contraceptive use in this population is also estimated to be low.[7] However, little emphasis has been placed on family planning as part of sexual and reproductive health

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Research in context

Evidence before this study

We searched MEDLINE, Embase, PsycINFO, and Popline on Jan 20, 2016, for peer-reviewed studies done with female sex workers in low-income and middle-income countries, published in English since Jan 1, 2000. Search terms included "sex work", "transactional sex", and related terms; a list of countries defined by World Bank as low-income and middle-income countries; and synonyms for low-income and middle-income. No studies were identified that tested interventions for female sex workers in low-income and middle-income countries to increase non-barrier contraceptive use or prevent unintended pregnancy. 25 studies measured unintended pregnancy incidence in this population, which was estimated at 27 per 100 person-years in a meta-analysis. Most studies focused exclusively on HIV or other sexually transmitted infections. Therefore, female sex workers in low-income and middle-income countries are at high risk of unintended pregnancy, but interventions to reduce this risk have not been evaluated.

Added value of this study

To our knowledge, this is one of only two trials of a behaviour change intervention for self-identified female sex workers in a low-income or middle-income country designed to prevent unintended pregnancy. Other trials in this population have been done to increase condom use but not other contraceptives, and to prevent HIV and other sexually transmitted infections rather than pregnancy. Our intervention aimed to address known knowledge gaps and misconceptions about pregnancy prevention and related sexual and reproductive health concerns,

with a particular focus on long-acting reversible contraceptives. The intervention was delivered by mobile phone short messaging service, which was deemed an acceptable and widely used medium by female sex workers. A two-arm, equal-attention, cluster-randomised controlled design was used, with participants enrolled from randomly selected sex-work venues (clusters) to minimise contamination. Retention was high and the intervention was well received by participants. Our study did not show an effect on unintended pregnancy incidence or use of long-acting reversible contraceptives. The intervention did result in improvements in dual method contraceptive use and contraceptive knowledge.

Implications of all the available evidence

This trial, along with previous research, has not identified effective strategies of preventing unintended pregnancy for female sex workers. A repeat search of MEDLINE on Sept 3, 2019, identified only one other intervention study, a randomised controlled trial of a mobile health intervention in Cambodia, but results were not yet available. Our trial confirmed that mobile phones are an important and acceptable means of engaging with this population, but that sexual and reproductive health messages delivered via this medium, when used in isolation, did not have a sufficient effect on contraceptive behaviour to modify biological outcomes. In view of the complex socioeconomic and structural barriers faced by female sex workers, more comprehensive interventions, for example combining mobile health with supply-side initiatives, might be required.

services for sex workers, and effective interventions to prevent unintended pregnancy have not been identified.

There are multiple individual, interpersonal, and structural barriers to the adoption and maintenance of effective contraception by sex workers who might become pregnant.[10] Myths and misconceptions, particularly in relation to long-acting reversible contraception, are especially common and salient. Low knowledge and fear of side-effects of contraception have been noted as substantial barriers for female sex workers,[7,11,12] consistent with findings for young women more broadly,[13] which could be amenable to modification by an individually focused mobile health (mHealth) intervention. Mobile phone coverage was approximately 87% in Kenya in 2016,[14] and higher among sex workers, who rely on mobile phones for maintaining social and business networks.[3] Short messaging service technology (SMS, or text messaging) is available on all mobile phones, and has been shown to influence health behaviour.[15,16] However, although some randomised controlled trials have studied the use of SMS for promoting safer sex behaviours,[17–19] few have focused on improving contraceptive use.[20–24]

We developed an SMS health promotion intervention for self-identified female sex workers in Kenya to address

their knowledge gaps and misconceptions around family planning, and to prevent unintended pregnancy. The intervention was developed using a participatory, theory-based approach and was well received by the female sex worker community in the pilot phase.[3] The aim of this study was to assess the effectiveness of the intervention to reduce the incidence of unintended pregnancy among sex workers in Kenya compared with an equal-attention control group receiving nutrition-focused messages.

Methods

Study design and participants

This two-arm, cluster-randomised controlled trial was done in sex-work venues in two subcounties of Mombasa, Kenya (Kisauni and Changamwe). A full description of the study protocol is provided elsewhere.[10] Trained community mobilisers and peer educators, all of whom were current or former female sex workers (self-reported), recruited participants from pre-identified sex-work venues. Venues ranged from nightclubs and brothels to informal drinking dens and public spaces. The sampling frame was based on an enumeration of sex workers done in 2014,[25] and consisted of 8516 self-identified female sex workers working across 757 venues in the two study areas.

The sampling strategy was two-staged. First, sex-work venues were randomly selected with a probability proportionate to the size of their estimated population of female sex workers. Second, at each venue, self-identified female sex workers were consecutively invited to participate in the study, with a fixed target of ten participants per venue (based on an estimated mean venue size of 11·2 women), until the required sample size was reached. The number of venues sampled was 102 plus an additional four, which were not approached because the required sample size had been reached. The number of venues sampled was increased from 86 to 95 to account for some venues that had small populations of female sex workers, and was then increased by about 10% to account for anticipated lack of access (eg, due to venue closure or security concerns).

Eligible participants were women aged 16–34 years; self-reported receiving money in exchange for sex at the venue of recruitment in the previous 6 months; were not pregnant or planning pregnancy within 12 months; resided within the study area; reported being able to read text messages in English; and had a personal mobile phone with one of two phone networks (Safaricom, which accounted for 71% of Kenyan mobile phone subscriptions at the start of the trial, or Airtel, which accounted for 18% of Kenyan mobile phone subscriptions). Participants were excluded if they had participated in another mHealth study (including the formative research for this study) or if they had a medical or non-medical condition detected through screening that hindered study participation, as confirmed by the local principal investigator. All participants provided written informed consent.

The study was approved by the Kenyatta National Hospital and University of Nairobi Ethics and Research Committee, Kenya (reference KNH-ERC/RR/493) and the Monash University Human Research Ethics Committee, Australia (reference CF16/1552—2016000812).

Randomisation and masking

Before recruitment, each de-identified sex-work venue was randomly assigned 1:1 to either the intervention (WHISPER) or control (SHOUT) group by the study statistician using random sequence generation. Opaque envelopes with the randomisation assignment were kept at the research office in Mombasa for participant allocation. Allocation was concealed from both participants and researchers until baseline data collection was completed for each cluster. The study coordinator then assigned that cluster to the relevant group via an online platform (operated by Viamo, Nairobi, Kenya), and set the date for delivery of text messages to both groups to commence.

Procedures

Participants who met prescreening criteria at their work venue attended one of two study clinics embedded in existing health facilities for full screening and data collection. Data collection included urine pregnancy testing (also used to assess eligibility), sexually transmitted infection and HIV tests, and a structured questionnaire administered by trained research assistants. The questionnaire captured detailed sociodemographic information including education, literacy, employment, income, family and living circumstances, health and illness, and sex work history. Sexual and reproductive health inquiries included previous pregnancies; 6-month pregnancy intention; contraception and condom use (including dual protection); reasons for discontinuation or non-use of contraception; contraceptive self-efficacy; sexual and reproductive health seeking and service use; sexual risk behaviours; sexual and reproductive health knowledge and attitudes; and relationship control and joint decision making with non-paying emotional partners. Additional data collection procedures for the control group are detailed in the protocol.[10] Data collection was repeated at 6 months and 12 months after enrolment, with participants reminded to attend each follow-up appointment by automated SMS.

The intervention and control groups both received text messages in English delivered two to three times per week for 12 months (137 messages in total), as well as additional on-demand messages that could be accessed at any time.[10] Members of each cluster were sent the same messages on the same days throughout the study period. Half of the messages were short, stand-alone texts providing information, and the other half consisted of longer, fictional narratives about female sex workers showing healthy social norms and behaviours (role model stories), recounted over several instalments. On-demand messages could be retrieved free-of-charge via SMS using a numerical code, and contained supplementary information and further options. Prompts to reply with numerical codes were included in many of the scheduled messages. The system and content were modelled on the Mobile 4 Reproductive Health service,[26] but with the addition of a directory of 12 local health facilities for female sex workers, describing their location and available services.

WHISPER message content focused on promotion of contraception, particularly long-acting reversible contraception and dual method contraceptive use. Messages also incorporated key domains of sexual and reproductive health that are known to influence pregnancy risk, including the prevention of HIV and sexually transmitted infections, alcohol and substance use, stigma, and violence.[10,26] Message content and structure were informed by behaviour change theories, including stages of change and social cognitive theory,[27,28] which posit that not only knowledge, but also personal factors such as self-efficacy and skill development are important influencers of behaviour;[29] hence these cognitive strategies were incorporated into messages. The intervention was co-designed and tested with self-identified female sex workers from the target

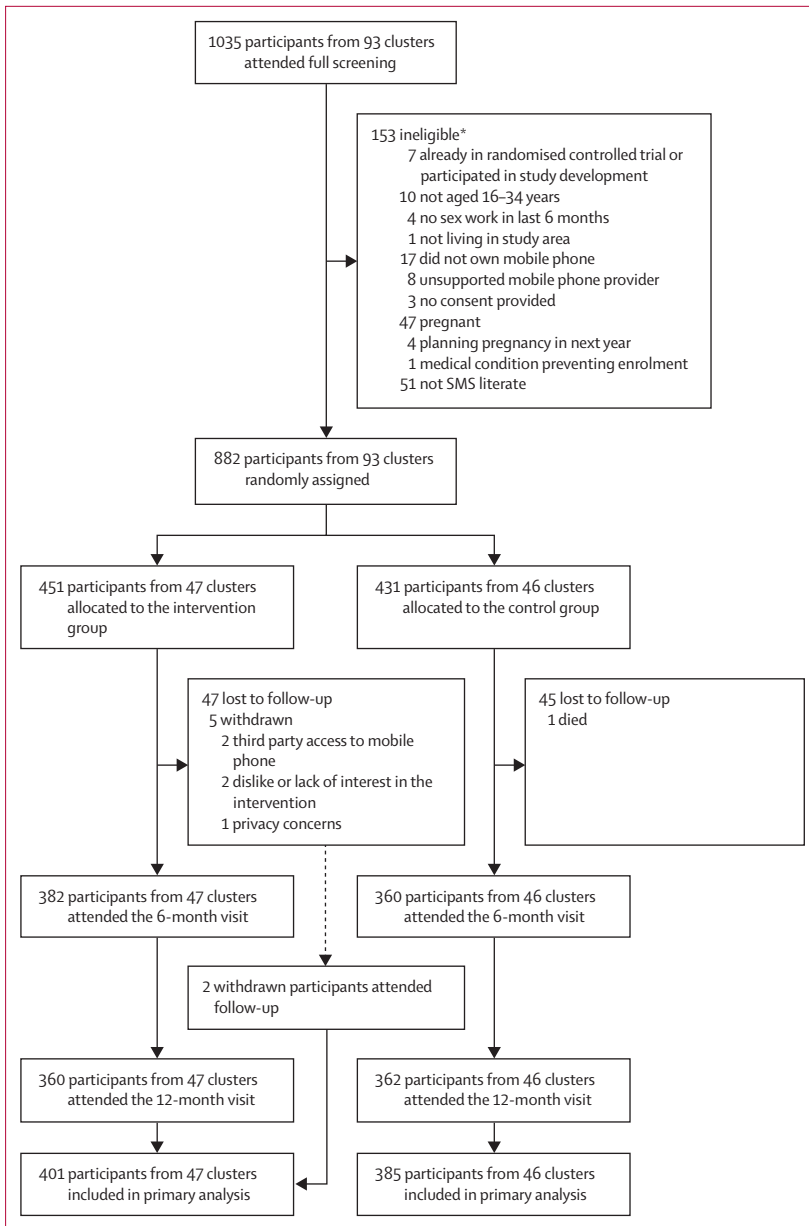For **information about Viamo** see https://viamo.io

Figure 1: Trial profile
SMS=short messaging service. *One reason for ineligibility is reported per participant; criteria were determined in the order shown.

communities.[3] Message content in the control group focused on the promotion of nutritional knowledge and practices, including food safety, food choices, food purchasing, and food preparation. Data from the SMS provider were monitored regularly to detect errors in message delivery.

Outcomes

All outcomes were measured at the individual level rather than at the cluster level and were centrally assessed. The primary outcome was the incidence of

unintended pregnancy measured at 6 months and 12 months after enrolment. Pregnancy was defined as either a positive result on a urine pregnancy test at the study clinic, or as self-reported by the participant when it occurred between study visits. Pregnancy intention was assessed using the London Measure of Unintended Pregnancy (LMUP),[30] a six-item scale administered for every reported pregnancy. A pregnancy scoring less than 10 out of 12 on the LMUP was defined as unintended.[31]

We assessed three secondary outcomes: long-acting reversible contraceptive use (current use of contraceptive implant or intrauterine device), dual contraceptive-method use, and contraceptive knowledge score. Dual method use was defined as the use of effective non-barrier contraception (intrauterine device, pill, implant, or injection) as well as consistent use of condoms with all of their sexual partners (clients and boyfriends or husbands) in the past month. Contraceptive knowledge was measured as a score in which one point was given for each of six correctly answered statements.

Other prespecified outcomes were: contamination between the two trial groups, measured by asking about sharing of health-related text messages at 12 months (contamination was considered to have occurred when the nominated topics of shared messages included those from the other study group); feasibility and acceptability of the intervention, assessed by SMS provider data on the number of messages successfully sent to each participant and engagement of participants with the pull menu; and self-reported engagement with the intervention assessed by follow-up questionnaires.

Serious adverse events and social events possibly related to SMS receipt (eg, physical violence inflicted by a participant's partner resulting from her participation) were reported to the Kenyan ethics committee. Where appropriate, assistance was provided by arranging for urgent medical treatment, counselling, and protection by community mobilisers.

Statistical analysis

Our target sample size (430 participants from at least 43 sex-work venues in each group) was based on an estimated 12-month unintended pregnancy incidence of 24% in the control group, an estimated 37% relative reduction in hazard (hazard ratio [HR] 0·63) of unintended pregnancy attributable to the intervention, and an expected attrition of 10%[7] (80% power and 5% significance). This included adjustment for inflation in standard error due to the complex-sampling approach used (design effect 1·18; estimated intracluster correlation coefficient 0·02; and mean cluster size of ten).[32]

The retention rate was calculated using follow-up time by counting 1 year for each participant who attended their 12-month appointment, or 0·5 years for those who attended the 6-month visit only. Unintended pregnancy incidence rate was calculated for descriptive purposes by counting only the first unintended pregnancy per

participant, to allow comparison with other estimates.[9] Exposure time was calculated as the time from the enrolment visit to the most recent menstrual period for women who became pregnant unintentionally, and total time in the study for those who did not. For those with missing data on the timing of their pregnancy, this date was imputed by taking the midpoint between the current visit and the most recent previous visit.

The primary outcome was analysed in all participants who were randomly assigned and attended at least one follow-up visit. Because the primary outcome was interval-censored (measured in 6-month intervals), discrete-time multiple-event survival analysis was done using a generalised linear mixed model with complementary log–log link function and binomial distribution. Up to two pregnancies per woman (one per 6-month period of discrete time) could be incorporated, and a random intercept was specified for each participant to account for within-subject dependencies. This provided an estimate of the HR of unintended pregnancy incidence in the intervention group compared with the control group. The model included data from all timepoints and was offset for the duration between interviews. Cluster robust standard errors accounted for clustering of participants by sex-work venue.

Secondary outcomes were analysed using multilevel models in the same population as for the primary outcome. Mixed three-level models specifying random intercepts for both individual participants and sex-work venues were fitted for dual contraceptive-method use using generalised linear modelling, and for contraceptive knowledge score using linear regression modelling. Long-acting reversible contraceptive use was assessed by a two-level random effects logistic regression model because of convergence issues with the three-level model. Correct standard errors were applied for clustering by venue. Joint inferential tests (Wald and likelihood ratio) were applied to determine whether there was an overall effect of the intervention on each outcome over time. For dual contraceptive-method use, the component outcomes (consistent condom use with clients, consistent condom use with boyfriends or husbands, and use of an effective non-barrier contraceptive method) were also analysed using generalised linear mixed models to explore the effect of each component on the overall measure.

The potential effect of intervention fidelity on the primary outcome was examined in an as-treated, exploratory analysis. High exposure to the intervention was defined as more than 100 text messages successfully sent to the participant (reported by the SMS platform provider for participants with Safaricom subscriptions only, therefore only participants with this subscription were included in the exploratory analysis). The primary analysis model was adjusted by including an interaction term of exposure by study group, to estimate whether the intervention effects differed across high and low levels of exposure.

All analyses used a significance level of 5% and no adjustments were made for multiple testing on secondary or exploratory analyses. All analyses were

	Intervention group (N=450)	Control group (N=431)
Age, years*	25·4 (4·5)	25·6 (4·8)
Marital status		
Married or cohabiting	29 (6%)	26 (6%)
Not married or cohabiting	421 (94%)	405 (94%)
Education		
None or some primary	60 (13%)	44 (10%)
Completed primary	225 (50%)	239 (55%)
Completed secondary	165 (37%)	148 (34%)
Religion†		
Protestant	190 (42%)	202 (47%)
Catholic	168 (37%)	142 (33%)
Muslim	89 (20%)	83 (19%)
Other	3 (1%)	2 (1%)
Gravidity		
0	117 (26%)	88 (20%)
1	136 (30%)	142 (33%)
2 or more	197 (44%)	201 (47%)
Location		
Kisauni subcounty	297 (66%)	273 (63%)
Changamwe subcounty	153 (34%)	158 (37%)
Sex-work venue		
Bar with lodging	215 (48%)	183 (42%)
Bar without lodging	66 (15%)	81 (19%)
Lodging or guesthouse	76 (17%)	64 (15%)
Street or beach	38 (8%)	48 (11%)
Other	55 (12%)	55 (13%)
Duration in sex work, years‡	4·5 (3·2)	4·9 (3·7)
HIV positive§	60 (13%)	47 (11%)
Currently has boyfriend or husband¶	260 (58%)	235 (55%)
Boyfriend or husband wants pregnancy‖		
Yes	68 (26%)	52 (22%)
No	114 (44%)	113 (48%)
Unsure or unknown	78 (30%)	69 (29%)
Total weekly income, Euros**	€37·16 (36·65)	€37·43 (35·06)
Contraceptive use		
Any modern method††	344 (77%)	346 (80%)
Long-acting reversible contraceptive‡‡	107 (24%)	110 (26%)
Dual methods§§	111 (25%)	124 (29%)

Data are n (%) or mean (SD). *N=877 (446 intervention, 431 control). †N=879 (450 intervention, 429 control). ‡N=871 (442 intervention, 429 control). §N=876 (447 intervention, 429 control). ¶N=879 (448 intervention, 431 control). ‖N=494 (260 intervention, 234 control). **Data from 12-month visit as not asked at baseline; conversion rate from Euros to Kenyan shillings as at Sept 15, 2016; N=722 (360 intervention, 362 control). ††Intrauterine device, implant, pill, injection, or consistent condom use with all partners in the past month; N=878 (448 intervention, 430 control). ‡‡N=879 (449 intervention, 430 control). §§N=873 (445 intervention, 428 control).

Table 1: Baseline characteristics

	Women with unintended pregnancy	Incidence per 100 person-years*	Hazard ratio (95% CI)	p value
Primary analysis (n=786)†				
Control group	53/385 (14%)	14·7	1 (ref)	..
Intervention group	57/401 (14%)	15·5	0·98 (0·69–1·39)	0·89
As-treated analysis (n=700)‡				
Low exposure				
Control group	10/68 (15%)	16·8	1 (ref)	..
Intervention group	9/75 (12%)	13·0	0·71 (0·29–1·71)	0·44
High exposure				
Control group	37/282 (13%)	13·8	1 (ref)	..
Intervention group	40/275 (15%)	15·7	1·05 (0·66–1·65)	0·84
Differential effect of exposure between groups§	..	..	1·48 (0·54–4·10)	0·45

Data are n/N (%) unless otherwise stated. *Time-to-first pregnancy analysis. †Discrete-time survival analysis including multiple pregnancies per woman. Generalised linear mixed model (complementary log–log link, binomial distribution, offset for log time between visits and random intercept for participants), with cluster robust standard errors for sex-work venue clustering. ‡As in the primary analysis, with the addition of group-by-exposure interaction term. §This interaction term represents the additional change in the outcome with increased exposure for the intervention group compared with the control group.

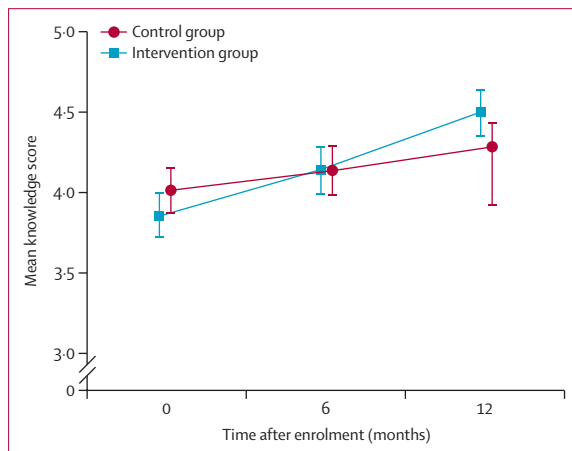*Table 2:* Analyses of unintended pregnancy incidence

Figure 2: Mean knowledge score by study group at each timepoint, predicted by mixed linear regression
Error bars represent the 95% CIs.

done in STATA (version 14.2). The trial was registered in the Australian New Zealand Clinical Trials Registry, ACTRN12616000852459.

Role of the funding source

The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results

Between Sept 14, 2016, and May 16, 2017, 102 sex-work venues were assessed for eligibility, nine of which were excluded due to closure and other logistical reasons, resulting in 93 venues accessed and randomly assigned to a study group (mean cluster size 11·1 [SD 2·5]). Recruiters approached 1728 individuals to take part, of whom 1155 (67%) were eligible for full screening. Of the 1035 individuals who were screened, 882 (85%) were eligible (mean cluster size 9·5 [SD 1·9]; figure 1). 451 participants from 47 venues were allocated to the intervention group (mean cluster size 9·6 [SD 1·9]), and 431 participants from 46 venues were allocated to the control group (mean cluster size 9·4 [SD 1·8]). 786 women (401 [89%] in the intervention group [mean cluster size 8·8; SD 1·3]; and 385 [89%] in the control group [8·7; 1·4]) attended at least one follow-up visit. Retention rate was 85% of total person-time (intervention group 84%; control group 87%). Follow-up was completed by July 31, 2018. Further details regarding recruitment, ineligibility, and baseline characteristics have been reported elsewhere.[33]

One individual left the study before enrolment procedures were completed, so 881 participants contributed to baseline data. Participant characteristics were similar between the study groups (table 1). Mean age was 25·4 years (SD 4·7). A majority of participants had been pregnant before, with 398 (45%) having had at least two previous pregnancies. 107 (12%) participants were HIV-positive.

131 participants became pregnant at least once during the study, with a total of 145 pregnancies. Of these, 122 were classified as unintended. The proportion of women with at least one unintended pregnancy was the same in each group (table 2). Last menstrual period was imputed for 32 (29%) of 110 women with unintended pregnancy (17 [30%] of 57 in the intervention group, 15 [28%] of 53 in the control group). The resulting incidence rates were 15·5 per 100 person-years in the intervention group and 14·7 in the control group, which were not significantly different (HR 0·98, 95% CI 0·69–1·39).

A time to first pregnancy survival analysis using generalised linear modelling showed similar results (adjusted HR 1·06, 95% CI 0·75–1·51; incidence data not shown). The exploratory as-treated analysis showed that the effect of the intervention was no different for participants who were exposed to more text messages (>100) than for those exposed to fewer messages (p=0·45; table 2). Other means of measuring exposure (whether or not the participant had accessed the pull menu and whether they had changed their mobile phone number) were also explored, but similarly had no effect on the primary outcome (data not shown). Full model outputs for both primary and secondary outcomes are available in the appendix (p 1).

There was a greater change in mean contraceptive knowledge score over time in the intervention group than in the control group (p<0·001; figure 2). This effect was observed over the full 12 months, but the difference

	Group comparison at each time point: intervention group *vs* control group			Differential effect over time (from baseline to follow-up) of the intervention group *vs* the control group*			p value for joint test of effect†
	Adjusted mean difference in knowledge score (95% CI)	Adjusted OR (95% CI)	p value	Adjusted mean difference in knowledge score (95% CI)	Adjusted OR (95% CI)	p value	
Knowledge score‡							
6 months	0·001 (–0·210 to 0·211)	..	1·00	0·154 (–0·034 to 0·343)	..	0·11	..
12 months	0·216 (0·004 to 0·428)	..	0·046	0·369 (0·179 to 0·560)	..	<0·0001	<0·0007
Long-acting contraceptive use§							
6 months	..	1·25 (0·52 to 3·00)	0·62	..	1·82 (0·87 to 3·82)	0·11	..
12 months	..	0·83 (0·30 to 2·30)	0·72	..	1·21 (0·45 to 3·24)	0·71	0·19
Dual method contraceptive use¶							
6 months	..	1·04 (0·54 to 1·99)	0·92	..	1·48 (0·83 to 2·62)	0·18	..
12 months	..	1·55 (0·78 to 3·09)	0·22	..	2·21 (1·19 to 4·09)	0·012	0·039

Data are adjusted mean differences (95% CI) or adjusted OR (95% CI) unless otherwise stated. OR=odds ratio. *Interaction terms from each model represent the additional change in the outcome over follow-up for the intervention group compared with the control group (mean difference for knowledge score and relative difference in odds for long-acting reversible contraceptive and dual contraceptive method use). †Likelihood ratio test for knowledge and dual contraceptive method use; Wald test for long-acting reversible contraceptive use. ‡Three-level linear mixed model with random intercepts for sex-work venue and female sex worker. §Two-level random effects logistic regression model with cluster robust standard errors for sex-work venue (because a three-level model exhibited convergence problems). ¶Three-level generalised linear mixed model with random intercepts for sex-work venue and female sex worker.

Table 3: The effect of the intervention on long-acting reversible contraceptive use, dual method contraceptive use, and contraceptive knowledge

	Proportion answered correctly at baseline		Proportion answered correctly at 12 months	
	Intervention group	Control group	Intervention group	Control group
Implants can make your period lighter, or stop it altogether (true)	288/449 (64%)	284/427 (67%)	258/359 (72%)	262/360 (73%)
One contraceptive injection, like Depo, will protect against pregnancy for 1 year (false)	198/449 (44%)	198/427 (46%)	219/360 (61%)	217/361 (60%)
I don't need to use condoms if I'm already using another type of family planning (false)	323/450 (72%)	314/430 (73%)	273/359 (76%)	271/360 (75%)
It is easy for most women to get pregnant soon after they stop using family planning (true)	379/447 (85%)	383/430 (89%)	320/360 (89%)	318/359 (89%)
The intrauterine device protects against pregnancy for up to 12 years (true)	203/449 (45%)	195/429 (45%)	225/360 (63%)	165/361 (46%)*
Family planning pills and injections provide some protection against HIV (false)	345/450 (77%)	357/430 (83%)†	319/360 (89%)	325/362 (90%)

*p<0·001 for the difference between the groups at each timepoint. †p<0·05 for the difference between groups at each time point.

Table 4: True or false statements included in the knowledge scale and the proportion of participants who answered correctly at baseline and at 12 months after enrolment

was not significant in the first 6 months (table 3). Most knowledge items were correctly answered at baseline, apart from those relating to the duration of action of intrauterine devices and contraceptive injections (table 4).

Approximately one-quarter of participants used long-acting reversible contraception at all timepoints (figure 3), and there was no significant difference in the use of this contraception over time between the two groups (p=0·19; figure 3). By contrast, the intervention was associated with increased odds of dual method contraceptive use relative to the control over time (p=0·039). This effect was observed over 12 months, but not in the first 6 months (table 3). This result reflected a significant decline in dual method contraceptive use between baseline and 12 months in the control group (adjusted odds ratio [OR] 0·36, 95% CI 0·23–0·56), compared with

no significant change in use in the intervention group (0·79, 0·51–1·21; figure 4).

More specifically, the use of the different aspects of dual method contraception differed across the two groups. First, the use of effective non-barrier contraception declined over 12 months in the control group (adjusted OR 0·58, 95% CI 0·38–0·89; p=0·011) but not in the intervention group (1·09, 0·72–1·67; p=0·66). Second, consistent condom use with clients increased in the intervention group (1·79, 1·17–2·72; p=0·007), but remained unchanged in the control group (1·13, 0·76–1·69; p=0·54). Lastly, consistent condom use with boyfriends or husbands declined significantly in both groups (intervention group: adjusted OR 0·39, 95% CI 0·27–0·58; control group: 0·38, 0·26–0·56). A current non-paying boyfriend or husband was reported
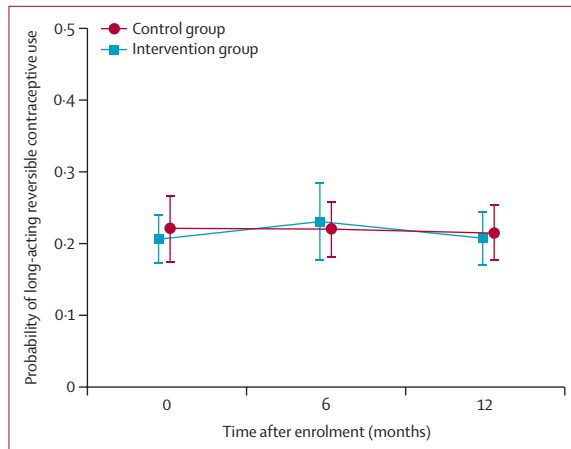
Figure 3: Probability of long-acting reversible contraceptive use by study group at each timepoint, predicted by random effects logistic regression
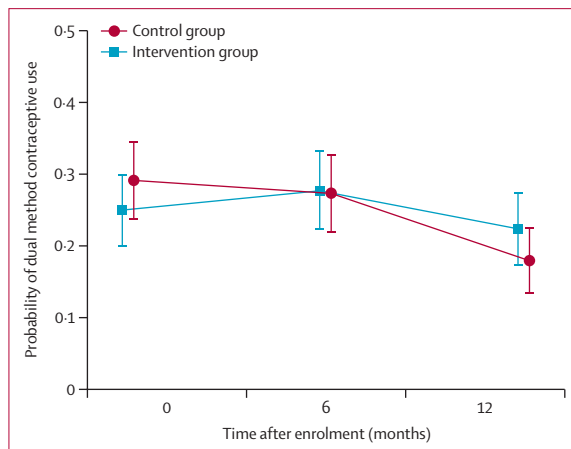Error bars represent the 95% CIs.

Figure 4: Probability of dual method contraceptive use by study group at each timepoint, predicted by generalised linear mixed model
Error bars represent the 95% CIs.

by 260 (58%) of 448 participants in the intervention group and 235 (55%) of 431 in the control group at baseline; at 12 months, 241 (67%) of 360 in the intervention group and 242 (67%) of 359 in the control group reported having a non-paying boyfriend or husband. One-third of women with a current boyfriend or husband had consistent condom use with that partner at baseline and just less than one-quarter did so at 12 months, with little difference between the groups (appendix p 2).

Only five women requested to stop receiving the SMS messages (all in the intervention group; figure 1), and 482 (55%) of 882 accessed additional pull messages at least once during the study (248 [55%] of 451 in the intervention group and 234 [54%] of 431 in the control group). Reliable exposure data were available for 787 participants who used Safaricom throughout the study, and of 137 total messages in the programme, these women received a median of 127 (IQR 106–133) messages each (intervention group

median 126 [IQR 102–133]; control group median 128 [107–133]). Women who changed their mobile phone number during the study received fewer messages. 93 (11%) of 882 women changed their phone number; including 49 (6%) of the 787 women with reliable exposure data. These 49 women received a median of 80 messages (IQR 70–109) each: 76 messages (62–125) each in the intervention group and 83 (74–107) in the control group. There were frequent reports of phones being misplaced or broken; one-quarter of participants reported that their phone was unavailable for at least 1 month during the study period (107 [27%] of 401 in the intervention group and 100 [26%] of 385 in the control group). Despite these interruptions, at 12 months, perceived receipt of messages was high, with 615 (86%) of the 715 who answered the relevant question stating that they had received messages at least twice per week (306 [86%] of 356 in the intervention group, 309 [86%] of 359 in the control group). 96 participants were lost to follow-up (50 in the intervention group and 46 in the control group); 32 (33%) of whom could not be contacted either by telephone or by physical tracing.

A quarter of participants at 12 months reported being shown messages by their peers (172 [24%] of the 717 who answered the question). 22 of these were from women in the other trial group. In addition, two participants were erroneously sent both intervention and control messages for 2–3 months, and one participant gave her SIM card to her sister in the other trial group. Therefore, cross-arm contamination occurred in 25 [3%] of 786 participants.

Five adverse events were reported to the ethics committees. There was one death and one case of physical assault that were not related to the intervention. Two participants reported that the messages had made their boyfriends angry, and in one case this exacerbated existing intimate partner violence; however, both participants decided to remain in the study. There was one inadvertent breach of a participant's HIV status to a woman later found to be impersonating the participant, and mitigating strategies were subsequently implemented.

Discussion
The intervention had no detectable effect on the biological outcome of unintended pregnancy, despite the fact that it was rigorously designed in collaboration with female sex workers, and was well received by participants.[3] The observed unintended pregnancy incidence was much lower in both study groups than anticipated based on previous research, particularly considering that our sample population was younger than in other incidence studies.[7,9] This result is consistent with a finding of contraceptive implant use in the cohort at baseline that was higher than usual[33] and, given the magnitude of the difference in unintended pregnancy incidence between this and other studies, probably reflects a real change in long-acting reversible contraceptive use and pregnancy incidence in the population over time. Alternatively, it is

possible that previous studies overestimated incidence because they did not use random samples of sex workers.[9]

Because there were fewer unintended pregnancies than we expected, the standard error of the primary analysis estimate was larger than anticipated, widening the CI (HR 0·98, 95% CI 0·69–1·39). Nonetheless, because the observed CI excludes our expected intervention effect (HR 0·63), this provides some evidence that the intervention was not effective in reducing unintended pregnancy incidence to a degree we defined as clinically meaningful. Despite this, we cannot exclude the possibility that a true difference of less than 37%, attributable to the intervention, is present in the population and that such a magnitude of effect might be considered meaningful.

The intervention was associated with improved knowledge about contraception, particularly intrauterine devices, as well as increased use of dual method contraception. Positive changes were observed in consistent condom use with clients, and to a lesser extent effective non-barrier contraceptive use. This is a promising result because dual method contraceptive use is a key behaviour related to pregnancy risk, and is crucial for maintaining the prevention of sexually transmitted infections. The improvement in dual method contraceptive use was not sufficient to affect the primary outcome as hypothesised, in part because of the higher than expected baseline use of contraceptive implants and lower than expected unintended pregnancy incidence.

The observed decline in consistent condom use with boyfriends and husbands was partly an artifact of the larger proportion of women in these non-paying emotional relationships at follow-up than at baseline. Regardless, at all timepoints, one-third or less of women with husbands or boyfriends used condoms consistently in these sexual encounters, and this was not influenced by the intervention. This is concerning for a population known to be at greater risk of unintended pregnancy from emotional partners than paying clients.[7] Interventions that can successfully influence sexual risk behaviour within female sex workers' emotional relationships have not yet been identified, although innovative models have been trialled.[34]

The fact that the intervention was correlated with change in use of some contraceptive methods but not long-acting reversible contraceptives suggests that, contrary to our hypothesis, addressing knowledge barriers might translate to behaviour change in relation to short-acting and user-controlled methods only. A similar result was observed in a study of post-partum women receiving an SMS intervention in Kenya.[22] Improving knowledge of long-acting reversible contraceptives and associated individual determinants such as attitudes and self-efficacy might have little effect without addressing supply-side barriers such as poor availability,[35] insufficient provider counselling,[33] and stigma from health workers.[36] Unlike short-acting methods, long-acting reversible contraceptives are usually only available in public facilities in Kenya,[37] which tend to have longer waiting times than private facilities.[36] Baseline data from this study showed that only male condoms were frequently supplied by drop-in-centres targeted at female sex workers,[33] despite these being the most acceptable health centres for this population.[36] Supply-side interventions have increased uptake of long-acting reversible contraceptives and reduced unintended pregnancy in the USA,[38,39] and a combined supply-side and demand-side intervention increased the use of these types of contraceptives in Kenya,[40] but similar approaches have not been adopted with female sex workers.

Overall, the results of our study suggest that provision of health education by mobile phone, in the absence of parallel interventions, is unlikely to result in substantial contraceptive behaviour change in a population with high baseline use of at least some form of contraception. A similar conclusion has been reached by other randomised controlled trials of SMS-based sexual health interventions.[18,23] In our study, this absence of effect was despite concerted efforts in intervention design to maximise translation from knowledge to behaviour change, because increased knowledge alone is often insufficient to change behaviour or clinical outcomes.[29] We adopted strategies from health promotion theory,[27,28] such as role modelling and skill development,[29] and bidirectional messaging, with an on-demand menu that allowed greater engagement and included a directory of local sexual and reproductive health services.[3] Non-automated bidirectional messaging with a health provider and tailoring of messages to individuals' current method of contraception might have had a greater effect,[22] but were not feasible to adopt in this intervention.

The messages addressed contextual and structural issues, such as alcohol use, violence, and rights; however, this might have resulted in too broad a scope and diluted the primary message of pregnancy prevention, or required a longer duration to have a measurable effect. Further research using qualitative methods is needed to better understand why participants could not or did not want to adopt safer contraceptive behaviours in response to this intervention.

Concurrent and complementary interventions might be needed so that women receive multiple reinforcing messages from different sources. A systematic review of mHealth for maternal and neonatal care in low-income and middle-income countries found that combining mHealth interventions with other interventions had promising results.[41] Similarly, a post-abortion intervention in Cambodia that used a combination of interactive voice response messages, contraceptive counselling by phone, and expedited links to long-acting reversible contraceptive insertion services, is one of few mHealth interventions shown to improve the use of these contraceptives.[20]

The need for combined approaches is likely to be greater for populations, such as sex workers with the

potential to become pregnant, that face entrenched supply-side and demand-side barriers to contraceptive use. We therefore recommend that the WHISPER intervention be adapted and trialled as part of a more comprehensive pregnancy prevention package for this population that addresses barriers on both the supply and demand side.

This study shows that mHealth interventions with female sex workers are not only feasible, but can be highly acceptable. Despite interruptions due to problems with mobile phones, participants received a large proportion of the scheduled messages and the majority sought further information. Some simple strategies were instituted to minimise loss of participants, such as testing their telephone number at registration, screening for number changes at follow-up visits, and periodically investigating participants with high SMS failure rates. The high rate of message sharing between participants is further evidence of their engagement with the intervention, and confirms the appropriateness of the cluster design, which accommodated the intended interactions of women within sex work venues. Sharing of messages, because it was mostly done within study groups, is likely to have enhanced rather than diluted any intervention effects.

Our study had several limitations. Measurement of outcomes ceased at the same time as the intervention, so we might have missed some participants' transition from contemplation of message content into action and its subsequent effect on biological outcomes. The second stage of sampling might have introduced selection bias, because recruiters sampled individuals consecutively until a target was reached, rather than randomly sampling or inviting all eligible sex workers from each venue (ie, using an intact second stage sampling unit). This was a pragmatic decision to ensure that participant selection was feasible and adapted to conditions in the field. The fixed number of second stage sampling units notionally provided a sample in which potential participants were sampled with equal probability, despite the unequal probability selection at the first stage. In addition, the number of venues and potential participants active in each venue might have changed between the enumeration in 2014 and recruitment for the study in 2016. This might have resulted in over-representation of some venues in the sample, and the exclusion of new venues.

It is possible that we underestimated unintended pregnancy incidence because of selective loss of pregnant participants from the study. There were five anecdotal reports of women who were pregnant not returning for study visits, either because of changes in living circumstances or concerns that they would not be able to remain in the study following pregnancy, which might have reflected a misinterpretation of eligibility criteria.

Unreliable reporting from the Airtel network that could not be rectified during the study meant that we were limited to measuring exposure only among women who used Safaricom for the whole year. Although this accounted for 89% of participants, it might have hidden differences in successful delivery between the two networks. The ability to accurately monitor message and call delivery is an important consideration for future mHealth programmes.

English-language SMS was used rather than Swahili text or voice messaging, on the basis of the preferences of participants in our formative work.[3] However, a small minority of participants did have difficulty with this format. Only 6% of women were found to be SMS illiterate on screening (data not shown), but the field team suspected that some women self-excluded on the basis of illiteracy before being screened. It might be preferable for future interventions to provide a voice message option to improve equity of delivery across literacy levels, and to reach women who might be at a greater disadvantage. Other authors have noted the risk of mHealth interventions not reaching those at greatest need.[20,23,42]

Despite these issues, we have shown that mobile phones are a feasible means of connecting with this population. Sex work is increasingly solicited via digital means, and models of health promotion and service delivery that are overly focused on physical locations will increasingly miss women who sell sex.[43] Mobile phones could be used to link to clinical and educational programmes, create support networks between peers, and provide information, and will need to be part of the means of delivery to this population in the future.

This study is notable for being one of few randomised controlled trials done among female sex workers in low-income and middle-income countries, for aiming to prevent unintended pregnancy, a crucial but under-recognised issue in this population, and for adopting a novel reciprocal control design. We showed that an mHealth intervention in isolation might improve both contraceptive knowledge and dual method contraceptive use. However, mHealth needs to be incorporated into more comprehensive approaches, particularly those addressing the role of female sex workers' emotional partners and the supply of longer-acting, more reliable contraception, to prevent unintended pregnancy and its associated detrimental impacts on the health and wellbeing of female sex workers.

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