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دانشگاه علوم پزشکی مشهد

MOBILE PHONE MESSAGES TO PROVIDE SUPPORT TO WOMEN DURING THE HOME PHASE OF MEDICAL ABORTION IN SOUTH AFRICA: A RANDOMISED CONTROLLED TRIAL

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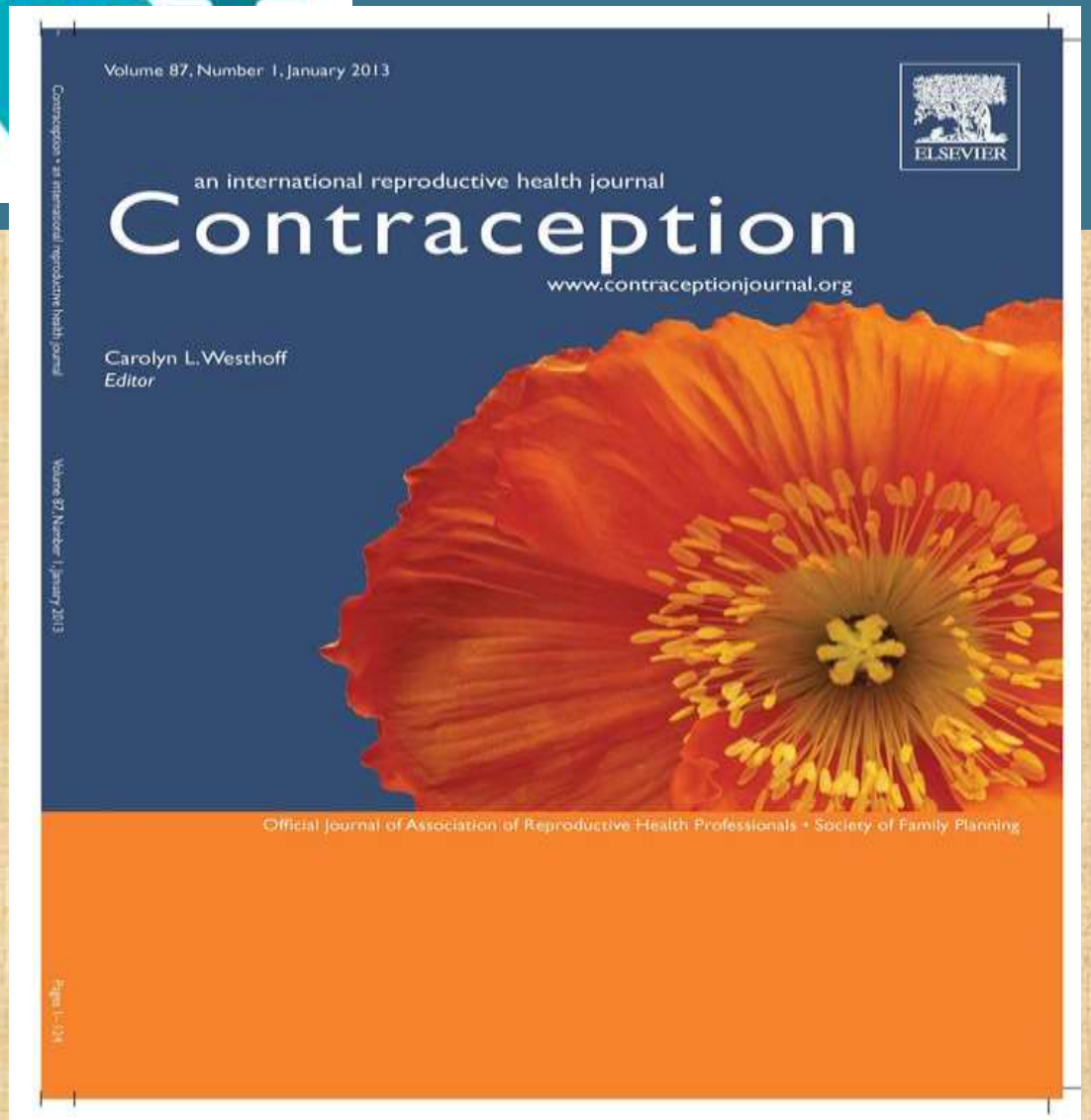

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INTRODUCTION

Medical abortion (MA) services using mifepristone followed by misoprostol have expanded in South Africa as an intervention to increase access to abortion services.

Compared to surgical methods, MA with home use of misoprostol is less burdensome for health care providers, as responsibility for managing symptoms after misoprostol ingestion is shifted to the woman without direct support from providers .MA in the first trimester has been shown to be highly acceptable to women in South Africa and elsewhere MA acceptability is dependent primarily on the success of the procedure, and may be moderated by experiences of pain, side effects and access to support.

Overall satisfaction and fewer adverse emotional reactions to the abortion have been associated with both the availability of psychosocial support and adequate preparation for expectations around the procedure .For women taking misoprostol at home, counselling and guidance by providers and the positive effect of sympathetic and nonjudgmental support systems are important components of effective care.

The use of **text messages on mobile phones** to strengthen sexual and reproductive health services in low- and middle income countries has shown promising and is considered feasible in settings where coverage and penetration of mobile phones is extensive or increasing .As in many parts of the world, mobile phone usage is commonplace in South Africa, especially in urban areas.

Remote support using the Internet or telephone to inform, to support and/or to assist women with assessment of their abortion has been successful in other settings .To our knowledge, text messaging has not been used previously to offer guidance and information for women managing their abortion symptoms at home. This research examined whether timed, automated text messages delivered between clinic visits for mifepristone and follow-up of MA could provide support and guidance in "real time" to women. Specifically, we hypothesized that a series of text messages could reduce anxiety and emotional discomfort experienced by women and better prepare them to manage abortion symptoms when at home and without provider care.

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2. MATERIALS AND METHODS

Women under going MAwere recruited from October 2011 to May 2012 at two nongovernmental organizations (NGOs) and two public sector primary care clinics in Cape Town, South Africa. Eligible women were scheduled to under go MA at the clinic, over 18 years old, willing to comply with visit schedules, accessible by mobile phone and comfortable with receiving abortion-related messaging following enrolment in the study.

مقیاس ها

- HADS
- ALDERS
- SBNE
- IBNE
- IESR
- لیکرت

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Table 1
Examples of the text messages, scheduling and type mapped to specific intentions

Message text	Day and time of delivery	Message content	Intention
Hi there, the pills u took at the clinic may make u bleed. If u do, it can be light, normal or heavy. But don't worry if u don't bleed. The pills you take at home tomorrow will make you bleed. Make sure u have pads and painkillers (Ibuprofen is good. Aspirin is bad so no Disprin or Grandpa).	Day 1 (day of mifepristone); 18 h	Information on symptoms and how to manage them	Reduce anxiety Improve preparedness
Hello! Just a reminder to take the pills you were given, 24 - 48 hours (1-2 days) after u took the pills at the clinic. Put a pill in each cheek and 2 under the tongue, and let them dissolve (break down) there. Take them without water! U can drink 30 min after.	Day 2; 09 h00	Reminders on how to take misoprostol correctly	Reassure on actions to be taken
When u take them, bleeding may start after 20 minutes (but later is OK too). If u vomit within 30 minutes of taking the pills, go back to the clinic for more.	Day 2; 09 h04	Information on symptoms	Improve preparedness
Hey more info on the pills: if u get cramps, use heat or take pain killers. It can be pretty sore - don't be scared. U may feel sick, vomit, or get a runny tummy. It's not a problem.	Day 2; 18 h00	Information on symptoms and how to manage them	Reduce anxiety Improve preparedness
Remember bleeding can be heavy! It's only a problem if u soak more than 6 maxi pads in 2 hours. Call or go to the clinic immediately if that happens.	Day 2; 18 h04	Information on danger signs	Reduce anxiety Improve preparedness
Hi just a reminder that bleeding can be heavier than a normal period, and cramping can be worse. It's OK! Look after yourself:-) If you haven't started to bleed, don't worry. It's only a problem if bleeding didn't start within 2 days after you took the pills at home	Day 3; 18 h00	Information on symptoms	Reduce anxiety Improve preparedness Social support
Hi just a note that if you get a fever more than a day after you took the pills at home, and the fever lasts over 6 hours, please call or go to the clinic.	Day 5; 09 h00	Information on danger signs	Reassure on actions to be taken
Remember that after the pills, bleeding usually lasts a week, but it can go on for as long as a month (that's unusual though!).	Day 7; 09 h00	Information on symptoms	Reduce anxiety Improve preparedness
Hi hope you're good. You may still be spotting (a bit of bleeding or brown bits). If you're bleeding like a normal period or more, make sure you tell them this at your clinic appointment.	Day 13; 09 h00	Information on symptoms, possible incomplete abortion	Reduce anxiety Reassure on actions to be taken

Participation in the trial lasted for 2-3 weeks

Instructions were sent messages, which included a phone number for 24-h support,

Of the 598 women approached, 58 declined to participate, and 71 were excluded due to ineligibility (Fig. 1).

Randomisation allocated 234 to the intervention and 235 to the control group. Table 2 shows the characteristics of participants. Study groups were similar at baseline for most characteristics with the exception of the HADS score for anxiety and the IBNE score, which were higher in the intervention group (p=0.007 and 0.017, respectively).

Loss to follow-up was higher in SOC than in the

SOC+ messaging group at the second interview (p=0.102) For those returning to the clinic for follow-up, there were no significant differences between study

groups for severity of pain (p=0.328) or bleeding experienced (p=0.193) during the abortion process. Internal consistency of the measurement instruments

(Cronbach's α) was 0.7 (baseline) and 0.8 (follow-up) for the

HADS anxiety subscale and 0.8 (baseline) for the HADS depression subscale. For SBNE and IBNE, α was 0.7 and 0.8

(SBNE) and 0.7 and 0.8 (IBNE) at baseline and follow-up, respectively. For IES-R subscales for intrusion and avoidance, α was 0.8 and 0.9, respectively.

For the primary outcomes at follow-up, both study groups had lower mean scores for anxiety, SBNE and IBNE than at baseline. Intention-to-treat analysis showed that anxiety decreased more in the SOC+messaging group than in the SOC group (β=1.3; 95% CI=0.3 to 2.4; p=0.013).

Differences in SBNE and IBNE between baseline and follow-up were not significant for the two study groups

(Table 3). The per-protocol analysis had similar results. Crude IES-R scores for avoidance and intrusion were similar for both groups at follow-up: intervention versus control for avoidance (mean=13.1, SD=7.3 vs. Mean=14.4,

SD=7.4, p=0.085) and for intrusion (mean=9.0, SD=8.1 vs. mean=9.5, SD=8.3, p=0.541).

When avoidance scores were adjusted for baseline anxiety, these were significantly lower

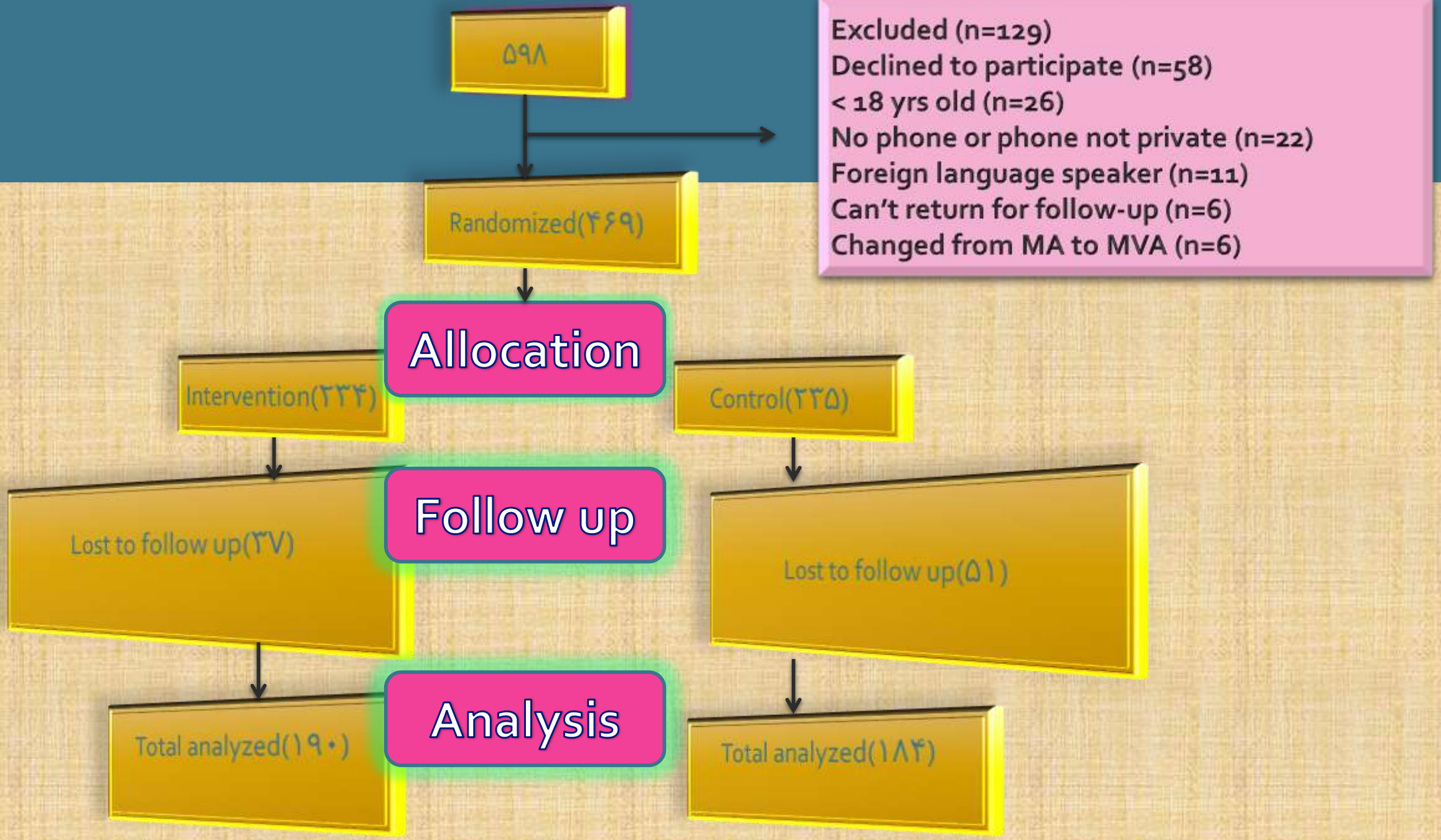
for the intervention group (β=−1.8, 95% CI=−3.2 to −0.4, p=0.015), but this was not so for adjusted intrusion scores (β=−1.4, 95% CI=−2.9 to 0.2, p=0.083).

The analysis was repeated excluding those receiving MVA at follow-up (3%), representing cases for whom the abortion was unsuccessful. Results showed similar small, but significant, decreases in anxiety for the intervention versus the control group between baseline and follow-up (β=1.5; 95% CI=0.5 to 2.6; p=0.004). Decreases in SBNE and IBNE were again similar for both study groups. The SOC+ messaging group IES avoidance score was lower when adjusted for baseline anxiety (β=−1.7; 95% CI=−3.1 to −0.2, p=0.025).

The subgroup analysis showed no evidence for heterogeneity of the intervention across subpopulations except for education, with the intervention appearing more effective forthose who had not completed high school than for those who had (p=0.047).

Outcomes measuring preparedness and acceptability of the abortion experience are shown in Table 4.

Secondary outcomes showed no difference between studyparticipants. One hundred eighty-six over one hundred ninety (98%) said that the messages helped them through their abortion, and 188/190 (99%) said that they would recommend them to a friend. No adverse events were associated with the intervention.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Excluded (n=129)
Declined to participate (n=58)
< 18 yrs old (n=26)
No phone or phone not private (n=22)
Foreign language speaker (n=11)
Can't return for follow-up (n=6)
Changed from MA to MVA (n=6)
Randomized(٤٦٩)
Allocation
Intervention(٢٣٤)
Control(٢٣٥)
Follow up
Lost to follow up(٣٧)
Lost to follow up(٥١)
Analysis
Total analyzed(١٩٠)
Total analyzed(١٨٤)

p Value associated with t tests for comparison of means, chi-squared tests for proportions.

Results: Between baseline and follow-up, anxiety decreased more (p=0.013), and less emotional stress was experienced (adjusted for baseline anxiety, p=0.015), in the intervention compared to the SOC group. Participants in the intervention group were also more likely to report that they felt very well prepared for the bleeding (p=.001), pain (p=0.042) and side effects (p=0.027) they experienced. Acceptability and other negative emotions relating to the abortion did not differ between study groups. Ninety-nine percent of the intervention group stated that they would recommend the messages to a friend having the same procedure.

Table 2
Baseline characteristics of participants

Characteristic	SOC, *n=235*		SOC+mobile, [a] *n=234*		p Value*
Mean age in years (SD)	25.6 (5.4)		26.0 (5.6)		0.461
Home language, *n*(%)					0.446
isiXhosa	115	49%	104	44%	
Afrikaans	14	6%	22	9%	
English	80	34%	85	36%	
Other Language	26	11%	23	10%	
High school degree, *n*(%)	187	80%	180	77%	0.484
Full-time job/student, *n*(%)	180	77%	184	79%	0.845
Formal housing, *n*(%)	198	84%	196	84%	0.884
Mean gravidity prior to this pregnancy (SD)	1.1 (1.1)		1.2 (1.3)		0.207
Gestational age: 7–9 weeks, *n*(%)	108	46%	104	44%	0.742
Had previous abortion, *n*(%)	39	17%	34	15%	0.537
Married or in a stable relationship, *n*(%)	188	80%	187	80%	0.982
Wanted to have this abortion, *n*(%)	222	95%	224	96%	0.528
Difficult decision to have this TOP, *n*(%)	130	55%	134	57%	0.671
Support at home during MA process, *n*(%)	159	68%	157	67%	0.896
Mean score for SBNE (SD)	2.9 (1.2)		3.1 (1.2)		0.257
Mean score for IBNE: (SD)	2.6 (1.0)		2.9 (1.0)		0.021
Mean score for anxiety (SD)	10.2 (4.4)		11.3 (4.8)		0.007
Mean score for depression (SD)	8.4 (4.7)		9.1 (5.0)		0.149

[a] SOC+mobile=intervention group (standard of care+messages).
* p Value associated with *t* tests for comparison of means, chi-squared tests for proportions.

Table 3

Anxiety and negative emotions measured at baseline (BL) and follow-up (FU) clinic visits for the abortion

Primary outcome:	SOC group (n=184)			SOC+mobile group (n=197)			p Value
	Baseline mean (SD)	Follow-up mean (SD)	Absolute difference (BL-FU) mean (SD)	Baseline mean (SD)	Follow-up mean (SD)	Absolute difference (BL-FU) mean (SD)	
Anxiety	10.2 (4.3)	8.0 (5.1)	−2.3 (5.0)	11.4 (4.5)	7.8 (5.3)	−3.6 (5.3)	0.013
SBNE	2.9 (1.2)	2.4 (1.2)	−0.6 (1.3)	3.1 (1.2)	2.4 (1.2)	−0.7 (1.32)	0.310
IBNE	2.6 (1.0)	2.1 (1.1)	−0.5 (1.1)	2.9 (1.0)	2.1 (1.0)	−0.7 (1.0)	0.099

Abbreviations: BL, baseline; FU, follow-up.

Table 4

Experience and acceptability of abortion

Outcome measure	SOC group (n=184)	SOC+mobile group (n=197)	p Value[a]
	N (%)[b]	N (%)[b]	
The information prepared the participant for[b]			
Bleeding experienced	139 (75.5)	177 (89.9)	<0.001
Pain experienced	129 (70.1)	156 (79.2)	0.042
Side effects experienced	136 (73.9)	164 (83.3)	0.027
Events as they occurred during the abortion	163 (88.6)	188 (95.4)	0.016
Expectations coincided with actual experience of events	103 (56.0)	128 (65.0)	0.073
Satisfaction	108 (58.7)	131 (66.5)	0.116
Would recommend abortion method to a friend	120 (65.2)	143 (72.6)	0.121
Would have same procedure again	93 (50.5)	110 (55.8)	0.301

[a] p Values for chi-squared tests.

[b] Categories were "very much" versus "somewhat"+"not really"+"not at all".

DISCUSSION

experience during or as a consequence of abortion anxiety and strength of negative emotions in this study were greater prior to the abortion than afterwards. Anxiety levels in both our study groups were slightly above clinically significant levels (N 10) at baseline and dropped to subclinical levels by follow-up. Similarly, post abortion stress and anxiety, particularly in the short term, has been shown to be strongly mediated by pre abortion levels.

study for anxiety and IBNE scores were unlikely to result from failure of allocation concealment; although, we cannot exclude this possibility. Women were allocated to groups only after completion of the baseline emotional assessment and study fieldworkers were all well known and experienced.

Stratifying by site showed similar anxiety and IBNE differences between groups at baseline for all sites; this was significant only at one NGO (p=0.054). To adjust for the baseline differences between study groups, we compared change in anxiety and emotions over the duration of the abortion process, rather than absolute values at follow-up.

However, given the higher baseline anxiety in the intervention group, it is possible that this intervention benefits women who have high levels of pre abortion anxiety, and this warrants further small baseline differences between groups in this The study has various limitations.

Firstly, there was a bias towards a better-resourced population than the national average: study participants had a higher level of education and employment than the general population; two thirds

were recruited at NGO clinics where they had to pay for services (as opposed to public sector clinics where abortion services are free); and all study clinics were in an urban setting.

The primary outcomes of anxiety and emotional discomfort are difficult to measure; however, the internal consistency of the instruments used in the study was good, with Cronbach's α values similar to those reported elsewhere. The instruments measuring anxiety and emotional discomfort in the study have been validated in abortion settings elsewhere; however, these had not been validated previously for this particular study population.

These results suggest that a timed text message program me can provide information preparing women for managing their abortion symptoms at home and reduce abortion-related anxiety and stress during this time. The messages guided women through the MA process using a supportive tone without overtly addressing negative emotions; this may account for the effectiveness of the

intervention for anxiety, as compared to SBNE and IBNE which typically arise in relation to the unwanted pregnancy and abortion decision.

CONCLUSIONS:

Text messages to women following mifepristone administration for early medical abortion may assist them in managing symptoms

and appear highly acceptable to recipients

In conclusion, text messages to women sent between their clinic visits for mifepristone and follow-up of early MA can provide information and lead to reduced anxiety and stress and can alert them to possible complications. Given a no-cost opt-out phone number that recipients could text to stop the messages, they are highly acceptable to recipients, and their privacy could be protected.

با تشکر از توجه شما

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