

EFFECT OF CELL-PHONE ASSISTED POSTPARTUM FAMILY PLANNING SERVICE ON THE USE OF LONG-ACTING REVERSIBLE CONTRACEPTIVES: A RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

OBJECTIVE:

To evaluate the effect of adding cell-phone reminders to the postpartum family planning service on the intake of postpartum women to long-acting reversible contraceptives (LARC).

STUDY DESIGN:

We conducted a randomized, open-label controlled trial (Clinical trials. Gov; NCT03135288) at a tertiary university hospital between July 2017 and March 2019. We had included women who delivered a live birth greater than 28 weeks' gestation and requested birth spacing for more than one year. Eligible women were recruited and randomized into two groups. The cell-phone assisted group who received a reminder for their first postpartum family planning visit five weeks and 48 hours before the scheduled visit. The control group received the standard postpartum family planning counseling without cell-phone reminders. The primary outcome was the rate of initiation of LARC method.

RESULTS:

The study included 1000 eligible participants (n=500 in each group). The rate of initiation and continuation of a LARC method was significantly higher in the cell-phone assisted group as compared with the control group (30.2% vs. 8.4% and 95.4% vs. 83.3% respectively; p <0.001). Three hundred eighty-two (76.4%) women of cell-phone assisted group had started any contraceptive method during the first six months as compared to 218 (43.6%) women in the control group (p <0.001).

CONCLUSIONS:

Using cell-phone reminders during the postpartum family planning service improves the intake of postpartum women to LARC methods with the potential enhancement of contraceptive continuation rate.

IMPLICATIONS: Using an easily readily available cell-phone as a reminder can enhance the postpartum family planning service.

KEYWORDS:

Contraception; LARC; cell-phone; family planning.

1. INTRODUCTION

Unplanned and closely spaced pregnancies are a major public health problem that affects both individuals and society [1]. Pregnancy occurring within six months of the last delivery holds a 7.5-fold increased risk for induced abortion, a 3.3-fold increase in miscarriage and a 1.6-fold increased risk of stillbirth. However, the use of contraceptive methods has been shown to reduce unintended pregnancy, high fertility, and maternal mortality rates [2].

Unplanned pregnancy during breast-feeding is a common problem encountered during the postpartum period, especially when breastfeeding is a prevalent practice [3]. Women in Egypt and many other countries usually depend on breastfeeding as a method of birth spacing without having enough knowledge when that is eligible or not [4]. As regards our setting (rural Egypt), 4.4% of our lactating women become pregnant within the first six months after delivery, and this number jumps to 15.1% after menses have resumed [5]. They usually rely over-rely on the contraceptive effect of breastfeeding, forgetting the due time that they should start their long-term contraceptive method. This could result in an unplanned pregnancy. The unplanned pregnancy is sometimes unwanted to the edge of induction of unsafe abortion [6].

The vital reasons for unplanned pregnancy during the postpartum period are that women fail to start contraception in due time, in-proper, or incorrect use. However, few studies have conducted to identify if family planning clinic-based interventions can improve contraceptive use [7]. Long-acting reversible contraceptives (LARC) are among the most effective contraceptives. They have special advantages, most importantly, being provider-dependent methods once in place; they do not require care beside long duration of action up to 10 years [8].

One of the potentially useful approaches for improving postpartum contraception is the use of the vastly available cell-phone which is in the hands of nearly every couple to increase women's intake and correct use of contraceptive methods especially LARC methods [9]. There is a good potential that cell-phone assistance can fulfill some women's contraceptive needs, can be a reminder for timely-intake, a simple way to answer women queries during the use and enhance contraceptive continuation. This can lead to a decrease in unplanned pregnancy during the postpartum period.

Up to our knowledge, there have no specific studies approaching the impact of cell-phone assisted postpartum family planning counseling on

the postpartum contraceptive service. Therefore, the current study aims to evaluate the effect of adding cell-phone reminders to the postpartum family planning service on the intake of postpartum women to LARC.

2. MATERIALS AND METHODS

2.1 STUDY TYPE, SETTING, AND DURATION

A randomized, open-label controlled study was carried out at a tertiary University Hospital's Postpartum Ward and Family Planning Clinic between July 2017 and March 2019. This study was designed and reported according to the revised recommendations of ClinicalTrials.gov for improving the quality of reporting RCTs (registered trial; NCT03135288). The institutional review board approved the study, and we obtained written informed consent from all participants before enrollment in the study.

2.2 STUDY PARTICIPANTS

We invited all women who delivered in the hospital during the study period to participate in the study. We included women with the following inclusion criteria: delivered a live birth at greater than 28 week's gestation, planning birth spacing for a year or more after delivery, holding and/or one of her family a cell-phone and accept to receive messages and phone calls to remind her with the contraceptive program.

We excluded women who were not eligible for using LARC Methods according to WHO eligibility criteria [10]. Additionally, we excluded women with anticipated difficulty of subsequent communication.

2.3 SAMPLE SIZE

Sample size calculation was based on the primary outcome (Initiation of LARC method within the first 6 months postpartum). Previous study by Shaaban and Glasier in 2008 reported that the initiation of any of the LARC methods in the first 6 months postpartum was 23.9% [5]. We assumed that cell-phone assistance can increase the initiation of LARC by 10%. Using two-sided chi-square (χ^2) test with α of 0.05, a sample size of 996 women is needed using 90% power to detect 10% difference between the two groups [odds ratio: 1.63] with anticipated 10% loss of follow up (Epi-info™, CDC, USA, 2017).

2.4 RANDOMIZATION

A statistician, not otherwise included in the study, prepared a computer-generated random table and placed the allocation data in serially numbered closed opaque envelopes. Each envelope had a card noting the group identifier inside. The key to the allocated group according to the serial numbers was kept until the end of the study with the statistician. After acceptance of eligible women to participate in the study, they were

assigned randomly to either cell phone assisted group or the control group. Once the allocation had been done, it was not changed.

2.5 STUDY INTERVENTION

One of the study investigators (TZ) approached all included women and collected the baseline data through a complete evaluation of the patient personal, obstetric and contraceptive history. She counseled all participants about the importance of postpartum family planning and its different options before discharge. This counseling included knowledge about LARC methods their safety, efficacy, advantages, side effects, possible complications and duration of use. Every woman was given a booklet containing comprehensive knowledge about family planning methods.

Then, women were allocated into one of the following groups:

Group A: Cell-phone assisted (study group): the investigator informed them that they were going to receive reminders of their postpartum family planning visit as the following:

- A phone call at 5th week after the delivery (one week before the scheduled visit)
- A phone call 48 hours before the scheduled visit.
- They also received two follow-up phone calls to answer any queries and to remind them of the follow-up visits after method initiation.

Group B: control group received the above adequate counseling without phone calls reminders.

Women in both groups were given a referral card to the outpatients' family planning clinic denoting her allocated group, serial number and with a specific date for postpartum family planning visits. They were also provided with a phone number working 5 days a week from 8 AM to 2 PM to answer any queries about her family planning program.

2.6 FOLLOW UP

Every woman was followed at the 6th week and the end of the 6th month postpartum during her visit to the outpatients' family planning clinic or by phone call for those who did not attend the service. We inquired about her attendance to family planning service, initiation of contraceptive methods, the continuation of the use of methods, adverse effects, and finally, the occurrence of a new pregnancy.

2.7 STUDY OUTCOMES

The primary outcome of the study was the difference in the rate of initiation of LARC methods in the first six months postpartum between the two groups. The secondary outcomes included the rate of initiation of any contraceptive method, the rate of continuation of the method in the first six

months after insertion and the rate of occurrence of unintended pregnancy.

2.8 STATISTICAL ANALYSIS

Data coding and data entry were done using the statistical package SPSS (Statistical Package for the Social Sciences) version 22 (SPSS software Chicago, IL, USA). Data were summarized as mean and standard deviation for quantitative data and as frequency and percentage for categorical data. The data were tested for normality using the Anderson-Darling test. Comparisons between quantitative variables were done using the unpaired T-test. For comparing categorical data, Chi-square (χ^2) test was performed. P-values <0.05 were considered statistically significant.

3. RESULTS

During the study period, 1156 women were assessed to be eligible for inclusion in the study. However, 156 women were excluded; so a total of 1000 women were eligible to participate. We randomly allocated 500 women in each group (Figure 1). The loss of follow up during the study period was 68 (13.6%) women in each group.

Both groups were similar regarding age, parity, BMI, duration of marriage, and residence (Table 1).

Table 1: The baseline characteristics of the study participants.

Characteristics	Cell-phone assisted group (n=500)	Control group (n=500)	P-value
Age (years)	27.38±5.956	27.92±5.852	0.12
BMI(kg/m ²)	27.1±3.04	27.9±2.43	0.44
Parity	2.91±1.455	2.96±1.392	0.41
Duration of marriage (years)	2.31 ± 0.816	2.41 ± 0.776	0.17
Rural residence	396(79.2%)	403(80.6%)	0.10

BMI; body mass index

Data are presented as mean ± SD or frequency and percentages

Table 2 shows the results of the first follow-up at six weeks postpartum. Women attending family planning clinic were significantly higher in the cell-phone assisted group as compared to control group (67.8% vs. 39.4% respectively; p <0.001). Three hundred four (60.8%) women of the cell-phone assisted group had started any family planning method during this visit as compared to 171 (34.2%) in the control group (p <0.001). Similarly, the rate of initiation of LARC method was significantly higher in the cell-phone assisted group versus the control group

(26.6% vs. 4.2% respectively, $p < 0.001$). No difference between both groups regarding the type of LARC method used ($p = 0.82$).

Table 2: Initiation of LARC and other family planning methods among study participants at 6 weeks postpartum

Characteristics	Cell-phone assisted group (n=500)	Control group (n=500)	P-value
Attended FP clinic	339 (67.8%)	197 (39.4%)	<0.001*
Not attended FP clinic	122 (24.4%)	256 (51.2%)	
Lost follow up	39 (7.8%)	47 (9.4%)	
Initiation of FP method	304 (60.8%)	171 (34.2%)	<0.001*
Initiation of LARC method	133 (26.6%)	21 (4.2%)	<0.001*
Type of LARC method	98 (73.7%)	16 (76.2%)	0.82
IUD	35 (26.3%)	5 (23.8%)	
Implant			

Data are presented as frequency and percentage

*Statistical significant difference

FP; family planning, IUD; intrauterine device, LARC; long acting reversible contraceptive

The overall contraceptive performance of the study participants is presented in table 3. The rate of initiation and continuation of a LARC method was significantly higher in the cell-phone assisted group (30.2% vs. 8.4% and 95.4% vs. 83.3% respectively; $p < 0.001$). Three hundred eighty-two (76.4%) women of cell-phone assisted group had started any contraceptive method during the first six months as compared to 218 (43.6%) women in the control group ($p < 0.001$). There were no cases of unplanned pregnancy in the cell-phone assisted group compared to ten cases (2.0%) in the control group ($p = 0.009$).

Table 3: Overall contraceptive performance among study participants at 6 months postpartum

Characteristics	Cell-phone assisted group (n=500)	Control group (n=500)	P-value
Attended FP clinic	367 (73.4%)	240 (48.0%)	<0.001*
Not attended FP clinic	65 (13.0%)	192 (38.4%)	
Lost follow up	68 (13.6%)	68 (13.6%)	
Initiation of FP method	382 (76.4%)	218 (43.6%)	<0.001*
Initiation of LARC method	151 (30.2%)	42 (8.4%)	<0.001*
Type of LARC method	113 (74.8%)	30 (71.4%)	0.57
IUD		12 (28.6%)	
Implant	38 (25.2%)		
Continuation of LARC use	144 (95.4%)	35 (83.3%)	<0.001*
Unplanned pregnancy	0	10 (2.0%)	0.009*

Data are presented as frequency and percentage

*Statistical significant difference

FP; family planning, IUD; intrauterine device, LARC; long acting reversible contraceptive

4. DISCUSSION

In the era of cell-phones, using the smart device to remind women about their contraceptive needs is an appealing idea. This work evaluated the implications of adding cell-phone reminders to postpartum family planning service. Our results have shown that these reminders could improve the timely-intake and continuation of use of LARC methods and can decrease the unplanned pregnancy during breastfeeding. To the best of our knowledge, this is the first study to evaluate the implications of adding cell-phone to the postpartum family planning service on the use of LARC methods.

Effective family planning could prevent one in every three maternal deaths globally by delaying motherhood, spacing births, avoiding unplanned pregnancies, and induced abortions [6]. Intrauterine contraceptive device and contraceptive implants (LARC) are provider-dependent methods in their initiation, and the user does not require repeated contact with

health care providers. Therefore, LARC common effectiveness is considered more effective than other client-dependent methods [11]. Thus, initiation of LARC use at the proper time could be the main target of contraceptive health policymakers in the near future. One of the potentially useful approaches for improving LARC timely-intake is communication with the couple through the cell-phone. Telephone-administered interventions constitute a potentially cost-effective and confidential way to reach individuals who cannot or may not be willing to return to a clinic on a regular basis [9].

The current study demonstrated that about three quarters (76.4%) of women in the cell-phone assisted group compared to 43.6% of women in the regular counseling group. Moreover, one-third of the women in the cell-phone assisted group had started one of the LARC methods compared to only 8.4% in the control group. This agreed with Agrwal and colleagues who assessed a mobile job aid for community health workers in Tanzania, and they found that the use of a mobile-based integrated counseling algorithm can improve the community-based family planning service delivery [12]. Additionally, Kirby et al. evaluated the impact of follow-up phone calls to female adolescent clinic patients on contraceptive use [9]. They reported that the majority of respondents said that the phone calls answered their questions about birth control (92%), helped them use birth control correctly (80%), use FP more often (77%), and return to the clinic on schedule (85%) [9].

On the other hand, Steenland et al. reported no significant differences between women received a follow-up telephone call compared to no telephone call regarding the measures of contraceptive use. They attributed their results to the poor completion rates of phone contact and this may explain the difference with our study results [13].

Smith et al. evaluated the development of a mobile phone-based (mHealth) intervention to support post-abortion family planning (PAFP) in Cambodia [14]. They found that there was limited evidence for this intervention to improve contraception and post-abortion family planning (PAFP) and the uptake of effective PAFP either immediately after abortion or at two-week follow up was 40.0 % [14]. Over 50 % of women did not return to the clinic for any reason within 12-months of having an abortion. About 4% of clients returned to the same clinic for repeat abortion within 12-months with 8% returning with repeat pregnancy. These differences may be due to the use of text messages, and most of the women could not read.

The present study revealed that there was a significant difference between the study and control groups regarding the continuation of using the contraceptive methods in the first 6 months postpartum. These findings disagree with Barden-O'Fallon et a., who found that the discontinuation rate for all methods was more than one third up to the 12-month [15]. This discrepancy in the results may be due to the difference in the follow-up duration between our study (6 months) and Barden O'Fallon and colleague study (one year).

According to the present study, there were no cases of unplanned pregnancy in the study group compared with ten cases in the control group ($p=0.009$). This result agrees with Tawfik and colleagues who randomly selected women to receive either postpartum FP counseling before discharge or standard postpartum care. FP counselors followed the women by phone at 3, 6, 12, and 18 months to obtain the postpartum FP use and pregnancy data, and to repeat the postpartum FP messages to women in the counseling group. At six months, the difference in pregnancy rate between the counseling and control groups was significant (5.8% vs. 21.9% respectively, $p<0.001$) [16]. Also, the study results

agreed with Lopez et al. who studied the strategies for improving postpartum contraceptive use, and they found that women in the experimental group were less likely to report a pregnancy by nine months postpartum than those in the control group [17].

The key strength of our study is the randomized design and the calculation of sample size with adequate power to detect a clinically significant difference in the primary outcome.

The current study had exhausted every effort to fulfill criteria of a good RCT; however, there were some of unavoidable limitations. Not all women delivered approached because of the extremely busy service and short hospital stay. Some women agree to participate, but their husband refused. Loss of follow up encountered in about 14% of the study participants after extensive effort to reach them.

In conclusion, using cell-phone reminders during the postpartum family planning service improves the intake of postpartum women to LARC methods with the potential enhancement of contraceptive continuation rate and decreasing unplanned pregnancies.

CONFLICT OF INTEREST

All authors confirm no financial or personal relationship with a third party whose interests could be positively or negatively influenced by the article's content.

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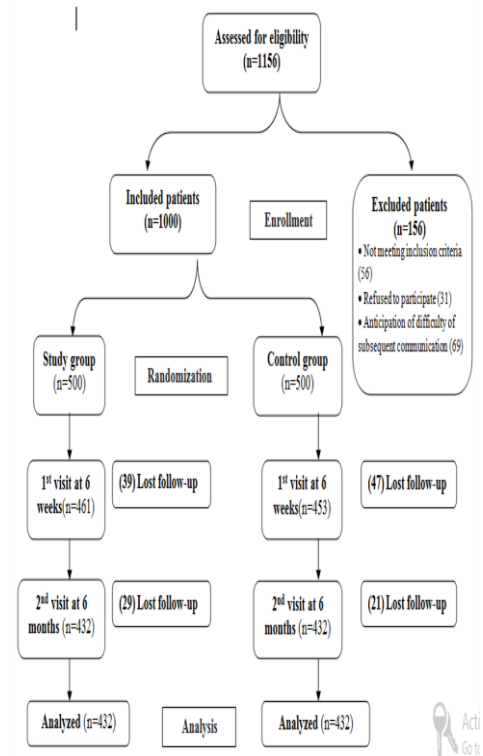


FIGURE CAPTIONS

FIGURE FLOWCHART OF THE STUDY PARTICIPANTS.