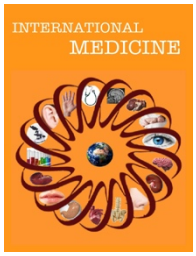
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Original Article

Standard days method: Comparison of CycleBeads and Smartphone app

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Abstract

Background: Standard Days Method (SDM) is a fertility awareness-based method. This study aims to make a comparison between the use of the conventional CycleBeads method and the smartphone application in terms of effectiveness, satisfaction, and continuity.

Methods: This study was planned on randomized control. Women who were 15 to 49 years of age, sexually active, and who own a smartphone and who do not use any contraceptive method or who use withdrawal received brief counseling about family planning methods in general. Then, they received detailed information about the SDM. Women who accepted to use SDM were randomized in the CycleBeads and android application groups. Others were included as part of the control group. The intervention group was observed on the 1st, 4th, and 12th month and the control group was observed on the 4th and 12th month.

Results: During the research, two unwanted pregnancies occurred in the CycleBeads group, three unwanted pregnancies occurred in the control group. There was not a statistically significant difference in terms of unwanted pregnancies between the intervention or the control group (Fisher's exact test, p=0.279; 0.194); in typical usage, effectiveness was 94.9% in the CycleBeads group, 100% in the android group. It was determined that there was not a statistically significant difference between the two groups in terms of general satisfaction and continuity (Independent samples t-test, p>0.05).

Conclusions: The intervention performed with CycleBeads and android application had similar effects in terms of effectiveness, satisfaction, and continuity.

Keywords: contraception; mobile application; natural family planning methods

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1. Introduction

Fertility Awareness Based Methods (FABM) are natural family planning methods based on fertility knowledge, and their use is limited worldwide (3.6%) due to lack of understanding that leads ineffective use and unintended pregnancies [1-5]. Standard Days Method (SDM) is one of them determined by calculating individual fertile days based on ovulation and pregnancy possibility. Fertile days are between the 8 to 19 days of the cycle for women who have regular periods within a range of 26-32 days [6]. Couples avoid sexual intercourse or use a barrier method during their fertile days, and can have sex without any protection in the remaining days. "CycleBeads" is a necklace made up of thirty-two beads in different colors developed for women to determine their fertile days by themselves. Also, a version of the Standard Days Method has been applied to smartphones for practical usage which is called as "CycleBeads app" [7]. SDM is effectively used by women who have regular cycles of 26 to 32 days; in a multicenter study its effectiveness is found to be 88% for typical use and 95.4% for perfect service [8]. The satisfaction rate was 47%; the continuation rate was 50%, the potential demand was 80.3%; effectiveness in typical use was 87.6%; the satisfaction rate was 63% according to other studies performed in Turkey [9,10].

"Smart" phones are used commonly for communication in our daily lives [11]. In recent years, their usage has been increasing for purposes outside of communication. Among clinicians, there is an increase in the usage of smartphone applications for medical purposes, mostly to make a change in people's health behaviors [12].

Aim: This study aims to make a comparison between the use of the conventional CycleBeads method and the smartphone application in terms of effectiveness, satisfaction, and continuation.

2. Methods

This study was approved by the Ethics Committee of Marmara University Institute of Health Sciences on 26.02.2016 with the title of “Standard Days Method: Comparison of CycleBeads and Smart Phone App”, to be conducted between 01.03.2016-01.03.2017 (Protocol number: 223).

2.1. Research type

Randomized controlled study

2.2. Research universe and sample size

This study was conducted in accordance with the Declaration of Helsinki and informed consent was obtained from all participants. Women 15 to 49 years of age who were sexually active and who own a smartphone and who do not use any contraceptive method even though they do not want to get pregnant or who use withdrawal method made up the universe of this research.

Typical use efficiency with the withdrawal method is assumed as 73% [13] and the efficiency in perfect usage of SDM is assumed as 95% [9]; with a 95% confidence level and 80% power, it was proposed to have 39 people in each intervention group; and 78 people to be in the control group. The entire sample group of 117, after two intervention groups were considered, was calculated to be 156 people total. The research's sample calculation was based on the success ratio of the control group's withdrawal method's typical usage to SDM's perfect usage (http://OpenEpi-Samplesize).

2.3. Inclusion criteria

The women between the ages of 15-49 years old and sexually active; smartphone users with regular periods. Periods' regularity has been defined as, having four or more period cycles after the last-born child and/or to have the last three periods within the expected time frame, and the period cycle between 26-32 days.

2.4. Exclusion criteria

Women with irregular periods <26 days or >32 days; oral contraceptive use in the last three months or use of injectable contraception in the previous six months.

2.5. Materials

Necklace (CycleBeads) that simulates the woman's menstrual cycle is made up of one red bead to indicate menstruation, twelve white for fertile days, and nineteen brown beads for infertile days, a total of thirty-two beads and also of a portable black rubber hoop. The woman puts a rubber hoop through another bead every day of the cycle [7]. While using the application, the user indicates the first day of her last period to determine her fertile and infertile days on CycleBeads or calendar visuals.

2.6. Data collection

Before the research, a survey to determine the awareness about the topic and the frequency of smartphone use for reproductive health purposes was conducted to find available participants. The study has been run among women who applied to the Family Medicine and Obstetrics and Gynecology polyclinics of the Marmara University Hospital, and women who meet the inclusion criteria were invited to participate in the research. A total of 815 women was reached, 198 fulfilled the requirements; a total of 74 women accepted to use the method.

These participants firstly received brief counseling about family planning methods in general, and then they received detailed information about the SDM. The interviews were conducted by one researcher, with standard content, assisted by educational material, and each lasting approximately 20 minutes. Women who accepted to use SDM were randomized in the CycleBeads and CycleBeads app groups.

2.7. Randomization

A formal meeting was realized with each woman (N=198), and those who accepted to use the method were randomly assigned into two intervention groups by order and women who did not accept were recruited into the control group. The participants of intervention Group 1 were given a CycleBeads and explained its usage. Intervention Group 2 received the same information; this group of women has been downloaded the Turkish version of "CycleBeads" apps. Their smartphone and its use have been explained as well intervention groups were suggested to avoid sexual intercourse or to use a condom on fertile days, and condoms were provided. During this period, in the case of unsuccessful condom usage such as condom ripping, information on emergency contraception has been provided. Control group has not been given any intervention.

2.8. Turkish translation of the smartphone app

Turkish version of the smartphone application has been performed in contact with Cycle Technologies Unit of Georgetown University Reproductive Health Center, the patent owner of the application, and all the consent and confirmations were taken. Turkish translation of the application was realized by the Turkish research team and approved and applied by Cycle Technologies to an easy, user-friendly, and free downloadable in all androids via Play store.

2.9. Follow-up

The observation of the method was conducted with phone calls on the 1st, 4th, and 12th month. 1st month was performed via a standard form to question the continuation, the correct use, the satisfaction, and the knowledge level about the method. The satisfaction was evaluated at the end of the first month and of the first year by asking the participants whether they were satisfied with the method and asking them to rate between 0 to 10 points their satisfaction level. During the 4th month, the participant's unwanted pregnancy condition, continuity to the SDM, and satisfaction of the participants and their partners. The same survey was repeated in the 12th month. The control group was interviewed similarly on the 4th and the 12th month via a standard form to question about unwanted pregnancy, their satisfaction with their method, and their willingness to continue to use it.

2.10. Statistical analysis

In the analysis of the variables, the SPSS 21.0 packet program was used. Descriptive statistics were performed; the significant difference between categorical variables was analyzed by using Chi-square and Fisher's exact test; for the significant difference between continuous variables t-test, and the relationship between two continually changing variables, the Spearman correlation analysis was used.

3. Results

A total of 129 women participated in the study (CycleBeads n=39; android n=35; control n=55). This study was conducted in four different centers by the same researcher. The intervention group participants were recruited from Pendik N0.9 Family Health Center (40.5%), 50% from Tuzla Education Family Health Center (EFHC), and 9.5% from Marmara University Family Medicine and Obstetrics and Gynecology polyclinics. The participants of the control group were from Tuzla EFHC. The average age value of all the participants was 32.8 ± 5.75; the average education years was 10.3 ± 4.5. The participants' other sociodemographic characteristics have been summarized in Table 1.

3.1. The first month follow up of intervention groups

3.1.1. Correct use (all the steps as explained by the researcher)

CycleBeads group (s=21) used the method correctly. In the android group (s=14), four participants have forgotten to turn on some alarming notifications on the app. CycleBeads participants 85% and the entire Android group were coherent with the calendar. There was no

statistical difference between the two groups in calendar coherency (Fisher's exact test, p=0.250). The participants' behaviors on unsafe days were summarized in Table 2.

Table 1. The participants sociodemographic characteristics

Sociodemographic Characteristics N=129	CycleBeads N=39		Android N=35		Control N=55		
	n	%	n	%		%	p**
Income level (TL)							
≤2000	17	43.6	10	28.6	13	23.7	
>2000-<3000	18	46.2	14	40	26	47.3	
≥3000	4	10.3	11	31.4	16	29.1	
Occupation							
Housewife	29	74.4	24	68.6	38	69.1	
Laborer	5	12.8	4	11.4	7	12.7	
Officer	2	5.1	6	17.1	5	9.1	**>0.05**
Self-employment	2	5.1	1	2.9	5	9.1	
Retired	1	2	0	0	0	0	
Social security							
ES, SGK	35	87.2	32	91.4	52	94.5	
No security	4	12.8	3	8.6	3	5.5	
Marriage status							
Married	39	100	34	100	55	100	

ES: Retirement fund; SGK: Social security foundation.
p* Independent samples t-test, p** Chi-squared test.

Table 2. The protection on the white days based on the groups

Protection on the white days (%)	Only condom	Only withdrawal	Abstinence	Generally abstinence and sometimes withdrawal	Generally abstinence and sometimes condom use	Total
CycleBeads	50.0	**20.0**	20.0	5.0*	5.0	100.0
Android	57.1	**14.2**	7.1	14.2	7.1	100.0

*In this group, two pregnancies occurred.

3.1.2. Knowledge status about the method

The results were summarized in Table 3.

3.1.3. Unwanted pregnancies, continuity, and satisfaction

Results were summarized in Table 4 for the 1st, 4th, 12th months follow up. The participants' education level was inversely correlated with the partner's satisfaction (Spearman correlation, p=0.011).

On the 12th month follow up, one unwanted pregnancy occurred in the CycleBeads group, and three unwanted pregnancies occurred in the control group. In contrast, no unwanted pregnancies occurred in the android group. The ones who have got pregnant all used the withdrawal method with their partner during fertile days. CycleBeads-control, android-control, and CycleBeads-android groups were compared separately for unwanted pregnancy; there was no statistically significant difference between groups (Fisher's exact test, p=1.000, 0.279, 0.194, respectively); in typical usage, effectiveness was 94.9% in the CycleBeads group, 100% in the android group.

All the participants in both groups stated that they would continue to use the method. The participants who quitted the technique have been asked for their reason for leaving. In the CycleBeads group, one person had an unwanted pregnancy, one had irregular periods, one kept forgetting to move the hoop, and one had been hysterectomized, and one person in the Android group had irregular periods.

Table 3. The distribution of the answers to the information questions for the intervention group

Information questions	CycleBeads n=20		Android n=14		*p**
	Knows % (n)	Doesn't know % (n)	Knows % (n)	Doesn't know % (n)	
What does the red bead/day express?	95 (19)	5 (1)	92.8 (13)	17.2 (1)	1.000
What does the white bead/day express?	90 (18)	10 (2)	100 (14)	0	0.496
What does the brown bead/day express?	90 (18)	10 (2)	100 (14)	0	0.496
What do you do if your period starts before the black hoop comes to the brown bead/day?	45 (9)	55 (11)	71.4 (10)	28.6 (4)	0.167
What do you do if your period doesn't start when it's the last bead on the CycleBeads/last day on the calendar?	65 (13)	35 (7)	71.4 (10)	28.6 (4)	**0.041**
On which bead days/on which colorful days on the calendar should you not be in sexual intercourse or use a barrier method?	95 (19)	5 (1)	92.8 (13)	17.2 (1)	1.000

*Fisher's exact test.

Table 4. 1st, 4th, 12th months follow-up

Assessment criteria of SDM	Follow up periods											
	1st Month				4th Month				12th Month			
	CycleBeads N=39		Android N=35		CycleBeads N=16		Android N=9		CycleBeads N=12		Android N=6	
	n	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Unwanted pregnancy (effectiveness)	0	0.0	0	0.0	1	2.5	0	0.0	1	5.1	0	0.0
Continuity	21	53.8	14	40.0	16	41.0	9	25.7	12	30.7	6	17.1
	p*=0.622				p*=0.164				p*=0.567			
Satisfaction (N)	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
Women Satisfied	21	0	14	0	16	0	9	0	12	0	6	0
Partner Satisfied	15	6	14	0	10	6	9	0	NQ		NQ	
	Mean (±SD)		**Mean (±SD)**		**Mean (±SD)**		**Mean (±SD)**		**Mean (±SD)**		**Mean (±SD)**	
The Average satisfaction score	47.7±3.03		47.4 ± 1.5		NQ***				42.12±8.6		47.5±6.1	
	p=0.011**								p**=0.179			
If you were able to rate your satisfaction from 10 to 0, what would you rate it as?	9.16±1.2		9.13±0.9		NQ				8.68±1.5		9.1±2.0	
	p**=0.951								p**=0.557			
	9.68±0.7		9.73±0.5		NQ				8.56±1.5		9.16±2.0	

To be able to remind the high and low probability days of getting pregnant	p**=0.825			p**=0.455	
Being able to track the period cycle	9.79±0.53	9.67±0.4	NQ	8.43±1.63	10.00±0.0
	p**=0.495			**p**=0.032**	
Being able to include the partner	9.11±1.56	9.20±0.6	NQ	8.06±2.2	9.16±2.0
	p**=0.828			p**=0.294	
Ease of the method	10±0	9.87±0.3		8.37±2.8	10±0.0
	p**=0.107			p**=0.184	

*Chi-squared, **Independent samples t-test, ***Not questioned.

4. Discussion

All the participants were smartphone users, withdrawal method users with regular menstrual cycles. There was no statistical difference between groups in terms of socioeconomic characteristics. SDM, as a natural contraceptive method, is preferred by women who do not want to use hormonal methods or intrauterine devices [5]. Therefore, women who did not use any contraceptive or used the withdrawal method were recruited in the study.

4.1. Effectiveness, satisfaction, continuity

There was no statistical difference between CycleBeads and the android app in terms of effectiveness, satisfaction, and continuity; no statistical difference was determined between each intervention and the control group separately.

4.1.1 Effectiveness

Like all the other contraceptive methods, SDM has a perfect and typical use. Perfect use means to avoid sexual intercourse on unsafe days. But in some studies, the perfect use has been defined as "to avoid sexual intercourse or to use a condom" during unsafe days; also, the official web site of the Georgetown University Reproductive Health Department recommends condom use during these days. In our study, the participants have been told also to avoid sexual intercourse or to use a condom on unsafe days. But some couples did not correctly apply the method, sometimes used withdrawal and sometimes used condom on the unsafe days, which means typical use. The effectiveness of the CycleBeads group was 94.9% with two pregnancies, and 100% in the android group with no pregnancy. In both intervention groups, women who used the method as explained, perfect use, have not been pregnant in one year. In a multicenter study performed in Bolivia, Peru, and the Philippines (1992 to 2001) among 478, 18-39 years old women, perfect use had been defined as "avoiding sexual intercourse in unsafe days", the effectiveness of SDM was determined as 95% [8]. For typical use, in two similar studies, performed in seven countries and with the participation of 1646, 1200 women respectively, the use of withdrawal and other methods in unsafe days was accepted as typical use; and the effectiveness of the method was determined as 86-90% [13,14]. The effectiveness of SDM in these studies was lower than our results. This difference can be explained by the high number of participants in these studies, which makes the results closer to the real rates.

4.1.2. Satisfaction

In our study, satisfaction was evaluated differently than other studies. The satisfaction reasons were listed as "ease of use, to be able to track period cycles, reminders for safe and unsafe days; partner inclusion" and the participants have been asked to score each item between 0 and 10.

At the end of 1st month, in the CycleBeads group, the item "easy to use" the highest appreciation average was 10 and 9.9 in the android group. At the end of one year, the highest average in the CycleBeads group was 8.6 for the item "reminding for safe and unsafe days"; in the android group the highest score was given to "ease of use and also to be able to track period cycles". The general satisfaction mean score was 42.12±8.61 in the CycleBeads group, and 47.5 ± 6.12 in the android group; the difference was not statistically significant. In other similar studies realized in El-Salvador, in Rwanda, "ease of use" and "having little symptoms and health problems", and "being affordable" were the items that caused high satisfaction [15]. In other studies, satisfaction has only been asked directly by the question "are you satisfied with the method?" and the satisfaction rates reported in two studies one performed in Congo and Burkina Faso were

93% and 90% respectively [15]. In our study, the same question is also used beside the other items in the 12th month; all the remaining participants answered positively to this question, the satisfaction rate can be accepted as 100%. But when 23 women who have quit the study because of unsatisfaction were taken into consideration satisfaction can be mentioned as 69% (n=27/39) for Cycle Beads and 68% (n=24/35) for the android group which are lower than that of the other studies.

4.1.3. Continuity

In this study in the 1st month, the continuity rate was 54% for the CycleBeads group, 40% for the android group; in the 4th month, these rates were 41% and 25%; in the 12th month, 31% and 17% respectively. The continuity rate in 6-months CycleBeads was 89% in Peru [16]. In another 6-months follow-up study in Burkina Faso; this rate was 48% [14]. In another study from India, this rate was 36% at the end of the first year [17]; in Bolivia, Peru, and Philippines 46% [8], and Turkey was 51% [10]. The difference between the continuity rates can depend on the method defined to be used during the unsafe days such as condom use or abstinence and also on the duration of the study.

4.2. Limitations of the study

SDM is not well known in Turkey; even the health providers do not have sufficient information about this method. The women were not willing to participate in the study, since this was a new and unexperienced contraceptive method for them so that their trust might be low, which might reduce the continuity rate.

The counseling was provided to the women in general since male partners could not participate in the interviews as a cultural characteristic, despite the invitation by the researchers. However, this method needs the participation of the male partner for sexual abstinence or the use of condoms. This could be a barrier to continue the method during the study.

4.3. The strengths of the research

This study has been realized in primary care which allows the follow-up of the patients closely.

4.4. Conclusion

The intervention performed with CycleBeads and smartphone application had similar effects in terms of effectiveness, satisfaction, and continuity; and they were similarly more effective than the control group. So, the android app can be presented as a choice to the potential users. SDM can also be suggested as an additional modern contraceptive method to the traditional withdrawal which is still primarily used since the nineties in Turkey.

Conflict of interest

There is no conflict of interest.

Funding

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