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Randomized comparison of two Internet-supported fertility awareness based methods of family planning*

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Abstract

Background: The aim was to compare the efficacy and acceptability of two Internet-supported fertility awareness based methods (FABM) of family planning.

Study Design: Six hundred and sixty-seven women and their male partners were randomized into either an electronic hormonal fertility monitor (EHFM) group or a cervical mucus monitoring (CMM) group. Both groups utilized a web site with instructions, charts, and support. Acceptability was assessed online at 1, 3, and 6 months. Pregnancy rates were determined by survival analysis.

Results: The EHFM participants (N=197) had a total pregnancy rate of 7 per 100 users over 12 months of use compared with 18.5 for the CMM group (N=160). The log rank survival test showed a significant difference ($p < .01$) in survival functions. Mean acceptability for both groups increased significantly over time ($p < .0001$). Continuation rates at 12 months for the monitor group were 40.6% and the mucus group 36.6%.

Conclusion: In comparison with the CMM, the EHFM method of family planning was more effective. All users had an increase in acceptability over time. Results are tempered by the high drop-out rate.

Keywords: fertility awareness based methods; natural family planning; family planning; fertility monitoring

1. Introduction

Unintended pregnancies are a major health problem for women in developed and developing countries [1-3]. Many of these unintended pregnancies are due to discontinuation of contraceptive methods and, in turn, discontinuation is often due to side effects [2,4]. On the other hand, fertility awareness based methods of family planning (FABM) are free of side effects, have comparable continuation rates due to dissatisfaction [2], and are accepted by many cultures and religions [5].

However, based on the 2006 National Survey of Family Growth, only about 0.1% of women in the United States in their reproductive years currently use modern FABM [6,7]. Major reasons cited as to why so few couples use FABM are: 1) they are ineffective; 2) they are not easy to provide or to use; 3) health professionals are reluctant to recommend FABM, and users struggle with the periodic abstinence and anxiety over unintended pregnancy [8-12].

To address these reasons for non-use of FABM, Researchers at Marquette University developed a new FABM system based on hormonal monitoring technology, conducted a number of cohort efficacy studies of the system [13-15] and simplified the system to be taught in a 10-12 min office session [10,16]. The method uses either cervical mucus or an electronic hormonal fertility monitor (or both) and a calendar-based formula as a double check for the beginning and end of the fertile phase. On a daily basis the woman rates her fertility as being low, high, or peak, and utilizes a fertility calendar-based formula for a double check.

Researchers also developed an online system to teach couples to use the new FABM to reach couples in a more secure fashion [16]. The online site (<http://nfpstudy.marquette.edu>) has free information on FABM, downloadable charting systems, access to protocols for special circumstances (e.g., using FABM while breastfeeding), and instructions for achieving and avoiding pregnancy. A unique aspect of the information section of the web site is a one-page

Quick Start instruction that allows users to begin charting and using FABM immediately.

Couples who register on the web site are able to access an electronic charting system, discussion forums, and receive consultation from health professionals with expertise in FABM. The online charting system also notifies the user of possible health problems, including unusual bleeding, infertility, and cycle dynamics that are out of the norm.

A pilot efficacy study was previously conducted with this online FABM system, which gave the woman user the choice of using the EHFm, cervical mucus monitoring (CMM), or both [16]. The purpose of the current study was to compare the efficacy and acceptability of two Internet-supported FABM (i.e., EHFm with traditional CMM) in aiding couples to avoid pregnancy.

2. Methods

This was a 12-month (13 cycles) prospective randomized clinical trial of the efficacy, acceptability and ease of use of the EHFm plus fertility algorithm FABM compared with the CMM plus algorithm FABM. The EHFm used for this study was the Clear Blue Easy Fertility Monitor (CBFM) manufactured and marketed by Swiss Precision Diagnostics GmbH (Geneva, Switzerland). The monitor is available through most major drug stores with prices ranging from \$150 to \$200. The monitor requires use of 10-20 urine test strips per menstrual cycle with most cycles (i.e., 80%) requiring 10 test strips. A box of 30 test strips range in cost from \$30-\$50.

In order to achieve 80% power assuming a pregnancy rate of 10% for the EHFm group, a 20% pregnancy rate for the CMM group and an expected discontinuation rate of 25%, the sample size was calculated to be 750 couples. Randomization was assigned by computer generation when couples registered online and consented to participate. All couples received a free EHFm but those in the CMM group received the monitor only after completing 12 months of online charting. All couples received \$10 for each menstrual cycle chart completed. This study

received IRB approval through the university Office of Research Compliance. The study was registered at ClinicalTrials.Gov with the ID number NCT00843336.

The inclusion criteria for female partners of the couple participants were that they needed to be between the age of 18 and 42 years, have a stated menstrual cycle range of 21-42 days, have no history of hormonal contraceptives for the past 3 months and if post breastfeeding, have experienced at least 3 cycles past weaning. Male partners were to have no known fertility problem and be between the ages of 18 and 50 years. Recruitment ran from April, 2008 through December, 2010 by online search engine ads, e-mail list serves, and through fertility blogs and social networking sites. All potential participants were contacted at least every 3 months by e-mail and encouraged to complete the study and contribute online charts.

All participants received online instructions with an audio slide show that lasted 12-13 min and completed a 10-item quiz to measure their understanding. Participants in the EHFMM group received a CBFMM, which detects rising levels of urinary estrone-3-gluconuride (E3G) and is 98.8% accurate in detecting the surge in urinary LH. [17,18]. The CBFMM is initiated when a user pushes a button on the monitor labeled “M” on the first day of her period. The monitor requests either 10 or 20 daily urine tests per cycle. When the monitor requests a test, the user exposes the strip to her urine stream for 3 seconds and places it in the monitor. The monitor will show a fertility status of “low”, “high” or “peak”. Participants were asked to record on an electronic fertility chart: their fertility status (low, high or peak), all coital acts and their menstrual bleeding days.

Women who were in the CMM group were asked to observe for cervical mucus on a daily basis and to chart the highest level observed. They were instructed to “think, look, check, and chart” the cervical mucus, i.e., to think about how the mucus feels all through the day, to look at the mucus when urinating or defecating and before bedtime, to check mucus every day, and to chart the most fertile mucus sign at end of day. Written, oral, and

visual descriptions (pictures) of the three levels of cervical mucus (i.e., low, high, and peak) were provided online. These are similar procedures used with other CMM and with the World Health Organization [WHO] multi-site, multi-country study of the ovulation method (OM) of fertility awareness [19].

All participants used the online electronic charting system to record their fertility status. The charting system automatically indicated (in light blue) the fertile phase (based on the algorithm) as the user charts and automatically notified the user of the possibility of a pregnancy when the luteal phase exceeded 19 days. When this happened, the user was prompted to obtain a pregnancy test and complete an online pregnancy evaluation.

All participants were instructed to avoid intercourse and genital contact during the fertile window – i.e., from the first day of fertility through the last day of fertility and to refrain from intercourse on all "high" and "peak" days. Initially, the fertile window: began on day 6 for the first 6 cycles and ended three days past the last peak day (of either mucus or monitor). After 6 cycles of use, fertility began on the earliest day of peak during the last 6 cycles minus 6 days. Fertility ended on the last peak day of the last 6 cycles plus 3 full days.

Three professional nurse FABM teachers evaluated all confirmed pregnancies by reviewing the charting system for the days of fertility, recorded intercourse, and the information on the pregnancy evaluation form which included a self-evaluation of the reasons for the pregnancy. Participant were asked to record their intention of either achieving or avoiding pregnancy and their level of motivation for avoiding a pregnancy, i.e., how hard and how much they were trying to avoid pregnancy on a scale of 1-10 before each menstrual cycle of charting. All conceptions were dated and compared to the predicted fertile time as designated by the monitor and/or mucus fertility algorithms and classified. Pregnancies were classified as *intentional* only when they (the couple) indicated

they used the method to achieve pregnancy. Pregnancies were classified as *perfect use* failures when the couple followed the instructions of the method. All other pregnancies were classified as *user failure*. [20] *Perfect use* (also known as *method*) pregnancy rates were calculated using the number of cycles of reported perfect use. *Total pregnancy* rates were determined by tabulating the number of all pregnancies and by the total number of all menstrual cycles in which there was correct use and imperfect use.

Acceptability and ease of use of the online FABM web site and fertility monitoring system were measured by using a 10-item questionnaire administered at 1, 3, and 6 months. The 10-item survey was a shortened form of an acceptability/ease of use questionnaire developed by Severy [21-23] for evaluating an EHFM [13]. The 10 items are ranked on a scale from 1 to 7 with a range of possible scores from 7-70.

Data were entered into a computer and analyzed with the Statistical Analysis System (SAS) and the Statistical Package for the Social Sciences (SPSS) software systems. All statistical analyses were carried out using significance level $\alpha = 0.05$. Cumulative pregnancy rates were calculated by survival analysis with two different censoring variables: perfect use and total cycles. Kaplan-Meier estimates were calculated for both the monitor and the mucus groups and the log rank test was used to determine if there was any significant difference in the survival functions of the two groups. In order to obtain an estimate of the hazard ratio and to test whether there was a significant difference in the two hazard functions, the proportional hazards regression model was used with the group variable as a covariate. Changes across time and differences between the EHFM and the CMM group mean scores of the acceptability survey were analyzed using a mixed model with repeated measures. If there was an indication of significant differences in certain fixed effects, Tukey's multiple comparison procedure was used to find where the differences lie.

3. Results

3.1. *Participants*

Six hundred sixty-seven couples seeking to avoid pregnancy with a FABM were randomized into either an EHF group (N=337) or a CMM group (N=330) (see Fig. 1). Of the 667 participants who enrolled in the study, 87 were excluded because they did not meet study criteria or they declined to participate. Five participants from the monitor group and 26 from the mucus group were excluded from the intention-to-treat analysis. Lost to follow-up included the participants who never started charting or had incomplete charting and those that discontinued the intervention. Reasons for discontinuation included seeking pregnancy or pregnancy; endometriosis, and menstrual irregularity (PCOS, menopause); method related reasons, such as, excessive charting requirements and dissatisfaction with randomization. The menstrual cycles of participants who provided at least one complete cycle were included in the analysis. The final number of participants in the monitor group was 197 and 160 in the mucus group. [see Fig. 1]

3.2. *Demographics*

Mean age, number of years married, number of living children, basal metabolic index, and age of husband/partner in the two treatment groups were similar (see Table 1). In both groups, the greatest percentages of participants were Caucasian and Catholic.

3.3. *Efficacy*

The *perfect use* and *total* unintended pregnancy rates of the two study groups are based upon 1,568 cycles of correct use (893 for the monitor group and 675 for the mucus group) and 2,621 total cycles of use (1,546 monitor and 1,075 mucus). The total number of pregnancies for both groups was 32, with a 22.7 pregnancy per 100 women at one year for the monitor group and 28.2 per 100 women at one year for the mucus group. However, when the intended pregnancies were removed from the calculation, the *perfect use* pregnancy rate per 100 women over 12

months of use was 0 for the monitor group and 2.7 for the mucus group. There were no significant differences between the two groups in perfect use pregnancy rates.

As shown in Table 2, the *total* (unintended) pregnancy rate for the monitor group was 7, and 18.5 per 100 women for the mucus group over 12 months of use. In this case, both the survival and hazard functions of the monitor and mucus groups were significantly different. The rate of pregnancy in the mucus group is 2.96 times that of the monitor group (see Fig. 2) $p < .0048$.

3.4. Acceptability

The EHFM and CMM groups showed no significant difference in the overall mean acceptability scores. The survey total did demonstrate a significant change over time among both groups. Because the covariance matrix was compound symmetric, a Tukey post hoc test was used. The results showed a significant increase over time, i.e., the overall acceptability mean at one month was 55.5 out of a total possible score of 70 ($SD = 9.9$) compared with 58.3 out of a total score of 70 ($SD = 10.7$) at the sixth month of use ($t(461) = 5.28$, $p < .0001$) effect size = 0.02. However, the number of respondents declined from 335 to 209 during that time.

3.5. Continuation rates

The continuation rates in use of the methods at 3, 6, 9, and 12 months by group are as follows: for the monitor group, 82.2%, 64.5%, 52.3% and 40.6%; for the mucus group, 66.4%, 50.6%, 45.1% and 36.6%. There was no statistical difference in the continuation rates between the two methods at 12 months of use.

4. Discussion

The failure rate of each method in perfect use is low, a 0 – 2 pregnancy rate per 100 women over 12 months of use comparable to other FABM cohort trials [19,24,25]. The differences in total pregnancy rates at 12 months between the monitor (7/100 women year) and mucus group (18/100 women year) are similar to the differences that were found in a previous

cohort comparison study of the monitor plus mucus versus mucus alone as two FABM [15]. The low unintended pregnancy rate (both perfect and total) are comparable to the pregnancy rates that were determined in a large European study that used mucus plus basal body temperature to define the at-risk days [26] and with the pilot cohort study of this online FABM system [16].

The only studies of the efficacy of these methods have been conducted by the authors [12-16]. However, an earlier study reported the efficacy of the Persona fertility monitor [27]. The Persona monitor uses urinary E3G and LH as biological markers of fertility in addition to menstrual history, the monitor displays a green light (indicating infertility), a red light (indicating the fertile phase), or a yellow light (indicating when testing is needed). The Persona's method pregnancy rate was 12.1 per 100 users at one year [27,28].

The total pregnancy rates for the monitor group in the current study are better than those reported by Trussell for FABM who reported a 25% first year pregnancy rate with typical use [24,25]. The pregnancy rate from the mucus group with 18 unintended pregnancies per 100 at one year is comparable but slightly better than what Trussell reported for the mucus-only. The reason for the better rates for the current CMM might be because of the double check with the use of a calendar based algorithm for determining the beginning and end of the fertile phase and by making the fertile phase automatically displayed in the online charting system. Another reason for the differences in unintended pregnancy rates might be due to a relatively small, motivated and rather homogeneous number of participants.

Continuation rates were similar and relatively high for both methods. High rates of discontinuation have been seen in other FABM trials with 64-74% of couples dropping out at one year [2,3,29]. There were no significant differences in acceptability between the monitor and mucus groups over time. There was a significant increase in acceptability and ease of use among all participants as they progressed through the study as has been seen in other FABM trials [13, 16]. This increase may be a result of significant numbers of unsatisfied participants dropping out

of the study. Similar results (i.e., increased satisfaction and acceptability over time) were found with use of an EHFM to achieve pregnancy [22,23].

The high discontinuation rate over time limits the generalization of the study results. Non-participation rates were also high, 125 participants who were provided with a \$200 monitor never provided any fertility charts despite the \$10 incentive provided for each fertility chart completed. The most frequent reasons for discontinuing were “lost to follow-up,” “no longer interested,” and “wishing to achieve pregnancy.”

Although all regions of the US were represented, study population was homogeneous, white, middle class, educated couples. Despite attempts to involve many Hispanics by having the web site in the Spanish language and having access to Spanish-speaking health professionals.

The findings of this study suggest that the use of an online system to enroll, randomize, and survey participants is an efficient way to conduct efficacy research for FABM. The challenge is maintaining participation. Future studies could use an online system to compare other established FABM such as the Standard Days Method or the Two Day Method, or even the older calendar-based formulas [30,31]. Another application of this method might be to enhance the ability of sub-fertile women to achieve pregnancy.

Increasing access of couples to this system may present challenges. Installing the system in convenient sites, like public libraries or health clinics might increase access, although the requirement for daily charting may pose a problem. Another approach would be to have online charting available through cell phones and other hand-held devices linked to a FABM website.

5. Conclusion

The use of an online web-based fertility education, charting, and professional support system to teach FABM can be very efficient and effective with correct use by highly motivated users. FABM with an online charting system and use of an EHFM is more effective method than the use of CMM in avoiding pregnancy. The EHFM provides more objective measures of the

fertile window of the menstrual cycle than use of CMM. There is a trend for greater satisfaction/ease of use for participants who use the online web site for tracking fertility and for use in family planning. High drop-out rates and reaching a more diverse population of users interested in FABM are the main challenges.

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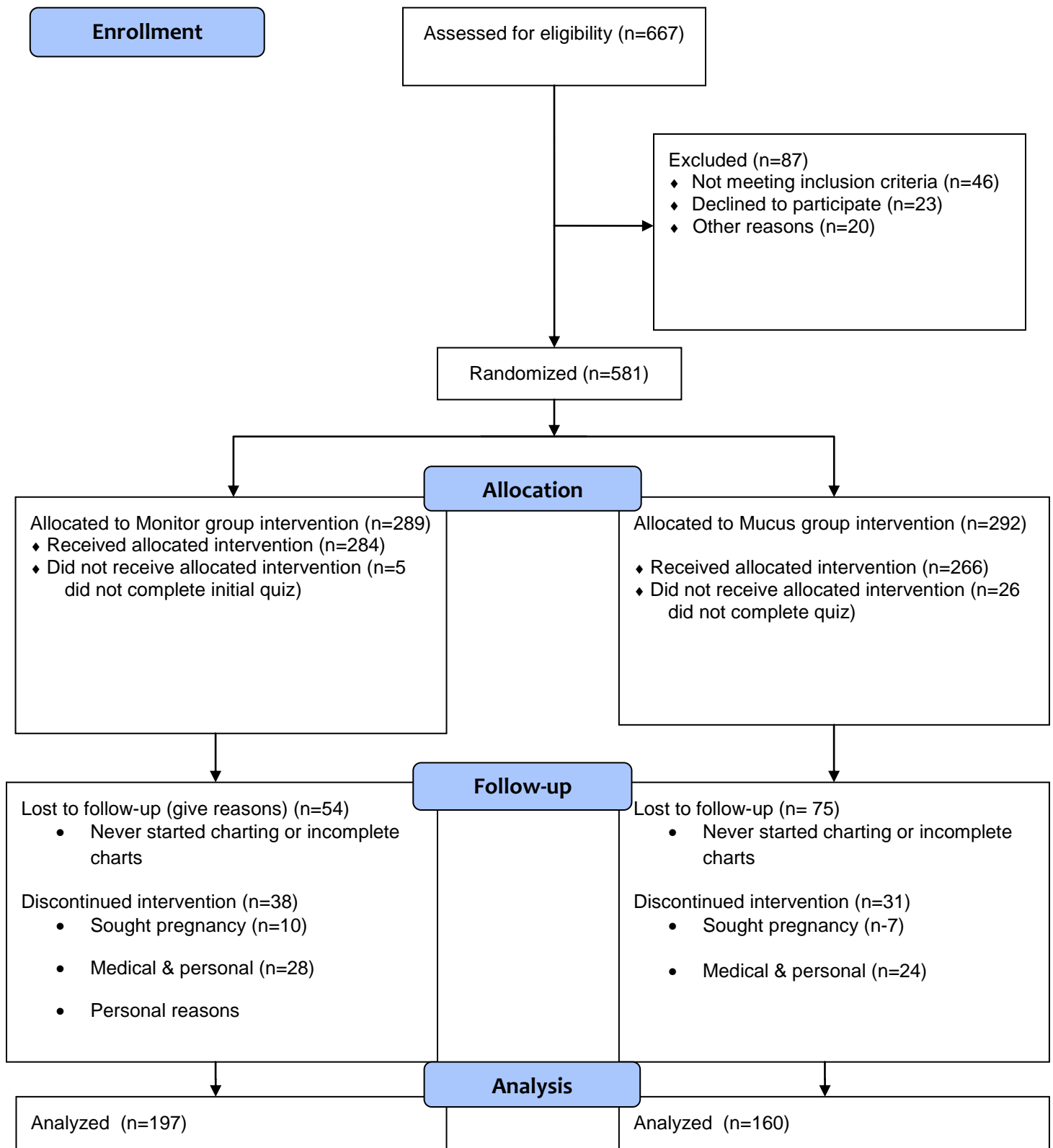
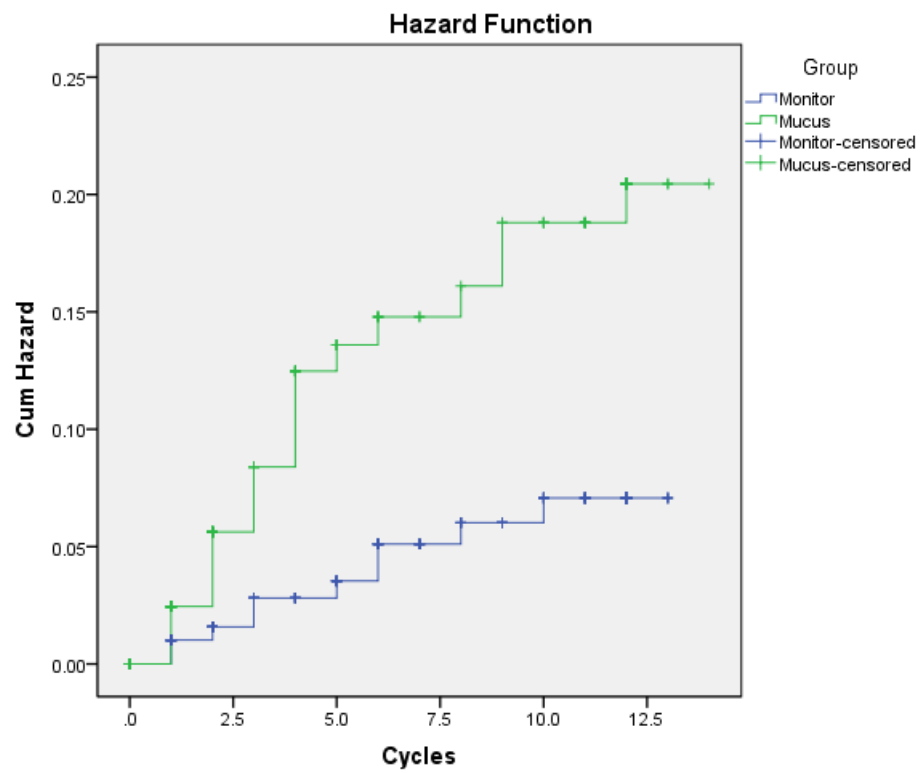


Figure 1. Participant enrollment and drop out flow diagram.



<i>Comparison</i>	<i>Hazard ratio</i>	<i>95% CI</i>	<i>Test statistic</i>	<i>p-value</i>
Monitor vs Mucus	0.338	(0.159, 0.718)	7.97	0.0048

Fig. 2. Hormonal monitor versus mucus monitoring total pregnancy rate hazard ratio curve

Table 1. Comparison of demographics between the monitor and mucus group by mean, standard deviation, and range of scores.*

	<u>Monitor group (N=197)</u>	<u>Mucus group (N=160)</u>
Mean age female	29.7 (SD=5.4; 21-42)	30.4 (SD=5.3; 19-42)
Mean age male	31.5 (SD=6.1; 20-44)	32.5 (SD=6.2; 22-47)
Mean years married	5.8 (SD=5.0; 0-18)	6.3 (SD=5.1; 0-20)
Mean # living children	1.8 (SD=1.9; 0-8)	2.1 (SD=1.9; 0-8)
Mean BMI female	24.7 (SD=4.7; 16.5-38.9)	25.3 (SD=5.9; 16.3-49.9)
% Ethnicity female	77% White/7% Hispanic	84% White/5% Hispanic
% Religion female	76% Catholic/18% Protestant	81% Catholic/14% Protestant

** There were no significant differences between the two study groups on demographic variables.*

Table 2**Total pregnancy rates by groups per 100 women over 12 months of use**

	<i>Monitor (N = 197)</i>			<i>Mucus (N = 160)</i>		
	Preg.	Rate	Std. Error	Preg.	Rate	Std. Error
3 months:	5	2.8	.01	11	8.2	.02
6 months:	3	5.0	.02	6	13.9	.03
9 months:	1	5.9	.02	3	17.3	.04
12 months:	1	6.8	.02	1	18.5	.04
Total pregnancies	10			21		

<i>Group</i>	<i>Kaplan-Meier estimate</i>	<i>St. error</i>	<i>Log rank T.S.</i>	<i>p-value</i>
Monitor	0.932	0.021	8.76	0.0031
Mucus	0.815	0.038		
