7-2013

# 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-based fertility awareness based methods of family planning (FABM).

**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 their reproductive years currently use modern FABM [6,7]. Major reasons why so few couples use FABM are: 1) they are ineffective; 2) they are not easy to provide or use; 3) health professionals are reluctant to provide FABM services, and users struggle with the periodic abstinence and anxiety over unintended pregnancy [8-12]. Although FABM, as it presently stands, has its drawbacks, there are many advantages as well. If the drawbacks to the use of FABM can be reduced, then these methods could become a realistic and relatively inexpensive way of increasing the proportion of pregnancies that are intended, as well as improving health outcomes, especially among women of reproductive age using no method of family planning and/or the self-devised rhythm method [7].

Researchers at Marquette University developed a new FABM system based on hormonal monitoring technology and conducted a number of cohort efficacy studies of the system [13-15]. They also simplified the system so that it could be initially 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. Whether the woman user observes cervical mucus or uses the electronic hormonal fertility monitor (EHFM), she rates her fertility as being low, high, or peak, and utilizes the same calendar-based formula for a double check.

Researchers also developed an online system to teach couples to use the new FABM [16]. It was determined that an online service system for FABM would be more efficient in being able to reach people around the country and world. 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. The web site includes a one-page Quick Start instruction that can be read in 5 min and allows the user to begin charting and using FABM immediately. In addition, couples are able to access an electronic charting system, discussion forums, and receive consultation from health professionals with expertise in the use of 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.

Although a pilot efficacy study was conducted with this online FABM system, the pilot site gave the woman user the choice of using the EHFM, cervical mucus monitoring (CMM), or both [16]. There is a need for randomized comparisons of FABM to determine which are more effective and easy to use. Therefore, 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. Since CMM is often confusing and subjective, we hypothesized that there would be more acceptability and fewer unintended pregnancies with EHFM.

## 2. Methods

This was a 12-month (13 cycles) prospective randomized clinical efficacy trial of the EHFM plus fertility algorithm NFP method in comparison with the CMM plus algorithm FABM. Six hundred sixty-seven couples seeking to avoid pregnancy with NFP were randomized into

either an EHFM group (N=337) or a CMM only group (N=330) (see Fig. 1). All couple participants (men and women) were assessed as to their perceived "acceptability and ease of use" with the online FABM system at 1, 3, and 6 months of use.

In order to achieve 80% power with a total unintended pregnancy rate of 10% for the EHFM group and a 20% pregnancy rate for the CMM group, a total sample size of 600 participants (300 per group) was pre-determined. An additional 150 couples were proposed as an over sample and to ensure that enough participants will complete the study, i.e., 75 participants for each group. The over sampling of 150 participants is based upon the typical discontinuation rate for modern FABM of approximately 25%. Randomization took place automatically 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 CMM 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 inclusion criteria for the 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. Six hundred sixty-seven couple participants were recruited (from April, 2008 through December, 2010) by online search engine ads, e-mail list serves, and by word of mouth through fertility blogs and social networking sites. Of the 667 participants who registered, 346 contributed online charting. 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 EHFM group

received a Clearblue Easy Fertility Monitor (CBFM), which is designed to detect the rising level of urinary estrone-3-gluconuride (E3G) and the surge in urinary LH. The CBFM is based on urinary hormonal immunoassay techniques. Product testing has shown the Clearblue monitor to be 98.8% accurate in detecting the LH surge [17,18]. The CBFM is initiated when the user pushes a button on the monitor labeled "M" on the first day of her period. The monitor then indicates which day of the cycle the user is on. The monitor requests either 10 or 20 daily urine tests per cycle. When the monitor requests a test, the user places the test strip under her urine stream for 3s. The test strip is then placed in the monitor and read. 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) and any intercourse that occurred on a daily basis as well as their menstrual bleeding.

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 going to the bathroom 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 were provided online to the CMM users. 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) [19].

All participants used the online electronic charting system which has designated sections for recording the results of CMM and the EHFM – as either L = low, H = high, or P = peak. The charting system provides a pop-up window for the user that illustrates the three levels of cervical mucus and the three levels provided by the fertility monitor. The charting automatically indicates (in light blue) the fertile phase (based on the algorithm) as the user charts. The electronic charting system automatically notifies the user of the possibility of a pregnancy when

the luteal phase goes beyond 19 days. The charting system then prompts the user to take a pregnancy test and complete an online pregnancy evaluation. The online charting system also cues the woman user to a link that launches a pregnancy evaluation form on each menstrual cycle that is charted.

All participants were instructed to not have intercourse or genital contact during the fertile window – i.e., from the first day of fertility through the last day of fertility. They were also informed to refrain from intercourse on all "high" and "peak" days and to use the following instructions for determining the fertile window: fertility begins on day 6 for the first 6 cycles and ends three days past the last peak day (of either mucus or monitor). After 6 cycles of use, fertility begins on the earliest day of peak during the last 6 cycles minus 6 days. Fertility ends on the last peak day of the last 6 cycles plus 3 full days.

Three professional nurse FABM teachers evaluated all pregnancies that occurred among the participants by reviewing the charting system for the days of fertility, the days of recorded intercourse, and the information on the pregnancy evaluation form. Each couple that achieved a pregnancy was asked to confirm the pregnancy with a pregnancy test kit (i.e., the ClearBlue Easy One Minute Pregnancy Test) and self-evaluate the reason for the pregnancy with the online pregnancy evaluation form. Each couple participant was asked to record their intention of either achieving or avoiding pregnancy and their level of motivation for avoiding a pregnancy, i.e., how hard they were trying to avoid pregnancy and how much they wanted to avoid it on a scale of 1-10. A determination was made if intercourse occurred during the fertile time as designated by the monitor and/or mucus fertility algorithms. Each pregnancy was classified according to classifications recommended by Lamprecht and Trussell [20]. Pregnancies were classified as intentional only when they (the couple) indicated that they were using the given method to achieve pregnancy. Pregnancies were classified as *perfect use* when the couple participant followed the instructions of the method and did not have intercourse during the estimated fertile

phase as determine by the algorithm of the given method. Pregnancies were classified as *user failure* when couples had intercourse during the estimated fertile phase (as determined by the given method) and/or they did not follow the instructions of the method. *Perfect use* (also known as *method use*) pregnancy rates were calculated using only perfect use menstrual cycles. *Total pregnancy* rates were determined by using both *perfect use* and *user failure* pregnancies and all menstrual cycles in the denominator of the equation.

Acceptability and ease of use of the online FABM web site and fertility monitoring system was measured by asking the woman participant and her male partner at 1, 3, and 6 months of use to respond to a 10-item questionnaire on whether the online web site was acceptable, easy to use, non-invasive, convenient in-home test of fertility, and provides clear and objective results. The 10-item survey was a shortened form of an acceptability/ease of use questionnaire developed by Severy [21-23] for evaluating an EHFM. The 10 items are ranked on a scale from 1 to 7 and ranged in score from 10-70. This is the same tool that was used in the prospective efficacy study of the EHFM plus CMM [13].

Information from participants was entered into a computer data set (by research assistants) in order to be 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. To compare efficacy of the EHFM group with the CMM group, 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*

Of the 667 participants who enrolled in the online study, 89 were excluded from the study because they did not meet study criteria or they declined to participate (see Fig.1). Examples of not meeting criteria include breastfeeding and living outside of the United States. Five participants from the monitor group and 26 from the mucus group did not complete the initial quiz and therefore have been categorized as not having received the intervention of viewing the instructional video. 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, medical reasons such as endometriosis, polycystic ovarian syndrome, miscarriage, early menopause or surgery, in addition to personal reasons such as being too busy to chart and wanted to be assigned to the other group. 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.

### *3.2. Demographics*

The mean age, number of years married, number of living children, body mass index (BMI) and age of husband/partner were similar and there were no statistical differences between the two treatment groups (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). By intention of use, the total number of pregnancies for both groups was 32, with a 22.7 pregnancy rate for the monitor group and 28.2 for the mucus group per 100 users over 12 months of use. 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 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 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).

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 ($SD$ = 9.9) compared with 58.3 ($SD$ = 10.7) at the sixth month of use ($t(461) = 5.28$, $p < .0001$) effect size = 0.02.

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% at 12 months of use; for the mucus group, 66.4%, 50.6%, 45.1% and 36.6% at 12 months of use. There was no statistical difference in the continuation rates between the two methods at 12 months of use.

**4. Discussion**

The net correct use efficacy of both the EHFM and CMM group is very good, i.e., 98-100% survival rate (or a 0 – 2 pregnancy rate per 100 women over 12 months of use) and

compares with what is found in the literature [24,25]. As hypothesized, the monitor group has better 12 month total pregnancy rate than the mucus group, i.e., 7 unintended pregnancies per 100 women users among the monitor group versus 18 among the mucus group. The differences in pregnancy rates between the monitor and mucus group 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 as a double check for the beginning and end of the fertile phase of the menstrual cycle [24] and with a pilot cohort study of the online FABM system conducted by the authors of this study, i.e., 9 unintended pregnancies per 100 among ovulating, non-breastfeeding participants [14].

There are no studies to compare the efficacy of using the same EHFM (i.e., the CBFM) as was used in this current study to avoid pregnancy other than those conducted by the current researchers [12-16]. However, an earlier study reported the efficacy of a similar EHFM called the Persona fertility monitor [12,17,27]. Like the CBFM, the Persona monitor uses urinary E3G and LH as biological markers of fertility but instead of providing low, high, and peak fertility as feedback, it provides a green light (indicating infertility), a red light (indicating the fertile phase), and an orange light (indicating when testing begins). The Persona's method pregnancy rate was 12.1 per 100 users [27]. After adjusting the E3G algorithm to provide a longer warning of the LH surge the annual pregnancy rate theoretically dropped to 6. The authors of this study were criticized for using wrong methods in calculating pregnancy rates [28]. The Persona monitor is not approved for use in the US by the Food and Drug administration but is available in Europe and Canada. The CBFM is readily available in the US for use as an aid to monitor fertility for the purpose of achieving pregnancy. The pregnancy rates from the efficacy study of the Persona

[27] cannot be compared to the current study since we used different algorithms to estimate the fertile phase.

The total unintended pregnancy rates for the monitor group in the current study are better than those reported by Trussell for FABM [24,25], i.e., 7 for the monitor group compared to 25 per 100 women by Trussell. The mucus group with 18 unintended pregnancies per 100 is comparable but slightly better than what Trussell reports for the mucus-only OM. The reason for the better rates for the current CMM might because of the double check with the use of a calendar based type method 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.

Although 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. The increase in acceptability may be a result of the significant amount of participants dropping out of the study, i.e., those who felt it was not acceptable might have dropped out in the earlier phase of the study. There was a similar continuation rate among both groups of participants. The increase in acceptability and satisfaction over time (for couples avoiding pregnancy) is not unusual for those learning and using FABM. Researchers found similar results (i.e., increased satisfaction over time) with a cervical mucus-only method [29]. The acceptability rates found among the participants were similar to those in past studies that investigated the efficacy of the monitor plus mucus method of family planning [13,16]. So too, the drop-out rate of randomized comparison studies of FABM has a precedence in one of the few comparison studies of FABM in the United States [30]. This earlier randomized comparison study showed that a FABM combining basal body temperature monitoring with cervical mucus monitoring was more effective than a cervical mucus-only

method in helping couples avoid pregnancy. However, the study had a 74% drop-out rate with the mucus-only method and a 64% with the combined method. In comparison, the mucus group in the current study was 63.4% and for the monitor group 59.4%.

The biggest limitation of the present study is the loss of participants across the 12 months of participation. Of note, there were 125 participants who consented, were randomized and enrolled into the monitor group, were provided with a $200 monitor and then never provided any fertility charts. It is probable that there was a sizable group that just wanted the free monitor. The study protocol included monthly attempts to encourage participants to provide data and reinforcing that they would receive $10 per fertility chart completed. The most frequent reason for dropping out was "lost to follow-up," then "no longer interested," and "wishing to achieve pregnancy." A good portion of the participants who were randomized into the mucus group never participated; it is speculated that they were disappointed that they did not receive a free fertility monitor at the beginning of the study. Some of the participants only enrolled into the study to receive a monitor and use it to achieve a pregnancy.

A strength of this study was that participants were from all regions of the United States. However, a limitation was that the participants were rather homogeneous, in that most were white, middle class, educated couples. As such, the results of this study apply only to a similar group of educated and motivated participants. An attempt was made to have a greater percentage of Hispanics by having the web site in the Spanish language and having access to Spanish-speaking health professionals. As pointed out, there was no difference in the demographic characteristics between the two groups of participants.

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. A recommendation for future efficacy studies of FABM is to enroll only participants who are new to FABM. There is a tendency of current users of

established FABM to compare their previous methods and to use them instead of the study method. 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 [31,32]. Another recommendation is to determine if use of hormonal fertility charting enhances the ability to achieve pregnancy among sub-fertile women.

A big challenge is to reach women and couples who do not have the financial means to be connected to the Internet and an online FABM system. One way to help this might be to have online computer services available at convenient sites, like public libraries or health clinics. Another approach would be to have online charting available through cell phones and other hand-held devices. Such a system could be linked to a FABM web site. An inexpensive text-based app system for inexpensive cell phones would be an ideal way to reach economically poor women who do not have access to the Internet and couples who wish to use FABM for religious, cultural, health, or personal reasons.

## 5. Conclusion

The use of an online web-based fertility education, charting, and professional support system to teach FABM is very efficient and effective with correct use among highly motivated users. Results indicate that the use of FABM in an online charting system is a more effective method of FABM (when used to avoid pregnancy) than the 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 is a challenge.

## Acknowledgements

We thank Susana Crespo, BSN, RN, for her monitoring and consulting with the Spanish-speaking participants in this study. This study was funded by a grant from the Department of

Health and Human Services, Public Health Service (Office of Population Affairs) number FPRPA006034-02-01. This study was registered at ClinicalTrials.Gov with the ID number NCT00843336 and title "Comparison of Two Internet Supported Natural Family Planning Methods." The trial web-site is: http://nfpstudy.marquette.edu.

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