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Randomized Comparison of Two Internet-Supported Methods of Natural Family Planning

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Final Report: Randomized Comparison of Two Internet-Supported Methods of Natural Family Planning

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RANDOMIZED COMPARISON OF TWO INTERNET-SUPPORTED METHODS OF
NATURAL FAMILY PLANNING

FINAL REPORT
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Introduction

Studies consistently show that women want safe, effective, easy to use, and convenient methods of family planning (Arévalo,1997; Severy 2001). Although Natural Family Planning (NFP) methods are free of side effects, they are often ineffective and complex to learn and use (Grimes et al. 2005). Efforts have occurred over the past 10 years to simplify the teaching and use of NFP methods and increase their efficacy. These efforts include the development of low tech calendar-based methods (Arévalo et al. 2004), simplifying instructions (Frank-Herrmann et al. 2005), and developing accurate biological markers of fertility (Guida et al. 1999).

A new high-tech electronic method to monitor fertility has recently been developed to help women determine their fertile window with ease, convenience, and accuracy (May 2001). This high-tech electronic hormonal fertility monitor (EHFM), called the ClearBlue Easy Fertility Monitor (Swiss Precision Diagnostics), measures urinary metabolites of estrogen and LH and provides the user with a daily indication of "low," "high" and "peak" fertility. A recent cohort study demonstrated that EHFM was effective when used as an aid to avoid pregnancy along with cervical mucus monitoring (CMM) as a second marker of fertility (Fehring, et al., 2007) and

users reported high satisfaction with the method (Severy et al. 2006). Despite this promising

research, there is one task that has not yet been accomplished. There are no randomized

comparison studies of EHFM NFP methods with NFP methods that utilize traditional biological

markers of fertility (i.e., the Ovulation Method with cervical mucus monitoring and/or the

symptom-thermal method with basal body temperature and cervical mucus monitoring

combined).

Other recent efforts to increase the ease of use and convenience of NFP methods are the

use of internet support for NFP instructions and automated online fertility charting (Fehring

2004; Fehring 2005; Weschler 2005). Although there have been studies to determine the

knowledge base of an online hormonal contraceptive program, there have been only one pilot

study to determine the efficacy of internet-based instructions for NFP methods used to avoid

pregnancy (Kaskowitz et al. 2007; Fehring et al., 2011) and to determine the efficacy and

satisfaction of using an online fertility charting system for NFP purposes (Fehring, et al., 2011).

Conceptual Model of Couple Motivation

A key component in the use of NFP or any type of behavioral focused method of family

planning is the motivation of both partners in the use of the method to avoid pregnancy (Sinai et

al. 2006). If only one of the partners is committed to the method it will be difficult to use and the

efficacy will most likely be lower. In the family planning and, in particular, the NFP

community, mutual motivation has been recognized as essential for NFP efficacy (Barnett 1996;

Miller, Severy and Pasta 2004; Speitzer 2006). There are, however, no recent studies

investigating this aspect of the use of NFP methods.

A classic study on the efficacy of NFP methods defined motivation by whether the couple

had limited their family size or are currently delaying pregnancy (Rice, Lanctót, & Garcia-

Devesa, 1981). The limiters had a pregnancy rate of 4.5% and the delayers 15%. There are no

studies that have directly investigated motivation on unintended pregnancy outcomes with

couples using NFP methods and in particular the motivation of the man and woman.

For this study the Model of Mutual Fertility Motivation (MMFM) was used as the

conceptual psychological base for this study (Miller, Severy, & Pasta, 2004). The MMFM

combines the individual level of fertility motivation with the couple level of fertility motivation

and realize that these differ and change over time. Furthermore, this model takes into

consideration the incremental behaviors that are designed to promote or prevent childbirth. This

model also stipulates that motivation entails communication, influence, and disagreement on

fertility desires between partners and that these dynamics will influence motivation to use or not

use a method of family planning. Little research has been conducted with NFP methods to

determine the effect of mutual partner motivation on NFP efficacy.   When there is concurrence

in motivation and when there is high motivation to avoid pregnancy by both partners, then

behavioral methods of family planning, and in particular NFP will be more effective. Other

factors such as acceptability and ease of use, and efficacy of the method of NFP to avoid

pregnancy are important as well. See mapping of model in Figure 1.

Figure 1: Mutual Motivation Model of Family Planning (FP)

Mutual Motivation Fertility Model
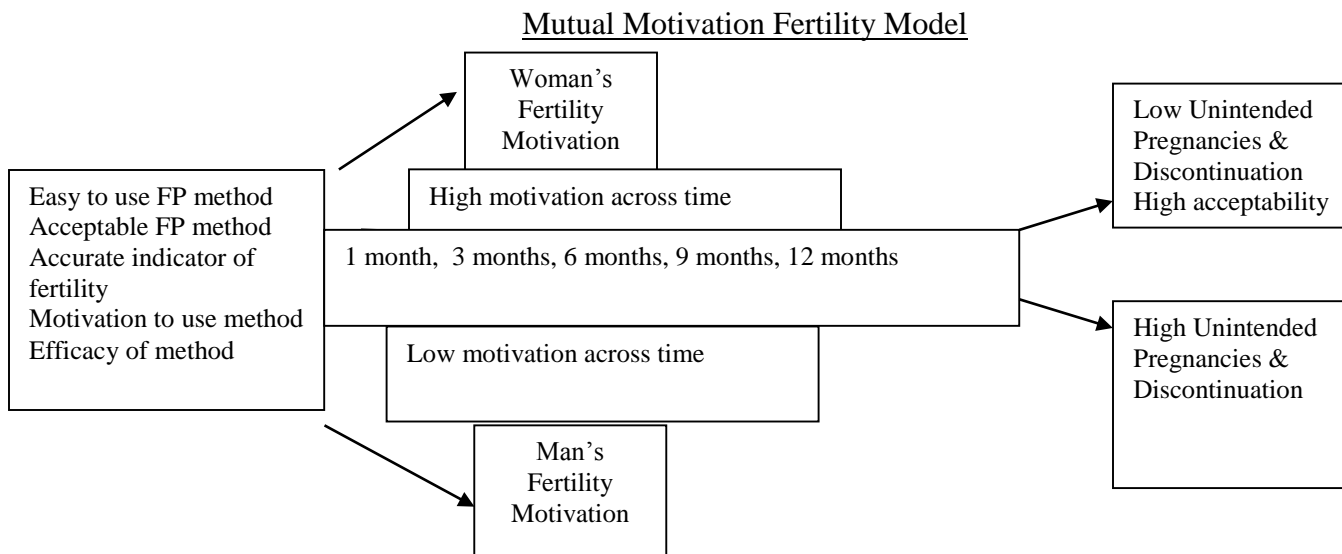
The Marquette Model of NFP

The method of NFP called the Marquette Model utilizes the ClearBlue Easy Fertility Monitor. Developed at Marquette University's Institute for NFP, this method was further simplified to be taught in a 12-minute office session. Called, the "Marquette Light Method," it makes use of either cervical mucus or an EHFM 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 EHFM, she rates her fertility as being low, high, or peak, and utilizes the same fertility calendar-based formula for a double check. This simplified method needed to be evaluated for its efficacy.

Researchers and NFP providers at Marquette University recently developed an online system to teach couples to use NFP. The NFP Web site (http://nfp.marquette.edu) has free information on NFP, downloadable charting systems, access to protocols for special circumstances (e.g., using NFP while breastfeeding), and instructions for achieving and avoiding pregnancy. A unique aspect of the information section of the Web site is a simple one-page feature, "Quick Start Instructions," that can be read in five minutes and allows the user to begin charting and using NFP.

Couples who register on the Web site are able to access an electronic charting system and discussion forums, and they can receive consultation from professional nurse NFP teachers and an obstetrician gynecologist with expertise in the use of NFP. 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. The Marquette online NFP system is presented in both the English and Spanish languages. Neither system has been studied for its efficacy and ease of use,

however. The efficacy of these systems will only be as good as the NFP method that they

provide.

Aims of Study

The specific aims of this study were as follows:

1. To determine and compare the efficacy in the use of two internet-supported methods of
    NFP (i.e., EHFM and CMM) in aiding couples to avoid pregnancy.

2. To determine and compare the satisfaction and ease of use in the use of two internet-
    supported methods of NFP (i.e., EHFM and CMM) in aiding couples to avoid pregnancy.

3. To determine and compare the mutual motivation in the use of two internet-supported
    methods of NFP (i.e., EHFM and CMM) in aiding couples to avoid pregnancy.

Methods

Research Design/Sample

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 NFP method.

Six hundred sixty-seven couples seeking to avoid pregnancy with a FABM were randomized into

either an EHFM (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 162 in the mucus group. [See Figure 1]

The menstrual cycles of participants who provided at least one complete cycle were included in

the analysis. 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. 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 partner 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.

Measures

Measurement of the fertile period by the Clearblue Fertility Monitor (CBFM)

The CBFM 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 (Unipath Diagnostics 2001). The CBFM detected the LH surge in 169 of 171 cycles from 88 women, in agreement with a quantitative radioimmunoassay for LH. Detection of urinary metabolites of urinary estradiol (E3G) has been recognized by the World Health Organization (WHO) as a reliable marker for the beginning of the fertile phase of the menstrual cycle. In a study with 90 women who used the CBFM for 1-4 cycles, in 352 cycles with an LH surge, the first day of High Fertility (i.e., the day of the first rise in E3G) was 3.01 ± 2.33 days before the LH surge (Behre et al. 2000).

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 3 seconds. The test strip is then placed in the monitor and read. The monitor will show a fertility status of "low," "high" or "peak." The user will be asked to record on the electronic NFP fertility chart her fertility status (low, high or peak) and any intercourse that occurred on a daily basis.

Measurement of the fertile period by cervical mucus monitoring (CMM)

For this study, cervical mucus was self-observed and classified at three levels—low, high, and peak. Observations are based on sensations and appearance of cervical mucus. When no mucus is observed or felt, or mucus that is slightly moist and sticky, minimal, thick, white, and holds its shape, will be classified as "low" fertile mucus. Mucus that feels wetter, increases in amount, becomes thinner, cloudy and slightly stretchy will be classified as "high" fertility mucus (this mucus can be considered transitional). Any mucus that feels slippery, is abundant, thin, clear, and stretchy (like egg white) will be classified as "peak" type mucus. The peak day is the last day of peak type mucus.

Women who are 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 feel for the sensation of cervical mucus (at the vulva) throughout the day and especially when voiding and before going to bed. They are also be asked to observe any mucus at eye level by lifting it off a tissue and testing it between their fingers. Written, oral, and visual descriptions (pictures) of the three levels of cervical mucus will be provided to the CMM users. These are standard procedures utilized in CMM NFP methods and utilized in the WHO multi-site, multi-country study of the OM (WHO 1981).

Measurement of acceptability/ease of use

Participants were asked to respond to a 10-item questionnaire on whether the online Web site was acceptable, easy to use, non-invasive, and a convenient in-home test of fertility, and whether it provides clear and objective results. The 10-item survey is a shortened form of an acceptability/ease of use questionnaire developed by Severy for evaluating an EHFM (Severy 2001). The 10 items are ranked on a scale from 1 to 7, with bipolar negative and positive

adjectives. This is the same tool that was used in the prospective efficacy study of the EHFM

plus CMM (Fehring et al. 2007).

Measurement of Motivation

Motivation was measured by the same system developed for the 2002 (cycle 6)

National Survey for Family Growth (Peterson and Mosher 1999). There are two questions asked

of participants (the woman and man): (1) how hard they are currently trying to not get pregnant

on a scale of 0–10 (with 0 means trying hard to get pregnant and 10 means trying hard to not get

pregnant); and (2) how much they want to avoid pregnancy at this time (with 0 means wanting to

get pregnant and 10 means wanting to avoid pregnancy). In order to be rated as a "High"

motivated couple they (i.e., the woman and her partner) need to have a score of 9 or better on the

two motivation questions. Both the woman user and her partner were asked to rate their

motivation levels before each menstrual cycle of use.

Marquette Online Charting System

The Marquette University NFP online electronic charting system 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 3 levels of cervical

mucus and the 3 levels provided by the fertility monitor. The charting system also has a place to

record menses on a scale of 1-3 with 1 = light; 2= moderate; and 3=heavy menstrual flow and a

row for recording acts of intercourse (= I). The top of the chart has room for recording intention

of use (to achieve or avoid pregnancy) for each cycle. The charting automatically indicates (in

light blue) the fertile phase (based on the Marquette algorithm) as the user charts. There is no

guessing as to whether the day is either fertile or not.

Classification of unintended pregnancy

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.

Two professional nurse NFP teachers evaluated all pregnancies that occurred among the

participants. The NFP teachers reviewed 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). Each pregnancy is classified (with agreement of

the couple) by two professional nurse NFP teachers according to the following classification as

recommended by Lamprecht and Trussell (1997): (1) pregnancies are classified as intentional

only when a couple reports prior to the pregnancy cycle an intention to use the method to

become pregnant; (2) all unintentional pregnancies are used in the analysis of pregnancy risk

during typical use; and (3) all unintentional pregnancies occurring during cycles in which NFP

rules were followed are used in the analysis of pregnancy risk during correct use.

Analysis of Evidence

The information from the online registration form, the online acceptability/ease of use

survey, the online data charts, and the pregnancy evaluations were 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. In order to compare the efficacy

of the EHFM group with the CMM group in avoiding pregnancy, cumulative pregnancy rates

were calculated by survival analysis with two different censoring variables: perfect use and total

cycles. Cumulative *perfect use* and *total* unintended pregnancy rates were calculated at 3, 6, 9,

and 12 cycles of use. In each analysis, the 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.

Results

Demographics

The mean age, number of years married, number of living children, weight, height, and age

of husband/partner were similar and there were no statistical differences between the two

treatment groups (see Table 1 below). In both groups, the greatest percentages of participants

were Caucasian and Catholic.

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

	Monitor group (N=197)	Mucus group (N=160)
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.

Efficacy

The perfect use and total unintended pregnancy rates of the two study groups are based upon 1,126 cycles of correct use and 2,780 total cycles of use. The perfect use pregnancy rate per 100 women over 12 months of use in the EHFM group 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 below, the total pregnancy rate for the monitor group was 7, and 19 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).

Table 2

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

_____

	Monitor (N = 197)			*Mucus (N =160)*		
	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		

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

_____

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

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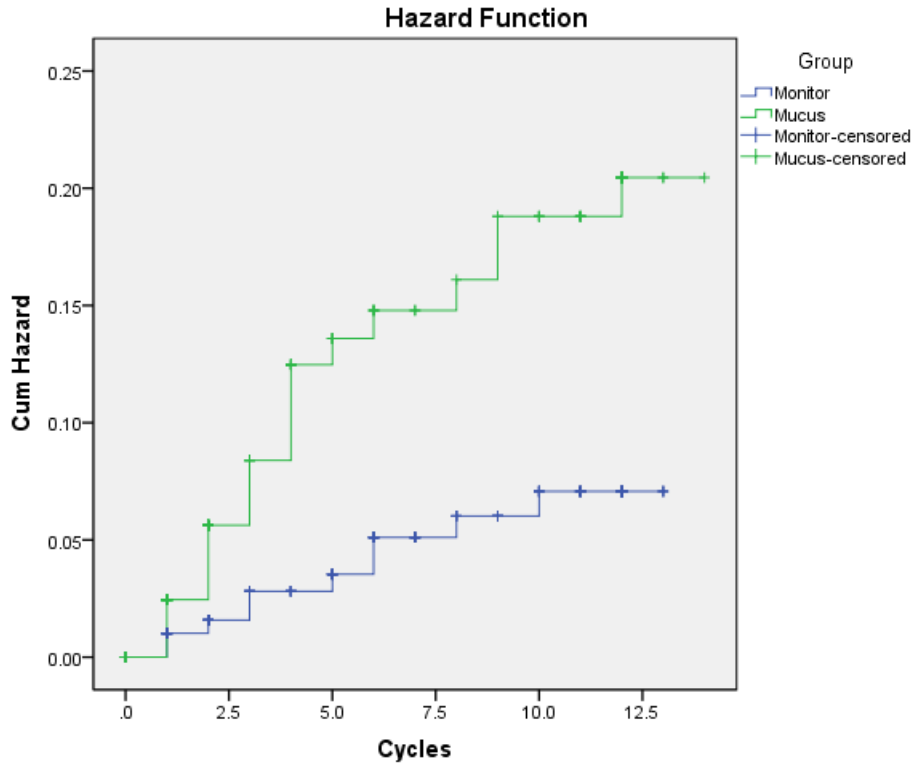
Comparison	Hazard ratio	95% CI	Test statistic	p-value
Monitor vs Mucus	0.338	(0.159, 0.718)	7.97	0.0048

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.

Motivation across time

In the repeated measures analysis, there was no significant difference in couple motivation between the EHFM and CMM groups. However, there was a significant change in motivation over time. In addition, the interaction between the two factors was significant, implying that the motivation scores have different rates of change in the two groups. Since the factors are significant, we investigate further using the Tukey post hoc test. We first consider the time variable. There was a significant difference between time 3 and time 12 as well as between time 6 and time 12.

For the interaction variable, we looked at the combinations of the two factors. We found that most of the difference came from the EHFM group. There is a significant difference in motivation for those in the EHFM group between time 3 and time 6 ($p = 0.0126$), time 3 and time 12 ($p < 0.001$), and time 6 and time 12 ($p < 0.001$).

Influence of Motivation

There were 28 pregnancies among the low motivation participants (N=60) and 16 among the high motivation participants (N=298). The 12 month pregnancy rate for the high motivation group was 8 per 100 women over 12 months of use and for the low motivation group 75 per 100

women over 12 months of use. The Hazard Function curves for the two groups are shown in

Figure 3 below. We found a significantly higher proportion of pregnancies among the low

motivation couples ($\chi 2 = 95.1$, $p < .001$) and 20 times a greater likelihood of an unintended

pregnancy with this group (OR = 20.3; 95% CI = 9.70-42.41).

Figure 3: Hazard Function Curve with 1.00 = High Motivation Group and 2.00 = Low Motivation Group
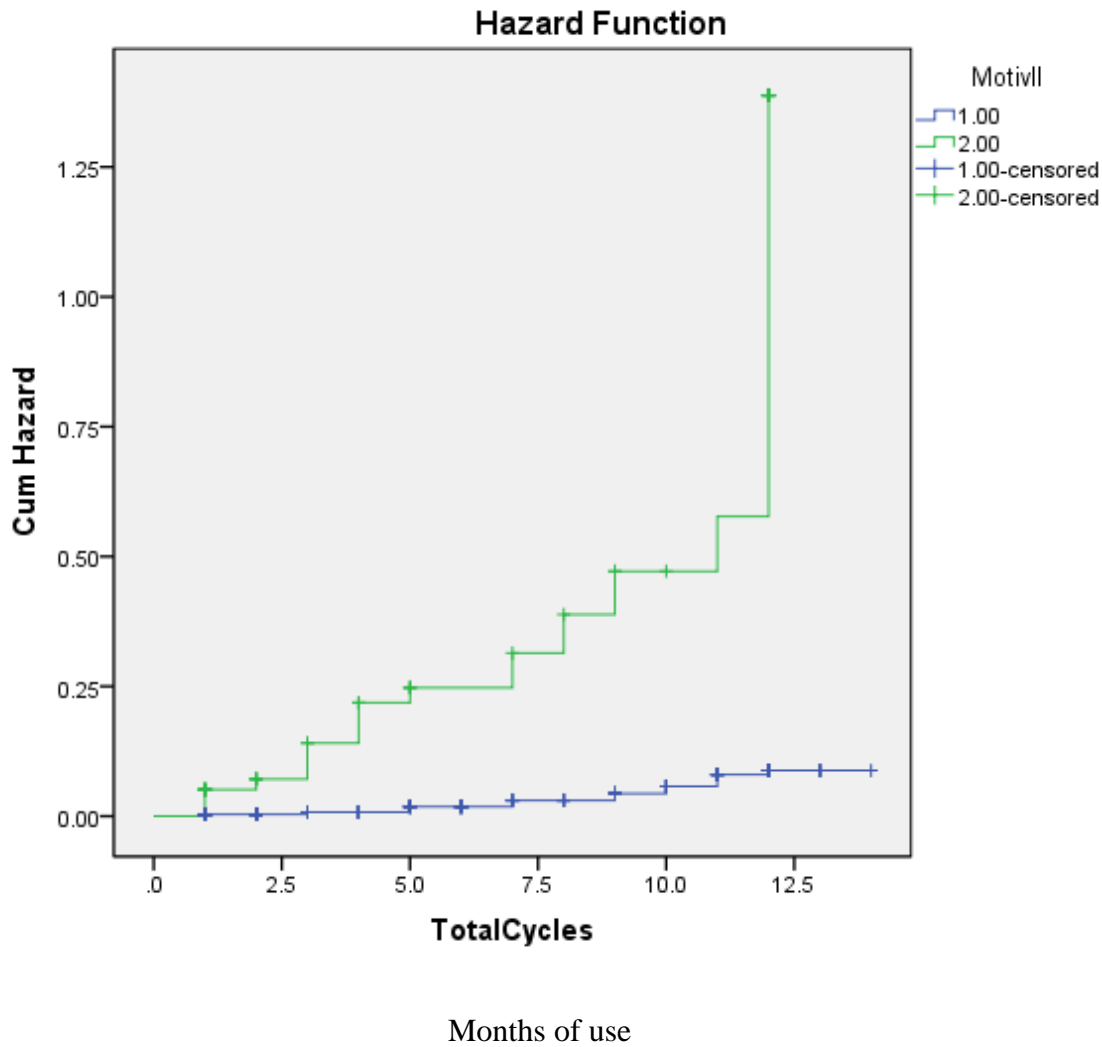
Months of use

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.

Discussion

Efficacy of Methods

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 (Trussell 2004; Trussell 2010). As hypothesized, the monitor group has better total pregnancy rates than the mucus group, i.e., a 7% unintended pregnancy rate 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 methods of NFP (Fehring, et al, 2009). 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 (Frank-Herrmann et al. 2007) and with a pilot cohort study of the online FABM conducted by the authors of this study, i.e., a 9% pregnancy rate among ovulating, non-breastfeeding participants (Fehring, et al., 2011).

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. However, an earlier study reported the efficacy of a similar EHFM called the

Persona fertility monitor (Bonner, Flynn, and Freundl, et al. 1999).   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 (infertility) and red light (fertility)

system. The Persona's method pregnancy rate was a disappointing 12.1% (Trussell, 1999).

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 (Trussell, 1999). 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. The

pregnancy rates from the efficacy study of the Persona (Bonner, Flynn, and Freundl, et al. 1999)

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 NFP methods (2011), 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.

Acceptability/Ease of Use and Continuation

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 NFP methods. Researchers found similar results (i.e., increased satisfaction over time) with a cervical mucus-only method (Fehring & Werner, 1993). 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 [Fehring, et al, 2007; Fehring et al., 2011]. So too, the drop-out rate of randomized comparison studies of NFP methods has a precedence in one of the few comparison studies of NFP in the United States (Wade, McCarthy, and Braunstein et al., 1981). This earlier randomized comparison study showed a FABM that combined 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%.

Motivation

Our study provides evidence that high motivation to avoid pregnancy is necessary by both partners in a relationship when using NFP methods to avoid pregnancy. We found that the likelihood for an unintended pregnancy was almost double for the low motivation group. There

are no NFP studies that provided evidence for a direct measure of motivation, however, the Rice,

Lanctót, and Garcia-Devesa (1981) study showed a difference of pregnancy rates between

couples who have completed their family size (4.5 pregnancies per 100 over 12 months) versus

those who were spacing children (14.5 unintended pregnancies). Our study had a greater

contrast in pregnancy rates between high motivation (i.e., 8 unintended pregnancies per 100)

versus 75 per 100 over 12 months of use for the low motivation group. The strength of our study

was that we measured motivation for each menstrual cycle in the analysis.

Our results also support the mutual motivation model, in that there is often a cycle to

cycle change in motivation with a significant decrease over 12 months of use. We also show that

once motivation decreases, the likelihood of an unintended and intended pregnancy increases.

Severy, Robinson, Findley-Klein, and McNulty (2006) found that there is an increase in

satisfaction in use of the fertility monitor in avoiding pregnancy over time and with the use of the

monitor to achieve a pregnancy. We did not find any influence of ease of use and acceptability

of the method to avoid pregnancy in our earlier comparison study (Fehring, et al, 2012).

However, we did find that motivation has to be very high (i.e., 9-10 out of 0-10) for acceptable

efficacy.

Of interest, is that the participants in the CMM group have greater motivation (at 3 and 6

months of use) to avoid pregnancy than the EHFM group. This is likely due to the number of

participants who enter the study intending to receive a free fertility monitor who are assigned to

the EHFM group, and then use the monitor to achieve a pregnancy, i.e., they intended all along to

achieve a pregnancy. The participants in the CMM group have more at stake in avoiding a

pregnancy and have to work hard to receive a free monitor at the end of the study. This is the

first study that has prospectively measured mutual motivation in the use of NFP methods. In a

previous study on the use of an EHFM to achieve pregnancy some of the participants had a

tendency to use the monitor to avoid pregnancy (Janssen & Lunsen, 2000).

Limitations

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.

Limitations of this study also could contribute to the results on motivation. Although the

participants were from all geographic areas of the country the participants were rather

homogenous in being middle class educated Caucasian Catholic couples. Finding similar results

might be actually more attenuated with more diverse participants that are financially poorer, and

with less stable relationships. Another limitation is the discontinuation and loss to follow-up

with the methods. However, if there is loss to use of the method due to satisfaction, we assume

that the motivation in use would decrease. We also had a large number of couples who signed

up for the study wishing to receive the fertility monitor for use in achieving pregnancy.

Although the participants consented to avoid pregnancy for one year, that was not the case. We

had over 100 participants who were provided monitors and did not provide any cycle

information. This loss of participants could have affected our power to detect differences, which

might explain why we did not find a greater difference in motivation between the monitor and

mucus groups across time.

Implications

Practice Implications

Based on our results and experience, we have a number of practice implications. First,

the online provision of NFP methods for both the simplified mucus method and the use of the

hormonal fertility monitor are effective and efficient. Overall there is a 100% method or correct

use efficacy and 93% typical efficacy with the use of the EHFM. Second, many women and

couples throughout the U.S. can be reached and taught how to use NFP through the Internet and

Internet-based online charting. Third, health professionals can efficiently provide health

consultation and information on women's health problems, menstrual cycle questions, and

related health topics through the Internet and Web- based forums. Such an online program

would be one way that Title X clinics could provide NFP and women's health services.

In regards to the influence of motivation on NFP efficacy we recommend that users and professional teachers of NFP methods (and other behavioral family planning methods) periodically assess motivation of both members of a couple in regards to their intention of use and level of motivation. A simple two question assessment of the woman and her partner could be used: 1) how much were they trying to avoid pregnancy and how hard were they trying to avoid pregnancy on a scale of 0-10, as we used in our study. When motivation decreases and they have a strong intention to avoid (or achieve) then a reminder to the couple (in-person or in an online format) or with a built in automatic monitoring system could be helpful to users when their motivation level decreases. This could be a part of the programming of fertility monitoring applications for smart phone type devices.

Policy Implications

The implication the findings have on policy is that Title X Family Planning clinics (and similar type clinics) could offer NFP services through the Internet in an efficient and effective manner by use of a NFP service and support program similar to that being studied with this federal grant. In fact, the NFP services could be offered in each of the Title X regions by having a NFP Web site Internet-based NFP service and support program. These sites could be managed by 2-3 professional nurses who are familiar with NFP. The other Title X clinics in each region could be linked into the sites or the clinics could help participate in the NFP services and support by enrolling women/couples and helping to follow those couples online. A similar model could be developed for diocesan NFP programs, i.e., each diocese could have its own Internet NFP service or support system or be linked to such service sites in larger diocesan or archdiocesan programs.

Research Implications

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 NFP. The challenge is maintaining participation. A recommendation for future efficacy studies of NFP is to enroll only participants who are new to NFP methods. There is a tendency of current users of established NFP methods 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 FABMs such as the Standard Days Method or the Two Day Method, or even the older calendar-based formulas [Arévalo, Jennings, Nikula, and Sinai, 2004].   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 system of FABM.   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. Another approach would be to have online charting available through cell phones and other hand held devices. We are now investigating developing such a system that could be linked to our NFP Web site.

Conclusions

The use of an online web-based fertility education, charting, and professional support system to teach a FABM is very efficient and effective with correct use. Results indicate that the

use of the EHFM 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.

As hypothesized and based on clinical evidence and conceptual thinking, we concluded that high motivation and in particular high mutual motivation is necessary for effective use of NFP to avoid pregnancy if couples wish to meet their stated intentions. Motivation also has to be very high for couples to behaviorally meet their family planning intentions. Strategies to assess and strengthen a couple's motivation to use NFP methods to avoid or achieve a pregnancy were provided.

Acknowledgement

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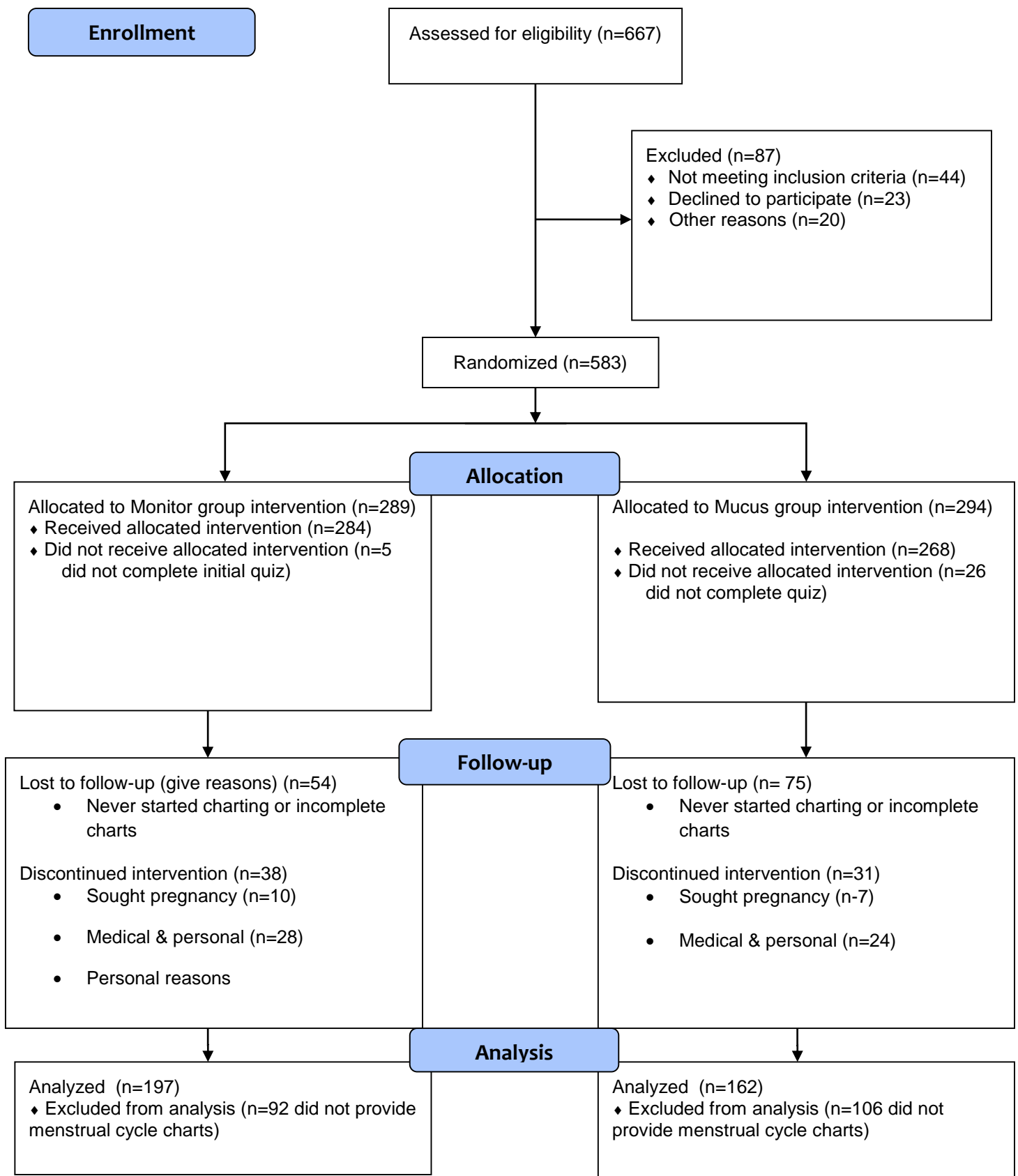
Figure 1. Participant enrollment and drop out flow diagram.