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Randomized Comparison of Two Internet-Supported Natural Family Planning Methods (Preliminary Findings)

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ABSTRACT

The aims of this study were to determine and compare efficacy, satisfaction, ease of use, and motivation in using an internet-based method of Natural Family Planning (NFP) that utilizes either electronic hormonal fertility monitoring (EHFM) or cervical-mucus monitoring (CMM). Four hundred fifty women (mean age 30.1) and their male partners (mean age 31.9) who sought to avoid pregnancy were randomized into either an EHFM (N=228) or CMM NFP group (N=222). Both groups utilized a Web site that provided NFP instructions, an electronic charting system, and support from professional nurses. Participants were assessed for satisfaction, ease of use, and motivation in use of their respective NFP method at 1, 3, and 6 months. Unintended pregnancies were validated by pregnancy evaluations and urine tests. Correct and total pregnancy rates were determined by survival analysis. Correct and total 12 month unintended pregnancy rates for the combined participants (N=450) were 1 and

9 per 100 couple users (Std. Error = .01 and .02) respectively. The EHFM participants (N=228), however, had a typical unintended pregnancy rate of 6 (Std. Error = .03) compared to the CMM group (N=222) pregnancy rate of 13 (Std. Error = .04) per 100 users over 12 months of use. The mean satisfaction/ease of use score for the EHFM group at 6 months of use was 46.1 compared to 42.9 for the CMM group ($p < .07$). Motivation to avoid pregnancy was stronger for the CMM group compared to the EHFM group at 3 and 6 months of use (37.9 and 38.8 versus 33.7 and 33.4, $p < .01$). Although both NFP methods were highly effective methods of family planning delivered through a nurse supported Web site, at this time, the unintended pregnancy rate was lower for the EHFM group and compared well with hormonal contraception. Although acceptability of the EHFM NFP was high, motivation to avoid pregnancy with that group decreased over time.

INTRODUCTION

Studies consistently show that women want safe, effective, easy to use, and convenient methods of family planning (Arévalo1997; 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 no studies to determine the efficacy of internet-based instructions for NFP methods used to avoid pregnancy (Kaskowitz et al. 2007). Nor have there been studies to determine the efficacy and satisfaction of using an online fertility charting system for NFP purposes.

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.

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 are 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

This is a 12-month (13 cycles) prospective randomized clinical efficacy study. A minimum of 600 couples seeking to avoid pregnancy with a method of NFP and who have no known infertility problems are being sought through an online NFP web site and randomized into either a EHFM group (N=300) or a CMM only group (N=300). Any pregnancies that occur among the participants over a 12-month period are recorded and evaluated as to whether they were intended, not intended user failure, not intended system failure, or unknown.

All couple participants (men and women) are assessed as to their perceived "satisfaction" and "ease of use" with an online measurement tool at 1, 3, and 6 months of use. Mutual motivation for avoiding pregnancy is assessed before each menstrual cycle.

Sample

In order to reach a significant level of analysis for a comparison of pregnancy rates between two groups, i.e., EHFM and CMM group, a minimum of 600 women/couple participants are being sought for completion of the study. In order to achieve 80% power to detect a 10% difference in pregnancy rates between each group there needs to be a minimum of 300 couples per group. This power analysis is based on a total unintended pregnancy rate of 10% for the EHFM group and a 20% pregnancy rate for the CMM group. These rates were projected from a retrospective study that compared the CMM only method with an EHFM method (Fehring et al. 2009).

Couples who seek the Marquette online NFP services and meet the criteria for the study have the opportunity to participate in the study. All couples receive a free EHFM but those in the CMM group receive the monitor only after completing 12 months of CMM. All couples receive $10 for each menstrual cycle chart completed.

The inclusion criteria for the female participant are as follows: must be between the age of 18 and 42; have a menstrual cycle range of 21-42 days; have not used depo medroxyprogesterone acetate (DMPA) over the past 6 months; have no history of oral, patch or sub-dermal hormonal contraceptives for the past 3 months; if post breast-feeding, have experienced at least 3 cycles past weaning; have no known fertility problems; not be using medications that interfere with ovulatory function; not smoke cigarettes; and not be pregnant. The male partners of the participants are to have no known fertility problem and be between the ages of 18 and 50.

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 is 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 are asked to observe for cervical mucus on a daily basis and to chart the highest level observed. They are 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 satisfaction and ease of use"

Participants are 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 is 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).

"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 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 evaluate all pregnancies that occur among the participants. The NFP teachers review the charting system for the days of fertility, the days of recorded intercourse, and the information on the pregnancy evaluation form. Each couple that achieves a pregnancy is 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.

"demographic information"

Each couple (male and female participant) who enters the study completes a 21-item demographic registration form developed by Gray and Kambic (1984). The registration form asks demographic information (e.g., ethnicity, religious status), number of children, cycle history, family planning history, and intention for using NFP. The registration form automatically pops up on the NFP Web site when the couple registers.

Analysis of Evidence

All statistical analysis was carried out using significance level alpha = 0.05. In order to determine the effectiveness of the EHFM plus a fertility algorithm in aiding couples to avoid pregnancy and the CMM plus a fertility algorithm in avoiding pregnancy, cumulative pregnancy rates were calculated by (Life Table) survival analysis utilizing a 95%

confidence interval and were calculated at 3, 6, 9, and 12 months/13 cycles of use. Differences between the EHFM and the CMM group mean scores of the satisfaction/ease of use, and motivation was analyzed using independent student T-tests.

PRELIMINARY RESULTS

Although it is still rather early to start to analyze the data to meet the three aims of this study, the following are some early results.

Demographics

Table One shows a comparison of the demographics between the female participants in the monitor and mucus groups. As can been seen in the table, the mean age, number of years married, number of living children, weight, height, and age of husband/partner are similar and there are no statistical differences. In both groups the greatest percentage of participants are White and Catholic.

Table One: Comparison of Demographics between the Monitor and Mucus group*

	Monitor group (N=228)	Mucus Group (N=222)
Mean age female	29.9 (SD=5.4)	30.3 (SD=5.3)
Mean age male	31.8 (SD=6.1)	32.1 (SD=6.1)
Mean Years Married	6.0 (SD=4.9)	6.3 (SD=5.1)
Mean # Living Children	2.1 (SD=2.0)	2.1 (SD=1.8)
Mean Weight Female	150.2 (SD=32.6)	153.6 (SD=34.7)
Mean Height Female	65.2 (SD=2.7)	65.2 (SD=2.5)
% Ethnicity Female	77% White/23% Other	84% White/20% Other
% Religion Female	81% Cath./14% Prot.	78% Cath./17% Prot.

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

Aim One: To determine and compare the efficacy in the use of two internet-supported methods of NFP (i.e., electronic hormonal fertility monitoring (EHFM) and traditional cervical mucus monitoring (CMM)) in aiding couples to avoid pregnancy.

Table Two:
Correct Use Gross and Net Pregnancy Rates: i.e., survival rates by groups per 100 women over 12 cycles of use.

Gross Correct Use Pregnancy Survival Rate

		Monitor (N = 227)			*Mucus (N = 219)*	
Months		reg.	Estimate	Std. Error	Preg. Estimate	Std. Error
3	1	.989	.001	1	.988	.012
6	0	.989	.001	0	.988	.012
9	0	.989	.001	0	.988	.012
12	0	.989	.001	0	.988	.012

Net Correct Use Pregnancy Survival Rate

	Monitor (N = 227)			*Mucus (N = 219)*	
Months	Preg.	Estimate	Std. Error	Preg.	Estimate	Std. Error
3	0	1.00	.000	1	.988	.012
6	0	1.00	.000	0	.988	.012
9	0	1.00	.000	0	.988	.012
12	0	1.00	.000	0	.988	.012

Tables Two and Three show correct and typical use gross and net unintended pregnancy rates of the two study groups, i.e., the EHFM (monitor) and CMM (mucus) groups. The rates are based upon 1,544 cycle of use. The *gross pregnancy rate* includes all pregnancies whether it was intended or not intended. The *net pregnancy rate* is based on pregnancies that occurred when couples indicated that they intended not to achieve a pregnancy.

As shown in Table Two, the gross pregnancy rate per 100 women over 12 months of use in both the monitor and mucus groups is 1; however, as shown in Table Two, the net correct use unintended pregnancy rate for the monitor group is just slightly lower than the mucus group, i.e., 0 for the monitor group and 1 for the mucus group.

Table Three shows that the gross typical use pregnancy rates for the monitor group (i.e., .25) is lower for the monitor group i.e., 25 versus 16 pregnancies per 100 women over 12 months of use; however, Table Three shows there is a remarkable shift in difference in net unintended pregnancy rates between the two groups, with the monitor group having an unintended pregnancy rate of 6 and the mucus group 13 per 100 women over 12 months of use.

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

Table Three:
Typical Use Gross and Net Pregnancy Rates: i.e., survival rates by groups per 100 women over 12 cycles of use.

Gross Correct Use Pregnancy Survival Rate

		Monitor (N = 227)			*Mucus (N = 219)*	
Months		reg. Estimate	Std. Error	Preg. Estimate		Std. Error
3	6	.9439	.021	5	.952	.026
6	4	.900	.029	3	.899	.036
9	6	.812	.043	0	.899	.036
12	3	.752	.052	2	.839	.053

Net Correct Use Pregnancy Survival Rate

	Monitor (N = 227)			*Mucus (N = 219)*		
Months	Preg. Estimate		Std. Error	Preg. Estimate		Std. Error
3	4	.968	.016	1	.955	.021
6	0	.968	.016	3	.902	.036
9	2	.939	.025	0	.902	.036
12	0	.939	.025	1	.873	.045

Ease of use and Satisfaction was measured with a 9 item questionnaire that ranked each item from 1 – 7 with 7 having better Ease of use/Satisfaction. The range of total scores is 9-63.

Table Four: Ease of Use/Satisfaction Mean Scores at 1, 3, and 6 months of use between Monitor and Mucus Groups

		Monitor		Mucus			
Months	*N*	*Mean/SD*	*N*	*Mean/SD.*	*t*	*Sig.*	
1	135	42.0/8.6	111	40.2/ 9.6	1.57		.12
3	96	43.6/9.5	66	41.3/11.0	1.42		.16
6	66	46.1/7.2	45	42.9/11.1	1.82		.07

Table Four shows that the mean "ease of use/satisfaction" scores increase from 1 to 3 months of use in both groups. The differences in the mean scores at 6 months of use almost reach statistical significance, with the monitor group having higher scores. That said, there is not enough statistical power at this time with the study.

Aim Three: 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

Table Five: Mean Motivation scores to avoid pregnancy at 1, 3, and 6 months between Monitor and Mucus Groups (female and male motivation scores combined)

		Monitor		Mucus		
Months	*N*	*Mean/SD*	*N*	*Mean/SD.*	*t*	*Sig.*
1	136	36.6/7.9	126	37.5/6.5	1.03	.31
3	101	33.7/11.9	72	37.9/4.3	2.83	.01
6	72	33.4/13.1	49	38.8/2.6	2.87	.01

As shown in Table Five, mutual motivation to avoid pregnancy decreases over time for the monitor group and slightly increases for the mucus group. At three and six months of use the mucus group has statistically higher mean motivation scores.

DISCUSSION

Efficacy of Methods

The correct use efficacy of both the monitor and mucus group is very good, i.e., 98-100% survival rate (or a 0 – 2 unintended pregnancy rate per 100 women over 12 months of use) and compares with what is found in the literature (Trussell 2004). As predicted (hypothesized), the monitor group has better typical use (NET) unintended pregnancy rates than the mucus group, i.e., 94% survival among the monitor group versus 87% among the mucus group. There is not, however, enough power yet to conduct a non-parametric comparison statistic. The differences in pregnancy rates between the monitor and mucus group is 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 correct and typical) 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).

Satisfaction/Ease of Use

There seems to be greater satisfaction and ease of use among the monitor group, especially as participants progress through the study. At 6 months of use, the mean difference between the groups almost reaches significance; however, there is not enough statistical power at this time

to determine differences, especially because of the low response rates. The greater satisfaction might be a result of the mucus group participants dropping out (i.e., the least satisfied) and not entirely due to the use of the monitor. The increase in satisfaction over time (for couples avoiding pregnancy) is not unusual for those learning and using NFP methods. Fehring and Werner (1994) found similar results (i.e., increased satisfaction over time) with a cervical mucus only method.

Motivation

Of interest, is that the participants in the mucus group have greater motivation (at 3 and 6 months of use) to avoid pregnancy than the monitor 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 monitor group, and then use the monitor to achieve a pregnancy, i.e., they intended all along to achieve a pregnancy. The participants in the mucus 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 electronic hormonal fertility monitor to achieve pregnancy some of the participants had a tendency to use the monitor to avoid pregnancy (Janssen and Lunsen 2000).

Practice Implications

Although this study is not completed (and will not be completed for over a year) three tentative practice implications can be identified. 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 99% method efficacy and 95% typical efficacy with the combined results of both methods. 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.

Policy Implications

The implication the findings have on policy (so far) 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

We are just beginning to consider research implications from the preliminary findings of our study. Some speculative implications are as follows: (1) the use of an online system to enroll, randomize, survey, and maintain participants is possible and an efficient way to conduct efficacy research for NFP methods; (2) future online efficacy studies of NFP methods should consider enrolling only participants who are new to NFP—the current users of other methods of NFP have a tendency to compare their previous methods and to use them instead of the study method; (3) we would not recommend allowing participants to do retrospective charting and to make that expectation clear in the beginning of the study; (4) we would recommend use of an online system to compare other standardized methods of NFP (such as the Standard Days Method or the Two Day Method); and (5) we would recommend use of a similar online fertility awareness and educational system to determine if use of hormonal fertility charting enhances the ability to achieve pregnancy among sub-fertile women. We already have developed a proposal for such a study, i.e., to compare electronic hormonal fertility monitoring versus random acts of intercourse in helping women with sub-fertility achieve pregnancy. This proposal has been submitted to the National Institute of Nursing Research.

One problem with online systems of NFP and research is the ability to reach women/couples who do not have online access and are unable to afford such services. 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. We are now investigating developing such a system that could be linked to our NFP Web site.

Conclusion

Our preliminary conclusion is that the use of an online Web-based fertility education, charting, and support system to teach a method of NFP is very effective. The overall unintended pregnancy rates of the combined methods are very low. Preliminary results indicate that the use of the EHFM in an online charting system is a more effective method of NFP (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 EHFM for tracking fertility and for use in family planning. Motivation to avoid, however, was stronger among those using CMM to avoid pregnancy.

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SOURCES CONSULTED

Arévalo, M. 1997. "Expanding the availability and improving delivery of natural family planning services and fertility awareness education: providers' perspectives." *Advances in Contraception* 13:275-281.

Arévalo, M., V. Jennings, M. Nikula, I. Sinai. 2004. "Efficacy of the new TwoDay Method of family planning." *Fertility and Sterility* 82:885-892.

Barnett, B. 1996. "NFP offers user-control, but requires discipline." *Contraceptive Update Network* 17:17-20.

Fehring, R. 2004. "The future of professional education in natural family planning." *Journal of Obstetrics Gynecological and Neonatal Nursing* 33:34-43.

_____. 2005. "New low and high tech calendar methods of family planning." *Journal of Nurse Midwifery and Women's Health* 50:31-37.

Fehring, R., C. Werner. 1993. "Natural family planning and Catholic hospitals: A national survey." *Linacre Quarterly* 60:29-34.

Fehring, R. J., M. Schneider, K. Raviele, M. I. Barron. 2007. "Efficacy of cervical mucus observations plus electronic hormonal fertility monitoring as a method of natural family planning." *Journal of Obstetric Gynecologic and Neonatal Nursing* 36:152-60.

_____. 2009. "Cohort comparison of two fertility awareness methods of family planning." *Journal of Reproductive Medicine* 54:165-170.

Frank-Herrmann, P., C. Gnoth, S. Baure, T. Strowitski, G. Freundl. 2005. "Determination of the fertile window: reproductive competence of women: European cycle databases." *Gynecology and Endocrinology* 20:305-312.

Frank-Herrmann, P., J. Heil, C. Gnoth, E. Toledo, S. Baur, C. Pyper, E. Jenetzky, T. Strowitzki, G. Fruendl. 2007. "The effectiveness of a fertility awareness based method to avoid pregnancy in relation to a couple's sexual behavior during the fertile time: a prospective longitudinal study." *Human Reproduction* 22:1310-1319.

Grimes, D. A., M. F. Gallo, V. Grigorieva, K. Nanda, K. F. Schulz. 2005. "Fertility awareness-based methods for contraception: systematic review of randomized controlled trials." *Contraception* 72:85-90.

Gray, R. H., R. Kambic. 1984. "Program evaluation and accountability." In Lanctot, C. Ed. *Natural Family Planning. Development of National Programs.* Washington, DC: International Federation for Family Life Promotion.

Guida, M., G. A.Tommaselli, S. Palomba, M. Pellicano, G. Moccia, C. DiCarlo, C. Nappi. 1999. "Efficacy of methods for determining ovulation in a natural family planning program." *Fertility and Sterility* 72:900-904.

Janssen, C. J. M., R. H. W. van Lunsen. 2000. "Profile and opinions of the female Persona user in The Netherlands." *The European Journal of Contraception and Reproductive Health Care* 5:141-146.

Kaskowitz, A. P., N. Carlson, M. Nichols, A. Edelman, J. Jensen. 2007. "Online availability of hormonal contraceptives without a health care examination: effect of knowledge and health care screening." *Contraception* 76:273-277.

Lamprecht, V., J. Trussell. 1997. "Effectiveness studies on natural methods of natural family planning." *Advances in Contraception* 13:155-165.

May, K. 2001. "Home monitoring with the ClearPlan Easy Fertility Monitor for fertility awareness." *The Journal of International Medical Research* 29 (Suppl 1):14A-20A.

Miller, W. B., L. J. Severy, D. J. Pasta. 2004. "A framework for modeling fertility motivation in couples." *Population Studies* 58:193-205.

Peterson, L. S., W. D. Mosher. 1999. "Options for measuring unintended pregnancy in cycle 6 of the National Survey of Family Growth." *Family Planning Perspectives* 31:252-253.

Severy, L. J., J. Robison, C. Findley-Klein, J. McNulty. 2006. "Acceptability of a home monitor used to aid in conception: Psychological factors and couple dynamics." *Contraception* 73:65–71.

Sinai, I., R. Lundgren, M. Arévalo, V. Jennings. 2006. "Fertility awareness-based methods of family planning: predictors of correct use." *International Family Planning Perspectives* 32:94-100.

Speizer, I. 2006. "Using strength of fertility motivation to identify family planning program strategies." *International Family Planning Perspectives* 32:185-191.

Trussell, J. 2004. "Contraceptive failure in the United States." *Contraception* 70:89-96.

UniPath Diagnostics. 2001. *Professional Information: ClearPlan Easy Fertilty Monitor.* Princeton, New Jersey: UniPath, P. C.

Weschler, T. 2005. *Taking Charge of Your Fertility*. New York, NY: Harper Collins.

World Health Organization. 1981. "A prospective multicentre trial of t h e ovulation method of natural family planning. II. The effectiveness phase." *Fertility and Sterility* 36:591-598.