11-1-2013

Executive Summary: Randomized Comparison of Two Internet-Supported Methods of Natural Family Planning

Richard J. Fehring
Marquette University, richard.fehring@marquette.edu

Mary Schneider
Marquette University, mary.schneider@marquette.edu

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

Final Report

11/1/2013

Richard J. Fehring, PhD, RN, FAAN
Professor Emeritus and Director
Institute for Natural Family Planning, College of Nursing, Marquette University

Mary Schneider, MSN, FNP-BC, NFPE, Assistant Director,
Institute for Natural Family Planning, College of Nursing, Marquette University

Introduction

Only 0.2% of US women use modern methods of natural family planning, i.e., the basal body temperature and the cervical mucus methods of natural family planning (NFP). The reason that such few women use NFP methods is because they are often ineffective, they are difficult to use, there is lack of access to properly trained NFP teachers, a lack of motivation to use a behavioral method, and health professionals are reluctant to prescribe NFP methods. One way to potentially increase the use of NFP methods is to provide easy access to an effective but simplified NFP method that uses a hand held electronic hormonal fertility monitor (EHFM), an internet based charting system, and online professional support. Mutual motivation is recognized as essential for effective behavioral methods of family planning. Few studies have studied this factor in family planning efficacy.

Specific Aims

The aims of this study were to determine and compare efficacy, acceptability/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).

Theoretical Conceptual Base

The Mutual Motivation Model contends that a key component of behavioral methods of family planning is the motivation of both partners. If only one or both partners are not committed to the method it will be inconsistently used and the efficacy will most likely be lower.

Methods

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. The participants had a mean age of 30.1 (*SD*=5.4), male partners (31.9; *SD*=6.1), and a mean of 1.9 living children (*SD*=1.9). Both groups utilized a Web site that provided NFP

instructions, an electronic charting system, and support from professional nurses. Participants were assessed for acceptability/ease of use of their respective NFP method at 1, 3, and 6 months. Unintended pregnancies were validated by pregnancy evaluations and urine tests.

All participants and (their male partners) indicated "how much" and "how hard" they wished to avoid pregnancy on a scale of 0-10 before each menstrual cycle charted over 12 month of use. This motivation scale is used in the National Survey of Family Growth as a measure of motivation. All pregnancies were verified with an online pregnancy evaluation and urine based pregnancy test. A combined motivation score was used in analysis.

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 final number of participants in the monitor group was 197 and 162 in the mucus group.

Results

Efficacy

Correct and total pregnancy rates were determined by survival analysis. Correct and total 12 month unintended pregnancy rates for the combined participants (N=359) were 1 and 9 per 100 couple users (Std. Error = .01 and .02) respectively. 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=164). The log rank survival test showed a significant difference ($p < .01$) in survival functions. Continuation rates at 12 months for the monitor group were 40.6% and the mucus group 36.6%.

Acceptability/Ease 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). . Mean acceptability for both groups increased significantly over time ($p < .0001$).

Motivation

There were 28 pregnancies among the low motivation participants (N=60) and 16 among the high motivation participants (N=298). At 12 months of use, there were 75 pregnancies per 100 users for the low motivation group and only 8 for the high motivation group. There was an 80% greater likelihood of a pregnancy with the low motivation group ($\chi2 = 25.5$, $p < .001$) OR = 1.80; 95% CI = 1.61-1.90). 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).

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.

Conclusions and Implications

Although both NFP methods were highly effective (and efficient) methods of family planning delivered through a nurse supported Web site with correct use, in comparison with the CMM, the EHFM method of family planning was more effective (with typical use) and users had an increase in acceptability over time. Results are tempered by the high drop-out rate.

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. Assessing motivation of both the woman and her male partner before prescribing NFP methods is recommended.

Future Plans

1. Analyze the differences in length of abstinence and coital frequency between the two online methods of NFP. This has been completed and a manuscript has been written and will be submitted to the *Journal of Midwifery and Women's Health*.
2. Analyze the probability of pregnancy with different (and less restrictive) algorithms based on the LH surge of the 2,000 plus menstrual cycles produced in this study and write a manuscript for publication.
3. Develop a fertility monitoring app for smart phone based on the EHFM method developed for this study – that is linked to an online web site. We already have developed the fertility monitoring app and now need to study the efficacy of such a system.