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## Current Medical Research: Summer/Fall 2016

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

Qiyang Mu  
*Marquette University*

***Nursing Faculty Research and Publications/College of Nursing***

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## Current Medical Research: Summer/Fall 2016

Richard J. Fehring

Marquette University College of Nursing

Qiyang Mu

Marquette University College of Nursing

### Natural Family Planning

New dynamic optimal timing (DOT) app now available for use in natural family planning

Many fertility applications (apps) have been developed for smart phones and other handheld electronic devices that are designed to help women monitor their menstrual cycle and for use in achieving and avoiding pregnancy. Most of the devices involve daily monitoring of natural indicators of fertility, i.e., cervical mucus changes, basal body temperature, cervical position, and luteinizing hormone (LH) surges in the urine. Most require daily monitoring and recording of these indicators and have some type of underlying calendar-based algorithm. Few of the apps have been tested for their accuracy or effectiveness to help women avoid or achieve pregnancy. A "simple to use" fertility monitoring app that does not require daily recordings, yet is accurate and effective for avoiding or achieving pregnancy, would be beneficial. There is an app from Georgetown University's Institute of Reproductive Health (IRH) using the Two Day method. This app provides a fixed-day calendar system (i.e., days 8 through 19 are considered fertile) and is only intended for women with menstrual cycle

lengths of 26 through 32 days in length. Due to this limit, IRH researchers set out to develop a simple fertility monitoring app called the Dynamic Optimal Timing (or DOT app) that only requires the woman to record the first day of her menses every menstrual cycle (Li et al. 2016). The app is based on day-specific probabilities of pregnancy and length of the menstrual cycle. The monitor “learns” the cycle lengths and provides the user with a daily percentage of the probability of pregnancy.

The DOT app was developed by use of three available data sets of menstrual cycles from three past studies, i.e., the North Carolina study ( $N = 68$  participants and 171 menstrual cycles of data), the Early Pregnancy Study ( $N = 221$  participants and 696 cycles of data), and the World Health Organization study of the ovulation method ( $N = 706$  participants and 8118 cycles of data). The North Carolina study and the Early Pregnancy Study was based on estimating the day of ovulation by ratios of daily measures of the metabolites of estrogen and progesterone, and the WHO study on cervical mucus changes and the peak day of fertile mucus. The development of the DOT app algorithm involved four steps. The first step was the use of linear regression to correlate the estimated day of ovulation with the length of the menstrual cycle. Step two involved calculating day-specific probabilities of fertility during the estimated fertile window based on previous research showing the following probabilities of pregnancy (0.04, 0.13, 0.08, 0.29, 0.27) during the biological six-day fertile window that includes the day of ovulation (the last day) and the five previous day. The two most fertile days are the two days before the day of ovulation. The probability outside these days = 0.01. The fourth step involved identifying what are called the “false days,” i.e., the days the users of the DOT app should avoid intercourse as they are high-risk pregnancy days. The researchers then estimated the theoretical unintended pregnancy rate using Bayesian analysis.

The researchers found a theoretical cumulative unintended pregnancy rate of 4.4% over 13 cycles of use with correct use among women with menstrual cycle lengths between 20 and 40 days and a range of cycle length differences less than or equal to 9 days. The researchers felt that a limitation of use with DOT would be the need to have a fairly regular menstrual cycle length, and rule out use with women who have polycystic ovarian syndrome, thyroid disorders, etc., or during excessive stress or exercise. They also pointed out that perfect use would not be expected when used by a large population of women.

## Comments

Other large portions of reproductive-age women that the DOT app would not work for due to irregularity in menstrual cycle lengths are postpartum breastfeeding women, peri-menopause women, early adolescents, and those women discontinuing hormonal contraception. A benefit or strength of this system of fertility monitoring is that it is easy to use and only requires entering the first day of the menstrual cycle. It remains to be seen how effectively this system will work with a large actual population of women. At this time a large prospective study is being conducted in the United States to determine the effectiveness of this DOT app in helping women avoid pregnancy. Catholic users should also be warned that the DOT app suggests that barrier methods be used during the fertile time if the user does not wish to be sexually abstinent. Clearly, this suggestion is not only problematic from a moral perspective but also from a methodological one as well.

## Source

Li, D., Heyer, L., Jennings, V. H., Smith, C. A., and Dunson, D. B. 2016. Personalised estimation of a women's most fertile days. *The European Journal of Contraception & Reproductive Health Care* 21 (4): 323–8. Google Scholar

Most available menstrual cycle tracking systems found to be inaccurate

According to the Pew Research Center, menstrual cycle tracking applications (apps) are the fourth most used health app among adults and the most frequent among adolescents. There are hundreds of menstrual cycle tracking apps available for smart phones but no guidelines as to how to judge their accuracy, quality, ease of use, security, and privacy. Recently a smart phone application scoring system was developed to grade the accuracy, features and functionality of smart phone apps. Health professionals, therefore, used this scoring system to review free menstrual cycle monitoring applications (Moglia et al. 2016). They hoped that this review would serve as a resource for health professionals on the features and functionality of smart phone fertility monitoring apps.

The Application Scoring System was modified for menstrual cycle tracking and included the following components and criteria:

Application comprehensiveness (which included ability to aid in conception, contraception or avoiding pregnancy, and fertility medications): 3 points

- Password protected: 1 point if protected
- Professional involvement: 1 point if present
- Literature cited: 1 point for at least one cited reference
- In-app purchases: 1 point for absent
- Connectivity: 1 point for internet connectivity not required
- Advertisement: 1 point for not present
- Technical support: 1 point if available
- Inter-platform availability: 1 point for Android version

Other features (such as track symptoms, alert for next menses, alert for fertility, track intercourse, Spanish language, social media, medical disclaimer, health education, data backup, custom reminder, etc.) 0 = 0–4 features; 1 point for 5–9 features, and 2 for 10 or more features)

Navigation ease: 1 point for navigation ease score of 3 or higher

Subjective presentation: 1 point for a subjective presentation score of 3 or higher

The highest total score possible = 15.

The fertility app evaluators were able to find 225 menstrual cycle tracking apps through an online search in the iTunes Apple app store, of these 177 were paid apps or apps requiring a subscription and 108 were free apps. Of the 108 free apps, the evaluators deemed only 20 to be accurate. Accuracy was defined as having the ability to enter three full previous menstrual cycle lengths of data. The thinking is that that is a minimum number of menstrual cycles needed in order to predict the next menstrual cycle length and relative fertile phase for use in natural family planning (NFP). The reviewers of the apps were the three physicians and two nurse practitioner authors of this review.

The reviewers found that only one app reported professional involvement and only one cited evidence-based literature. They also found that 19% of the apps contained erroneous medical information. The highest scored app missed points for not having the ability to track medical treatments and not indicating professional involvement. Most apps (80%) included information on conception, and 50% for avoiding pregnancy. Most (80%) did not require Internet connectivity, 55% were password protected, 65% had no advertisement, 70% provided technical support, 70% tracked menstrual flow, 70% tracked other body symptoms and 75% tracked intercourse, 65% provided alerts for next menses, and 55% provided daily fertility levels. A limitation of the study, as defined by the authors, was that they only included free apps. They did discuss a concern that use of the apps for pregnancy avoidance could result in unintended pregnancy. They expressed that these fertility monitoring apps could be good tools to help women track their menstrual cycle for health information and as a vital sign of health.

## Comments

It is commendable that the reviewers adapted an existing app scoring system and systematically reviewed free apps. I disagree with their definition of accuracy of the ability of the apps to track the menstrual cycle. Accuracy should be based on the natural indicators of fertility that they could enter, i.e., basal body temperature, cervical mucus changes, and urinary-based hormones such as LH. Most modern menstrual cycle tracking systems are prospective and do not rely on previous menstrual cycle lengths to accurately define the phases of the menstrual cycle. They do not require three menstrual cycles of charting to do so.

## Source

Moglia, M. L., Nguyen, H. V., Chyjek, K., Chen, K. T., and Castano, P. M. 2016. Evaluation of smartphone menstrual cycle tracking applications using an adapted applications scoring system. *Obstetrics & Gynecology* 127: 1153–60. Google Scholar

## Most fertility monitoring apps are not designed for avoiding pregnancy

Another group of clinicians and researchers also mentioned the prevalence of fertility monitoring apps and conducted an evaluation review (Duane et al. 2016). The evaluation for this study, however, only included fertility monitoring apps that were developed to help women and couples avoid pregnancy. These researchers also used criteria for evaluating medical apps and modified them for evaluating fertility monitoring apps for avoiding pregnancy.

The evaluation included ten criteria, four of which were indicated as “Very important” and were weighted times three, four “Important” criteria and weighted times two, and “Helpful” criteria weighted times one. Each criterion was rated on a scale from 1 to 5, with 5 being the highest rating. The very important criteria were Authority (i.e., based on established rules from existing NFP methods), Accuracy (based on evidence for avoiding pregnancy from an existing method of NFP), Accuracy (of observation of predicting fertile days), and Support (based on ways to have questions answered). The mid-level important criteria were Adaptability (in entering data and with irregular menstrual cycle lengths), Cost/pricing (included transparency in pricing), Ease of use (ease to learn and use the app), and Confidentiality (presence of a user agreement for confidentiality). The helpful criteria were the Developer/sponsor being associated with a recognized NFP or fertility awareness provider, and Platform available (i.e., availability on multiple platforms). The researchers also tested the apps by entering a standardized set of daily fertility indicators for seven cycles of daily fertility observation for each of the reviewed apps.

Ninety-five apps were identified through a search of Apple iTunes, Google, and Google Play; however, of these, 55 were not identified for use to avoid pregnancy or were not based on an existing, recognized, evidenced-based method of NFP. Of the 40 remaining apps, 30 were designed to predict days of fertility, and 10 did not. The authors ranked the remaining apps on the criteria of accuracy and authority and found only 6 apps had a perfect score for accuracy (in identifying the fertile days). The authors concluded that most fertility apps were not designed for avoiding pregnancy nor are they based on the authority of existing and evidenced-based methods of NFP. That said, fertility monitoring apps may have some value in helping women monitor their menstrual cycle as a vital sign for their reproductive health.

#### Comment

The authors noted that they based the authority on existing methods of NFP and those that have published evidence for avoiding pregnancy. Furthermore, they stated that these methods have correct use pregnancy rates similar to commonly used forms of hormonal birth control. However, typical use rather than correct use is what clinicians can expect for general use, and many of the common forms of NFP have high unintended pregnancy rates with typical use. Also, the authors play down the role of ease of use in using a fertility monitoring app. If the app is difficult to use, it will not be used for long and thus has a greater risk of entering false or missing data that could lead to unintended pregnancies.

#### Source

Duane, M., Contreras, A., Jensen, E. T., and White, A. 2016. The performance of fertility awareness-based method apps marketed to avoid pregnancy. *Journal of the American Board of Family Medicine* 29 (4): 508–11. Google Scholar

## Contraception

Increased use of contraceptives found to be prime proximal reason for decline in adolescent fertility in U.S.A. from 2007 to 2012

There has been a significant decrease (36%) in adolescent birth rates (i.e., among adolescents aged 15–19) and from the time period of 2007–2014, and more so from 2007 to 2011, i.e., 70 pregnancies per 1,000 women in 2007 to 52 pregnancies per 1,000 in 2011 and down to 24.2 per 1,000 in 2014. Reasons for these declines could be from distal factors such as the economy or politics but also proximally due to individual sexual behaviors, e.g., a decrease in sexual activity or increase in use of contraception. Recently researchers were more interested in determining the direct factors responsible for the decline in adolescent pregnancy rates due to sexual activity and contraceptive use (Lindberg et al. 2016). They therefore, sought to determine if adolescent sexual activity and contraceptive use influenced adolescent fertility risk in the United States from 2007 to 2013 by using data from the National Survey of Family Growth (NSFG).

The NSFG is a population-based survey of men and women between the ages of 15 and 44 years that is implemented every few years to assess sexual activity, contraceptive use, and related variables in the US. For this study the researchers used only women between the ages of 15 and 19 at the time of interview, with 1,085 participants from the 2007 survey, 1,199 from the 2009 survey, and 1,037 from the 2012 survey. The researchers then calculated what they called the pregnancy risk index (PRI) based on the frequency of intercourse in the past three months and the contraceptive failure rate from the type or types of contraceptive method used in the same time period. An adolescent that used no

method of contraception and was sexually active would receive a score of 85, i.e., based on known pregnancy rates over 12 months with unprotected random intercourse. Regression analysis was used to determine change over time during the three survey time periods, i.e., 2007, 2009, and 2012.

The researchers found that the frequency of sexual activity from the last three months did not change significantly from 2007 to 2012. However, there was a significant increase in the use of contraceptive methods (from 78 to 86%,  $p = 0.046$ ), multiple contraceptive methods (26 to 37%,  $p = 0.046$ ), and highly effective methods (38 to 51%,  $p = 0.01$ ). They also found that the PRI decreased at an annual rate of 5.6% ( $p = 0.071$ ) from the 2007 to the 2012 time period. The authors concluded that the major proximal factor for the decline in adolescent pregnancy rates was the use of and improvements in contraceptive methods. They recommended that sexual education programs for adolescents should be “comprehensive” and include information on contraceptive methods.

### Comments

Although the increased use of contraceptives and more effective contraceptive methods by adolescents was the most likely cause of a decrease in pregnancy rates from 2007 to 2012, one wonders if there are more distal factors, such as the economy (i.e., not enough jobs for youth) or lack of chastity in the media and entertainment fields, which are significant. The fact that comprehensive sexual education programs do not discourage sexual activity and promote use of contraceptives might be a reason for the lack of decline in sexual activity. The authors called the decrease in pregnancy rates a decline in fertility among adolescents. The true decline in fertility, however, might be a result of the high and increasing rate of sexually transmitted diseases (STDs) among adolescents and young adults. They did not look at the rates of STDs among adolescents in this same time period and the number of sexual partners. According to the Centers for Disease Control (2015), there was an increase in STDs from 2013 to 2014 in all four reported categories, i.e., a 2.8% increase in chlamydia, a 5.1% increase in gonorrhea, and a 15.1% increase in primary and secondary syphilis, among young people aged 15–24 years, and a 27.5% increase in congenital syphilis among live births. The approximately 1.4 million cases of chlamydia represented the highest number of cases ever reported to the CDC. The report also points out that many cases of STDs are not reported or diagnosed and that there are many types of STDs (e.g., herpes simplex virus and human papillomavirus) that are not required to be reported to the CDC. In fact the report admits that what is reported is only a fraction of the cases in the United States. Many of the adolescents and young people who are sexually active and using contraceptives are at risk for damaging their actual fertility and might impact their future plans of having children. Of interest is that there was a significant (but small) increase in the use of “Rhythm” from 2009 to 2012—an increase of 0–2%.

### Sources

Lindberg, L., Santelli, J., and Desai, S. 2016. Understanding the decline in adolescent fertility in the United States 2007–2012. *Journal of Adolescent Health* 59 (5): 577–83. Google Scholar

Centers for Disease Control (CDC) National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention. 2015. Reported STDs in the United States: 2014 national data for chlamydia, gonorrhea, and syphilis. CDC Fact Sheet. Google Scholar

Depression found to be associated with hormonal contraception use especially among adolescents

There have been few studies that have investigated the effect of low-dose hormonal contraception on the incidence of depression among reproductive-age women. Most of the studies are not prospective, and none have looked at the temporality of use of hormonal contraception and depression. Danish researchers conducted a large, population-based temporal study to assess the influence of specific types of hormonal contraceptives on the risk for first use of antidepressants and first diagnosis of depression in an inpatient or outpatient psychiatric setting (Skovlund et al. 2016).

The researchers used the Danish Sex Hormone Register Study that includes all women in Denmark. In their study they observed women aged 15–34 years at any time from January 1, 2000, to December 31, 2013, and in the previous 5-year period who had no prior depression diagnosis or other major psychiatric diagnosis nor redeemed a prescription for antidepressants. The study population was 1,061,997 women with a mean age of 24.4 years with a follow-up of 6.4 years and 6,832,938 person-years of observation during the study period. The two major outcome measures were first redeemed prescription of an antidepressant as recoded in the Danish National Prescription Register and first discharge diagnosis of depression from the Psychiatric Central Research Register which includes all inpatient and outpatient psychiatric departments in Denmark since 1995.

They discovered that compared to non-users of hormonal contraception, users of combined oral contraceptives had an RR of a first use of antidepressant of 1.23 (95% CI; 1.22 to 1.25). Users of progestogen-only, the patch (norgestrolmin), and vaginal ring (etonogestrel), and users of a levonorgestrel intrauterine system all had significant RR of a first use of antidepressants that was significantly higher than non-users (i.e., 1.34–2.0). For the outcome of depression diagnoses, they found similar or slightly lower estimates when compared to non-users of hormonal contraceptive methods. Analysis of adolescents (15–19 years old) showed higher RRs with first use of antidepressants and first diagnosis of depression. Compared to non-adolescent users, adolescent users of combined oral contraceptives had a 1.8-fold higher rate (95% CI; 1.75–1.84) with first use of antidepressants, and users of progestin-only pill experienced a 2.2-fold higher rate. The authors concluded that use of hormonal contraception, especially among adolescents, was associated with subsequent use of antidepressants and a first diagnosis of depression, suggesting depression as a potential adverse effect of hormonal contraceptive use. They advocated for further research on the potential adverse effect of depression with use of hormonal contraception. They also called on physicians to be more observant of depressive symptoms when prescribing hormonal contraception.

#### Comments

Strengths of this study included that they had a large population of over 1 million participants that included all women aged 15–34 years living in Denmark. They were followed for 14 years and had no loss to follow-up. Finally, they eliminated recall bias by obtaining information on contraceptive use through bar codes. Of interest is that the theory behind the hypothesized increase in depression was progesterone involvement in the etiology of depression. This theory seems to challenge the use of progesterone to treat women who have depression. It also could be hypothesized that the use of any contraceptive method, by objectifying women, might be linked to subsequent depression. I would add to the caution of the authors that NFP providers be observant of depressive symptoms when prescribing progesterone for various women's health problems.



## Source

Skovlund, C. W., Merch, L. S., Kessing, L. V., and Lidegaard, O. 2016. Association of hormonal contraception with depression. *JAMA Psychiatry* 73 (11): 1154–62. Google Scholar

## Menstrual Cycle

### The effect of luteal phase support with vaginal progesterone on pregnancy rates

The use of intrauterine insemination (IUI) with menstrual cycles that have been stimulated with gonadotropins is thought to be a less burdensome, less costly, and more accessible form of infertility treatment than other assisted reproductive technologies (ART), e.g., in vitro fertilization (IVF). Evidence has shown that use of vaginal gel administered luteal phase progesterone support is effective in increasing pregnancy rates in IVF treatment cycles. Although there is some evidence that use of progesterone support increases pregnancy rates in IUI cycles, the evidence is weak due to non-randomization studies with low statistical power and lack of concealment of treatment. Researchers and clinicians conducted a multicenter randomized study to test the hypothesis that use of vaginal progesterone gel for luteal phase support with gonadotropin-stimulated menstrual cycles will result in a higher clinical pregnancy rate compared to the pregnancy rate of a control group that did not receive the progesterone luteal phase support (Peeraer et al. 2016). Besides the main outcome variable of clinical pregnancy rates, they also measured live birth rates, miscarriage rates, and the length of the luteal phase as secondary outcomes.

Nine clinical centers in Belgium participated in this study from April of 2011 until January of 2015. The participants were blocked randomized (in groups of 10) before initiation of the study. To be eligible for the study, participants had to have either unexplained infertility, mild male factor infertility, or mild endometriosis. In addition, the female patients needed to have normal ovulatory menstrual cycles, be less than 43 years old, have a body mass index less than 30, at least one patent fallopian tube, normal uterine cavity, and a male partner with a total motile sperm count of greater than 5 million. All participants received recombinant follicular stimulating hormone, and when there was a maximum of two mature follicles present per ultrasound, ovulation was triggered with human chorionic gonadotropin. The control group received no luteal phase support. The treatment group received progesterone 8% vaginal gel on the day of the IUI and then daily until there was a positive pregnancy test. A clinical pregnancy was defined as a fetus with heartbeat per ultrasound at 6–8 weeks gestation. Live birth was defined as a live birth beyond 24 weeks of gestation, and the luteal phase was the length of the days from the LH peak until the next menses.

There were 393 couples in the study with 202 randomized to the luteal support group and 191 to the control group. Although a power analysis indicated a sample size of 502 couples, the study was stopped after 4 years due to disappointing accrual of participants. Researchers found however, that there were no statistically significant differences in clinical pregnancy rates nor live birth rates between the two groups, i.e., the luteal support group had a 16.8% pregnancy rate and a 11.0% live birth rate, and the control group had a 14.9% pregnancy rate and a 9.4% live birth rate (RR 1.54: 95% CI, 0.89–2.67;  $p = 0.12$ , and RR 1.60; 95% CI, 0.89–2.87:  $p = 0.12$  respectively). There was a significant difference in the luteal phase length with the treatment group being about 2.1 days longer (mean difference 2.1 days; 95% CI, 1.58–2.56;  $p < 0.0001$ ). Finally there was no statistical difference in the miscarriage rates between the two groups (RR 0.8; 95% CI, 0.18–3.8;  $p = 0.80$ ). The authors concluded that although there was no significant difference in the pregnancy rate or live birth rate, there was a clinical trend in

the right direction. They felt that the major limitation was that this study was underpowered but could contribute to a future meta-analysis that would engender greater statistical power. The authors emphasized that the progesterone luteal support used in this study (i.e., 8% vaginal gel with a total dose of 90 mg) only applies to gonadotropin-stimulated IUI cycles.

#### Comments

Although it is commendable that the authors were seeking less intrusive and less expensive artificial reproductive technology, IUI is still an intrusive, embarrassing, and morally questionable treatment as it separates the unitive and procreative aspects of the marital act (NB: some Catholic theologians might argue that it “could” be moral if semen were obtained licitly; see Klaus 2009). Since all of the participants in this study had normal ovulatory menstrual cycles, it would have been interesting to compare just couples who used focused intercourse on the optimal fertile days using NFP methods versus non-focused intercourse, or at least a comparison of gonadotropin-stimulated cycles with those menstrual cycles with no stimulation but with focused intercourse.

#### Sources

Klaus, Hanna. 2009. Reproductive technology (evaluation & treatment of infertility): Guidelines for Catholic couples. <http://www.usccb.org/nfp/resources/upload/Reproductive-Technology-Evaluation-Treatment-of-Infertility-Guidelines-for-Catholic-Couples.pdf>. Google Scholar

Peeraer, K., D'Hooghe, T., Laurent, P., Peickmans, S., Delvigne, A., Laenen, A., Weikenhuysen, M., Wyns, C., and De Neubourg, D. 2016. Impact of luteal phase support with vaginal progesterone on the clinical pregnancy rate in intrauterine insemination cycles stimulated with gonadotropins: A randomized multicenter study. *Fertility and Sterility* 106 (6): 1490–95. Google Scholar

#### Intensive brief weight-loss intervention found to improve reproductive outcomes

Obesity is a risk factor for infertility and is associated with polycystic ovarian syndrome, anovulatory cycles, and other ovarian dysfunctions. The National Institute for Health and Care Excellence recommends weight loss for women with a basal body index (BMI) of  $> 30 \text{ kg/m}^2$  and the American College of Obstetricians and Gynecologists recommends optimal control of obesity before conception and that physicians use motivational counseling for obese women to lose weight and modify their diets and exercise. Obese women (and couples) who wish to achieve pregnancy and have difficulty in achieving pregnancy are often impatient to undergo assisted reproductive techniques. A brief, intensive weight-loss (IWL) protocol would aid obese, sub-fertile women in their desire for pregnancy and offer a treatment option for health providers. However, there is no research that provides evidence for demonstrating whether a brief, IWL program is beneficial for reproductive indicators and pregnancy outcomes. Researchers at the University of Michigan conducted a pilot study to test whether a brief, IWL program compared with a brief, standard-of-care, nutritional counseling (SNC) intervention was feasible and whether the intervention was acceptable to obese, sub-fertile women seeking ovulation induction (Rothberget al. 2016). The researchers hoped to determine feasibility of recruitment, randomization, intervention implementation, and retention of participants as outcomes. They also recorded pregnancy rates and other anthropometric and laboratory measures.

The eligible participants were women 18–40 years of age, with a BMI between 35 and  $45 \text{ kg/m}^2$ , had infertility (i.e., were unable to conceive after 12 months of intercourse without contraception), have ovulation dysfunction (irregular cycles, or low progesterone levels of  $< 10 \text{ ng/mL}$  in the luteal phase),

and evidence of normal uterine anatomy. The researchers were able to recruit 14 participants out of 25 they found eligible, i.e., 11 did not wish to delay ovulation induction. Seven participants each were randomized into the IWL group and the SCN group, but one withdrew from the IWL group and two from the SCN group. The brief IWL included 12 weeks of a 800 kcal/day liquid protein diet, then 2 weeks of a food-based meal plan of 1,000–1,200 kcal per day, and then 2 weeks of a conventional meal plan to maintain weight. The SCN consisted of a 12-week, food-based diet with a suggested intake of about 1,200 kcal/day. All participants received clomiphene citrate at 50 mg on cycle days 3–7. If a low progesterone level was found in the luteal phase of the next menstrual cycle, then the dose was increased by 50 mg.

The remaining 11 participants had a mean age of  $32 \pm 4$  years and a mean BMI of  $41 \pm 3$  kg/m<sup>2</sup>. At baseline there was no difference in glycemic indexes between the two groups. After 12 weeks of intervention, the IWL lost significantly more weight than the SCN group, i.e., a mean of 14 kg versus 6 kg ( $p < 0.05$ ). In addition fasting glucose and fasting insulin levels improved in the IWL group compared to the SNC group ( $p < 0.05$ ). The IWL group had three confirmed pregnancies and three live births, and the SNC group had 0 even though the SNC group had more ovulation induction cycles. The authors concluded that this study showed a high rate of ineligibility for IWL, a reluctance to be randomized, reluctance to delay ovulation induction, and a high initial dropout rate. The treatment group had greater weight loss and more improvements in insulin sensitivity than the comparison group. The authors called for larger multisite studies to compare brief IWL with SNC and to follow the women participants through delivery.

#### Comments

Use of a brief IWL for obese women seeking pregnancy could be a moral intervention for aiding conception. Lifestyle change, however, even for couples seeking pregnancy, is not easy. It might be easier or more prudent to offer this intervention in pre-conception counseling rather than waiting for indications of sub-fertility, i.e., waiting for 12 months of random, non-protected intercourse before initiating any lifestyle modification, focused intercourse, or medical treatment.

#### Source

Rothberg, A., Lanham, M., Randolph, J., Fowler, C., Miller, N., and Smith, Y. 2016. Feasibility of a brief, intensive weight loss intervention to improve reproductive outcomes in obese, subfertile women: A pilot study. *Fertility and Sterility* 106 (5): 1212–20. Google Scholar

## Sexual Behavior

Sexual intercourse more than once a week does not increase satisfaction and happiness among married couples

Conventional wisdom, fueled by portrayals in the media, postulates that the more frequently couples have sexual intercourse the more sexual satisfaction they will experience, and as a result, their relationships will be of a better quality. In addition, there is the notion that couples who practice NFP to avoid pregnancy have less frequent intercourse and therefore, less sexual satisfaction than couples who use contraception. Interestingly, psychological and behavioral researchers speculated that there is a limit to the frequency of sexual intercourse that will result in couple well-being (Muis et al. 2016). They mentioned that, with busy lives, career demands, and children, participating in frequent intercourse would be daunting and even stressful for young couples. These researchers carried out

three studies to test their theory that there is a limit to the relationship of sexual frequency with satisfaction, furthermore, that relationship satisfaction mediates the relation between sexual frequency and well-being.

The first study involved use of data from the General Social Survey (GSS) a population-based national study that is conducted in the United States almost every year since 1973. The analysis for this study involved participants from 14 GSS time points from 1989 to 2012, and 25,510 (11,285 men and 14,225 women) participants with an age range from 18 to 89 ( $M = 45.13$ ;  $SD = 16.94$ ). The two variable questions used from the GSS were “About how often did you have sex during the last 12 months?” and a question to rate general happiness, i.e., “taken all together, how would you say things are these days—would you say that you are very happy, pretty happy, or not too happy?”. They discovered that there was a significant lineal relationship between sexual frequency and happiness for people who have sex once a week or less, and no association for people having sex more than once a week. Furthermore, they discovered that these relationships only existed for married participants. They found no linear nor curvilinear relationship between sexual frequency and well-being among sexually active, single people.

The second study was conducted to confirm the proposition that frequency of sexual intercourse was associated with relationship well-being. This study involved 335 participants (138 men and 197 women) who currently were in a sexual relationship and who were obtained from an online, crowd-sourcing work site. They ranged in age from 18 to 64 years ( $M = 31.0$ ;  $SD = 9.11$ ). The participants were paid sixty cents to complete a satisfaction-with-life well-being scale that included a 5-item satisfaction-with-life scale and a 5-item satisfaction-with-their-relationship scale. They were also asked to record frequency of intercourse from less than once a month to daily. The researchers found that there was a positive relationship between sexual frequency and relationship satisfaction but, as in the previous study, only with sexual frequency of once a week or less.

Study three involved 2,400 couples who completed at least one wave of the National Survey of Families and Households (NSFH). The NSFH included an item in which participants recorded the frequency of intercourse in the past month and an item of rating their happiness in their marriage from 1 = very unhappy to 7 = very happy. As in the previous two studies, they again found that the relationship between sexual frequency and relationship satisfaction only held (was significant) at six times or less per month.

The authors indicated that the evidence from these three studies help to dispel the notion that sexual intercourse has a limitless benefit for well-being, i.e., at least for individuals in a romantic relationship. They consistently found that sexual frequency is no longer associated with well-being with a frequency greater than once a week. They also indicated that one reason that this relationship holds is that sexual frequency is also associated with greater relationship satisfaction. The relationship of frequency of intercourse did not hold for single people not in a committed romantic relationship.

## Comments

The threshold of sexual intercourse frequency of once a week as the limit for well-being among couples in a relationship (and not sexually active, single people) has implications for the dynamics of practicing NFP. Studies have shown that couples who practice NFP have on average 4–6 acts of intercourse per menstrual cycle. This is also the threshold for marital well-being. Couples using NFP do not have to feel that the practice of NFP and periodic abstinence reduces sexual and relationship satisfaction.

## Source

Muise, A., Schimmack, U., and Impett, E. A. 2016. Sexual frequency predicts greater well-being, but more is not always better. *Social Psychological and Personality Science* 7: 295–302. Advanced online publication. Google Scholar

## Under the microscope

In-depth review of research on fertility-knowledge education programs: Can education be the right approach to improve fertility knowledge among young men and women? An evaluation of the published fertility-knowledge education programs

Qiyang Mu, BSN, PhD candidate, Marquette University, Milwaukee, Wisconsin, USA

### Introduction

Fertility knowledge is a dynamic concept that includes information related to men's and women's fertility throughout their lives. In recent years, fertility knowledge has been increasingly recognized as a critical component that may impact people's sexual and reproductive behavior and outcomes (Dougall et al. 2013; Institute of Reproductive Health [IRH] 2013; Witt et al. 2013). A lack of knowledge of female fertility and the fertile window may lead many young men and women to use less reliable contraceptive methods (Berger et al. 2012; Nettleman et al. 2007). Despite their intention to protect their future fertility, many young people do not know that risky sexual behavior or sexually transmitted infections can cause infertility (Goundry et al. 2013; Quach and Librach 2008; Sabarre et al. 2013). Meanwhile, studies also indicate that women and couples have unintentionally delayed their childbearing due to the misperception of the impact of age on female fertility (Cooke et al. 2012; Dougall et al. 2013).

Results from multiple studies have shown that fertility knowledge is generally inadequate and inaccurate among diverse populations from different countries. Using the same questionnaire, researchers have assessed young college students' fertility knowledge from Sweden, the USA, and Hong Kong (Chan et al. 2015; Lampic et al. 2005; Peterson et al. 2012; Tydén et al. 2006). Their findings indicate that young college students generally lack an accurate understanding regarding female fertility decline and they tend to overestimate the success rates of ART in treating age-related infertility. Similarly, two surveys among general populations also have shown that many Canadian men and women of reproductive age believe their fertility knowledge is higher than their actual fertility-knowledge level (Daniluk and Koert 2013; Daniluk et al. 2012). For 282 Australian women who tried to improve their fertility knowledge to aid their conception attempts, only 12.7% could accurately identify their fertile time and timed their intercourses correctly (Hampton et al. 2013).

Both scholars and women have called for better fertility education and promotion (Barron 2013b; Dougall et al. 2013; Everywoman 2013; Hampton et al. 2013). However, much debate exists regarding how to deliver effective fertility education to individuals. For instance, attempts to improve fertility knowledge on a large scale using public campaigns have caused protests and resistance from women (Gray 2013; Soules 2003). Furthermore, questions remain about how effectively fertility education can improve people's knowledge and perception about fertility and influence their reproductive decisions and behaviors. This article will provide an evaluation of the available fertility-knowledge education programs that have been described in the literature.

## Method

A literature search was conducted using key words such as “fertility knowledge,” “fertility awareness,” “fertility,” “fertility education,” “health education,” and “education.” The electronic databases searched were CINAHL, Web of Science, PubMed, and Google Scholars. The search years were from 2010 to 2016. A total of five peer-reviewed publications related to fertility-knowledge education were located. These five articles described five fertility-knowledge education programs from five different countries (Table 1). A detailed evaluation and comparison of these five programs was done based on the following aspects: study design, study participant, program setting and material, and program outcomes.

*Table 1 A summary of five fertility-knowledge education programs*

Author	Study participant	Program setting and material	Evaluation	Outcomes
Wojcieszek and Thompson 2013	<ul style="list-style-type: none"> <li>137 male and female undergraduate students (M = 19)</li> <li>Australia</li> </ul>	<ul style="list-style-type: none"> <li>Online</li> <li>Educational brochure</li> </ul>	<ul style="list-style-type: none"> <li>Knowledge of fertility and IVF</li> <li>Desired age for beginning/completion of childbearing</li> <li>Survey</li> </ul>	<ul style="list-style-type: none"> <li>Significant increase in fertility for the intervention group</li> <li>Significant decrease in desired age to start /complete childbearing for the intervention group</li> </ul>
Stern et al. 2013	<ul style="list-style-type: none"> <li>299 female college students (M = 23)</li> <li>Three randomized groups</li> <li>Sweden</li> </ul>	<ul style="list-style-type: none"> <li>In person consult</li> <li>Educational brochure</li> </ul>	<ul style="list-style-type: none"> <li>Six knowledge questions about reproduction</li> <li>2-month telephone interview</li> </ul>	<ul style="list-style-type: none"> <li>Significant increase of fertility knowledge for the intervention group</li> <li>Significant decrease in desired age to have their last child for the intervention group</li> </ul>
Daniluk and Koert 2015	<ul style="list-style-type: none"> <li>199 currently childless men and women</li> <li>18–35 years old (M = 28)</li> <li>Canada</li> </ul>	<ul style="list-style-type: none"> <li>Online</li> <li>10 online posts related to fertility information of MyFertilityChoices.com</li> </ul>	<ul style="list-style-type: none"> <li>26 knowledge/belief questions</li> <li>Pre-post online survey</li> <li>6-month follow-up survey</li> </ul>	<ul style="list-style-type: none"> <li>Significant increase in knowledge score immediately after the online education</li> <li>Decreased intention to have children at a later age</li> <li>The results were not sustained at 6-month follow-up</li> </ul>
Garcia et al. 2016	<ul style="list-style-type: none"> <li>201 candidates of oocyte donation (M = 25)</li> <li>Three randomized groups</li> <li>Spain</li> </ul>	<ul style="list-style-type: none"> <li>In person</li> <li>Educational brochure and personalized oral information</li> </ul>	<ul style="list-style-type: none"> <li>10 fertility question items</li> </ul>	<ul style="list-style-type: none"> <li>Significant increase in fertility knowledge only for the tailor group</li> </ul>
Maeda et al. 2016	<ul style="list-style-type: none"> <li>726 men and 729 women</li> <li>20–39 years old (M = 30)</li> <li>Three randomized groups</li> <li>Japan</li> </ul>	<ul style="list-style-type: none"> <li>Online</li> <li>Educational brochure</li> </ul>	<ul style="list-style-type: none"> <li>Cardiff fertility knowledge scale</li> <li>Childbearing desire anxiety</li> </ul>	<ul style="list-style-type: none"> <li>Significant increase of fertility knowledge for the intervention group</li> <li>Significantly higher anxiety for the intervention group</li> </ul>

## Results

### Study design

All five studies used pre-post interventional designs to evaluate the effect of providing fertility-knowledge education, and three of the studies were randomized control trials (RCT). For the two pre-post intervention studies, Wojcieszek and Thompson (2013) had one intervention group that read a fertility educational brochure and one control group that read an unrelated educational brochure. Daniluk and Koert (2015) exposed participants to 10 fertility knowledge items in a question-and-answer format from an online fertility website and evaluated their knowledge pre-post and six-months later. For the three RCTs, differences were noted among their study designs. Stern et al. (2013) employed one intervention group that received both fertility-related education and standard gynecologic care and two control groups that had only standard gynecologic care. Garcia et al. (2016) utilized an RCT design with three groups, which included one tailored group, one untailored group, and one control group. The tailored group received both a written brochure and personalized oral information about fertility, while the untailored group received only the educational brochure. The

control group received either an educational brochure or oral information. Maeda et al. (2016) also used an RCT design with three groups. Their three groups consisted of one intervention group that was exposed to fertility education and two control groups that received educational materials unrelated to fertility.

### Study participants

These fertility-knowledge education programs focused on educating men and women of reproductive age from a variety of populations, including young college students, candidates for oocyte donation, and men and women of reproductive age from the general population. Three of the studies included both men and women (Daniluk and Koert 2015; Maeda et al. 2016; Wojcieszek and Thompson 2013), and the other two studies only had women as participants (Garcia et al. 2016; Stern et al. 2013).

These five studies used different methods to recruit their study participants. Wojcieszek and Thompson (2013) recruited undergraduate students who had no children from a large metropolitan university. Stern et al. (2013) enrolled female college students who visited a student health center for gynecologic services. Garcia et al. (2016) drew their sample from women who were candidates for oocyte donation at a large, private fertility center. Both Daniluk and Koert (2015) and Maeda et al. (2016) utilized a professional survey company to recruit women and men of reproductive ages from the general population. The sample size varied greatly among these studies, ranging from 137 (Wojcieszek and Thompson 2013) to 1455 (Maeda et al. 2016).

### Program setting and materials

The five fertility-knowledge educational programs were carried out in a variety of settings. Stern et al. (2013) had nurse midwives provide in-person education to female college students at a student healthcare center on a university campus. Garcia et al. (2016) also carried out their fertility education in a healthcare setting, however, their participants only included women who were candidates for oocyte donations in a large, private fertility center. The rest of the three educational programs were delivered online (Daniluk and Koert 2015; Maeda et al. 2016; Wojcieszek and Thompson 2013). Overall, these educational encounters were very brief and were one-time-only events.

The main educational materials used were brochures that were developed by the researchers, and diverse topics of fertility knowledge were covered in these brochures. Wojcieszek and Thompson (2013) developed an educational brochure on delayed childbearing, age-related fertility decline, and the effectiveness of IVF. Stern et al. (2013) designed their pamphlet based on the CDC's (2014) reproductive life plan (RLP) tool and included a comprehensive list of fertility-related information to guide the midwife's consultation. Daniluk and Koert (2015) used 10 fertility posts from an online fertility website which included information related to fertility history and lifespan, impact of sexually transmitted infection on fertility, fertility testing and preservation, health and life-style factors' effect on fertility, and ART. Garcia et al. (2016) designed their educational brochure to cover topics such as the fertile window, women's fertility lifespan, infertility risk factors, criteria for seeking fertility consultation, and oocyte donation. Maeda et al. (2016) created their educational brochure focusing on infertility facts and infertility risk factors.

### Program outcomes

All five studies measured participants' fertility knowledge pre- and post-education, and the results were significant for all five studies. Two of the studies also measured long-term effects of the education program on people's fertility knowledge and childbearing intentions. Stern et al. (2013)

conducted a structured telephone interview with the participants two month after their clinic visits. They did not, however, evaluate the participants' fertility knowledge at the follow-up interview. Daniluk and Koert (2015) conducted a six-month follow-up to evaluate the long-term effects of online fertility-knowledge education. Their findings indicated that the participants' fertility knowledge had returned to the pre-education level at six months.

Besides measuring fertility knowledge as a main outcome for these educational programs, several studies also evaluated participants' outcomes such as their fertility beliefs, their intended ages for childbearing, and anxiety. For example, four studies compared participants' believed ideal ages for childbearing and noticed a decrease in their preferred ages to have children after receiving fertility-knowledge education (Daniluk and Koert 2015; Garcia et al. 2016; Stern et al. 2013; Wojcieszek and Thompson 2013). However, Maeda et al. (2016) did not find changes in participants' preferred ages for childbearing after their intervention. Furthermore, the decrease in preferred age to have children did not sustain six months after the education program (Daniluk and Koert 2015; Maeda et al. 2016) also evaluated participants' anxiety pre- and post-education and noted that participants experienced significantly higher anxiety in the intervention group compared to the control groups. The report of anxiety seemed to increase linearly with increased age for both men and women.

## Discussion

Overall, these fertility-knowledge education programs have focused on educating men and women of reproductive age on a variety of fertility topics, including fertility changes throughout life, the impact of lifestyle factors on fertility, many preventable infertility risks, and ART. The utilization of an educational brochure was relatively inexpensive and an easy way to deliver intended educational material to a large group. However, several limits exist with this approach. For all the online fertility-knowledge education programs, the participants were provided the educational brochure without any professional consultation or interaction. It is difficult to evaluate how or if participants read and comprehend the fertility- knowledge contents. Furthermore, the educational material was brief and did not provide in-depth information about fertility. In order for an individual to comprehend fertility knowledge and appreciate fertility knowledge at the personal level, it is important for the participants to be able to ask questions and clarify their understanding. The study conducted by Stern et al. (2013) provided such an example. In this study, the midwife provided fertility-knowledge education based on the women's current fertility need using an RLP tool. Their education not only improved these young women's current fertility knowledge but also encouraged these women to consider consulting a midwife for more reproduction questions in the future (Stern et al. 2013).

It seems that educating young women about their fertility within their own life context can produce a long-term impact on these women. Barron (2013a, 2013b) suggested incorporating fertility care and education into primary care as a possible approach to improve both men's and women's fertility health and overall health. Another possible approach could be NFP programs. Currently, NFP programs focus on assisting couples to live with their fertility throughout their lives. Such programs already have the structure and environment to expand into fertility-knowledge education programs. Nevertheless, this expansion requires the change of mindset to understand the comprehensiveness of fertility knowledge and the application of fertility knowledge in men's and women's sexual and reproductive life.

Positive outcomes of increased fertility knowledge were noted with these fertility-knowledge education programs. At the same time, much of the knowledge improvement did not sustain six months after the education (Daniluk and Koert 2015). Several potential reasons may help explain the



unsustainable knowledge improvement. The initial increase of fertility knowledge could be a direct result of just reading the educational brochure. Many of the young participants may not feel a need for fertility knowledge at their current stage of life. The information, therefore, may not be meaningful for young people to retain. Daniluk and Koert (2015) suggested that fertility-knowledge education should be based on personal relevance and need. The evaluation of an individual's fertility knowledge should be a continuing process. If fertility-knowledge education is incorporated into either primary care or NFP programs, it is possible to regularly evaluate an individual's fertility knowledge and provide individualized education.

It is also important to note that men and women may have differences in learning fertility knowledge. Daniluk and Koert (2015) noted that women consistently had higher fertility knowledge before and after the education. Although both men and women experience increased anxiety after the exposure to fertility information, women seem to feel more anxious at much younger ages compared to men (Maeda et al. 2016). This anxiety may be due to their increased awareness of age-related, female fertility decline. It is necessary to explore how and when to start educating men and women about their fertility. In recent years, both RLP and preconception care have been increasingly recognized as essential components of health promotion and disease prevention for men and women of reproductive age (American College of Obstetricians and Gynecologists 2016; CDC 2014). The goals of RLP are to assist men and women in making informed, short- and long-term, reproductive life decisions while the focus of pre-conception care is to help them get and stay healthy throughout their reproductive years (CDC 2014). Fertility-knowledge education should be provided as an ongoing part of this comprehensive RLP for individuals throughout their reproductive years.

## Conclusion

Fertility is a continuously changing phenomenon throughout an individual's life. Many modifiable factors, including lifestyle and sexual behavior, will have a profound impact on an individual's current and future fertility (Macaluso et al. 2010). The complexity and changing nature of fertility warrants a comprehensive approach to address an individual's knowledge and understanding related to his or her own fertility throughout their reproductive years. Fertility-knowledge education seems a viable approach to improve the currently inadequate and inaccurate fertility knowledge among diverse populations. Nevertheless, one-time education is not effective in producing sustainable, long-term changes in knowledge. Strategies should focus on how to provide fertility-knowledge education in an ongoing fashion. Longitude study is needed to evaluate the long-term effects of fertility-knowledge education.

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#### Biographical Note

Richard J. Fehring, Ph.D., R.N., FAAN, is professor emeritus at Marquette University and director of the Institute for NFP.

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