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A Cluster Randomized Controlled Trial of the MyFamilyPlan Online Preconception Health Education Tool

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## A Cluster Randomized Controlled Trial of the MyFamilyPlan Online Preconception Health Education Tool

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#### Abstract

**Purpose:** To evaluate whether exposure to MyFamilyPlan—a web-based preconception health education module—changes the proportion of women discussing reproductive health with providers at well-woman visits.

**Design:** Cluster randomized controlled trial. One hundred thirty participants per arm distributed among 34 clusters (physicians) required to detect a 20% change in the primary outcome.

Setting: Urban academic medical center (California).

**Participants:** Eligible women were 18 to 45 years old, were English speaking, were nonpregnant, were able to access the Internet, and had an upcoming well-woman visit. E-mail and phone recruitment between September 2015 and May 2016; 292 enrollees randomized.

**Intervention:** Intervention participants completed the MyFamilyPlan module online 7 to 10 days before a scheduled well-woman visit; control participants reviewed standard online preconception health education materials.

**Measures:** The primary outcome was self-reported discussion of reproductive health with the physician at the well-woman visit. Self-reported secondary outcomes were folic acid use, contraceptive method initiation/change, and self-efficacy score.

Analysis: Multilevel multivariate logistic regression.

**Results:** After adjusting for covariates and cluster, exposure to MyFamilyPlan was the only variable significantly associated with an increase in the proportion of women discussing reproductive health with providers (odds ratio: 1.97, 95% confidence interval: 1.22-3.19). Prespecified secondary outcomes were unaffected.

**Conclusion:** MyFamilyPlan exposure was associated with a significant increase in the proportion of women who reported discussing reproductive health with providers and may promote preconception health awareness; more work is needed to affect associated behaviors.

#### Keywords

preconception health, health education, reproductive health, pregnancy, internet, randomized controlled trial

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#### **Purpose**

The importance of preconception care, or the optimization of a woman's health prior to pregnancy, is widely accepted in the fields of women's health and primary care. Data confirm positive impacts of preconception counseling on pregnancy outcomes via changes in maternal health behaviors.<sup>1</sup> Evidence links preconception counseling to improved nutrition, folic acid supplementation, decreased substance use in early pregnancy, and the early initiation of prenatal care.<sup>2-4</sup> The content of a comprehensive preconception health assessment includes reproductive life plan development (ie, defining goals regarding seeking/deferring pregnancy), obstetric history, nutrition, vaccinations, sexual health, chronic medical conditions, substance use, current medications, psychosocial health, and contraception.<sup>5,6</sup> Almost half of annual pregnancies in the United States are unwanted or mistimed; thus, it is important to identify women at risk of pregnancy during routine primary care visits.<sup>7,8</sup> Every well-woman visit—a primary care visit focused on preventive services and health screenings for a woman patient-provides an opportunity for preconception counseling and care. As described above, most recommended content for a preconception visit centers on health education, behavior change, and anticipatory guidance-thus, the well-woman visit is a venue that lends itself to a focus on these issues.

Despite these demonstrated benefits, most women do not receive preconception counseling. Data from the 2010 Pregnancy Risk Assessment Monitoring System show only 32.6% of post-partum US women reported the receipt of preconception counseling prior to their most recent pregnancy; women with known risk factors for adverse pregnancy outcomes (ie, younger age, lower income, a prior preterm birth) were least likely to receive this service.<sup>9</sup> Other studies demonstrated significant knowledge gaps regarding healthy preconception behaviors in women both at average and increased risk of adverse pregnancy outcomes.<sup>10-12</sup>

Few evidence-based preconception health promotion tools are available to patients. Even fewer have been rigorously evaluated with respect to their impact on patient outcomes and behaviors. The most widely used format for preconception health promotion materials is the preconception health "risk assessment," which helps a woman to identify particular preconception interventions specific to improving her health prior to pregnancy. Pilot studies have found that preconception health risk assessments are acceptable and subjectively useful to patients and providers in primary care settings, though the publications reviewed made no comparisons to usual care.<sup>13-18</sup> Most of these risk assessments are either performed by providers or completed in writing by patients. Small studies suggest webbased versions of these patient-completed preconception health assessments are reliable and valid when compared to those administered by a health-care professional.<sup>19,20</sup> Most efficacy/effectiveness studies of preconception health assessments have been uncontrolled, blurring the measurable effects of these interventions in the context of what is provided in usual primary care.<sup>21-25</sup>

Our study tested a web-based preconception health education module called "MyFamilyPlan" among nonpregnant

women of reproductive age using a cluster randomized controlled trial (RCT) design. The MyFamilyPlan intervention tested in our RCT is a web-based, patient-centered healtheducation tool designed to promote discussion of preconception health issues during primary care visits. MyFamilyPlan is an online self-assessment tool using branching logic to provide women with recommendations regarding preconception health optimization based upon pregnancy intent and individual health risk factors (Figure 1). The module concludes by suggesting the patient discuss her identified preconception health risks and concerns with her medical provider. We hypothesized that exposure to this intervention would increase the proportion of patients reporting a discussion of preconception health with their care providers. We also secondarily hypothesized that women exposed to MyFamilyPlan (vs the control group) would be more likely to initiate folic acid supplementation, initiate or change a birth control method, and schedule another health-care appointment to discuss reproductive health issues with a provider.

#### Methods

#### Design

This study was designed as a cluster RCT of the MyFamilyPlan web-based preconception health education tool, with 34 physician well-woman care providers as the units of analysis (clusters). Twenty of the providers specialized in obstetrics and gynecology, and 14 providers specialized in general internal medicine. These 34 physicians were drawn from 4 large practices within the urban academic medical center in which the study was set. We selected this cluster design, rather than patient-level randomization, to protect against baseline physician-level variation in preconception counseling practices and contamination between control and intervention participants within a given provider's patient panel. Physicians from both specialties were included to allow provider type to be evaluated as a covariate.

Prior to patient enrollment, the 34 participating providers (clusters) were randomly assigned to the control or intervention arm using random number generation. Provider randomization was stratified by physician specialty (eg, obstetrics and gynecology vs internal medicine) to evenly distribute this characteristic between the 2 study arms. Participants, providers, and the study research assistant responsible for patient enrollment were blinded as to whether participants had been randomized to the control or intervention arm. Providers could not access survey or MyFamilyPlan responses; similarly, providers did not know which patients had enrolled in the study. The lead investigator was not blinded to arm of randomization, to allow for provision of intervention and control materials to study participants.

The health system institutional review board approved this study (protocol 15-001313). A waiver of written signed informed consent was obtained, given that all study surveys and educational materials were administered online (no direct patient contact). This study was registered with ClinicalTrials.-gov prior to participant enrollment (protocol NCT0252952).

Are you taking a vitamin containing folic acid every day?	
Yes	
No	Recommendation: Folic acid and pregnancy
I'm not sure	Mothers who take folic acid before AND during their pregnancies can prevent certain birth defects. Every woman who could become
Click <u>here</u> and use the online calculator to find your body mass index (BMI). You will need to	pregnant should take folic acid or a prenatal vitamin every day. Start today!
enter your height and weight. Choose the category that describes your BMI:	>>
20-25	
>>	

Figure 1. MyFamilyPlan captured screen images.

#### Sample

The study took place in an urban academic medical center in California. Participants included English-speaking nonpregnant women aged 18 to 45 years with a "well-woman," "physical" or "annual" type visit scheduled with a participating provider in the study's medical center. Participants were excluded if they reported undergoing a prior procedure precluding pregnancy (eg, sterilization, hysterectomy, or bilateral salpingo-oophorectomy). Pregnancy intent was assessed in all participants via an item in the pretest survey that read "Are you currently trying to become pregnant?" Pregnancy intent was not an inclusion or exclusion criteria for this study. Given that so many pregnancies are unintended, preconception health education could benefit women regardless of pregnancy intention. As MyFamilyPlan is a web-based intervention, participants were required to have Internet access. Eligible potential participants were identified from electronic clinic schedules and were contacted for recruitment by e-mail or phone 7 to 10 days prior to the scheduled visit.

#### Intervention

The MyFamilyPlan web-based preconception health education and self-assessment tool includes 27 items and associated individualized education in several domains (ie, nutrition, immunizations, substance use, family/genetic history, environmental exposures, medications, obstetric history, and chronic medical conditions) identified in national preconception health guidelines.<sup>6</sup> These domains, and sample items, are presented in Table 1.

Patients using MyFamilyPlan were presented with questions about their pregnancy plans and health histories; their

#### Table 1. Preconception Health Domains Included in MyFamilyPlan.

MyFamilyPlan Domain	Sample Item
Reproductive life plan	Do you plan to have any (or any more) children at any time in your future?
Contraception	What birth control method do you use to avoid pregnancy now?
Sexual health screenings	Have you ever been tested for HIV and syphilis?
Obstetric history	Were any of your other babies born before 37 weeks of pregnancy?
Birth spacing	How many years do you plan to wait between your deliveries?
Family history	Were any of your parents or siblings born with heart, neurologic, or severe learning problems?
Immunizations	Check the boxes next to any of the vaccines you have received
Chronic medical conditions	Have you been diagnosed with any of these conditions?
Hazardous exposures	Are you exposed to any of these things at home or at work?
Weight and nutrition	Are you taking a vitamin containing folic acid every day?
Substance use	Do you ever smoke cigarettes?
Fertility concerns	Do you have any concerns about your fertility (your ability to become pregnant)?

responses were used to generate individualized recommendations regarding preconception care issues to discuss with their health-care providers. Figure 1 includes captured screen images of the MyFamilyPlan self-assessment tool as viewed by a participant. Self-assessment questions were designed as "multiple-choice"-type questions; feedback from patient education and suggestions were provided as brief written (textbased) recommendations. Pregnancy intention was assessed using the "Reproductive Life Plan" language developed by the Centers for Disease Control and Prevention (CDC): "Do you plan to have any (more) children at any time in your future?"<sup>26</sup> For example, a woman who desired pregnancy and had a diagnosis of type 2 diabetes mellitus received advice to discuss optimizing glycemic control with her physician prior to conception. If a patient responded that she was not planning a pregnancy, she received information on contraception, folate supplementation, sexual health, cervical cancer screening, and maintaining a healthy weight. MyFamilyPlan was developed in English by study authors; items underwent cognitive testing with 8 participants of interest (ie, nonpregnant Englishspeaking women aged 18-45 years receiving care in the study setting). Feedback from this cognitive testing (ie, understanding of language, format of items) was used in an iterative process to improve and edit the MyFamilyPlan tool. Approval was obtained from the institutional review board of the University of California, Los Angeles, for the cognitive testing of the MyFamilyPlan self-assessment questions and educational recommendations (protocol 15-000104).

We believed that MyFamilyPlan would change the primary outcome of a patient-reported preconception health discussion with a provider via an increase in self-efficacy; the intervention was grounded in Fishbein's reasoned action approach to health promotion.<sup>27</sup> We anticipated previsit exposure to MyFamily-Plan—which provided actionable, specific preconception health recommendations and encouragement to discuss them with physicians—would empower patients to initiate discussions of reproductive health with their well-woman care providers. We hypothesized that, within the Fishbein's model, the preconception health recommendations and encouragement might have an effect on participant behavior via changes in reported self-efficacy.

All participants received 2 e-mails 7 to 10 days prior to their scheduled well-woman visits. The first e-mail contained a secure link to a previsit survey including items about covariates of interest (eg, demographics, pregnancy plans). In the second, participants receiving care from providers randomized to the intervention arm received a link to the MyFamilyPlan educational self-assessment, while control participants received an e-mail with a link to standard preconception health information from Krames Patient Education. Each participant received 1 e-mail reminder to complete her previsit survey and review her online educational material (intervention or control) on the day prior to her scheduled visit. Participants received a poststudy survey via a secure e-mail link 7 to 10 days following their well-woman visits to assess study outcomes. Study surveys and the MyFamilyPlan preconception health education tool were administered using the Qualtrics web platform (2015 version; Qualtrics, Provo, Utah). Participants were able to complete MyFamilyPlan securely on any device with access to the Internet (desktop, tablet, or mobile phone), as the Qualtrics platform

was compatible with all of these options. All participants received a US\$20 gift card incentive for participating.

#### Measures

Study outcomes were collected via participant self-report using online surveys administered 7 to 10 days after the participant's well-woman visit. The study's primary outcome, whether a participant reported discussing preconception care with her provider during her well-woman visit, was determined by an item reading "Did participating in this study lead you to talk to your health-care provider about your reproductive health at your most recent visit?" The phrase "reproductive health" was selected because "preconception health" was unfamiliar to women during cognitive testing of MyFamilyPlan items. This item was also selected to measure the study's primary outcome because it was similar to nationally used CDC survey questions about preconception health.<sup>28</sup> Measured secondary outcomes included whether the participant had initiated folate supplementation, whether she had initiated or changed her birth control method, and/or whether she had scheduled an additional appointment to address her reproductive health after her wellwoman visit. Changes in these secondary outcomes were also assessed at 7 to 10 days after the well-woman visit, via items in the postvisit survey. Patient-reported self-efficacy with respect to pregnancy planning was also a measured secondary outcome; 6 items assessing self-efficacy from the Reproductive Health Attitudes and Behavior (RHAB) instrument were included in surveys prior to and following study participation (pretest/posttest design).<sup>21</sup> Though initially developed for young women with diabetes, the RHAB instrument has items that specifically evaluate self-efficacy with respect to preconception health. Items from this scale were adapted for this study (Online Appendix).

#### Analysis

In determining the appropriate sample size for this study, we assumed a baseline prevalence of the primary outcome (ie, patient-reported discussion of preconception health with the provider) of approximately 30% in our population, based on estimates from national CDC data.<sup>27</sup> A sample size calculation indicated a minimum of 206 participants would be needed (ie, 103 per study arm) to detect a 20% change in the primary outcome with 80% power and an  $\alpha$  of .05. This sample size was adjusted for potential clustering given the study design; assuming a relatively high intracluster coefficient of 0.05, the total sample size was increased to 259 participants. We planned to recruit a minimum of 130 participants (approximately 8 participants per cluster/provider) per arm. The institutional review board approval from University of California, Los Angeles, was obtained for up to 340 participants to protect against possible attrition over the 2-week study period (ie, 1 week prior to and 1 week following the patient's well-woman visit).

Univariate and bivariate analyses were used to describe study participants and findings with respect to all primary and secondary outcomes. Multilevel logistic regression, adjusted

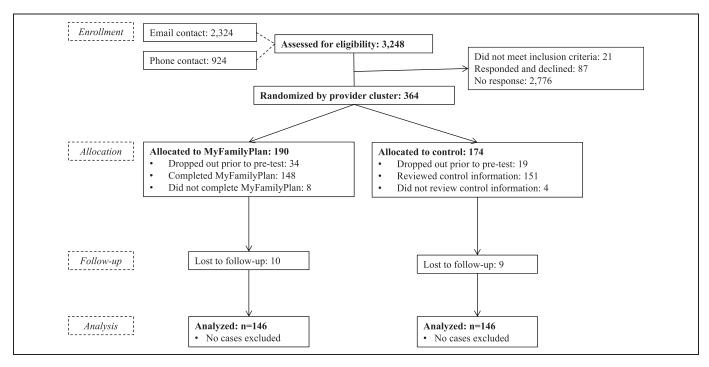


Figure 2. Flow diagram for participant enrollment.

for cluster, was used to identify any significant associations between primary outcome (patient-reported discussion of preconception health at the well-woman visit) and predictor (exposure to the MyFamilyPlan intervention), as well as prespecified covariates. Regression was also used to investigate significantly identified associations between secondary outcomes and trial arm in bivariate tests. An a priori plan was made to include a regression term for the interaction between trial arm and provider type (obstetrician–gynecologist versus internist). Odds ratios (ORs) and significance values from regression equations were reported. Analyses were performed using an intention-to-treat approach with Stata version 14.1 (StataCorp, College Station, Texas).

#### Results

Figure 2 presents the participant flow diagram. A total of 3248 potentially eligible participants were identified using electronic clinic schedules and were contacted regarding enrollment via email or telephone between September 1, 2015, and June 1, 2016. Eligibility criteria were confirmed during these communications. Potentially eligible participants were contacted 7 to 10 days prior to a scheduled well-woman visit with a participating internal medicine physician or obstetrician-gynecologist. Among those women contacted, 364 women agreed to enroll; 53 participants dropped out of the study prior to any participation, and a total of 19 participants were lost to followup prior to completing the poststudy survey. Data from the remaining 292 participants (146 per arm) were included in the analyses. Up to 10 participants were recruited from each of 34 physician panel clusters-the mean number of patients per cluster was 8.8 (median: 10, range: 1-10). Among these women, 97.9% of intervention participants completely reviewed MyFamilyPlan and 100% of control participants opened the preconception materials provided to them. Intervention arm participants spent an average (mean) of 23.4 minutes completing MyFamilyPlan. Analyses were performed in keeping with original trial arm allocation (intention-to-treat approach). There were no adverse events, and no participants were excluded from the study by the investigators.

Baseline participant characteristics are presented in Table 2. All prespecified patient-level covariates were equally distributed between the 2 study arms, demonstrating effective cluster randomization. The majority of participants in both arms identified as white, had employer-based health insurance, and had relatively high baseline self-efficacy with respect to planning a healthy pregnancy per RHAB scale scores (mean scores of 52.6 and 52.3, respectively, in control and intervention participants, of a maximal score of 60). Few participants reported a history of chronic disease (hypertension and/or diabetes) or that they were planning to become pregnant (Table 2).

Significant associations between exposure to the MyFamily-Plan intervention and study primary and secondary outcomes were determined using  $\chi^2$  tests. In these analyses, which were adjusted for cluster design, participants completing the MyFamilyPlan health education module prior to a well-woman visit were significantly more likely to report that study participation led them to discuss reproductive health with their physicians (P = .02). No statistically significant changes were seen in 3 of the 4 study's secondary outcomes: initiating folate supplementation, scheduling an additional appointment to discuss reproductive health, and mean self-efficacy scores. A significant negative association was noted between exposure to

#### Table 2. Baseline Participant Characteristics.<sup>a</sup>

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Characteristic	Control—With Specified Characteristic	Intervention—With Specified Characteristic	P Value <sup>b</sup>
Age $\geq$ 35 years	49 (33.6%)	54 (37.0%)	.54
Nonwhite race/ethnicity	48 (33.3%)	62 (42.5%)	.11
Employer-based insurance	117 (81.3%)	123 (84.3%)	.87
Planning to become pregnant	10 (6.9%)	10 (6.9%)	1.00
Previous pregnancy	67 (46.9%)	58 (39.7%)	.22
Diabetes and/or hypertension	10 (6.9%)	4 (2.7%)	.10
Internist (vs obstetrician/gynecologist)	44 (30.1%)	46 (31.5%)	.80
Baseline self-efficacy score-mean (SD), range: 0-60	52.60 (10.8)	52.28 (9.4)	.24

Abbreviation: SD, standard deviation.

 ${}^{a}N = 292.$ 

 ${}^{b}\chi^{2}$  test for categorical variables; Wilcoxon rank-sum test for continuous variables.

 Table 3. Adjusted Logistic Regression—Primary Outcome: Self-Reported Discussion of Reproductive Health With Provider.

Predictor	Odds Ratio (95% CI)	P Value
MyFamilyPlan intervention	1.97 (1.22-3.19)	.01
Obstetrician/gynecologist provider	1.49 (0.89-2.52)	.13
Currently planning a pregnancy	1.24 (0.48-3.18)	.66
Previous pregnancy	0.83 (0.49-1.41)	.49
White	0.72 (0.44-1.17)	.19
Age >35 years	0.71 (0.41-1.21)	.21

Abbreviation: CI, confidence interval.

MyFamilyPlan and the secondary outcome of initiating or changing a birth control method in  $\chi^2$  analyses (P = .03). Multivariate logistic regression analyses were performed for outcomes demonstrating significant relationships with the primary predictor (MyFamilyPlan exposure): discussion of reproductive health with the provider (*primary outcome*) and initiating or starting a birth control method (*secondary outcome*).

Multivariate logistic regression models were fitted and adjusted for cluster effects and prespecified covariates: provider type (ie, internist vs obstetrician), intent to become pregnant, parity, race/ethnicity, and age  $\geq$ 35 years. In this adjusted model, exposure to the MyFamilyPlan intervention remained the only significant predictor of the study's primary outcome: self-reported discussion of reproductive health with the healthcare provider (OR = 1.97, 95% confidence interval: 1.22-3.19). Adjusted ORs resulting from this logistic regression model are presented in Table 3. Notably, the intracluster coefficient for the data included in this model was <0.001, suggesting negligible within-cluster effects.

In cluster-adjusted multilevel logistic regression, controlling for covariates, trial arm (OR = 0.44, P = .03) and provider type (OR = 5.18, P < .01) were initially found to be significantly associated with patient-reported change in birth control method. However, after inclusion of the prespecified interaction term between trial arm and provider type, only 1 provider type, obstetrician–gynecologist, was positively and significantly associated with self-reported change in birth control method (OR: 5.39, P = .01). In the poststudy survey, participants were queried regarding acceptability of the MyFamilyPlan web-based preconception health education tool. The majority (75.3%) of participants in the intervention arm reported they liked the MyFamilyPlan online format. Among the women who did not like MyFami-lyPlan, reasons cited included: that the information was too general/basic and that it seemed to be more tailored toward women intending to become pregnant. Only 64.4% of these participants responded positively when asked if they would recommend MyFamilyPlan to a friend. Participants cited the ease of use and online availability of MyFamilyPlan as a reason to recommend the tool to a friend; that the information was too "generic" or "basic" was cited by more than 1 participant as a reason that she would not recommend it to a friend.

#### Discussion

#### Summary

Consistent with our study hypothesis, we found that exposure to the MyFamilyPlan web-based preconception healtheducation tool was associated with a significant increase in patient-reported discussion of reproductive health with a provider during a well-woman visit (primary outcome). The study was not powered to detect differences in hypothesized effects of exposure to MyFamilyPlan on secondary behavioral outcomes. The secondary outcome of change in birth control method was found to be significantly associated only with encounters with obstetrician-gynecologists. Many women may be seeking contraceptive care specifically from specialist providers. The meaning of this finding is also limited by a lack of contextual information about a participant's feelings about her current contraceptive method (eg, satisfaction, duration of use). Future studies of MyFamilyPlan investigating these behavioral outcomes will require more comprehensive patient-reported assessments and measures.

As could be expected from the high baseline level found in our study population, no significant difference was seen in patient-reported self-efficacy with respect to planning a healthy pregnancy. MyFamilyPlan may have had a significant effect on the primary outcome of interest through pathways other than self-efficacy. Future tests of this intervention could look for changes in patient knowledge and other factors that may be influenced by MyFamilyPlan. Although many providers agree preconception health issues are best addressed at every wellwoman encounter, challenges exist in delivering preconception care in the context of the limited time constraints and competing needs/issues at such visits. As an educational resource developed specifically for preconception care, MyFamilyPlan could activate and empower women to initiate conversations regarding preconception health, thereby directing providers to address relevant interventions. This study shows that a guideline-driven, web-based preconception health education tool can have a measurable impact on the patient-provider interaction in the areas of reproductive health and preconception care. A discussion of preconception health between a woman and her provider is a very early "process measure" and an important first step in the chain of events leading to the provision of preconception care. Implementing the MyFamily-Plan intervention-which is administered online and relies on participants to review educational points and recommendations-was a relatively low-burden intervention in terms of health systems' resources and provider/staff time. Participant feedback regarding features of MyFamilyPlan that they did or did not like will be used to further refine and improve the education tool prior to future studies.

#### Limitations

Participation in this intervention was low despite the short follow-up period and provision of patient incentives—only 9% of individuals approached via phone or e-mail enrolled. The majority of eligible participants were first contacted via e-mail—perhaps the volume of e-mails received by participants on a daily basis diluted the impact of recruitment e-mails for this study. This suggests that implementing My-FamilyPlan through an entire health system would be feasible only once acceptability is improved in a wider population.

This study did not demonstrate changes in select preconception health behaviors associated with this brief intervention. Sure enough, this study was not powered to capture changes in these secondary outcomes. Additionally, the 1-week followup period in this study might not have realistically been enough time for health behavior changes to occur. In future studies of MyFamilyPlan, an extended follow-up period will be employed to allow for a better assessment of meaningful behavior changes. Future studies involving behavior changes associated with MyFamilyPlan will include balancing behavioral outcome variables, in an attempt to strengthen the case that the intervention is in fact affecting the preconception health behaviors it was designed to target. The broader adoption of health promotion interventions should be guided by downstream effects on more tangible health behaviors and outcomes. Still, providing MyFamilyPlan to women of reproductive age prior to well-woman visits could be a simple way to begin to

improve the provision of preconception care through patient engagement and education.

Results must also be interpreted in the context of several limitations in study design. First, all study outcomes were measured by participant self-report, opening results to reporting bias. In future studies of this behavioral intervention, self-reported outcomes could be corroborated with medical record data, though this additional data resource can introduce additional biases. As candidate measures for preconception care quality are newly being explored, and the preventive and counseling services comprising preconception care are not easily coded for reimbursement, routine documentation of preconception care might not be recorded in the health record.<sup>29</sup> Additionally, it is unknown whether the reproductive health discussion was truly patient initiated and what the quality (eg, duration, content) of this discussion was. In future studies of MyFamilyPlan, better methods will be used to measure more nuanced outcomes, including effects on the "patient centeredness" of care.

Second, the generalizability of the findings of this study to the larger population of women of reproductive age is limited. Participants recruited from our academic medical center practices were largely white, healthy, and privately insured. Participation was acceptable to less than 10% of potentially eligible women offered enrollment, raising questions about feasibility and acceptability in a real-world setting. Unfortunately, we were not able to access demographic or clinical data about women who chose not to enroll-thus, we cannot say how these women differed from participants. Additionally, the MyFamilyPlan intervention was available only in English. The impact of MyFamilyPlan needs to be demonstrated in a more representative population reflecting all US women of reproductive age. Next steps for this intervention include Spanish-language translation and validation (ie, cognitive testing) of MyFamilyPlan items and format, with continued prospective study in more diverse populations. Clearly, approaches to preconception health education must be developed to be culturally and linguistically appropriate; community-partnered research approaches might work best to achieve these goals. This work will be critical in demonstrating the utility and acceptability of this and other preconception health education tools at the population level.

#### Significance

While other studies of patient-focused preconception health promotion tools have demonstrated the acceptability of such interventions to patients, none has been tested using a randomized controlled design. Additionally, MyFamilyPlan is grounded in recent national guidelines in the areas of reproductive life plan development and preconception care. These findings, and the continuing refinement and larger-scale study of MyFamilyPlan, could have significant implications for improving preconception care delivery. With health systems increasingly shifting toward patient-centered care and electronic health records with patient-facing portals, this study demonstrates that web-based education modules can be integrated into existing care workflows and can positively impact patient care.

### So What? Implications for Health Promotion Practitioners and Researchers

#### What is already known on this topic?

Existing research suggests that preconception health education and counseling can positively affect health behaviors in women of reproductive age. However, very few preconception health promotion tools and interventions have been rigorously evaluated with regards to inspiring behavior change.

#### What does this article add?

This study introduces a novel and guideline-based preconception health education tool – MyFamilyPlan – that may be accessed by women of reproductive age via the Internet. Using a randomized controlled design, this study found that exposure to this web-based educational intervention before a primary care visit was associated with patient-reported increases in discussions of preconception care with a healthcare provider. Though further study is certainly required, MyFamilyPlan may add to the small existing toolkit of education tools available in the area of preconception health.

# What are the implications for health promotion practice or research?

As health systems shift towards focusing on patient engagement, preventive care, and a reliance on electronic health records, this study demonstrates that interactive web-based educational modules can be implemented and may positively impact patient care.

#### **Authors' Note**

Clinical trial registration: ClinicalTrials.gov, www.clinicaltrials.gov, NCT02529527.

#### **Declaration of Conflicting Interests**

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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#### Supplemental Material

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#### References

- Johnson K, Posner SF, Biermann J, et al. Recommendations to improve preconception health and health care—United States. A report of the CDC/ATSDR Preconception Care Work Group and the Select Panel on Preconception Care. *MMWR Recomm Rep.* 2006;55(RR-6):1-23.
- Williams L, Zapata LB, D'Angelo DV, Harrison L, Morrow B. Associations between preconception counseling and maternal behaviors before and during pregnancy. *Matern Child Health J*. 2012;16(9):1854-1861.
- American College of Obstetricians and Gynecologists. ACOG Committee Opinion number 313, September 2005. The importance of preconception care in the continuum of women's health care. *Obstet Gynecol*. 2005;106(3):665-666.
- Office of Disease Prevention and Health Promotion. Healthy People 2020. 2016. http://www.healthypeople.gov/. Accessed March 15, 2017.
- 5. Lu MC. Recommendations for preconception care. *Am Fam Physician*. 2007;76(3):397-400.
- Jack BW, Atrash H, Coonrod DV, Moos MK, O'Donnell J, Johnson K. The clinical content of preconception care: an overview and preparation of this supplement. *Am J Obstet Gynecol.* 2008; 199(6 suppl 2):S266-S279.
- Finer LB, Zolna MR. Declines in unintended pregnancy in the United States, 2008-2011. N Engl J Med. 2016;374(9):843-852.
- Moos MK, Dunlop AL, Jack BW, et al. Healthier women, healthier reproductive outcomes: recommendations for the routine care of all women of reproductive age. *Am J Obstet Gynecol*. 2008;199(6 suppl 2):S280-S289.
- Oza-Frank R, Gilson E, Keim SA, Lynch CD, Klebanoff MA. Trends and factors associated with self-reported receipt of preconception care: PRAMS, 2004-2010. *Birth*. 2014;41(4):367-373.
- Coonrod DV, Bruce NC, Malcolm TD, Drachman D, Frey KA. Knowledge and attitudes regarding preconception care in a predominantly low-income Mexican American population. *Am J Obstet Gynecol.* 2009;200(6):686.e1-e7.
- Chuang CH, Velott DL, Weisman CS. Exploring knowledge and attitudes related to pregnancy and preconception health in women with chronic medical conditions. *Matern Child Health J.* 2010; 14(5):713-719.
- Harelick L, Viola D, Tahara D. Preconception health of low socioeconomic status women: assessing knowledge and behaviors. *Womens Health Issues*. 2011;21(4):272-276.
- Levis DM, Westbrook K. A content analysis of preconception health education materials: characteristics, strategies, and clinical-behavioral components. *Am J Health Promot.* 2013; 27(3 suppl):S36-S42.
- Agricola E, Pandolfi E, Gonfiantini MV, et al. A cohort study of a tailored web intervention for preconception care. *BMC Med Inform Decis Mak.* 2014;14:33.
- Bello JK, Adkins K, Stulberg DB, Rao G. Perceptions of a reproductive health self-assessment tool (RH-SAT) in an urban community health center. *Patient Educ Couns.* 2013;93(3):655-663.
- Wade GH, Herrman J, McBeth-Snyder L. A preconception care program for women in a college setting. *MCN Am J Matern Child Nurs*. 2012;37(3):164-170; quiz 170-172.

- Dunlop AL, Logue KM, Miranda MC, Narayan DA. Integrating reproductive planning with primary health care: an exploration among low-income, minority women and men. *Sex Reprod Healthc.* 2010;1(2):37-43.
- Gardiner P, Hempstead MB, Ring L, et al. Reaching women through health information technology: the Gabby preconception care system. *Am J Health Promot.* 2013;27(3 suppl):eS11-eS20.
- de Weerd S, van der Bij AK, Cikot RJ, Braspenning JC, Braat DD, Steegers EA. Preconception care: a screening tool for health assessment and risk detection. *Prev Med.* 2002;34(5):505-511.
- Landkroon AP, de Weerd S, van Vliet-Lachotzki E, Steegers EA. Validation of an internet questionnaire for risk assessment in preconception care. *Public Health Genomics*. 2010;13(2):89-94.
- Charron-Prochownik D, Wang SL, Sereika SM, Kim Y, Janz NK. A theory-based reproductive health and diabetes instrument. *Am J Health Behav.* 2006;30(2):208-220.
- Fischl AF, Herman WH, Sereika SM, et al. Impact of a preconception counseling program for teens with type 1 diabetes (READY-Girls) on patient-provider interaction, resource utilization, and cost. *Diabetes Care*. 2010;33(4):701-705.
- 23. Dunlop AL, Logue KM, Thorne C, Badal HJ. Change in women's knowledge of general and personal preconception health risks

following targeted brief counseling in publicly funded primary care settings. *Am J Health Promot*. 2013;27(3 suppl):S50-S57.

- Hillemeier MM, Weisman CS, Chase GA, Dyer AM, Shaffer ML. Women's preconceptional health and use of health services: implications for preconception care. *Health Serv Res.* 2008;43(1 pt 1):54-75.
- Jack BW, Culpepper L, Babcock J, Kogan MD, Weismiller D. Addressing preconception risks identified at the time of a negative pregnancy test. A randomized trial. *J Fam Pract*. 1998;47(1):33-38.
- Centers for Disease Control and Prevention. Reproductive Life Plan Tool for Health Professionals. 2010. http://www.cdc.gov/preconcep tion/documents/rlphealthproviders.pdf. Accessed March 15, 2017.
- Fishbein M. A reasoned action approach to health promotion. *Med Decis Making*. 2008;28(6):834-844.
- Centers for Disease Control and Prevention. Pregnancy Risk Assessment Monitoring System (PRAMS) questionnaires. 2012. http://www.cdc.gov/prams/questionnaire.htm. Accessed March 15, 2017.
- Frayne DJ, Verbiest S, Chelmow D, et al. Health care system measures to advance preconception wellness: consensus recommendations of the Clinical Workgroup of the National Preconception Health and Health Care Initiative. *Obstet Gynecol.* 2016; 127(5):863-872.