APPENDICES

Appendix A. The MyNewOptions Study Protocol

Reducing Unintended Pregnanies Through Reproductive Life Planning and Contraceptive Action Planning

The MyNewOptions Study

PCORI Contract CD-1304-6117

Protocol

ClinicalTrials.gov Identifier: NCT02100124

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1. Summary

In 2008, over half of all pregnancies in the United States were unintended, representing an increasing incidence over the prior decade. Research has shown that when contraception is provided at no cost, women are more likely to use medical contraception and to choose more effective and more expensive methods over less effective, less expensive methods. The Patient Protection and Affordable Care Act (PPACA) mandates that most women of reproductive age with private health insurance have full contraceptive coverage with no out-of-pocket costs, creating an actionable time for women to evaluate their contraceptive choices without cost considerations.

The MyNewOptions study is a three-arm randomized controlled trial designed to test web-based interventions aimed at assisting privately insured women make contraceptive choices consistent with their reproductive goals. Privately-insured women between the ages of 18 and 40 not intending pregnancy will be randomly assigned to one of three groups: 1) a reproductive life planning (RLP) intervention, 2) a reproductive life planning enriched with contraceptive action planning (RLP+) intervention, or 3) an information only control group. Both the RLP and RLP+ will guide women to identify their individualized reproductive goals and contraceptive method requirements. The RLP+ additionally includes a contraceptive action planning component, which uses if-then scenarios that allow the user to problem solve situations that make it difficult to be adherent to their contraceptive method. All three groups will have access to a reproductive options library, containing information about their contraceptive coverage and the attributes of alternative contraceptive methods. Women will complete a baseline survey and follow-up surveys every 6 months over 2 years concurrent with intervention boosters. Study outcomes include contraceptive use and adherence.

Results from the MyNewOptions study will demonstrate whether web-based reproductive life planning, with or without contraceptive action planning, helps insured women make patient-centered contraceptive choices compared with an information-only control condition.

2. Background and Rationale

2.1. General Overview: Unintended Pregnancy in the U.S.

Avoiding unintended pregnancy is important to women due to the adverse associated personal, economic, and health consequences. In 2006, 49% of U.S. pregnancies were unintended, which has not improved since 1994 and is the highest among developed countries.[2-5] In 2001, 42% of unintended pregnancies resulted in abortion.[2] Women with unintended pregnancies are more likely to have delayed or no prenatal care, smoke or drink alcohol during pregnancy, experience depression or domestic violence during pregnancy,[6] and are less likely to breastfeed.[7] Births associated with unintended pregnancies are associated with increased likelihood of preterm birth, low birth weight, and other negative physical and mental health outcomes for women and children.[1, 6] The U.S. Department of Healthy People 2020 campaign has set the goal of reducing the proportion of pregnancies that are unintended from 49% of pregnancies to 44% of pregnancies by 2020,[8] however no clear strategy for achieving this goal currently exists.

2.2. Why Unintended Pregnancies Occur: Contraceptive Use, Discontinuation, and Adherence

Unintended pregnancies occur when contraception is not used, not used continuously, not used perfectly (adherence), or when contraceptive failure occurs. Contraceptive nonuse is often due to access barriers, such as not having a regular health care provider or insurance coverage. The Patient Protection and Affordable Care Act (ACA) removes the cost barrier for most privately insured women, as it requires all FDA-approved contraceptive methods (including sterilization) and contraceptive counseling to be provided without copays or deductibles. Prior studies have shown that when contraception is provided at no cost to the patient, more women tend to choose the more effective and more expensive methods over less effective, less expensive methods.

Discontinuation and poor adherence occur commonly—a decision analysis estimated that 20% of the 3.5 million unintended pregnancies that occur each year in the U.S. are attributable to poor adherence or discontinuation of oral contraceptives.[9] Discontinuation occurs when side effects and health concerns arise that could be addressed with more individualized contraceptive counseling aimed at reassuring women about the nature of side effects and how to manage them, or assisting women with the selection of another method.[10] Poor adherence occurs when women use contraceptives that do not suit their lifestyle (e.g., requiring frequent ongoing action) or they have poor self-regulation skills needed to achieve better adherence. Based on these reasons for contraceptive failures, our intervention includes goal-setting (through reproductive life planning) and skills building (through action planning) to help women improve contraceptive adherence for their chosen contraceptive method.

2.3. Previous Interventions for Improving Contraceptive Continuation and Adherence

Systematic reviews of interventions aimed at improving continuation or adherence to hormonal methods of contraception have found that few interventions are effective.[11-13] However, these older interventions were aimed at improving continuation and adherence to methods that women were already using (without determining if they were the methods

best suited for each individual woman), were not theoretically-based, did not include skills building, and did not remove out-of-pocket contraceptive cost.

The Contraceptive CHOICE Project is an ongoing research study based on the premise that women would choose more effective contraceptive methods if provided at no cost. This St. Louis-based intervention project has enrolled nearly 10,000 women who: (1) received structured contraceptive counseling aimed at promoting the most effective methods—long-acting reversible contraceptives (LARCs) and (2) were provided free access to all contraceptive methods. In the CHOICE Project, 75% of participants chose a LARC (compared with 5% nationally), with early results demonstrating a significant decline in unintended pregnancy with an abortion rate among participants that is one-fifth of the national level.[14] While structured contraceptive counseling aimed at promoting LARCs in the context of free access to contraceptive methods is effective at reducing unintended pregnancy, structured face-to-face counseling is not easily disseminable. In the CHOICE Project, contraceptive counselors underwent 6 hours of training, and on average the structured contraceptive counseling took 13 minutes per participant.[15] Even with ACA-mandated coverage for contraceptive counseling, it is not feasible to add 13 minutes of face-to-face counseling for contraception in most current primary care practices. Other less labor-intensive models need to be developed and tested for real world effectiveness that can be easily disseminated and minimize use of provider time, given the already limited resources in clinical settings. Also, the CHOICE Project promoted the use of LARCs—our approach is to encourage women to use the contraceptive method that best suits their individual reproductive goals and personal contraceptive requirements.

2.4. Innovation and Potential for Improvement through Research

This study is innovative for a number of reasons. First, we partner with a major private health insurer—*Highmark Health*—to test an intervention aimed at helping women formulate and achieve their reproductive goals. The ACA mandates that private health insurers provide full coverage for all FDA-approved contraceptive methods and counseling, making insurers major stakeholders in ensuring access to contraceptive services. By partnering with Highmark, we are also able to measure contraceptive adherence with medication possession ratios (MPRs) using pharmacy claims data. Second, we will conduct the first systematic assessment of "reproductive life planning," a practice endorsed by the Centers for Disease Control and Prevention (CDC)[16] and reproductive health experts to help women achieve their personal reproductive goals. The CDC has called for the development and evaluation of reproductive life plan tools, but none have been formally tested. Third, we will integrate "action planning" (also known as "if-then planning," "implementation intentions," or "contingency planning"), into a reproductive life planning intervention for improving contraceptive adherence. Fourth, the intervention will be *entirely online*, making it easy to disseminate while avoiding barriers to providing behavioral change interventions in health care settings, including a lack of time and counseling skills on the part of primary care providers.

2.5. Impact on Health Care Performance

Our traditional methods for providing contraceptive counseling have been in clinical settings with face-to-face interactions between patients and health care providers—usually primary care providers, gynecologists, family planning providers/counselors, or nurses. However, primary care providers, who are the point of first contact for privately insured

women, often lack comprehensive knowledge of the full range of contraceptive options and may not be well informed about method effectiveness. For example, primary care providers underestimate the rate of unintended pregnancy and the risk of pregnancy associated with commonly used contraceptive methods,[17] and even gynecologists may have incorrect knowledge about the risks associated with IUD use.[18] Thus, in addition to the challenge of lack of time in primary care visits, face-to-face contraceptive counseling in primary care settings may not be optimal or patient-centered.

With the rise in Americans using the Internet as a source of medical information, web-based tools could be effective in addressing a variety of health issues. According to the Pew Internet and American Life Project, 81% of U.S. adults had access to the Internet in 2012.[19] Women are more likely than men to use the Internet for health information, with the highest percentage among women aged 25-34 (65.8%).[20] Web-based approaches may be desirable for women because they are private and avoid disclosing personal or sexual information to a provider. A computerized tool for reproductive life planning could potentially be more patient-centered than a tool disclosed to a health care provider, in that it makes no judgments about a woman's plans. While not all insured women in our target age group will have access to the Internet or even desire using the Internet to receive health information, this is a modality that has potential to reach a large and growing segment of the target population and should be explored.

2.6. Listening Sessions

Women in our target population aided in the development of the RLP and RLP+ interventions. Listening Sessions (focus groups) were conducted with reproductive-age women who were privately insured, sexually active, not currently pregnant or trying to get pregnant in the next year, and had not had a hysterectomy or tubal ligation. Participants included women who had not had children and women who reported having completed childbearing. Most of the women were using oral contraceptives. First, we sought input for adapting the CDC's reproductive life plan tool into a patient-centered, interactive web-based format designed to help women formulate their reproductive goals and identify their personal requirements for contraception. Second, we sought feedback on the content of an action planning exercise aimed at improving contraceptive continuation and adherence through skill-building. The ideas generated from the listening sessions shaped the development of the RLP and RLP+ interventions.

Our listening session participants were enthusiastic that the RLP was a useful tool. Women reported it was helpful to put their reproductive goals down on paper—one participant said, *"When I started having kids I didn't think about myself at all. This made me think about myself, it made me think of my needs as a mom and a person—that is really helpful."* The listening session participants were overwhelmingly positive that the RLP tool could help them with contraceptive decision-making, because it was difficult for them to find time to seek contraceptive counseling with their health care providers—*"my biggest issue is finding time to have a provider. It is too hard for women who are working or have kids."* Several of the women reported that they used birth control pills because they had comfortably used them for a long time, and were not as familiar with the newer methods—*"there are always new forms of birth control. It would be helpful to learn about what the website would suggest for me."* Other women were aware that there were myths about IUDs that have been disproven (*"they don't make women infertile anymore"*), but they did not have enough information to know if IUDs were a good choice for them. Additionally, they

were reluctant to consider certain methods because of the cost, and were largely unaware that their insurer now covers the cost of contraception without copays. Several of the women were surprised to learn that the typical failure rate in the first year of oral contraceptives use was as high as it is—*"I like the visual [for communicating pregnancy risk], but it makes birth control pills look less effective than I want them to be."* Another woman said, *"Everyone assumes their method is better than it really is."* At the end of the listening sessions, women either validated their current contraceptive method choice (*"I'm a perfect [pill] user, I use it well, I don't forget to take it, so it works for me."*) or were considering that other methods may be better suited for their needs (*"This helped me think the IUD is better for me."*).

3. Overview of Trial Design

3.1 Design

MyNewOptions is a two-year, three-arm parallel group design randomized controlled trial testing a Reproductive Life Planning web-based intervention (RLP) vs. a Reproductive Life Planning plus action planning intervention (RLP+) vs. an information only control group.

The inclusion criteria are (1) women; (2) privately insured through Highmark Health; (3) age 18 – 40; (4) Pennsylvania residents; (5) not covered by an employer group with a religious exemption; (6) Internet access; (7) sexually active (within the past 6 months or expected in the next 6 months); and (8) wish to avoid pregnancy for at least the next 12 months. Women were excluded if they had a tubal ligation, hysterectomy, a partner with a vasectomy or if they are unable to read and write English.

3.1.1. Primary Hypothesis and Primary Outcome

Compared with random assignment to an information only control group, random assignment to a reproductive life planning tool (RLP) or a reproductive life planning tool plus a contraceptive action planning tool (RLP+) will increase contraceptive use and adherence. The primary outcome variable is contraceptive use when not intending pregnancy, defined as whether the participant is using any contraceptive method to prevent pregnancy (e.g., hormonal methods, barrier methods, withdrawal, natural family planning, etc.).

3.1.2. Secondary Hypotheses

Compared with random assignment to an information only control group, random assignment to a reproductive life planning tool (RLP) or a reproductive life planning tool plus a contraceptive action planning tool (RLP+) will:

- Lead to the use of more effective contraception
- Result in more continuous use and better method adherence during the two year study period.
- Improve contraceptive method satisfaction
- Result in lower rates of unintended pregnancy (exploratory outcome)

3.1.3. Interventions

Privately-insured women between the ages of 18 and 40 not intending pregnancy will be randomly assigned to one of three groups: 1) a reproductive life planning (RLP) intervention, 2) a reproductive life planning enriched with contraceptive action planning (RLP+) intervention, or 3) an information only control group. Both the RLP and RLP+ will guide women to identify their individualized reproductive goals and contraceptive method requirements. The RLP+ additionally includes a contraceptive action planning component, which will utilize if-then scenarios to help users problem solve situations that make it difficult to be adherent to their preferred contraceptive method. All three groups will have access to a reproductive options library, containing information about their contraceptive coverage and available contraceptive methods. Women will participate in the study for two years, completing a baseline survey and follow-up surveys every 6 months concurrent with intervention boosters.

3.1.4. Patient Engagement

Patient engagement is a critical component of this trial. We will convene a group of 10-12 women who will meet the same eligibility criteria as our research participants. These women will meet with investigators six times over the course of the research study to help develop each aspect of the research study.

3.1.5. Provider Engagement

We will convene a group of 10-15 health care providers (women and men) who will advise us on critical aspects of this research study. These women and men will meet with investigators three times over the course of the research study to discuss study results, dissemination of findings, and future directions for the research study.

3.1.6. Study Population

The MyNewOptions study will recruit women with private health insurance between the ages of 18 and 40. The specific inclusion and exclusion criteria are described in section four. These criteria are intended to select a population that is at risk of experiencing an unplanned pregnancy.

3.2. Sample Size Justification

The planned sample size for the study is 972 randomized participants (324 for each of the three study groups). The binomial regression analysis described for the binary outcomes of Specific Aim 1 drive this sample size calculation because binary outcomes contain the least amount of information (and hence, yield the lowest statistical power). The assumptions that lead to this sample size of 972 randomized participants are as follows:

1. binomial regression with the proportion of occurrences out of four time points
2. 90% statistical power
3. two-sided, 0.025 significance level test (Bonferroni correction) comparing RLP to control, RLP+ to control, and RLP to RLP+ within each stratum
4. effect size of 0.10 (difference between rates of 0.25 and 0.35)
5. 10% lost to follow-up per year, 10% lost per year for women who change their minds about intending pregnancy, and another 10% lost per year for those women who become pregnant (intentionally or unintentionally)

4. Study Population

The eligibility criteria for the MyNewOptions Study aim to identify women who are not currently pregnant and not intending pregnancy for at least the next 12 months. All participants will be privately insured through Highmark Health and range in age from 18 to 40.

4.1. Eligibility Criteria

Eligibility is established via an online screening tool. Eligibility criteria are as follows:

- **Highmark Health Member:** Only members of Highmark Health will receive an invitation and are eligible to participate.
- **Age:** Individuals 18-40 years old are eligible.
- **Gender:** Only women are eligible.
- **Sexually Active:** Women must have been sexually active with a male partner in the past 6 months or anticipate being sexually active in the next 6 months.
- **Residence:** Participants must live in the state of Pennsylvania at the time of the eligibility screening and baseline survey completion.
- **Race and Ethnicity:** All racial and ethnic groups are eligible for the study.
- **Pregnancy Status:** Participants may not be pregnant or planning to become pregnant at the time of enrollment until at least 12 months after joining the study.
- **Willingness to participate:** Participants must be willing to give informed consent, be willing to be randomized to the RLP, the RLP+ or the control intervention, and to follow the protocol for the group to which they have been assigned.

4.2. Exclusion Criteria

Women will not be eligible to join the study if they have had a tubal ligation, a hysterectomy, their partner has had a vasectomy, or if they are unable to read and write English.

5. Recruitment and Retention

5.1. Recruitment

The recruitment goal of the MyNewOptions study is to enroll 972 participants over a six-month period. Highmark Health will identify members with prescription medication coverage who meet the following criteria: 18-40 years of age, women, reside in Pennsylvania, are not covered by an employer group with a religious exception, and have not had a previous Highmark claim for a tubal ligation, hysterectomy, or infertility-related service. Highmark will identified a random sample of 15,000 members who meet these criteria and invite them to participate in the MyNewOptions study by mailing the following recruitment material: 1) a pre-invitation postcard, 2) a study invitation (one week following the postcard), and 3) a reminder (two weeks following the study invitation). The study invitation and reminder will be mailed in sealed envelopes with Highmark's return address visible on the outside. Both the invitation and reminder will include a unique invitation code that links to the list of eligible women, maintained by Highmark Health. Mailings will invite women to visit the MyNewOptions website to learn more about the study, or to call study staff at the Penn State College of Medicine if they have questions. Trained research staff will monitor phone, email and website generated questions and respond to each inquiry within one business day. Study enrollment must be completed online.

5.1.1. Screening Process

The homepage of the My New Options study website will include a written and video description of the study. Women will be prompted to enter their unique invitation code at a designated spot on the study homepage if they are interested in proceeding. The code will be required to gain entry past the homepage of the study website. This authentication process is designed to ensure that only women invited to be in the study are able to enroll and participate. Potential participants will then view the study details, eligibility criteria, and the consent documents. Women who indicate interest in proceeding will be directed to REDCap (Research Electronic Data Capture), a secure, web-based application designed exclusively to support data capture for research studies (Harris et al., 2009), where eligibility will be assessed (criteria listed above).

5.2. Retention and Drop-out Recovery

5.2.1. Identifying Secondary/Proxy Contacts

Participants will be asked to provide study personnel with their email address, secondary email address, preferred phone number(s) (home, work, cell), and mailing address. Participants will also be asked to provide contact information for one person in case study personnel are not able to reach the participant through their provided contact information. Personal contact information is required to participate but providing a supplemental contact person is not.

5.2.2. Retention Promotion Efforts

One week before participants are due for their follow up survey, they will receive an automated email letting them know that they are eligible to complete their next survey. The

email message will contain study contact information and a link to the participant's REDCap survey.

5.2.3. Drop-out Recovery Efforts

If participants have not completed their scheduled survey by the date due, they will receive a series of reminders at one-week intervals as follows:

- 1st E-mail reminder that they are now due to complete their survey.
- 2nd e-mail reminder that they are due to complete their survey but time is running out. Email will also be sent to any secondary email addresses they listed at enrollment.
- Telephone call asking if participants have received our reminders and, depending upon their response, asking for an updated email address, asking them to check their junk folder, or sending them a new link.
- Text message stating that we have lost touch and asking participant to please call or email with updated contact information.
- Mailed letter stating that we have lost touch and to please call or email with updated contact information.

A final email will be sent out one week prior to taking the survey off line. The email will state that participation is very important and alert them to the fact that the survey will be taken off line by a given date.

5.3. Monitoring Recruitment and Retention

5.3.1. Retention and Efforts to Maintain Contact with Inactive Participants

- **Contact Person**. If we are unable to reach the participant, we will attempt to contact the participant's contact person. We will explain to the contact person how we got their name and the purpose of our call. The contact person will then be asked for updated contact information for the participant or asked to pass along a message to the participant that it is time to complete their next survey.
- **Newsletters.** Project newsletters will be sent to participants every six months approximately one month before their next scheduled survey. Each newsletter will remind participants to call or email us to update their contact information if anything has changed. Newsletters will also attempt to engage participants in study findings.

5.3.2. Monitoring and Quality Control of Recruitment and Retention

The MyNewOptions Research Committee will receive monthly reports about recruitment and retention. They will closely monitor the process and provide input and suggestions as needed.

6. Measures and Procedures

6.1. Informed Consent

Signed informed consent will not be required for participation in this study because the act of voluntarily participating in the online enrollment process is considered implied consent. However, participants will be required to check a box during the eligibility process assenting to the Summary Explanation of Research document, which will describe the study in detail including the rights of the research participant and potential risks associated with study participation. This document will inform potential participants that a Certificate of Confidentiality was requested and granted by the National Institutes of Health in order to protect the research team from being forced to share court ordered information about participants. Participants will also assent by checking a box to allow Highmark Health to provide the MyNewOptions study investigators with participant contraceptive pharmacy claims and health care utilization claims occurring 6 months prior to study enrollment through the end of the 2-year study period.

6.2. Measures

- **Pregnancy history and pregnancy intentions and ambivalence**
  We will ascertain how many times women have been pregnant in the past, as well as the outcomes of those pregnancies including number of spontaneous abortions, elective abortions, and live births. Women will be asked if they are intending future pregnancy using standard measurement,[49, 50] which categorizes women as intending future pregnancy, not intending future pregnancy, or ambivalent (not sure if intending future pregnancy or not). The concept of ambivalence has become increasingly important, as studies have indicated that ambivalence is associated with inconsistent contraceptive use and risk for unintended pregnancy.[51, 52] We hypothesize that the RLP and RLP+ interventions, which prompt women to repeatedly consider their reproductive goals, will result in decreased ambivalence. Women will also be asked how important it is to them to avoid pregnancy (very important, somewhat important, a little important, and not important) within the next year.[52]
- **Marital and relationship history**
  Relationship variables include marital/cohabiting status, relationship duration, number of sexual partners in the past 6 months, frequency of intercourse in the past 6 months (≥2x/week, 2-4x/month, ≤1x/month),[52] happiness with relationship, and happiness with partner's parenting (if applicable).[53] Changes in relationship over time will be measured, as changes in partner status are expected to be key predictors of changes in pregnancy intentions and contraceptive status.
- **Sexual and contraceptive history**
  Using standard measures from the NSFG, we will determine history of contraceptive methods use, as these variables have been shown to be predictors of nonadherence in previous studies.[2, 54]
- **Perceived control/fatalism toward contraception/preventing pregnancy**
  Using a 5-point Likert scale, women will be asked if they agree/disagree with the statement, "It doesn't matter whether I use birth control or not; when it is time to get pregnant, it will happen."[52] Our previous work has suggested that fatalism

toward contraception and preventing pregnancy may affect contraceptive adherence.[55]

- **Health history**
  Women will be asked their general health status, height/weight, perception of weight, health conditions (including conditions affecting hormonal birth control use), depression scale (PHQ-9), perceived stress scale (PSS-4), Intimate partner violence scale (HARK screen) plus reproductive coercion items (NISVS), and prescription medications contraindicated in pregnancy.
- **Health behaviors**
  Women will be asked their tobacco habits and whether they have tried to quit, their alcohol consumption, physical activity (IPAQ) and their folic acid use.
- **Health care access and utilization**
  Items will assess health care utilization, including seeking care for contraceptive services.[56] Specifically, we will ask about source of insurance coverage, whether they had a contraceptive visit in the past year (if not, why not), type of place of care, type of doctor, cost constraints to seeking care and general medical care access and utilization.
- **Sociodemographic data**
  For descriptive purposes, the following participant characteristics are collected: age, race, ethnicity, living situation, marital status, household composition, education, employment status, household income, occupation, and religion.

6.3. Randomization

6.3.1. Final Eligibility Assessment

Women will complete their eligibility screening and consent process online. After REDCap verifies that women are both eligible and have indicated their consent to participate in the study, an email containing a web link to the baseline survey will be sent to their email address. The baseline survey is designed to take approximately 20 minutes to complete. After the baseline survey is complete and submitted, women will seamlessly be redirected to the MyNewOptions study website where they will create a unique username and password. Once their email address has been verified, participants will be randomized to one of the three study conditions and begin their assigned intervention.

6.3.2. Randomization Scheme

Each eligible participant will be randomized to one of the three study conditions by means of a permuted-block algorithm to achieve 1:1:1 allocation into one of the following groups: 1) RLP, 2) RLP+, or 3) information only (control).

6.3.3. Masking or Blinding

In the MyNewOptions study, the research team is blinded to participant intervention assignment.

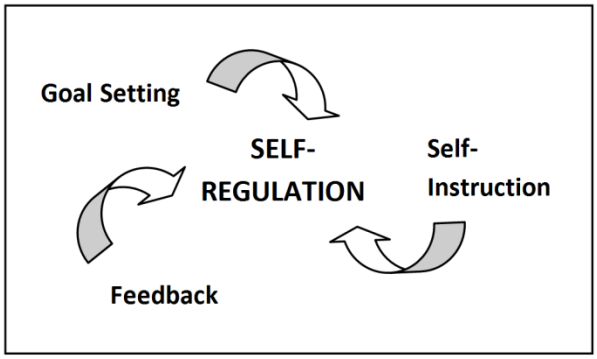
7. Interventions

7.1. Intervention Theory and Goals

7.1.1. Intervention Theory

The framework for the proposed RLP and RLP+ interventions is based on principles of self-regulation from Social Cognitive Theory (Figure 1).[27, 28] Self-regulation involves controlling one's behaviors through self-monitoring, goal setting, feedback, self-reward, self-instruction, and enlistment of social support.[28] The proposed intervention will engage women through *goal setting* (through reproductive life planning), *self-instruction* (through action planning), and *feedback* (by providing feedback on one's contraceptive behavior and adherence).

Figure 1. Improving Contraceptive Use through Self-Regulation



7.1.2. Intervention Goals

The actual patient-oriented outcome we aim to improve with this research is achievement of an individual's personal reproductive goals through avoidance of unintended pregnancy and achievement of desired pregnancy spacing.

7.2. Reproductive Life Planning Intervention (RLP)

The CDC recommends that every woman, man, and couple have a *reproductive life plan*—i.e., a plan for whether, when, and how to have future children. However whether the *reproductive life plan* helps individuals or couples achieve their reproductive goals has not been tested. Merry-K. Moos (Consultant) developed the *reproductive life plan* endorsed by the CDC[29] based on her extensive research and clinical experience with pregnancy planning and contraceptive behavior.[30] Our listening session group members worked with the CDC's *reproductive life plan* to make it suitable for an interactive web-based format, provided feedback on how best to communicate pregnancy risk associated with contraceptive methods, and reflected on their own responses to completing the reproductive life plan intervention. This work resulted in the interactive web-based RLP intervention, which was designed to achieve two objectives: (1) to help women formulate reproductive goals for having or not having children, and (2) to help women make individualized contraceptive choices to achieve those goals.

Like the CDC's *reproductive life plan*, the RLP guides women to make a plan for future pregnancies based on their lifetime goals for school, marriage/partnership, job/career, finances, and other important things in life.[16] When applicable, the woman is provided with information that may help her in her decision making, such as risks associated with older age (e.g., decreased fertility, increasing risk of chromosomal abnormalities) and benefits of pregnancy spacing. Using the RLP, she specifies if she plans to have future children, how many children she plans to have, and when she plans on having them. The RLP emphasizes that a woman's reproductive life plan is not set in stone, but can be fluid over time.

The second objective of the RLP intervention is to help women make contraceptive choices that are best suited for their *personal reproductive goals* and *personal requirements* for a contraceptive method—i.e., reversibility, effectiveness, frequency of use, side effects that are or are not acceptable, medical conditions or health behaviors that may limit contraceptive choices, whether protection from sexually transmitted infections (STIs) is needed, and whether non-contraceptive benefits of certain methods are important. For example, a woman currently using oral contraceptives who occasionally misses pills may decide that the 9% typical-use failure rate is unacceptable and may wish to choose a more effective method. Another woman may indicate that she is not willing to manage her contraception on a regular basis, and would rather *"get it and forget it."* Another woman may decide not to use any method.

After a woman identifies her reproductive goals and personal requirements for a contraceptive method, the RLP intervention provides information about the contraceptive method(s) that meet all or most of her requirements, some of her requirements, or none of her requirements, so she can choose the method that best suits her individual contraceptive needs (or to confirm her current method is a good choice, or that no method is her current choice). After completing the tool, the participant will be able to print, save, or email herself her personal *reproductive life plan,* specifying her goals for future pregnancy, when she wants to be pregnant, how far apart she wants her children, and how she plans to prevent pregnancy until she is ready to be pregnant. If a woman decides to change her method as a result of the RLP intervention, she will be directed to contact her health care provider if it requires a prescription or procedure. If she does not have a current health care provider, the RLP intervention directs her to the Highmark member services website from which she will be able to choose a provider practicing in her area.

7.2.1. Contact Mode and Frequency

Participants will complete their intervention online. The RLP intervention consists of a web visit repeated every six months for two years for a total commitment of five intervention sessions. We anticipate the RLP intervention will take approximately 30 minutes to complete.

7.2.3 Adoption Phase

In the MyNewOptions study, women assigned to the RLP group will complete the RLP intervention at baseline after randomization.

7.2.4. Maintenance Phase

At 6 month intervals (6-months, 12-months, 18-months), the RLP group will be emailed and asked to login to the website and participate in a "booster" of the intervention.

The RLP "booster" will allow the participant to view and confirm her previous reproductive life plan, or develop a new plan. She can review her contraceptive requirements and make any modifications. Once again, if a woman decides to change her method as a result of the RLP "booster", she will be directed to contact her health care provider if it requires a prescription or procedure. If she does not have a current health care provider, the RLP intervention will direct her to a Highmark member services website from which she can find a provider practicing in her area.

7.3. Reproductive Life Planning Intervention plus Action Planning (RLP+)

The Reproductive Life Planning Plus (RLP+) intervention is the RLP intervention described above plus an additional *action planning* step with the objective of improving contraceptive adherence. Action planning interventions (also known as "if-then planning," "implementation intentions," or "contingency planning") are based on self-regulation, defined as a "goal-guidance process, occurring in iterative phases, that requires the self-reflective implementation of various change and maintenance mechanisms that are aimed at task- and time-specific outcomes."[31] While action planning interventions vary, they tend to have several elements in common. First, they present participants with common situations that make it difficult to perform a behavior. Second, they ask participants to make a specific plan for what they will do when faced with the specific situational barrier (i.e., "If situation *X* is encountered, then I will initiate goal-directed behavior *Y.*"). By specifying when, where, and how one will act, action planning passes control of behavior to future environmental cues, reducing the need for cognitive control and effort.[32, 33] A common design for these interventions is the use of a worksheet that has two columns—the left column lists the difficult situations and the right column lists the actions to overcome the difficult situation. Users are then asked to identify the difficult situations they may encounter, and then "link" the situation to an action that they will now be prompted to do if they encounter the situation. An example from our oral contraceptive action planning tool is shown below in Figure 1.

Action planning interventions have been shown to be highly effective at improving many behaviors, including weight loss,[34, 35] smoking,[36] alcohol intake,[37] physical activity,[38, 39] and fruit and vegetable consumption.[40] In 2006, Gollwitzer and colleagues published a meta-analysis of 94 action planning interventions, which observed a mean effect size of Cohen's d = 0.65, consistent with a medium to large effect.[32] While most action planning intervention studies reviewed in that meta-analysis only used a single intervention "dose," Armitage (Consultant) and colleagues have since observed that a "booster" dose significantly increased the impact of the intervention,[41] so we have designed 6-month booster doses in the RLP+ intervention.

Figure 1. Excerpt from Contraceptive Action Plan for Oral Contraceptives

What would I do IF…	**THEN…** Check all the actions you would consider. Also think about actions not listed here
…I go away on vacation and	☐ …I will call my pharmacy right away and see if they can

forget to bring my pills? *Missing pills increases the risk of accidently getting pregnant.* *Emergency contraception (Plan B, Next Step) is birth control pills that are taken after unprotected sex that are available at pharmacies without a prescription. Using emergency contraception as soon as possible after unprotected sex greatly reduces the risk of having an accidental pregnancy.*	transfer my prescription to a local pharmacy. Often the large pharmacy chains (CVS, Rite Aid, etc.) can easily do this. ☐ ...I will call my health care provider's office and ask them to call a prescription to a local pharmacy. ☐ ...I will use a backup method (like condoms) or not have sex for now. When I return home, I will start a new pack of pills and continue to use condoms or not have sex until I have been back on the birth control pills for 1 week. ☐ ...I will use emergency contraception (Plan B, Next Step), which is available without a prescription in pharmacies. ☐ …I will talk with my health care provider about switching to a birth control method that does not require me to worry about when I am on vacation. ☐ Other:

Action planning interventions are ideally suited for contraceptive continuation and adherence, because effective contraceptive use requires a series of behaviors to occur that are repeatedly met with certain barriers—e.g., obtaining a prescription, filling/refilling the prescription from a pharmacy, and taking a pill every day. In a U.K. study by Martin and colleagues, contraceptive action planning for oral contraceptive and condom users was shown to improve contraceptive adherence and reduce unintended pregnancy.[42, 43] Teenage girls (n=261) presenting to a family planning clinic were randomized to either the control or the if-then planning intervention. The intervention involved completing a questionnaire consisting of "if-then" action plans for contraceptive use. For example, oral contraceptive users were asked what time of day they would take the pill, where they would take it, and how they would overcome typical barriers (e.g., "What if you forget to take your pill?"). The intervention group was a third less likely to have requested emergency contraception, 20% less likely to have presented for a pregnancy test,[42] and pregnancy rates were 43% lower in the intervention group.[43] These results show that action planning improves contraceptive adherence in teenage girls attending one clinic in the U.K., however whether a web-based action planning intervention can improve contraceptive adherence in adult U.S. women has not been tested prior to this study.

Contraceptive action planning worksheets were developed by our listening sessions based on the U.K. intervention and expanded to include other known barriers to

contraceptive adherence—such as forgetting to get prescriptions refilled, being away from home/travelling, changes in sleep schedule, and having an irregular work/school schedule.[44] Not surprisingly, all the women who participated in our listening sessions have struggled with contraceptive adherence themselves—this was true of women throughout the reproductive-age spectrum. Participants reported it was helpful to think in advance about how they would deal with certain situations—for example, one woman said it was not until she had run out of pills one weekend that she realized her pharmacy was not open on Sundays. She stressed the importance of knowing your pharmacy's hours *in advance*, so you can plan when to get your refills. Other women recommended using mail order pharmacy plans that allow 90-day supplies. By considering obstacles in advance, action planning allows women to have a toolbox of actions in mind if they encounter the obstacle.

7.3.1. Contact Mode and Frequency

Participants will complete their intervention online. The RLP+ intervention consists of a web visit repeated every six months for 18 months for a total commitment of four intervention sessions. We anticipate the RLP+ intervention will take approximately 45 minutes to complete.

7.3.2 Adoption Phase

In the MyNewOptions study, women assigned to the RLP+ group will complete the RLP+ intervention at baseline after randomization.

7.3.3. Maintenance Phase

At 6 month intervals (6-months, 12-months, and 18-months), the RLP+ group will be emailed and asked to login to the website and participate in a "booster" of the intervention. The RLP+ "booster" will allow the participant to view and confirm her previous reproductive life plan, or develop a new plan. She will be able to review her contraceptive requirements and make any modifications. Once again, if a woman decides to change her method as a result of the RLP+ "booster", she will be directed to contact her health care provider if it requires a prescription or procedure. If she does not have a current health care provider, the RLP+ intervention will direct her to a Highmark member services website from which she can find a provider practicing in her area.

7.4. Education Library

Women in the RLP intervention, the RLP+ intervention and the information only control group will have access to a reproductive options library, containing information about their contraceptive coverage and contraceptive methods (appendix C). From the library, women may view information about the contraceptive coverage mandate as required by ACA and have access to information about all FDA-approved contraceptive methods, using patient education materials from the American College of Obstetricians and Gynecologists (ACOG)(The American Congress of Obstetricians and Gynecologists, 2015), the National Campaign to Prevent Teen and Unplanned Pregnancy (The National Campaign to Prevent Teen and Unplanned Pregnancy, 2015), and the Association of Reproductive Health Professionals (Association of Reproductive Health Professionals, 2015)

7.5. Strategies for Keeping Participants Involved in the Intervention

7.5.1. Adherence and Monitoring

REDCap delivers women to the intervention website after they complete their Baseline, 6-month, 12-month, and 18-month surveys. Participants must then sign into the website in order to select their participation gift cards. The website is password protected and includes a reset button for women who forget their password. Women are also welcome to call or email research personnel for help.

Research personnel will closely monitor women who have completed each survey to see that they also select their gift card. Research personnel will contact women who do not select their card in order to find out if they need help accessing the website or have forgotten to complete the intervention part of the study.

8. Participant Safety and Confidentiality

8.1. Risks and Discomforts

The potential risk to the participants is minimal. Contact with the participants will be limited to phone (for recruitment) and electronic (via email, REDCap and the study website). There will be no face-to-face contact with the participants. The survey assessments and intervention materials involve discussion of potentially embarrassing topics (i.e., contraceptive use).

8.1.1. Intimate partner violence and depression questions

During the survey we will ask all women about domestic violence. Once the questions have been answered, the following message will appear on the screen (regardless of their answers): *If someone you know has hurt you or threatened to hurt you, please call the free and confidential National Domestic Violence hotline number. This line is answered 24/7 by caring individuals who can tell you about services and options. The number is 1-800-799-SAFE (1-800-799-7233)*.

We will also be asking women questions about their state of mind, specifically depression related questions. As with the domestic violence questions, all women will see the following message regardless of their answers:
If you feel like hurting yourself, please call the free and confidential National Suicide Prevention Lifeline at 1-800-273-8255 or visit their website: www.suicidepreventionlifeline.org. Caring individuals are available 24 hours a day to help you.

8.2. Confidentiality

There is potential risk for loss of confidentiality; participants will be informed that we will have attempted to minimize those risks by keeping all identifiable data in password protected electronic data files, that all data will be de-identified once data collection is completed, and that no participants will be identified in any analyses or reports. Data for this study will include: 1) self-administered computer surveys and 2) medical and pharmacy claims data abstracted from Highmark Health. Confidentiality of data will be maintained by assigning project-specific identification numbers to each participant for the purpose of linking the survey data with the abstracted claims data. Once the survey data are collected and linked with the clinical data abstracted from the registries, all identifying information will be destroyed, creating a de-identified dataset for analysis. This study has also applied for and received an NIH Certificate of Confidentiality.

9. Patient and Provider Engagement

9.1. Listening Sessions

A priority of the MyNewOptions study is to include patients in all phases of the study design and execution. During proposal development, 12 insured women of reproductive age participated in 2 listening sessions, which were group sessions for the research team to obtain input from women on how to adapt the CDC's reproductive life plan tool (Centers for Disease Control and Prevention) into a patient-centered, interactive web-based format. Women discussed what kind of reproductive planning was realistic for them (e.g., unrealistic to make a life plan, but realistic to make a 5-year plan). Women in the listening sessions also shared their personal challenges with contraceptive adherence, which were then used to identify the barriers included in the contraceptive action planning intervention. The women also suggested strategies for reporting information summaries back to the website user after participants complete their reproductive life planning and contraceptive action planning exercises.

9.2. Patient Advisory Group

The most important stakeholders in this research are the target population – Insured adult reproductive-age women at risk for unintended pregnancy. A Patient Advisory Group (PAG) will be formed to provide patient stakeholder input during all stages of study execution. Approximately 15 reproductive age women who are privately insured will form the PAG, with one woman serving as the PAG coordinator. The PAG coordinator will be a member of the MyNewOptions research team and attend monthly investigator meetings. The PAG is expected to provide substantive input to the research team on intervention refinement. The PAG is expected to meet twice a year for the duration of the study (three years).

9.3. Provider Advisory Group

A Provider Advisory Group (PrAG) consisting of 10 to 15 members will be convened to consult on the proposed research. The proposed interventions were intentionally designed to take place outside of the clinical setting, due to the extremely limited provider time and resources in primary care settings. However, women seeking further information or a contraceptive method will need to see their health care providers to receive counseling and request prescription methods of contraception. Thus, primary health care providers for reproductive-age women are key stakeholders in the success of the study.

We plan to invite local physicians and mid-level providers who routinely provide primary care for adult reproductive-age women to participate in the PrAG. These providers will represent primary care (internal medicine and family medicine) and obstetrics and gynecology in both community and academic practices. The PrAG is expected to meet once a year for the duration of the project (3 years).

10. Data Management and Quality Control

10.1. Screening and Survey Completion

A web-based application will be used to screen participants for the MyNewOptions study. Vanderbilt University's Research Electronic Data Capture (REDCap) tool was specifically developed to help investigators build and manage online surveys and databases. REDCap is HIPAA compliant, entered data is encrypted and stored on a secure server, requires user authentication with password to access, allows functionality based on study personnel's role within the project, and records logging and audit trails on all data interactions. REDCap can remove identifiers from a dataset prior to exporting for analysis to create either a limited data set or a safe harbor data set. A safe harbor data set is the removal of the 18 pieces of information considered identifiers for the purposes of HIPAA compliance.

10.2. Randomization and Intervention Completion

The MyNewOptions website will be used to randomize eligible women to the study and will contain all of the intervention components. The website will utilize the network structure of the Penn State Hershey Medical Center which includes hardware and software resources enabling network connectivity, communication, operations and management of the enterprise network as well as communication path and services between users, processes, applications, services and external networks/the Internet.

10.3. Data Entry, Verification and Quality Control

REDCap will be used to build parameters or set acceptable ranges for participant question responses. If data issues are identified, we will attempt to verify data with participants whenever possible.

Once data collection is complete, data will be de-identified. No participants will be identified in any analyses or reports. A de-identified dataset will be maintained on a secure Hershey Medical Center server. Research statisticians will maintain the study database and insure the integrity of the data. Statisticians will devise our randomization scheme and verify its functionality before the study starts. Study team members will keep thorough records describing eligibility fails, dropouts and study adherence. No data will be analyzed until our statisticians have cleaned and reviewed the data.

10.4. Management of Administrative Data

REDCap will be used to facilitate the flow of information and increase the level of communication between MyNewOptions research team members and participants. In addition, a shared, password protected server will be used to maintain research records including all meeting agendas and minutes; IRB documents and status reports; participant communication and payment records; copies of abstracts, manuscripts and presentations; and any other pertinent study information.

11. Statistical Consideration

11.1. Introduction and Aims

MyNewOptions is a randomized controlled trial designed to test interventions for assisting privately insured women to formulate and achieve their reproductive goals and avoid unintended pregnancy.

- **The primary aim** is to assess whether women in the RLP and RLP+ intervention groups are more likely to use contraception when not intending pregnancy than women in the control group. Secondary outcomes include effectiveness of contraceptive methods chosen, method satisfaction, and contraceptive self-efficacy.

- **The secondary aim** is to assess whether women in the intervention groups have more continuous contraceptive use and contraceptive adherence over a two-year follow-up period than women in the control group.

11.2. Analysis Plans

11.2.1. Primary Outcome Variable (Aim 1)

11.2.1.1. Contraceptive use

Using standard measurement, participants will be asked at each assessment if they are currently doing anything to prevent pregnancy (Y/N).[49, 50] The primary outcome measure for Aim 1 will be the proportion of 6-month intervals women are reporting any contraceptive use out of the number of 6-month intervals women are not intending pregnancy. Duration of contraceptive method use will also be assessed. Whether any contraception is being used is defined as a binary variable (yes/no) at each 6-month interval post-baseline (6, 12, 18, and 24 months). We will construct a proportion for each participant as the number of time periods in which the participant is using contraception, divided by the number of time periods in which the participant is not intending pregnancy.

11.2.2. Secondary Outcome Variables (Aim 1)

11.2.2.1. Contraceptive method effectiveness

If women are using a method of contraception, the type of contraception will be identified.[49, 50] Contraceptives will be classified into groups based on known efficacy, determined by published typical failure rates, as shown in Table 2.[57] Contraceptive efficacy will be measured ordinally as: no method, less effective methods, more effective methods, and most effective methods.

Table 2. Categorization of contraceptive efficacy

Method	Typical-use failure rate in 1st year
No method	85
Less Effective Methods	
Withdrawal	22
Fertility-awareness methods	24
Condom (female)	21
Condom (male)	18
More Effective Methods	
Oral contraceptives	9
Evra patch	9
NuvaRing	9
Depo-Provera	6
Most Effective Methods	
IUD—copper T	0.8
IUD—Mirena	0.2
Contraceptive implant	0.05
Sterilization (female)	0.5
Sterilization (male)	0.15

11.2.2.2. Satisfaction with contraceptive method

A validated 5-item contraceptive satisfaction measure will be used that measures satisfaction with ease of use, effectiveness, side effects, cost, and overall satisfaction.[58] Additional validated items will be included to indicate satisfaction with partner support of the contraceptive method.[59]

11.2.2.3. Contraceptive self-efficacy

We developed and pilot tested a 9-item contraceptive self-efficacy scale for adult women for the purposes of this study. While a validated scale to measure contraceptive self-efficacy in adolescents exists,[60, 61] it was not applicable for adult women. Pilot testing indicated good internal reliability with a Crombach's alpha of 0.78.

11.2.3. Primary Outcomes Variables (Aim 2)

11.2.3.1. Continuity of Contraceptive Use and Adherence

Continuity of contraceptive use describes whether women use contraception continuously, or have periods where they stop using contraception while at risk for pregnancy. Items will assess contraceptive method use throughout the preceding 6 months to determine episodes of contraceptive use, gaps in contraceptive use, and risk for pregnancy during gaps in use. Contraceptive continuation over each 6-month assessment interval will be measured using an ordinal longitudinal contraceptive use typology as described by Frost and colleagues: 1) continuous contraceptive users of one method, 2) continuous users with at least one method switch, 3) non-continuous users with gaps in use when not at risk for pregnancy, 4) non-continuous users with gaps in use when at risk for pregnancy, and 5) continuous nonusers.[52, 62] This typology has been shown to be associated with risk for unintended pregnancy.[49, 61]

11.2.3.2. Contraceptive adherence

Contraceptive adherence will be classified as high, medium, and low using self-report and pharmacy claims data, depending on the type of contraception being used. For women who have had a sterilization procedure (male or female) or LARC initiation since study enrollment, adherence will be categorized as high. For coital-dependent methods, standard self-reported adherence measures[63, 64] will be used to define adherence categories as shown in Table 3.

Table 3. Definition of Contraceptive Adherence

Methods	Measurement	Definitions	Adherence Category
Sterilization or LARCs (i.e., IUD, contraceptive implant)	Self-report	Adherence assumed	High
Coital dependent methods (i.e., spermicides, withdrawal, sponge, condoms, diaphragm, fertility awareness methods	Self-report: What percent of time did you use your birth control method during sex in the past 6 months?	Always (100%)	High
		Most of the time (71-99%)	
		Often (51-70%)	Medium
		Sometimes (31-50%)	
		Occasionally (1-30%)	Low
		Never (0%)	
Oral contraceptives, contraceptive patch, contraceptive ring, DMPA	Pharmacy claims data: Medication Possession Ratio	MPR >90%	High
		MPR 80-90%	Medium
		MPR <80%	Low

While self-report measures of oral contraceptive adherence have been the standard in research of this type,[65] self-report has been poorly validated against electronic mediation monitors and biochemical assays of medication metabolites.[66,67] In light of this, we will measure adherence to prescribed contraceptives (i.e., oral contraceptives, patch, shot (DMPA), or ring) using *pharmacy claims data* through Highmark to determine medication possession ratios (MPR). The MPR is the sum of days supply for all prescription fills in the study period, divided by the number of days in the study period. Using pharmacy claims data in this manner can help characterize poor adherence to prescribed medications,[68] including hormonal contraceptives.[65, 69] Since direct observation of medication use is not possible in this study, acquisition of timely refills serves as an appropriate surrogate.[70, 71] Medication adherence has generally been accepted to be an MPR>80%,[68, 71] however this is likely too low when studying contraception.[72] Thus, we will define high (MPR>90%), medium (80-90%), and low adherence (<80%) categories. Highmark preliminary data shows that 6% of members disenroll annually. For participants who are no longer enrolled in Highmark, we will be unable to obtain MPR data for prescription contraceptives. In those cases we will use retrospective self-report measures on contraceptive compliance over the past 6 months. A recent study shows that retrospective report of oral contraceptive use in this manner is equivalent to prospective medication diaries.[73]

11.2.4. Other Outcomes

11.2.4.1. Unintended pregnancy

The incidence of unintended pregnancies throughout the 2-year study period will be studied as an exploratory outcome measure. At each follow-up assessment, participants will be asked if they have been pregnant in the past 6 months since the previous assessment. We will be able to define pregnancies as intended or unintended based on *prospective* measurement, which is a major strength of this longitudinal approach. Incident pregnancies will be considered intended if the woman reported intending pregnancy in the next year at the preceding interview, and unintended if she stated she was not intending pregnancy in the next year. Traditional measures of pregnancy intention have been criticized for being measured retrospectively, where women are asked after they have given birth to think back to before they got pregnant and recall whether or not they were intending pregnancy at that time.[74] Our previous work has demonstrated that prospective measurement of pregnancy intention strongly predicts future pregnancy over a 2-year period.[75] We will measure the unintended pregnancy rate in each of the 3 study groups in 2 ways: 1) the proportion of pregnancies that are unintended (49% of pregnancy unintended in U.S.)[2] and 2) the incidence of unintended pregnancies per 1000 women per year (there were 51 unintended pregnancies per 1000 U.S. women per year in 2001).[2]

11.2.4.2. Satisfaction with each condition

We will assess participant satisfaction with each of the 3 conditions and how easy they were to use.

11.3. Analytic Methods

11.3.1. Specific Aim 1

The outcome variables are binary (contraception use; satisfied with contraceptive method) and ordinal (contraceptive method effectiveness), and will be measured at four time periods post-baseline (6, 12, 18, and 24 months). For the binary outcome variables, we will construct a proportion for each participant as the number of time periods in which the participant's response is positive, divided by the number of time periods in which the participant is not intending pregnancy. The denominator will be four, except for those participants who withdraw consent from the study, change their minds about intending pregnancy during the study, or become pregnant. Therefore, we will apply a binomial regression analysis to these proportions. We will use intervention group assignment (intention-to-treat analysis) as the sole regressor in the primary analysis, but we will investigate in secondary analyses the effects of selected covariates on the proportional response (demographics; pregnancy history; sexual and contraceptive history; perceived control/fatalism toward contraception; relationships; compliance with log-in requirements). In terms of the three randomized groups, we will construct two-sided test statistics for comparing: 1) RLP to control, 2) RLP+ to control, and 3) RLP to RLP+. Therefore, we will impose a Bonferroni correction factor to the significance level (alpha = 0.0167). We will apply additional secondary analyses that are longitudinal, in which we invoke a logistic regression model with random participant effects to investigate if there are any time period effects and/or time period by intervention interactions for the binary outcomes. Finally, we will invoke a shared parameter model[76] to account for the informative censoring that could occur due to participant withdrawal in a longitudinal study. In our setting, the shared parameter model includes a Weibull time-to-event regression model for the time to participant withdrawal in conjunction with a logistic regression model with random participant effects for the binary outcome.

For the ordinal outcome variable of contraceptive method, we will code it for each participant as 0 (no method), 1 (less effective method), 2 (more effective method), or 3 (most effective method), and we will construct an average score for each participant across those time periods in which the participant is not intending pregnancy. We will apply a weighted regression analysis to these average scores, in which the weighting factor for a participant is the variance of her estimated average. Then the statistical analysis will proceed in a similar manner to that described above for the binary outcomes, and we will embed an ordinal logistic regression model with random participant effects to investigate if there are time period effects and/or time period by intervention interactions.

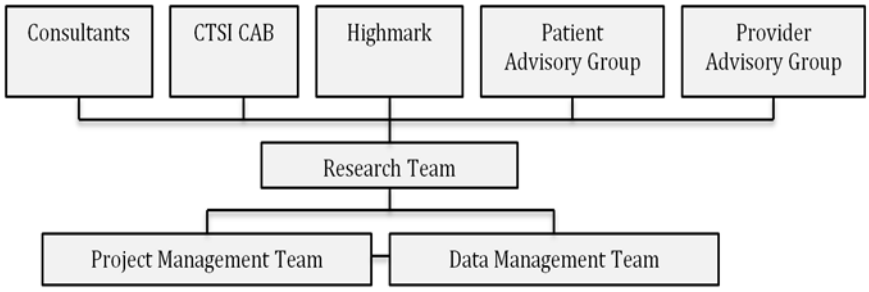
11.3.2. Specific Aim 2

The outcome variables are ordinal (continuity of contraceptive use; contraceptive adherence), and will be measured at four time periods post-baseline (6, 12, 18, and 24 months). For the contraceptive continuation, we will code it for each participant as 0 (continuous non-use), 1 (non-continuous use with gaps when at risk for pregnancy), 2 (non-continuous use with gaps when not at risk for pregnancy), 3 (continuous use with at least one method switch), or 4 (continuous use of one method).[62] For the contraceptive adherence variable, we will code it for each participant as 0 (none), 1 (low), 2 (medium), or 3 (high). We will analyze these ordinal outcomes in the same manner as described above for the ordinal outcome in Specific Aim 1.

12. Trial Organization

The governance plan for the proposed project was created so the Research Team could have continuous input from external consultants, community representatives, Highmark Health, patients, and health care providers (Figure 2).

Figure 2. Governance Plan



12.1. Consultants

Two consultants have joined the research team to provide specific expertise.

- **Merry-K. Moos, RN, FNP, MPH** is a Research Professor Emeritus in the Department of Obstetrics and Gynecology at the University of North Carolina at Chapel Hill. She is a leader in the field of preconception care whose reproductive life plan was adopted and endorsed by the CDC, and which we have adapted for our RLP/RLP+ interventions.

- **Christopher Armitage, PhD** is a Professor of Health Psychology at the University of Manchester, United Kingdom. He is an expert in action planning ("implementation intentions")—the skills building strategy in the RLP+ intervention. Dr. Armitage's work has suggested that "boosters" can be very successful in action planning interventions, and can significantly increase the impact of an intervention. Accordingly, he helped design the "boosters" to be used in this research study.

12.2. Community Advisory Groups

Four groups help guide the research team: the Penn State Clinical and Translational Science Institute's Community Advisory Board, Highmark Health, the Patient Advisory Group and the Provider Advisory Group.

- **Penn State Clinical and Translational Science Institute's Community Advisory Board (CTSI CAB):** This group is comprised of local community representatives who are stakeholders in the health of Pennsylvania residents. The CAB has identified the health of reproductive-age women as a health priority area for the Central Pennsylvania region and has specifically identified prevention of unintended pregnancy as a long-term goal for community-engaged research within the Penn State CTSI. CAB members include representatives of local communities and service agencies (including family planning providers) who have contributed to the design

of this project by helping to introduce the project to Highmark, by contributing insights from patient populations, and by providing information about Internet access in the target population in the Central Pennsylvania region.

- **Highmark Health:** A full-service private health plan that operates health insurance plans in Pennsylvania, Delaware, and West Virginia serving 4.9 million members. Highmark, which has the 4th largest membership of all Blue plans nationwide, has partnered with this research team in the development and execution of the proposed research. Highmark has been an enthusiastic partner in the development of this proposal not only because of the need to comply with ACA mandate for contraceptive and contraceptive counseling coverage, but also due to their desire to be leading innovative strategies for health insurers to assist female members achieve their individual reproductive goals. If the intervention proves to be successful, Highmark will have a significant role to play in determining how the intervention can be incorporated into the Highmark Wellness Program that is available for all members, as well as disseminate the intervention to other private and public insurance carriers.

- **Patient Advisory Group (PAG):** The most important stakeholders in this research are the target population—Highmark members who are adult reproductive-age women at risk for unintended pregnancy. Women from this target population participated in the listening sessions that were key to the development and refinement of the RLP and RLP+ interventions. A group of 10-12 members will be assembled for the three year study. All PAG members will meet the eligibility requirements of the study participants. The PAG members will meet six times throughout the study to give feedback on the proposed web-based materials for the intervention, finalize strategies for recruitment and retention, provide advice on the conduct of the research study, interpretation of findings, and future dissemination plans. Members will be compensated $100 for each of the meetings, plus any childcare and travel reimbursement.

- **Provider Advisory Group (PrAG):** To lend their experience and consult on this research, we will convene a 10-12 member group of providers. The proposed interventions were intentionally designed to take place outside of the clinical setting, due to the extremely limited provider time and resources in primary care settings. However, women seeking further information or a contraceptive method will need to see their health care providers to receive counseling and request prescription methods of contraception. Thus, primary health care providers for reproductive-age women are key stakeholders in the success of this trial.
  We will invite local physicians and mid-level providers who routinely provide primary care for adult reproductive-age women to participate in the PrAG. These providers will represent primary care (internal medicine and family medicine) and obstetrics and gynecology in both community and academic practices. The PrAG will meet annually during the course of the study. Their consultation will be especially important in interpreting the findings, developing dissemination plans and planning next steps.

13. Study Timeline

	Year 1				Year 2				Year 3			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
IRB submission	X											
Final website production	X	X										
Patient Advisory Group Meeting		X		X		X		X		X		X
Provider Advisory Group Meeting							X					X
Participant recruitment and randomization		X	X									
Baseline assessments		X	X									
Baseline intervention: RLP, RLP+, or control		X	X									
6-month assessment				X	X							
6-month booster: RLP and RLP+				X	X							
12-month assessment						X	X					
12-month booster: RLP and RLP+						X	X					
18-month assessment								X	X			
18-month booster: RLP and RLP+								X	X			
24-month assessment										X	X	
Data analysis				X	X	X	X	X	X	X	X	X
Abstract and manuscript preparation				X	X	X	X	X	X	X	X	X

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