IN Control: Contraception Navigator Program for Adolescents and Young Adults in Indiana

NCT05691270

IRB Approval Date: April 23, 2018

Protection of Human Subjects

1. Risks to Human Subjects

a. Human Subjects Involvement, Characteristics and Design

For this portion of the research proposal (Aim 2), we will focus on conducting a pilot study of the Youth Contraception Navigator (YCN) to demonstrate feasibility and effectiveness of the intervention. Specifically, we will examine whether our intervention was successful at addressing self-efficacy and barriers (both environmental and personal) to contraception access encountered at all stages of the process. The YCN, which builds upon previous work in the field of adolescent contraception access and utilization, will be comprised of both an "outreach strategy" and a "navigator program" which were developed as part of the work in a pervious Aim of this proposal. My central hypothesis is that facilitating access and utilization of contraception through the YCN intervention will result in an increased use of contraception and a decreased rate of unplanned teen pregnancy.

We will implement the outreach strategy created in Aim 1b to target adolescents within Marion County, Indiana (See Section 4.3.1). The outreach strategy will provide interested adolescents with two options to initially engage with the YCN: a) Communicate directly with navigator staff via a phone call, text, or email. Following that phone call, the adolescent would be sent a link (by email and/or text) to the *My Birth Control (Navigator Version)* decision aid b) Go directly to the website where they will be directed to complete the *My Birth Control (Navigator Version)* decision aid.

After completing *My Birth Control (Navigator Version)* the adolescent will be provided with a summary that includes the methods of contraception they have indicated interested in and a ranked listing of environmental and personal barriers the adolescent is most concerned about. At this point, they will be asked if they would like to receive additional support from a navigator staff member to answer any additional questions or help in overcoming their barriers to contraception access and use. They will be asked to provide their name and preferred manner of contact (in-person, email, phone, texting). Navigator staff will then reach out to them to inquire what assistance is needed and which services might be of assistance to the adolescent.

All adolescents who engage with the YCN (see Section 4.3.4.2) will be asked if they would like to formally enroll as a study participant after completion of the *My Birth Control (Navigator Version)* decision aid. Interested adolescents will be screened for eligibility online, which includes being an English-speaking female between the ages 15-17 who lives within Marion County (determined by zip code of primary residence) and is seeking contraception. Eligible adolescents will be asked to supply their contact information and will then be contacted to a navigator staff member in order to confirm eligibility and provide verbal assent in order to participate in the study. Adolescents who do not wish to formally enroll as study participants will still be able to utilize the services of the YCN, however additional data will not be collected.

We anticipate formally enrolling 50 adolescents in our study. Additionally, after the navigation process is complete, we will ask a sub-set of study participants to provide feedback through a Post-Pilot debriefing. We anticipate recruiting 30 participants for the debriefing but will recruit until we reach thematic saturation.

b. Study Procedures, Materials, and Potential Risks

Data will be obtained from study participants at enrollment and program completion. Study participants will receive a $25 gift card at each data collection point. If selected to participate in the Post-Pilot debriefing interview, they will receive an additional $40 gift card.

Demographic Data. We will collect demographic characteristics such as age, race, ethnicity, zip code, and previous contraception use at study enrollment. Data will also be collected on a voluntary de-identified basis from non-study participants after completion of the *My Birth Control (Navigator Version)* decision aid.

Effectiveness and Feasibility of the YCN Intervention. We will collect the following data from study participants:

1. Satisfaction with the Contraception Navigator Program measured via an online survey filled out upon program completion to assess satisfaction with the outreach strategy, *My Birth Control (Navigator Version)* decision aid, navigator staff, and services of the navigator program.
2. After the navigation process is complete, we will ask a sub-set of study participants to provide feedback through a Post-Pilot debriefing. Our target sample size is 30 participants chosen equally from our three racial/ethnic populations for the debriefing but will recruit until we reach thematic saturation. Feedback

will be collected via a 30-minute telephone interview. Topics to be explored will include adolescent's reasons for seeking help to obtain contraception, how they learned about the YCN and why they ultimately contacted the program. We are also interested in views about the program's impact on access to contraception, changes occurring as a result of participation, reflections on the outreach and navigation process, barriers encountered not addressed through the program, and overall impression of the program.

Additionally we will assess the following statistics:

• Number of unique website visitors • Number of website visits • Number of phone or email inquiries to Navigator Staff • Completion rate of the *My Birth Control (Navigator Version*) decision aid (i.e., # of individuals who start compared to # of individuals who complete the decision aid) • Rate of YCN Program Interest (i.e., # of individuals who request contact from navigator staff compared to # who do not)	• Contact Success Rate (i.e. ,# of individuals endorsing wanting additional help from navigator staff compared to the # of individuals successfully contacted by navigator staff) • Penetration Rate (i.e., # of completed *My Birth Control (Navigator Version)* decision aids compared to estimated eligible target population within Marion County.

*Success of the YCN at addressing self-efficacy as well as our selected environmental and personal barriers. W*e will collect the following data from formally enrolled study participants only:

1. Contraception self-efficacy assessed at enrollment and compared to post-program completion using the validated Contraception Self-Efficacy scale.[153] This scale measures the strength of sexually active adolescent's conviction to obtain contraception using 15 situational questions.
2. Knowledge of contraception assessed at enrollment compared to knowledge post-program completion using the validated Contraception Knowledge Assessment.[154]
3. Environmental and Personal Barriers addressed by the navigator program measured as the number of barriers successfully addressed divided by the number of barriers identified via the barrier assessment included in the *My Birth Control (Navigator Version)* tool.
4. Contraception method preferred from *My Birth Control (Navigator Version)* compared to contraception ultimately obtained.

There are two primary risks associated with our work:

1. Loss of confidentiality is a potential, although unlikely risk.
2. There is the potential of minimal psychological risks or discomfort associated with participating in interviews, activities and/or discussions regarding sexual activity and contraception.

2. Adequacy of Protection Against Risks

a. Informed Consent and Assent

All adolescents who contact the Youth Contraception Navigator Intervention will be asked if they would like to formally enroll as a study participant. This study has IRB Approval and a waiver of parental consent was granted. Interested adolescents ages 15-17 will be asked to provide written assent at the time of study enrollment. Adolescents who do not wish to formally enroll as study participants will still be able to utilize the services of the Youth Contraception Navigator Intervention, however additional data beyond that required to utilize the services of the program will not be collected.

During the consent process, participants will be fully informed about the purpose of the study, potential risks and benefits of participation, and that their participation is voluntary. In instances where personal identifying information must be collected in order to coordinate and plan the interviews/group sessions, provide compensation, participants will be reassured that identities will not be linked to the information they provide.

Protocols, any associated tools/instruments used for data collection, and consent/assent forms will be approved prior to collecting data.

b. Protections Against Risk

Loss of confidentiality is a potential, although unlikely risk. Data access will be limited to the PI and relevant study personnel, who will use passwords for their encrypted computer system, and be trained in confidentiality procedures offered by Indiana University. All electronic data files used for data analysis purposes will be completely de-identified and anonymous. Data collected during the course of this study in the form of video or audio files will be kept in a locked file cabinet in the PI's office, which is also kept locked, and is located in a building with keycard access. This is also true for any handwritten notes from in-person interviews/group sessions. At the end of the study we will destroy all audio and video recordings and all hard-copy data will be shredded per Indiana University requirements. Any publications or presentation of data that may result from

this research will be completely de-identified. In instances in which participants are required to provide their name and contact information so that they can be contacted or provided with compensation, this information will be decoupled from research data and stored in a separate, password-protected database on an encrypted PC accessible only by the study PI and relevant study personnel.

We will try to minimize any potential psychological risks associated with participating in the activities/interviews/discussions for Aim 2 by informing participants that answers provided will be de-identified; that any and all data associated with this research will be treated with the highest levels of security. Additionally, participants will be informed that there are no right or wrong responses and they can choose to not answer questions. We will also identify a point of contact that is trained to help persons experiencing psychological distress should any participants require such assistance.

We feel that all these procedures will be effective to minimize potential risks to participants.

c. Vulnerable Subjects, if relevant to your study

The focus of our research is adolescent females between the ages of 15-17 who are sexually active or contemplating sexual activity, and this population can certainly be considered a vulnerable population. We have chosen this group of adolescent in particular to be the subjects of our study because they are at high risk of barriers to contraception access and thus could have a resulting unplanned pregnancy. However, we believe that the risk to participation is minimal (see 2a) and the additional protections outlined in section 2b will be in place for the participants of the study.

3. Potential Benefits of the Proposed Research to Research Participants and Others

For Aim 2, the direct benefit to participating in the Youth Contraception Navigator Intervention pilot is to receive personalized assistance with obtaining hormonal contraception as well as compensation if they decide to participate in the de-briefing interviews.

There is a significant benefit to the State of Indiana and society at large, as the results of this research has the potential to help adolescents access contraception and prevent unplanned pregnancy, the results of teen pregnancy, both for the parents (higher rates of unemployment and poverty, lower educational achievement and health outcomes) and the children (poorer educational, behavior and health outcomes and higher rates of pre-term birth) born to them—can be avoided.

All of these benefits will accrue with minimal risk to subjects.

4. Importance of the Knowledge to be Gained

We will pilot test the feasibility of a Youth Contraceptive Navigator Intervention to activate adolescents to seek help in obtaining hormonal contraception through this program. We will learn about the frequency of certain environmental and personal barriers experienced and the ability for adolescents to overcome them and ultimately access contraception with the help of the Youth Contraception Navigator Intervention. The knowledge gained through this pilot testing will help inform and improve the program before it is scaled-up to improve access to contraception for adolescents in a larger geographic area within the state.

Research has shown that improving access to contraception decreases unplanned pregnancy rates. Therefore, if the Youth Contraceptive Navigator Interventionis able to improve access and subsequent utilization of contraception for adolescents, the rate of unplanned pregnancy in the state of Indiana could ultimately be lowered in the long term. This has direct implications for adolescents themselves, but also the community in which they live and could be a model that is replicated in other states or geographic areas throughout the country.