Official Title:
Effectiveness of LARC Forward Contraceptive Counseling and Same Day Placement in a Community College Population: A randomized intervention project

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1) Protocol Title

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2) Objectives

Hypothesis: Contraceptive options counseling highlighting LARC methods in combination with same day, LARC placement will increase overall LARC uptake within a Community College population as compared to LARC forward counseling and referral to a secondary clinic for LARC placement.

Primary objective: To determine whether same day, on site provision of LARC methods compared to standard off-site provision will increase LARC uptake within a community college population.

Secondary objectives:

1. To examine the effect of LARC usage within a community college population on overall unplanned pregnancy rates.
2. To evaluate the effect of LARC usage within a community college population on the 2-year certificate completion rate and continuation of education (exploratory).

Intermediate outcomes:

1. To measure continuation rates of the participants chosen method of birth control.
2. To assess student satisfaction with the intervention group at 6 and 12 month follow up surveys.

3) Background

Among the 50% of pregnancies that are unintended in the United States[2], about half of these women report current contraceptive use[3][8]. Long acting reversible contraceptive (LARC) methods are known to be more effective than shorter acting, user dependent methods such as oral contraceptive pills as they are not dependent on any action by the user once they have been placed[8]. While intrauterine devices (IUDs) have failure rates similar to permanent contraception (0.1% to 0.8% in the first year of use), the typical first year failure rate for oral contraceptives is 9%[8]. However, in 2012 only 9.3% of women at risk of unintended pregnancy in the U.S. were using an IUD for contraception and 1.2% were using the contraceptive implant[5], the two forms of LARC available. The CHOICE study found that women tended to both underestimate the effectiveness of LARC methods and overestimate the effectiveness of short acting methods such as the pill, patch and vaginal ring, but after counseling over 70% chose a LARC method[13]. This highlights the importance of directed structured counseling regarding typical use failure as a motivating factor to increase LARC usage (LARC forward counseling). Recent studies by Bednarek, et al. demonstrated that same day placement of an IUD after an abortion instead of standard delayed insertion may prevent as many as 70,000 unplanned pregnancies per year in the U.S[8]. Additionally, of women who seek abortions, recent studies have shown that delayed placement may increase the risk of repeat unintended pregnancy as 25% to 68% of patients will not return to the clinic for IUD placement if they are not provided with same day insertions[2][8].

The risk of unintended pregnancy is increased in patients of minority racial and ethnic backgrounds, of low socioeconomic status and in those less than 25 years of age[13]. Research has shown that LARC methods are less likely to be used by women in these groups[7]. According to the National Health Statistics Report in October 2012, only 31% of teenagers aged 15-19 years use any form of contraception at the time of the interview, though 59% of the women in this age group reported either never having intercourse or no intercourse in the last 3 months[7]. Of those teenagers who did report using contraception, 53% of those women use the pill, despite the fact that fertility is higher in these women and they are at greater risk of contraceptive failure. Conversely, only 10% of women

aged 40-44 years use the pill for contraception, while over 30% have chosen permanent contraception[7]. In 2008, the most recent year national data on unplanned pregnancy rates is available, the unplanned pregnancy rate was 5 times higher in women below the poverty level compared to women at 200% of the poverty level[14]. The unplanned pregnancy rate in women below the poverty level was 137 per 1000 women as opposed to 26 per 1000 women at higher socio-economic statuses, which significantly contributes to the overall national rate of 54 unplanned pregnancies per 1000 women[14]. Oregon's unplanned pregnancy rate among women aged 15-44 is lower than the national average at 41 per 1000[14]. This is in large part due to the ability of women to access effective contraception through a combination of programs including Medicaid, Title X and CCare. Obviously more needs to be done, as this is still a significant unplanned pregnancy rate.

A variety of programs exist both nationally and within Oregon to assist with the cost of contraceptive care for low-income women. Title X is the only federally funded grant program dedicated to providing family planning services. It was enacted in 1970 as part of the Public Health Service Act[15]. Any public or nonprofit entity within the U.S. may apply for a Title X family planning services grant[16]. Through this program, family planning services may be provided to patients 100% or below the federal poverty level on a specified sliding scale. While this program makes contraceptive options more financial feasible for many women, it requires clinics to apply for and receive a Title X grant, which takes the control out of the patient's hands and requires the individual clinics to ensure these services are provided. Under the Patient Protection and Affordable Care Act of 2010, women who have health insurance can receive FDA approved forms of contraception with no additional cost beyond their annual premiums. However, this requires women be enrolled in an insurance plan. In 2013, 13.4% of the population did not have health care for the entire year[17].

In Oregon, women can access all methods of contraception either through their private insurance or through various publically funded sources for low-income families. Women in Oregon have an additional option referred to as Oregon Contraceptive Care (CCare). Within this program, residents of Oregon who are legal US citizens who make $566/week or less qualify for a one year supply of birth control of their choice or full coverage of LARC methods, which remain effective for three to 10 years depending on the device[18]. Despite this, LARC methods remain underutilized among certain populations[19][20]. Simply removing cost barriers is not always enough to increase LARC usage among high-risk populations[21]. Same day insertion significantly increases LARC uptake[2]. However, programs such as CCare and Title X that help to remove the cost barrier for these populations may require prior approval[15], which prohibits same day placement. In other words, the cost of the device may be covered but then these women have to take additional time off work (or miss classes in our study population), find child-care and/or transportation back to the clinic for a second appointment once the device has been approved. This in itself may be cost prohibitive and an often-unrecognized barrier.

The community college population is a diverse and unique population within the U.S. Students tend to be within a lower socioeconomic bracket prior to starting school, unlike many students who pursue a traditional 4-year college or university education[9]. At Mount Hood Community College, our proposed study site, 34.5% of students surveyed reported an annual household income of less than $10,000 and over 70% reported an income of less than $25,000. These students have chosen to pursue their education thereby potentially improving their socioeconomic standing. An event such as an unplanned pregnancy may delay or even prevent their completion of their educational goals. As described in the 2015 Reproductive Health Technologies Project, women must have the opportunity to plan their pregnancies "in order to have the best opportunity to achieve their education, employment and economic goals" as their reproductive years overlap with their time in school and entering into the workforce[10]. Pregnancy is the major reason for teenage girls dropping out of school in the U.S[21] and it can be inferred that this is also a significant contributing factor within a community college population. At our proposed study site, approximately 34% of the student body is non-white, approximately 55% of the student body is female (14,521 students in 2014-2015) and about half are degree seeking[22][23]. However, in 2014 only 1.8% were noted to have completed their 2-year associates degree or equivalent certificates within the program's allotted timeframe[11]. It is unknown whether unintended pregnancy contributes to poor completion rates for women.

The Contraceptive CHOICE project, more commonly known as the CHOICE Study is a highly successful intervention project which enrolled 9256 women between 2007 and 2010 in the St Louis, Missouri area. The goal of this study was to decrease the high unintended pregnancy rate in the city by increasing uptake of LARC methods of birth control[13]. All women in the study received standardized contraceptive counseling, after which they were provided the contraceptive method of their choice free of charge for up to 3 years. By removing both financial and knowledge barriers, LARC usage within the study population was increased to 67%[3]. The cost of this project limits its utilization in other settings but components of it may prove just as successful. The study has made its counseling script, as well as English and Spanish version counseling videos available online for continued use outside of their study. The increased patient knowledge of contraceptive options alone is expected to increase LARC usage among patients. Our study will use the contraceptive options counseling made available by the CHOICE Study to counsel all study participants. Another aspect of the CHOICE Study that could be beneficial in a variety of populations is increasing access to same-day LARC placement. Studies of immediate post-partum and post-abortion LARC placement have shown increased LARC usage at 6-month follow-up, highlighting the importance of same day placement over interval placement[2][8][24].

The primary aim of our study is to determine whether a “LARC forward” counseling method similar to the Choice Study, and the availability of on-site same day LARC placement will increase the usage of LARC methods in a community college population. We plan to randomize women to same day/on-site placement or referral. While the overarching goal of our research is to help decrease unplanned pregnancies in female students to help them complete their certificate (2 year degree), our primary outcome will be the proportion of each group using a LARC method at 6 months.

We anticipate that by providing LARC forward contraceptive counseling with same-day on campus LARC provision, we will be able to significantly increase LARC usage among at-risk female students at Mount Hood Community College. Additionally, we anticipate that by increasing LARC usage we will decrease the rate of unplanned pregnancies and observe a higher rate of certificate completion. This study, however, is limited to an 18-month period. Results of this study will inform future efforts in which follow-up of participants will include a greater number of years to assess certificate completion rate as well as to evaluate the financial/social impact of same-day LARC access on this population. The community college population has thus far been a little studied population within the contraceptive literature. This study will be the first step in filling in this gap in the literature and providing the groundwork for further studies within this population.

The community college population is rarely a focus in the contraceptive literature. This project will be one of the first to examine contraceptive use in this population. It will provide critical information on methods to increase LARC usage within this population. Additionally, by showing that LARC usage is increased with same day on site placement, this study may help inform policies supporting the return of funding to student health clinics in Oregon. We plan to provide on site LARC placement within facilities at Mount Hood Community College of Gresham, Oregon. We will recruit female students and after informed consent randomize them to counseling with or without same day LARC placement. Our primary outcome will be the proportion using a LARC method at 6 months, we plan to follow subjects for at least one year after to evaluate not only uptake but also the effect this has on their continuation in school. Results of this study will inform future efforts in which follow-up of participants will include a greater number of years to assess certificate completion rate as well as to evaluate the financial/social impact on this population.

4) Study Design

This prospective randomized controlled study will evaluate if LARC forward counseling in combination with same-day LARC placement increases overall LARC uptake within a community college population compared to LARC forward counseling and referral to a secondary clinic for LARC placement. The study will be conducted at Mount Hood Community College (MHCC) in Oregon. Currently, no opportunity exists to receive same-day LARC placement on-campus at MHCC, as no

student health clinic exists at this site. Currently, a space at MHCC is being remodeled into clinic space and an exam rom in which the research visits would take place. During the study period, the Principal Investigator (PI) or another provider listed on the study protocol will be present to place LARC devices to study participants.

Participants will be enrolled into three groups. All groups will receive the same standardized contraceptive counseling ("LARC forward counseling"). After the participant has made a decision to use a LARC method, she will be randomized to same day (intervention) or referral for (usual) LARC placement. Participants who chose a short-acting hormonal method (e.g. contraceptive pills, ring, or patch) will receive a prescription to the pharmacy of their choice, as is the current practice for students who present for contraceptive services. For women that elect to use a vaginal diaphragm, the one size Caya device will be prescribed. Women that chose non-LARC methods will be followed the same as women picking a LARC method, but will not be randomized. Included in the follow-up questionnaires will be a question on if they have experienced a pregnancy since their initial study visit and the outcome of that pregnancy, including termination.

Baseline demographic information and reproductive health practices and knowledge will be obtained prior to contraceptive counseling. A post-placement survey completed three months after the initial visit and additional questionnaires at six and 12 months will be completed for all groups (see Appendix). These questionnaires will be used to determine ongoing contraceptive use and satisfaction.

Questionnaires will assess if participants:

1) are still using the contraceptive method initiated at the study onset
2) are happy with this method
3) would recommend the method to a friend
4) have had any unplanned pregnancies during the study period as well as the outcome of that pregnancy.

In addition to the standard research participation consent, participants will be consented to allow our team access to electronic medical records for care outside of OHSU pertaining to pregnancy and contraception and to access their student records to confirm completion of their certificate at MHCC in the case that they are lost to follow up.

Study Events by Study Arm

	Non-LARC group	**Control group**	**Intervention group**
Encounter 1			
- **Intake Questionnaire**	X	X	X
- I**nformed Consent**	X	X	X
- **Enrollment**	X	X	X
- **Standardized "LARC forward" Counseling**	X	X	X
-Participant chooses birth control method	X	X	X
-Randomization of participants choosing LARC	**-**	X	X
- **Same-day LARC offered**	-	-	X
- Post-LARC placement survey (3 months)	X	X	X
Encounter 2			
- 6-month Questionnaire	X	X	X
Encounter 3			
12-month Questionnaire	X	x	x

5) Study Population

a) Number of Subjects

OHSU personnel will recruit all participants from MHCC. We anticipate that of all participants randomized to the control and intervention groups that desire a LARC, 60% in the control group will have had them placed by the 3-month follow-up and 85% in the intervention group will continue to be using their LARC method at the 3-month follow-up. Using PASS software, we determined that a sample size of 100 (50 in each of the control and intervention groups) allows us to determine this 25% difference in LARC uptake between groups (e.g., OR of 1.25) with an 80.9% power and an alpha of 0.05.

The CHOICE Study saw a 67% increase in LARC uptake with their interventions. From this we anticipate that 70% of our study population will be interested in LARC. We anticipate approximately 150 total participants in the study if 30% choose short acting methods. However, as the short acting arm of the study is for descriptive purposes only, we will not limit this arm to exactly 50 participants as in the control and experimental LARC arms of the study. Given that we anticipate approximately 100 screen fails, we anticipate approximately 250 participants will initially be enrolled in the study prior to screening.

A second goal of this study is to estimate the difference in LARC uptake between the two populations. Based on these same parameters and assumptions the study will enable us to report the difference in proportions with a precision (95.0% confidence level) of approximately plus/minus 0.17 points. Specifically, an observed difference of 0.25 would be reported with a 95.0% confidence interval of 0.08 to 0.42. The precision estimated here is the approximate expected precision.

Power calculations were not performed for our secondary outcomes as we anticipate that given the short time period of the study, they will be descriptive only.

b) Inclusion and Exclusion Criteria

Subjects: Subjects will be recruited from the female student population at Mount Hood Community College. All subjects will be pre-screened using the telephone screening script to ensure eligibility prior to signing consent and enrollment into the study.

Inclusion criteria:

1. English or Spanish-speaking women.
2. 17-30 years of age.
3. Currently enrolled in a 2-year certificate program at Mount Hood Community College.
4. At risk for pregnancy (sexually active with men or anticipate becoming sexually active in the next 6 months).
5. Do not desire pregnancy within the next 12 months.
6. No contraindications to LARC according to the CDC MEC (medical eligibility criteria) [23][24].

Exclusion criteria:

1. Women who are not currently sexually active with men and who do not anticipate becoming sexually active with a male partner in the next 6 months.
2. Women who have had a tubal ligation or other sterilization procedure.
3. Women who desire pregnancy within the next 12 months.
4. Women currently already using a LARC method for contraception.

Any participant who does not meet the above inclusion and exclusion criteria will not be enrolled in the study and all PHI will be stored confidentially with the research study information in a

locked cabinet and archived with other study-specific documents at the close of the trial (see Privacy, Confidentiality, and Data Security for more information).

c) Vulnerable Populations

No vulnerable populations will be specifically recruited or included in this study. Subjects under the age of 18 may be enrolled in this study, but will not be considered a vulnerable population since research procedures involve providing birth control information and services.

d) Setting

This study will be conducted by OHSU personnel and will undergo an OHSU Institutional Review Board. All participants will be recruited from Mount Hood Community College (MHCC) and the initial visit will occur on the MHCC campus. MHCC does not have an IRB and no additional IRB approval will be required. Participants will complete follow-up questionnaires online via REDCap. The REDCap database will be maintained through OHSU and all analysis of study data will take place at OHSU.

e) Recruitment Methods

Participants will be recruited from MHCC through a combination of flyers on campus, emails, and mailed recruitment letters sent to all female students fitting our inclusion criteria. The MHCC Student Government has agreed to assist with this process. With the assistance of the student government at MHCC, we will send recruitment letters to all eligible female students. Students will be eligible if they are enrolled in a 2-year certificate program at MHCC with at least one semester remaining, 17 – 30 years of age, and needing/ seeking contraception with no known contraindications to LARC, similar to the CHOICE study [11]. Informed written consent, including consent to obtain participants medical records concerning pregnancy, abortion and contraception via CareEverywhere and from surrounding clinics and hospitals, will be obtained. We anticipate a two-month recruitment process, during which time each of the above methods will be utilized once. If adequate recruitment has not been achieved by this time, additional e-mails will be sent to eligible students. Subjects that are interested in the study will be screened using a telephone script prior to enrollment in the study.

Participants will receive a $50 gift card at time of enrollment if they qualify for the study and agree to participate. They will receive an additional $10 gift card for completion of the 3 and 6 month-questionnaires and an additional $50 at the completion of the 12-month questionnaire if they have completed all 3 questionnaires. Participants completing the final questionnaire who have missed one or more previous questionnaires will receive a $10 gift card for each questionnaire they completed but not the total $120 available to participants who complete all questionnaires.

f) Consent Process

After initial intake confirming potential participants fit our inclusion and exclusion criteria (see above), individual students will attend their first research appointment at the MHCC health clinic space and complete an informed consent form confirming their participation in the initial study visit and their willingness to be contacted for follow-up questionnaires for up to one year after their initial visit. The consent will include pregnancy testing for all participants, and explanation of the randomization process and allowing for follow-up questionnaires for a minimum of 12 months after their enrollment in the study, with the potential for an additional 2 years of follow-up. A one page, plain language description of the project will be provided to all participants upon initial presentation. This will include an explanation that participants may withdraw from the study at any time if they so chose. The study coordinator, PI or co-investigator will then be available to answer any additional questions the participant may have concerning the study.

All questionnaires will be conducted electronically via REDCap. Participants will be initially contacted via e-mail with a link to the follow-up questionnaires. They will receive weekly reminder e-mails via the REDCap system. If they have not completed their questionnaire within 30 days of the first reminder, they will be contacted via phone by study personnel and a reminder with the REDCap website will be mailed to them if they cannot be reached by phone.

Modifications to the Consent Process

All participants will be consented with an OHSU IRB approved consent form at the start of the study to receive the LARC forward counseling and choose a method of birth control, once eligibility is confirmed. Consents will take place prior to randomization. For participants who chose a LARC method and are randomized to same day placement, they will then be consented using the manufacturer's standard consent form for the LARC device of their choosing at the time of placement.

Non-English Speaking Subjects

All documentation and consents will be available in both English and Spanish to provide participants with documentation in their primary language.

Assent of Children and Parent Permission

No minors will be included in this study and parental permission is not required.

Adults Unable to Consent/Decisionally Impaired

All participants in the study must be capable of informed consent for themselves.

6) Procedures

Potential participants who respond to recruitment methods will be screened over the phone by study staff to verify they meet basic inclusion and exclusion criteria, including absolute contraindications to IUD and Nexplanon usage. This will take about 15 minutes. If they meet criteria they will then scheduled for their initial intake visit. Every effort will be made to schedule participants not currently on a highly effective form of contraception during the first two weeks of their menstrual cycle to facilitate same day placement.

At the initial visit, participants will be consented for the study and an initial questionnaire including demographic information (age, race, BMI, obstetric history, sexual history, prior contraceptive use, current contraceptive use) and contraceptive knowledge (efficacy of sterilization, LARC methods, Depo-Provera, pills/patches/ring, condoms and withdrawal) will be administered. The participants will then watch a standard LARC forward counseling video (available at http://larcfirst.com/sessions.html). After the counseling video is complete, either the PI, co-investigator or Research Coordinator will then discuss with the participant their contraceptive method of choice, establish if they have any contraindications to that method and answer any questions they have concerning their contraceptive options. Participants desiring a short acting method such as pills, the patch or the ring will be provided with a prescription to be filled at their convenience. Participants desiring Depo-Provera will receive their first injection at that time with a prescription for repeat injections every 3 months to be received at one of the surrounding clinics. All participants requesting a short-acting method will receive the same list of local clinics as the delayed LARC placement group for their reference for future refills, Depo-Provera injections or if they desire a LARC at a future date. For participants choosing LARC methods, they will then be randomized to either the same day placement group or the control group using block randomization of groups of 6 and 8. Those randomized to the same day placement group will receive their method of choice that day (or within 2 weeks at their convenience) on the MHCC campus within

the designated research space. For participants randomized to the control group, they will receive a listing of local clinics with the capability to place the device of their choice. The initial visit will take between 1-2 hours depending on the method of birth control they choose, and which group they are randomized into.

Participants will receive a 3-month follow-up questionnaire asking what contraceptive method they chose at their initial visit and if they received this method to evaluate if those participants in the control group did in fact pursue LARC placement at another facility as well as to assess the expulsion and discontinuation rates of the same day placement group. All participants will receive 6- and 12-month follow-up questionnaires to evaluate our secondary and intermediate objectives. Multiple attempts will be made to contact each participant over a 2-month period, including reminder emails and phone calls to participants who have not completed their follow-up surveys. If they do not respond within a 60-day window, after the target completion date they will be considered lost to follow-up for that survey period and their EMR data and MHCC student data will be used for that period only. Participants who do not respond to the six-month questionnaire will again be contacted to complete the 12-month questionnaire. Each survey will take about 10 minutes to complete.

Study participation will last approximately one year. Patients have the right to withdraw from the study at any time. The reason for their withdrawal will be recorded if known. Additionally, as this is frequently a transient population we may have a proportion of our sample that is lost to follow-up and not available for inclusion in our secondary aims. Participants who choose to discontinue their LARC device will not be discontinued from the study, but the timing and reason for removal will be documented within the study. Removal of devices is not included within the scope of the study protocol.

7) Data and Specimens

a) Handling of Data and Specimens

All participant responses will be de-identified, assigned a randomly generated study ID number and stored in a secure database for analysis. We will use REDCap, an online data management platform, for the initial intake questionnaire and to screen for eligibility for study participation. All follow-up questionnaires will also be administered via REDCap, both to allow the participant to maintain confidentiality and to allow them to access the questionnaires even after they have graduated and/or moved from the local area.

No laboratory evaluations will be conducted as part of this study except for a urine pregnancy test. Other evaluations will take place according to standard of care but will not be study related. Specifically, for participants enrolled in the same day placement group, all will receive urine GC/Chlamydia testing per standard of care. Additionally, for those participants choosing an IUD who require a pap smear, these will be performed at the time of their pelvic exam. Participants requiring further follow-up based on their pap results will be referred to their PCP for further management.

b) Sharing of Results with Subjects

We anticipate sharing the de-identified results of the study with MHCC prior to publication, specifically any information on student certificate completion and student satisfaction with having an on-site reproductive health clinic.

Additionally, for participants in the same day placement group who undergo GC/CT or pap testing, the results of their tests will be provided to them. All GC/CT and pap testing will be sent to OHSU to be performed at the OHSU lab.

c) Data and Specimen Banking

No specimen banking will be utilized in this study. However, all data collected during the intake, initial visit and questionnaires will be stored in REDCap for future analysis. The de-identified results and data

will be stored in the WHRU Repository (IRB# 6748) and follow all storage guidelines and policies outlined by the repository.

8) Data Analysis

Our primary outcome of interest is the proportion of LARC uptake among women, by group assignment. This will be evaluated based on participants' self-reported LARC usage on the 3-month questionnaire. Additional outcomes of interest will be evaluated using the 6- and 12-month follow-up questionnaires.

Primary outcome:

1. LARC uptake. This will be measured on the 3-month questionnaire and will be defined as the prevalence of LARC uptake in the study group after the initial visit. The 3-month questionnaire will be used to compare LARC uptake in the control and study groups using a test for two independent proportions (Chi Squared). We will perform descriptive analyses of the demographic information obtained for each group. If there is a statistically significant difference in the demographics between the groups, we will instead us a logistic regression model to adjust for these confounders

Secondary outcomes:

3. Unplanned pregnancy rate. Unplanned pregnancy will be defined as any pregnancy while using a highly reliable form of birth control or any pregnancy defined as unplanned by participant questionnaire response. It will be measured at 6- and 12-months using the questionnaires. Data from CareEverywhere, a database that links multiple medical records, will be used to validate a subsample of self-report responses. (All groups) However, the actual number of unplanned pregnancies in this study group is expected to be to small to perform any meaningful quantitative analysis.
4. 2-year certificate completion rate and continuation of education will be measured both by participant self-reported questionnaire and student record review at MHCC. Success will be defined as either certificate completion within the parameters defined by the college or continued enrollment in classes for those participants who were in their first year of study at the time of enrollment in the study.

Intermediate outcomes:

1. Continuation of birth control method: We will also measure the continuation rates of the birth control provided at the initial visit on the 6- and12-month questionnaires, the results of which will be used both for descriptive purposes and to evaluate LARC continuation rates at 12 months post placement. To evaluate this, we will perform a survival analysis using a Kaplan-Myer curve for the 3 groups and a Rogue Length Test will be used to compare the three curves for a significant difference between them. Any discontinuation of the birth control method will be considered discontinuation, even if they have restarted their birth control method by the subsequent questionnaire.
2. Life satisfaction. Life satisfaction will be measured using the participant responses provided in the 6- and 12-month follow-up questionnaires. Scores on this measure range from not at all, a little bit, somewhat, quite a bit, to very much and will be analyzed as a categorical variable using a Fischer's exact test. (all groups).
3. Satisfaction with their birth control method will be measured by participant response to the question "How satisfied are you with your current method of birth control" with responses ranging from very satisfied, satisfied, somewhat satisfied, unsatisfied and very unsatisfied.

<u>Tests of hypotheses</u>

The three -month follow-up questionnaires will be used to compare our primary outcome of LARC uptake between our two randomized groups. We can use a test for two independent proportions (Chi-Squared) for this analysis assuming our two randomized groups are similar. If there is a statistically significant differences in the two groups we will instead use a logistical regression model. We will estimate the effect of forward-counseling plus immediate placement on LARC uptake using logistic regression analysis. Odds Ratios and 95% confidence intervals will be generated. We will also use a Chi-Squared analysis to evaluate demographic information we collected from participants and their contraceptive choices. A multivariate analysis will be performed to control for age, socio-economic status, history of prior pregnancy termination and prior contraception usage if there is any significant difference in the 2 groups. To determine socio-economic status, not only will we ask household income but we will also ask questions on parent's education level and occupation, as well as if students are eligible for any government programs (such as food stamps and Section 8). We will also be looking at whether women continue to use the contraceptive method they initially chose and if they are still satisfied with this method (all groups). To look at the change in usage and satisfaction between the 6- and 12-month questionnaires we will use a logistic mixed effects model.

To calculate the unplanned pregnancy rate, we will use a Fisher exact test, as it can be considered a rare event. However, we do not anticipate a large enough sample of events to perform any meaningful quantitative analysis. We will collect self-reported data from the participants on if they completed their course of study at the 12-month follow-up questionnaire. Their completion/enrollment status will be confirmed with MHCC. The difference between the two groups will be evaluated using a Chi-Squared test. We will also obtain data from MHCC on their overall certificate completion rates in 2015 (the year prior to initiating the study) compared to 2016-2017 (the years incorporated in the study) for descriptive purposes.

9) Privacy, Confidentiality and Data Security

Standard institutional practices will be followed as described in the OHSU Information Security and Research Data Resource Guide (http://ozone.ohsu.edu/cc/sec/isg/res_sec.pdf) to maintain the confidentiality and security of data collected in this study. Study staff will be trained with regard to these procedures. Paper files will be stored in locked filing cabinets in restricted access offices at OHSU and MHCC. Electronic data is stored on restricted drives on the OHSU network and stored in a web-accessible REDCap database housed on an OHSU secure server. Access to data/specimens is restricted to study personnel. Access to data requires OHSU ID/password authentication. Upon enrollment, subjects will be assigned a code that will be used instead of their name, medical record number or other personally identifying information. Electronic files for data analysis will contain only the subject code.

Codes will not contain any part of the 18 HIPAA identifiers (initials, DOB, MRN) The key associating the codes and the subjects personally identifying information will be restricted to the PI and study staff. The key will be kept secure on a restricted OHSU network drive a in a limited access folder.

The collecting of PHI for phone screening follows HIPAA requirements and standard institutional practices and is stored in a confidential and secure manner. The phone screens are stored in a secure location and kept in a locked file or password-protected document on a password protected computer. This access is restricted to the study staff. Upon enrollment, the phone screening will be added to the protected research record and follow all coding procedures for that record.

All telephone screenings and website submission forms will be stored in a locked office at OHSU and MHCC, with access limited to study staff. For subjects electing to enroll in the study, this information will become a part of their protected research record. For subjects choosing not to enroll or who screen fail, all PHI will be stored confidentially with the research study information in a locked cabinet and archived with other study-specific documents at the close of the trial. All potential participants that contact the department for research studies will be added to a password-protected log listing their contact information, only accesible through OHSU password-protected computers by study staff. Phone screens (including for individuals who choose not to participate or are ineligible) and the

log containing potential participants' information are saved to ensure that our department has a record of contact with the participant and to monitor our recruitment outreach efforts. Confidentiality of personal health information will be maintained according to HIPAA requirements for research and all data will be kept in locked files or in a password-protected document on a password protected computer.

10) Provisions to Monitor the Data to Ensure the Safety of Subjects

The investigators and study staff are responsible for recording the data, and they will be verifying its accuracy throughout the process. Dr. Jacqueline Lamme, the PI, will be reviewing the data in-depth periodically throughout the study. The PI will also be overseeing that the study procedures are being carried out as per the approved protocol via close supervision of the study visit and procedures and through frequent communication with the other investigators and staff. Anytime that an AE, SAE, UP or protocol deviation is reported by an investigator or study staff, the PI will review and assess the data, and proceed as per OHSU reporting policy. Otherwise, the PI entity will be reviewing the records periodically throughout the study. All adverse events will be assessed and reportable UPs will be submitted to the IRB, if judged related to the study protocol. All data will be stored within the REDCap database at the completion of the study for future analysis and stored in the WHRU Repository.

11) Risks and Benefits

a) Risks to Subjects

Possible risks of the study include a low risk of breach of confidentiality.

The Principal Investigator (Dr. Lamme) will oversee the project. A Research Coordinator will assist with participant recruitment, intake and enrollment, and LARC forward counseling sessions, and regulatory paperwork. A licensed practitioner listed on the protocol (either the PI or additional investigators) will perform all birth control prescriptions or on-site insertion of LARC devices as per standard clinical practice. This study does not include any additional risks of these devices than those found during routine use. All devices used within this study are FDA approved devices. Any adverse events associated with the LARC placements (uterine perforations, device expulsion, infection, etc.) will be tracked in the password secured database with the other study data. This entry will be completed by the Research Coordinator and verified by the PI and reported to the Oregon Health and Science University (OHSU) Institutional Review Board (IRB). Any complications requiring additional procedures (uterine perforation, etc.) will be managed by the PI and associated clinical staff at OHSU. All participants who receive an IUD or Nexplanon device will be given a standard research clinic phone number, which they can call and be evaluated for complications and treated as indicated.

b) Potential Benefits to Subjects

Participants in the study will receive highly effective contraception counseling. Those desiring a short acting method, with no contraindications to this method, will receive a written prescription for one year, which they can fill at a pharmacy of their choice. For those participants choosing a LARC method, the 50 participants randomized to the same day placement group will receive the LARC device of their choice, free of charge, that day. For the participants randomized to the delayed placement group, they will be provided resources including a list of local clinics that provide LARC placement either utilizing their insurance, Title X or CCare.

Additionally, if the study shows that student retention is increased by providing on site LARC placement or that student satisfaction is increased by having an on site reproductive health clinic, this

data may help to support the inclusion of a Student Health Clinic within the newly planned Allied Healthcare building or elsewhere on campus.

12) Drugs or Devices

All birth control drugs and devices used within this study are FDA approved. Please see appendix D-H for prescribing information on the devices that will be provided during the course of the study.

1.8 References

[1] Family Planning | Healthy People 2020 n.d. http://www.healthypeople.gov/2020/topics-objectives/topic/family-planning (accessed January 25, 2016).
[2] Harper CC, Rocca CH, Thompson KM, Morfesis J, Goodman S, Darney PD, et al. Reductions in pregnancy rates in the USA with long-acting reversible contraception: a cluster randomised trial. The Lancet 2015;386:562–8. doi:10.1016/S0140-6736(14)62460-0.
[3] Secura GM, Allsworth JE, Madden T, Mullersman JL, Peipert JF. The Contraceptive CHOICE Project: reducing barriers to long-acting reversible contraception. Am J Obstet Gynecol 2010;203:115.e1–7. doi:10.1016/j.ajog.2010.04.017.
[4] Finer LB, Zolna MR. Shifts in Intended and Unintended Pregnancies in the United States, 2001–2008. Am J Public Health 2014;104:S43–8. doi:10.2105/AJPH.2013.301416.
[5] Jones et al. Contraceptive Use in the United States n.d. http://www.guttmacher.org/pubs/fb_contr_use.html (accessed August 24, 2015).
[6] Finer LB, Jerman J, Kavanaugh ML. Changes in use of long-acting contraceptive methods in the United States, 2007–2009. Fertil Steril 2012;98:893–7. doi:10.1016/j.fertnstert.2012.06.027.
[7] Jones et al. National Health Statistics Reports, Number 60 October 18, 2012 - nhsr060.pdf n.d. http://www.cdc.gov/nchs/data/nhsr/nhsr060.pdf (accessed August 24, 2015).
[8] Bednarek PH, Creinin MD, Reeves MF, Cwiak C, Espey E, Jensen JT. Immediate versus Delayed IUD Insertion after Uterine Aspiration. N Engl J Med 2011;364:2208–17. doi:10.1056/NEJMoa1011600.
[9] Laska MN, Pasch KE, Lust K, Story M, Ehlinger E. The differential prevalence of obesity and related behaviors in two vs. four-year colleges. Obes Silver Spring Md 2011;19:453–6. doi:10.1038/oby.2010.262.
[10] Reproductive Health Technologies Project. Two Sides of the Same Coin: Integrating Economic and Reproductive Justice. 2015.
[11] personal communication. Personal Communication with Dean of Student Affairs Mount Hood Community College n.d.
[12] Sonfield A. Popularity Disparity: Attitudes About the IUD in Europe and the United States n.d. https://www.guttmacher.org/pubs/gpr/10/4/gpr100419.html (accessed December 11, 2015).
[13] Mcnicholas C, Madden T, Secura G, Peipert JF. The Contraceptive CHOICE Project Round Up: What We Did and What We Learned. Clin Obstet Gynecol 2014;57:635–43. doi:10.1097/GRF.0000000000000070.
[14] State Facts About Unintended Pregnancy: Oregon - OR.pdf n.d. http://www.guttmacher.org/statecenter/unintended-pregnancy/pdf/OR.pdf (accessed November 21, 2015).
[15] Title X Family Planning n.d. http://www.hhs.gov/opa/title-x-family-planning/index.html (accessed November 23, 2015).
[16] Program Requirements for Title X Funded Family Planning Projects - ogc-cleared-final-april.pdf n.d. http://www.hhs.gov/opa/pdfs/ogc-cleared-final-april.pdf (accessed November 23, 2015).
[17] Income, Poverty and Health Insurance Coverage in the U.S.: 2013 n.d. http://census.gov/newsroom/press-releases/2014/cb14-169.html (accessed November 23, 2015).
[18] What is CCare? | Oregon CCare n.d. http://public.health.oregon.gov/HealthyPeopleFamilies/ReproductiveSexualHealth/OregonContraceptiveCare/Pages/whatsavailable_t1.aspx (accessed November 23, 2015).

[19] Sonfield A. The Case for Insurance Coverage of Contraceptive Services And Supplies Without Cost-Sharing - gpr140107.pdf n.d. https://www.guttmacher.org/pubs/gpr/14/1/gpr140107.pdf (accessed December 12, 2015).
[20] Grady CD, Dehlendorf C, Cohen ED, Schwarz EB, Borrero S. Racial and ethnic differences in contraceptive use among women who desire no future children, 2006–2010 National Survey of Family Growth. Contraception 2015;92:62–70. doi:10.1016/j.contraception.2015.03.017.
[21] Gilmore K, Hoopes AJ, Cady J, Amies Oelschlager A-M, Prager S, Vander Stoep A. Providing long-acting reversible contraception services in Seattle school-based health centers: key themes for facilitating implementation. J Adolesc Health Off Publ Soc Adolesc Med 2015;56:658–65. doi:10.1016/j.jadohealth.2015.02.016.
[22] Mt. Hood Community College - MHCC - The College Board n.d. https://bigfuture.collegeboard.org/college-university-search/mt-hood-community-college# (accessed July 28, 2015).
[23] Mt Hood Community College n.d. http://www.educationnews.org/career-index/mt-hood-community-college/ (accessed July 28, 2015).
[24] Levi EE, Stuart GS, Zerden ML, Garrett JM, Bryant AG. Intrauterine Device Placement During Cesarean Delivery and Continued Use 6 Months Postpartum: A Randomized Controlled Trial. Obstet Gynecol 2015;126:5–11. doi:10.1097/AOG.0000000000000882.
[25] Medical Eligibility Criteria for Contraceptive Use. World Health Organization; 2015.

APPENDICES

Appendix A: Initial Intake questionnaire

Initial Study Intake and Clinical Questionnaire

Patient Information		
LAST NAME:	FIRST NAME:	TODAY'S DATE:
DATE OF BIRTH:	AGE:	
ETHNICITY: ___ Not Hispanic or Latino ___ Hispanic or Latino ___ Not reported	RACE: ___ White ___ Black ___ Asian ___ American Indian or Alaska Native	___ Native Hawaiian or Other Pacific Islander ___ Other:_____ ___ Declines
PRIMARY GYN HEALTHCARE PROVIDER:		
INSURANCE COMPANY:		

Smoking History		
SMOKER _____Yes _____No	If yes, for how many years?	Current # of cigarettes _____per day/week

Socioeconomic status: **Please answer the below questions for YOURSELF**		
What is your employment status? (choose only one) ___Employed full-time ___Employed part-time ___Unemployed ___Other: _____	**What is your yearly income? (choose only one)** ___10,000 or less ($833 per month or less) ____$10,001 – $30,000 ($834 - $2,500 per month) ____$30,001 - $50,00 ($2,501 - $4,166 per month) ____$50,001 - $70,000 ($4,167 - $5,833 per month) ____$70,001 - $100,000 ($5,834-$8,333 per month) ____More than $100,000 (more than$8,334 per month) ____Don't know	**How many people living in your household are supported by this income (including subject)? _____** ____ Don't know

Socioeconomic status: **Please answer the below questions for your PARENTS**	
What is your mother's employment status? ____Employed full-time ____Employed part-time ____Unemployed ____Other ____Don't know **What is your father's employment status?** ____Employed full-time ____Employed part-time ____Unemployed ____Other ____Don't know	**What is your family's yearly household income? (choose only one)** ___10,000 or less ($833 per month or less) ____$10,001 – $30,000 ($834 - $2,500 per month) ____$30,001 - $50,00 ($2,501 - $4,166 per month) ____$50,001 - $70,000 ($4,167 - $5,833 per month) ____$70,001 - $100,000 ($5,834 – $8,333 per month) ____More than $100,000 (more than $8,334 per month) ____Don't know
How many years of school did your mother <u>complete?</u> ____Less than 8 ____Some high school (9-11 years) ____High school of GED (12 years) ____ Some college or associate's degree or Technical school ___College (Bachelor's Degree) ____ Graduate or professional school ____ Other, specify: ____ ____ Don't know **How many years of school did your father <u>complete?</u>** ____Less than 8 ____Some high school (9-11 years) ____High school of GED (12 years) ____ Some college or associate's degree or Technical school ___College (Bachelor's Degree) ____ Graduate or professional school ____ Other, specify: ____ ____ Don't know	**How many people living in your household are supported by this income (including subject)? _____** _____ Don't know

Contraception Information	
Current Contraception:	
Consistent use:	Date of last use:

_____Yes _____No		_____/_____/_____	
How long has participant been using this method? _____ years _____months _____days			
Desired Method(s) (check all that apply):			
____ Hormonal IUD	____ Copper IUD	____ Diaphragm	____Patch
____ Birth Control Shot	____ Birth Control Pill	____ Vaginal Ring	____Nothing
____ Condoms	____ Implant	Other (specify):	

Contraception Knowledge	
Please rank the below methods of birth control from most effective to least effective (#1 is most effective and #10 is least effective)	
	Birth Control Pill
	Condoms
	Patch
	Implant
	Birth control shot
	Rhythm method
	Hormonal IUD
	Copper IUD
	Diaphragm
	Nothing
	Vaginal Ring
	Other (specify): _____

Gynecological History		
Last Menstrual Period (LMP): ____/____/_____ (MM/DD/YYYY) _____ Too long ago to remember _____ Have never had a period		
Periods are: _____Regular		_____ Irregular
Periods come every: _____ to _____ days		_____Too irregular to tell
Periods are painful: _____ Yes		_____ No
Flow is: _____ Light ____Normal		_____ Heavy
Bleeding lasts: _____ to _____days		_____ Too irregular to tell
Last Intercourse: ____/____/____ (MM/DD/YYYY)		_____ Used a condom
Year of last Pap Smear: ____/____/_____	_____ Unknown	_____ Never had a pap
Result of last pap: _____Normal	_____ Abnormal	_____ Unknown

If Currently Pregnant	
Gestational Week: _____	Estimated Due Date: _____

Obstetrical History	
Number of pregnancies: _____	Date(s):
# of term births (>37 weeks): _____	Date(s):
# of premature births (<37 weeks): _____	Date(s):

# of miscarriages (< 20 weeks): _____	Date(s):
# of stillbirths (>20 weeks): _____	Date(s):
# of elective abortions: _____	Date(s):
# of ectopic pregnancies: _____	Date(s):

Infection History		
Have you ever had or do you currently have any of the following Infections? (Check all that apply)		
___ Gonorrhea	Date(s) diagnosed:	Dates treated:
___ Chlamydia	Date(s) diagnosed:	Dates treated:
___ Trichomoniasis	Date(s) diagnosed:	Dates treated:
___ Syphilis	Date(s) diagnosed:	Dates treated:
___ Genital Herpes	Date(s) diagnosed:	Do you take medication for it? If yes, what?
___ Genital Warts	Date(s) diagnosed:	Dates treated:
___ HPV	Date(s) diagnosed:	Has it resolved? If yes, when?
___ Bacterial Vaginosis	Date(s) diagnosed:	Dates treated:

Allergies	
Allergies	_____ No Known Drug Allergies
1. 2. 3.	

Current Medications		
Medication	Dose	How many times a day?
1.		
2.		
3.		
4.		

Surgical History	
Surgery	Year Performed

Medical History

Have you ever had any of the following?						
			Currently Being Treated?			
Condition	No	Yes	No	Yes	Resolved	N/A
Cancer Type: _____						
HIV:						
Hypertension:						
Heart attack:						
Stroke/CVA/TIA:						
Migraines: If yes, with Aura:						
High Cholesterol						
Blood Clot (thromboembolism):						
Diabetes:						
Gestational Diabetes:						
Thyroid problems:						
Liver Disease:						
Pelvic infection (PID):						
Abnormal Vaginal Bleeding:						
Uterine Fibroids:						
Uterine Abnormalities						
Depression Anxiety:						
Wilson's Disease:						
Other:						

General Health Information		
HEIGHT _____feet _____inches	WEIGHT (LBS)	BLOOD PRESSURE _____/_____mmHg
URINE PREGNANCY TEST		
_____Negative	_____ Positive. Explain:	
_____Not done because pregnancy terminated/miscarriage in last 4 weeks (circle)		
_____Not done because patient currently pregnant		
NOTES:		

Signatures
Form Completed by: _____ Signature: _____ Date: _____/_____/_____
Form Reviewed by: _____

Signature: _____ Date: _____/_____/_____		
Method Approved?	_____Yes	_____ No If no, explain:

Appendix B: Counseling video (go to http://larcfirst.com/sessions.html)

Appendix C: Post-counseling video script

Post-video script to be read by PI, co-investigator or Research Coordinator after participant has finished watching the LARCFirst video.

"*The video you just watched discussed the different types of birth control options available. One clarification that we would like to mention is that there are now two types of hormonal IUD available. They both contain the same hormone, levonorgestral and work in the same manner. The Mirena IUD was the one mentioned in the video and is good for 5 years. The Skyla IUD has the same hormone but is slightly smaller, has a lower dose of hormone, and is good for 3 years not 5. If you think you are interested in a hormonal IUD for birth control, we can talk about these options in more detail.*
Do you have any questions about the methods of birth control discussed in the video?
Which of the types of birth control discussed do you think would be right for you?"

Appendix D: Prescribing information for Nexplanon (http://www.merck.com/product/usa/pi_circulars/n/nexplanon/nexplanon_pi.pdf)

Appendix E: Prescribing information for Paragard (http://www.drugs.com/pro/paragard.html)

Appendix F: Prescribing information for Mirena (http://labeling.bayerhealthcare.com/html/products/pi/Mirena_PI.pdf)

Appendix G: Prescribing information for Depo-Provera (http://www.drugs.com/pro/depo-provera.html)

Appendix H: Prescribing information for Skyla (http://labeling.bayerhealthcare.com/html/products/pi/Skyla_PI.pdf)

Appendix I: Letter of support from Mount Hood Community College (MHCC)

MT. HOOD COMMUNITY COLLEGE

Mt. Hood Community College
Student Union
David Sussman, Manager
26000 SE Stark Street
Gresham, OR 97030
Phone: 503-491-7258 · Fax: 503-491-6077
Email: david.sussman@mhcc.edu

December 1, 2015

To: Jacqueline Lamme

Re: Research Collaboration

I am pleased to support your research proposal titled “Effectiveness of LARC Forward Contraceptive Counseling and Same Day Placement in a Community College Population: A Randomized Intervention Project.”

This project intends to increase the usage of Long Acting Reversible Contraception (LARC) within the Community College population at Mt. Hood Community College (MHCC) with the goal of decreasing unplanned pregnancies and increasing certificate and degree completion rates within this population. This research project benefits the female student population at MHCC and we are very excited about the potential to support it through our participation.

At this time, we anticipate that our College’s current community partner, Wallace Medical Concern, will be using their Mobile Healthcare Van to place intrauterine devices in study participants who desire that method of birth control. This will be done on the day that the mobile van is already present on the MHCC campus. Administrative portions of the study (participant enrollment, counseling, provision of other types of birth control not requiring a pelvic exam) will be performed in administrative offices provided by MHCC, not Wallace Medical Concern. The Associated Student Government of MHCC will assist in distributing promotional materials to eligible female students at MHCC

Again, we are very enthusiastic to support this mutually beneficial community research project through this partnership, and we look forward to collaborating with you on this work. Best of luck with your grant application.

If you have any questions, or if I can be of any help, please feel free to contact me.

Sincerely,

David Sussman

David Sussman
Manager, Student Union, Student Life, and Specialized Student Services
Mt. Hood Community College

Appendix J: Follow-up questionnaire (3-month)

3-Month Questionnaire

1) What method of birth control did you receive on the day of your first study visit?
___Birth Control Pill Prescription
___Hormonal IUD (Mirena, Skyla)
___Copper IUD (Paragard)
___Birth Control Shot
___Implant
___Vaginal Ring Prescription
___Birth Control Patch Prescription
___Diaphragm
___Condoms
___Referral information for IUD/Implant placement at a different clinic
___Other:

2) Did you go to another clinic to get your birth control method?
___Yes
___No
If yes, where:

3) Are you still using this method of birth control?
___Yes
___No
If no, why not?

4) Are you happy with your current method of birth control?
___Yes
___No
If no, why not?

5) Have you seen a healthcare provider in the last 3 months because of problems or concerns about your birth control method?
___Yes
___No
If Yes, describe concerns/problem:
(We may follow up with you to collect more information about this)

6) Did you like having the clinic available on campus to find out about birth control options and receive them?
___Yes
___No
What did you like about this setup?

Appendix K: Follow-up questionnaire (6- and 12-month)

6 and 12-Month Questionnaire

1) What method of birth control did you receive on the day of your first study visit?
___Birth Control Pill Prescription
___Hormonal IUD (Mirena, Skyla)
___Copper IUD (Paragard)
___Birth Control Shot
___Implant
___Vaginal Ring Prescription
___Birth Control Patch Prescription
___Diaphragm
___Condoms
___ Referral information for IUD/Implant placement at a different clinic
___Other:

2) Did you go to another clinic to get your birth control method?
___Yes
___No
If yes, where:

3) Are you still using this method of birth control?
___Yes

___No
If no, why not?

4) If no, when did you stop using the birth control method provided at your initial visit?
Date:

5) How satisfied are you with your current method of birth control?
__Very satisfied
__Satisfied
__Somewhat satisfied
__Unsatisfied
___Very unsatisfied

7) Would you recommend this method of birth control to a friend?
___Yes
___No
If no, why not?

8) Have you seen a healthcare provider since your first study visit because of problems or concerns about your birth control method?
___Yes
___No
If Yes, describe concerns/problem:
(We may follow up with you to collect more information about this)

9) I am content with the quality of my life right now.
__Not at all
__A little bit
__Somewhat
__Quite a bit
___Very much

10) Have you completed your certificate in your area of study at MHCC?
__Yes. Go to #11
__No. Go to #10

11) If no, are you still enrolled in school?
__Yes
__No
If no, why not?

12) Are you planning further education?
___Yes
___No

13) Have you become pregnant since enrolling in the study?
___Yes, go to question 13
___No, stop questionnaire

14) If yes, what was the date of your last period before that pregnancy?

15) If yes, what was the outcome of that pregnancy?
___Miscarriage
___Abortion
___Delivery

16) Where did you receive care for the above pregnancy?

17) Were you using the birth control you received at your initial visit when you became pregnant?
___Yes, stop questionnaire
___No, go to question #16

18) What method of birth control where you using when you became pregnant?
___Birth Control Pill
___Hormonal IUD
___Copper IUD
___Birth Control Shot
___Implant
___Vaginal Ring
___Birth Control Patch
___Diaphragm
___Condoms
___Nothing
___Other:

Appendix L: Supplemental Student Questionnaire

Due to unforeseen enrollment challenges with this study, an anonymous survey will be distributed to Mt Hood Community College students to gather information to better understand the lack of enrollment. The survey will be distributed electronically via Qualtrix. An invite to participate in the survey will be sent to students via email, MHCC student life app, the MHCC Facebook page, and in person to students at tabling events on campus. For use of the MHCC student life app and Facebook page, the "email/social media" text will be used as the post with a link to the survey. The first page of the electronic survey will be an information sheet and the first question will be asking them to agree to participate in the survey.

Appendix M: Elimination of Month 6 and Month 12 surveys

Due to unforeseen enrollment challenges that resulted in enrolling 3 students in the study, who each selected a SARC method of birth control, the follow data collection will be limited to 3 month surveys only. The 3 month surveys will be useful for understanding student's perception of the Birth Control Resource Center. The 6 month and 12 month surveys are not considered necessary at this point, due to the low enrollment number, and the lack of enrollment in the LARC arm. All currently enrolled subjects will be notified of this change in the study protocol.