A study of two interventions to increase adherence with oral contraceptives and condom use among adolescents and young adults

By

Abbey B. Berenson, MD, MMS

Dissertation
Presented to the Faculty of the Graduate School of
The University of Texas Medical Branch
In Partial Fulfillment
Of the Requirements
For the Degree of

Doctor of Philosophy

The University of Texas Medical Branch
November 8, 2011

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Abbey B. Berenson, MD, MMS
The University of Texas Medical Branch, 2011

Supervisor: Jean Freeman

A randomized, controlled trial was conducted to examine the effectiveness of two different interventions on adherence with oral contraception (OC) and their effect on dual use (oral contraception and condoms). A total of 1,155 women 16-24 years of age who requested oral contraception at one of five reproductive health clinics were recruited to participate and randomized to receive either (1) face-to-face behavioral counseling and education at their baseline clinic visit (C group); (2) this same intervention followed by monthly phone calls for 6 months (C+P group); or (3) standard care (S group). Phone interviews at 3, 6, and 12 months after the initial visit assessed whether women developed a cue (defined as use of an object or action to help them remember to take their medication), duration and correctness of contraceptive use, method satisfaction, clinic follow up, condom use with and without hormonal contraceptive use (dual use), and rates of pregnancy and sexually transmitted infections (STIs). Bivariate analysis demonstrated that women in the C+P group were more likely to use their pills correctly in only one out of the 12 months of follow up. Analysis using General Estimating Equations showed that those in the C group were actually more likely to switch brands of OC and less likely to recommend their method to a friend. Those randomized to C+P were more likely to report condom use at last intercourse, but not more likely to use condoms while taking OC. Furthermore, use of a cue was associated with a longer period of correct OC use, regardless of the intervention. No differences were observed between those in either intervention group and standard care in contraceptive discontinuation, satisfaction rates, correct use of their method, or STI rates. Finally, the Mantel Haenszel test revealed no differences in pregnancy rates between groups during the 12 months of follow up. In conclusion, this study demonstrated that clinic based education with or without phone follow up is not effective in helping young women use OC for a longer duration or more accurately. Furthermore, it does not increase rates of dual use.

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Chapter 1: Specific Aims and Hypotheses

The purpose of this study is to finalize and test two different interventions (a clinic-based intervention and a clinic-based plus telephone intervention) which have been designed to increase the percentage of young women who use oral contraception consistently. The number of women in each intervention arm who use condoms along with birth control pills (dual use) was also measured. Women 16 to 24 years old from three racial/ethnic groups (white, black, and Hispanic) who were initiating use of birth control pills were recruited at five different family planning clinics to achieve the following specific aims:

1. Pilot test and finalize two different interventions (a clinic-based intervention and a clinic-based plus telephone intervention) to improve adherence to oral contraceptive regimens and increase condom use.

2. Conduct a randomized, controlled study to determine the effect of these interventions on contraceptive adherence and dual use of condoms over 12 months among women 16 to 24 years old attending federally funded family planning clinics.

3. Determine if the effect of these interventions on pill and condom use differs after 12 months by age group, eg, among those 16 to 19 years old versus those 20 to 24 years old.

Specific hypotheses examined include:

1. Individuals randomized to receive the clinic-based plus telephone intervention will be twice as likely to be adherent with their oral contraceptives for the following 12 months as those randomized to receive standard care. No difference will be observed between individuals randomized to receive the clinic-based intervention only and those who receive standard care.

2. A higher rate of dual use (condoms plus oral contraception) will be observed at 12 months among individuals randomized to receive the clinic-based plus telephone intervention than those who are randomized to receive the clinic-based intervention or standard care.

3. The effect at 12 months of the clinic-based plus telephone intervention will be greater among women 16 to 19 years old than among those 20 to 24 years old.

Chapter 2: Background

Approximately 82% of teen pregnancies are unplanned.[1] In the United States, both the pregnancy and birth rates for females aged 15–19 years continue to exceed those of all developed countries, as much as nine-fold. For example, in 2008, the birth rate in US teens was 1.5 times higher than that of the UK, which has the highest teen birth rate in Western Europe. [2] Canada reported a birth rate among teens of 14.1/1000 in comparison to the US rate of 42.5/1000, nearly three times higher, among women of the same age.[2] The rates in the US were 6 to 9 times higher than those in Denmark, the Netherlands, Sweden, and Switzerland.[1,2]

One reason for the large number of unintended pregnancies is reliance on the birth control pill. In the US, birth control pills are the leading method for women under 30 years of age.[3] Many young women, however, experience difficulty in using this method consistently or correctly which can result in an unintended pregnancy. [4] Overall, pill discontinuation rates range from 18% at 6 months to 32% at 12 months. [5] Moreover, among young users, almost half discontinue use of this method within 6 months of obtaining a prescription. [6,7] These young women are at high risk of an unintended pregnancy because they often fail to use any contraceptive method after discontinuing their pills. In one study of women who discontinued oral contraceptives, 33% of 13 to 19 year olds and 18% of 20 to 22 year olds reported that they did not use any method for at least 1 month after stopping their pills, even though they did not wish to become pregnant.[8]

Further compounding the problem is that among those who continue to use birth control pills for at least 6 months, a large proportion fails to take them correctly. In one nationwide study of 943 women (mean age 25 years), 47% of pill users missed one or more pills per cycle and 22% missed two or more. [4] Increased odds of missing two or more pills were associated with lacking an established pill-taking routine, not reading or understanding all of the informational material accompanying the pill package, or experiencing side effects. [4] Likewise, a national survey noted that nearly 30% of sexually active women using oral contraceptives as their only method of contraception missed one pill in 3 months and 13% missed two or more pills.[9] Difficulty with adhering to a daily routine of taking pills is even more pronounced among high school and college age women. In one study, which included women recruited from university student health clinics, only 52% of those prescribed birth control pills took each active pill over the first 3 months. [10] A study of 211 teens using birth

control pills in southeast Texas reported that nearly 60% missed one or more pills within the last 3 months of use and 10% missed at least three pills in the last cycle. [6]

From these data, it is apparent that interventions must be developed and tested to improve the consistency and correctness of contraceptive use among young women who are sexually active. To assist with this goal, an interdisciplinary group of researchers and service providers, funded by the National Institutes of Health (NIH), recently met and published their observations.[11] Foremost, they noted that the current system used by most clinics of providing contraception at a single brief visit—which must meet health care, counseling, and educational needs—is not effective. During a single visit, providers can spend only a few minutes on education; this may be limited to only 3 minutes during a 12-minute medical visit.[12] This brief amount of time is not sufficient to meet the needs of younger women, especially with regard to pregnancy and sexually transmitted infection (STI) prevention. This problem is compounded by the fact that the next follow-up visit does not occur until several months, or even a year, later.

In their review, the NIH group proposed several solutions to this dilemma. One is to add Health Educators to clinic staff. Another is to extend contact between patients and providers by adding phone call interactions between visits.[11] This latter strategy has been endorsed by others, such as Cramer, who suggested that providers give birth control pill users a toll-free telephone number that they could call if they miss pills, experience breakthrough bleeding, or are confused about when to start a new package.[13] Patients could then call this number and select a recording that would provide information about how to handle their particular situations.

An examination of the literature, however, demonstrates that few studies on young women have actually evaluated the effectiveness of additional education or extended contact in the clinical setting on hormonal contraceptive adherence. Furthermore, most of those that have been published are somewhat limited in their usefulness due to small sample sizes. [14-16] For example, Gilliam demonstrated that a multicomponent intervention consisting of counseling, watching a videotape, and receiving additional written material increased contraceptive adherence from 40% to 67% among young African American women. [14] This study, however, had a small sample size (N = 33) and included only one racial group (African Americans). Furthermore, complete data at 12 months were available on less than half of the women randomized. In another study, Winter observed that adolescents who received in-depth counseling in metropolitan family planning clinics were less likely to report difficulty dealing with method-associated problems, more likely to

continue the method despite problems, and more likely to be using the method 12 months later.[17] This study, however, also had a high attrition rate (61%–62%) and was not randomized.

One randomized study was recently conducted on 805 women 14-18 years of age who were taking oral contraceptive pills. Those who received an intervention involving phone calls after their clinic visit were no more likely to be adherent than controls.[18] Another randomized, controlled invention study was conducted on hormonal contraceptive adherence that focused on 15 to 18 year old males. In this study, those who watched a 30-minute slide program and received a personal health consultation from a nonphysician provider at their clinic visit, were significantly more likely than those who did not to report 12 months later that their partner was using birth control pills.[19] However, this investigation included only adolescent males—the vast majority of whom were white and from middle to upper class families. Thus, these findings may not be applicable to young women or to minorities of low socioeconomic status.

Furthermore, most intervention studies on contraceptive adherence do not measure direct outcomes, such as unintended pregnancy rates. As a result of the limited number of studies on this topic, the authors of a comprehensive review recently concluded that there has not been a reliable evaluation of the effectiveness of counseling or other techniques in reducing unintended pregnancies in the United States.[20] The proposed study will fill that gap in the literature by finalizing and testing two comprehensive interventions designed to increase contraceptive adherence among young women **(Specific Aims 1 and 2).** Those randomized to the clinic-based intervention will receive educational information and counseling from a Health Educator at the time of their clinic visit. Those randomized to the clinic-based plus telephone intervention will receive the same education and counseling at their visit, but they will also be called by the Health Educator for 6 months following their clinic visit. A number of outcomes will be compared between those individuals randomized to one of the interventions and those randomized to standard care, including duration of oral contraceptive use, correctness of use, unintended pregnancy rates, and STI incidence. Based on studies conducted with other types of medications and pilot data, it is hypothesized that individuals randomized to receive the clinic-based plus telephone intervention will be twice as likely to be adherent with their oral contraception for the following 12 months as those randomized to receive standard care **(Hypothesis 1).**

Furthermore, the efficacy of these interventions in increasing dual method use will be tested, defined as the joint use of a condom for protection from STIs and a highly effective

method for pregnancy protection,[21] e.g., oral contraceptive pills (Specific Aim 2). Although condom use by young individuals has increased in recent years, numbers still remain low. According to data from the National Survey of Family Growth 2002, 45% of contraceptors <20 years of age and 36% of those 20 to 24 years of age reported current condom use. However, dual method use (condom and birth control pill) was reported by only 15% of women under 20 and 11% of those in the older group.[3] A report from 2006 – 2008 showed a slight increase in numbers, but still only about one in five sexually active female teens (21%) reported having combined the condom and a hormonal method the last time they had sex.[22] One reason for the low rate of dual use is that young women frequently do not understand that hormonal methods do not offer protection against STIs. A survey of 519 adolescents conducted by the Kaiser Family Foundation revealed that one in four pill users thought that their birth control method would also protect them against STIs. [23]

Clinic-based intervention programs have demonstrated that supplemental education beyond what is routinely offered at a clinic visit can increase condom use and thus is an important first step toward that goal. For example, in a study of 209 adolescent girls who tested positive for chlamydia, condom use increased over the next 5 to 7 months in those who (1) received one-on-one education about STIs, (2) watched demonstrations of and participated in practice sessions on correct condom use, and (3) practiced negotiating condom use.[24] Another program designed to increase condom use among adolescents demonstrated that those who received comprehensive STI prevention information from their physician in the form of written materials and face-to-face discussions were more likely to report use of condoms during the next 3 months than those who did not receive the intervention.[25] Similarly, a study of Hispanic and African American women with a mean age of 21 years showed that participation in a behavioral intervention decreased the risk of contracting a STI over the next 12 months.[26] These programs demonstrate that even brief, modest, clinic-based interventions can increase condom use and decrease the risk of participants contracting a STI.

However, only two studies have investigated how to increase condom use among young women using hormonal contraception. [27,28] In one randomized intervention study on this topic, African American youth from 9 to 15 years old randomized to attend seven 1.5-hour sessions and one all-day session focused on decision making were more likely to report dual use after 6 and 18 months than those randomized to view educational videos on HIV prevention on a weekly basis.[27] Although encouraging, this extensive intervention is not feasible for clinic implementation. The second study used a computer based intervention to

promote dual use and observed that the intervention was associated with an initial increase in dual use, but it was not sustained. [28] Thus, additional interventions are needed which are suitable for a clinical setting to decrease the risk of STIs among young women. This study will fill that gap in the literature. Based on the previous randomized intervention study, it is hypothesized that those randomized to the clinic-based plus telephone intervention will report a greater increase in dual use after 12 months than those randomized to the clinic-based intervention or to standard care **(Hypothesis 2)**.

If these interventions are successful, it will be important to determine if they are equally effective among individuals of different ages. To accomplish this, an equal number of subjects 16 to 19 years old and 20 to 24 years old will be recruited to examine outcomes within each age group **(Specific Aim 3).** Stratifying by age will be a unique contribution to the literature because no randomized, controlled intervention studies on contraceptive adherence have examined differences by age. Interventions that are effective in women under 20 years old are especially needed as previous studies have said they are at higher risk of not using effective birth control and of missing pills than women 20 to 24 years old. [29] For example, the National Survey of Family Growth demonstrated that 23% of women 15 to 19 years olds inconsistently used pills compared with 15% of 20 to 24 year olds.[30] Based on these data, it is likely that those 16 to 19 year old women enrolled in this study will have lower baseline rates of contraceptive adherence and, thus, will have greater room for improvement than their older peers. This is in agreement with observations during a prior contraceptive study conducted at University of Texas Medical Branch (UTMB). In that study, 16 to 18 year old oral contraceptive users who received more education by participating in a contraceptive study had significantly better adherence with their method over a 6-month interval than those women of the same age seen in the regular clinic (73% vs 57%, respectively). However, no differences among women 21 to 24 years old were observed between those seen in the regular clinic and those participating in the contraceptive study. Thus, it is hypothesized that the effect of the clinic-based plus telephone intervention will be greater among participants who are 16 to 19 years old than those who are 20 to 24 years old **(Hypothesis 3).**

In conclusion, 40% of women 15 to 19 years old and 63% of women 20 to 24 years old seek public or private family planning services to avoid an unintended pregnancy. [3] These young women overcome significant psychological, financial, and other barriers in order to visit a health care provider. Most are prescribed birth control pills for contraception. Unfortunately, a large number of these women still experience an unwanted pregnancy

within 1 year because they use the pills for only a few months. In a previous study, I observed that 25% of women ≤18 years old who obtained birth control pills at the federally funded UTMB clinic in Galveston experienced an unintended pregnancy within 12 months.[31] To reduce the number of unintended pregnancies among these young women, it is imperative that the medical community develop, test, and implement programs that increase the percentage of young women who use effective contraception for an extended period of time. Interventions aimed at women seen in public clinics should be a high priority because significant resources are already being spent to provide them with free contraception. The World Health Organization recently suggested in an extensive report on adherence to long-term therapies that patients who have difficulty adhering to their prescribed regimen should be supported and not blamed. [32] This study was developed in an attempt to help a significant number of young adults avoid the adverse sequelae of an unplanned pregnancy or STI and, ultimately, help them lead healthy and productive lives.

Chapter 3: Preliminary Studies

As part of a 5-year study on the effects of DMPA and oral contraceptives on bone density, I recruited over 700 women. These women were followed every 3 months for up to 3 years. Results from this study demonstrated that contraceptive continuation rates among young women using the pill were much greater for study subjects than for those regularly seen in the UTMB family planning clinics, even though (1) the same office suite was used for all visits, (2) the socioeconomic group served were similar, and (3) both the BMD study and family planning clinics received their contraception on site at no cost. For example, continuation rates for pill users ≤18 years old at the regular clinic were 57% after 6 months[33] compared with 73% among the BMD study subjects. After 12 months, continuation rates for the birth control pill were 34% among family planning clinic patients as compared with 64% among BMD study patients.

The dramatic differences in contraceptive continuation rates among pill users seen in the BMD study versus the regular (family planning) clinic after 6 and 12 months prompted me to investigate why these differences occurred. A literature search on the primary reasons that young women do not use their contraception consistently or correctly revealed that some of the most common reasons are that women (1) frequently run out of medication because they do not return to the clinic on schedule; (2) forget to take their pills on schedule; (3) discontinue use because they do not expect to have sex, do not understand how to take their medication, or do not know what to do when they miss doses.[34] Next, the care received in the regular clinic was compared to the care received by women in the BMD study. This comparison revealed that study subjects enjoyed a number of “interventions” that addressed these common reasons for nonadherence that did not occur in the regular clinic. For example, they received intensive one-on-one education from a nurse practitioner at their initial visit. She reviews a one-page handout with them on how to use their method of contraception. This handout is written in a simple style that is easy to comprehend. As the nurse practitioner reviews it with the patient, she assesses their level of understanding and repeats items as needed. She uses visual aids such as a pill package containing the type of pills they are being prescribed. She instructs them to continue using their method, even if they do not expect to have sex that month. She informs them of the non contraceptive benefits of their method. She also warns them about possible side effects they may experience, such as abnormal bleeding, and discusses how they should prepare for this. For

example, she instructs them to keep minipads at work or school because the bleeding could occur at any time.

The nurse practitioner also uses behavioral techniques to increase patient adherence to the prescribed regimen. All patients are seen for their first visit when they are on their menstrual period. This allows the nurse practitioner to instruct them to start their pills on the same day as their appointment (same day start). In fact, she has them take their first pill in front of her. She then labels their next three pill packs with the date they should be started and hands all packages to the patient when she leaves. All women are given a toll-free number prior to leaving the clinic that they can call 24 hours a day if they need assistance or have questions regarding their medication. She encourages them to use this number if they are uncertain about how to take their pills by telling them, “I have messed up taking my pills before. Don’t feel bad if you mess up. Call me and I will help you.”

Next, these observations were used to design two interventions. Both contain educational and behavioral components similar to those currently being used in the BMD study. The interventions have been slightly modified from what is being done in the BMD study so that patients can be seen in the clinic on days when they are not on their period; this is necessary because women schedule their appointments for the family planning clinic weeks in advance. Instead, the Health Educator instructed those patients on their period at the clinic visit to start their pills that day. Patients randomized to the clinic-based plus telephone intervention were called on a weekly basis following their visit and guided through their first dose over the telephone, if needed.

Chapter 4: Methods

A randomized, controlled trial was conducted to examine the effect of both a clinic-based intervention and a clinic-based plus telephone intervention on contraceptive adherence among young women initiating use of oral contraception during the first 12 months of use. Furthermore, rates of dual use of oral contraception and condoms were compared between the two intervention groups and the standard care group. Women from 16 to 24 years old who request oral contraception at one of five UTMB clinics were recruited to participate. After providing informed, written consent, all participants completed a paper-and-pencil survey to ascertain demographic and reproductive characteristics as well as a detailed history of their use of contraception. In addition, they completed measures to assess health literacy, pregnancy attitudes, and perceived severity and susceptibility to pregnancy. All of these measures were available in English or Spanish. Participants were randomized to receive the clinic-based intervention (C), the clinic-based plus telephone intervention (C + P), or standard care. Both the C and C + P interventions included multi-component face-to-face counseling and patient education using educational and behavioral techniques at the time of the baseline clinic visit. The C + P intervention also included phone calls to the participant for the first 6 months of contraceptive use. Inclusion of both the clinic-based only and combined clinic plus telephone interventions allowed us to efficiently determine, in a single study, the comparative benefit of each of the two approaches. The effect of each intervention was measured on (1) consistent and (2) correct use of contraceptive pills; and (3) dual use of condoms among both intervention groups and the standard care group by phone interviews conducted at 3, 6, and 12 months after the baseline visit. Furthermore, other indicators of effective use of condoms and hormonal contraception were evaluated, such as overall pregnancy rates, attendance at a 3-month follow-up clinic visit for a new supply of pills, and STI cultures for *Neisseria gonorrhoeae* (gonorrhea) and *Chlamydia trachomatis* (chlamydia). Statistical models were used to evaluate indicators of adherence, while controlling for age, sexual activity and other variables of interest.

This study was approved by the UTMB Institutional Review Board (Protocol #06-060).

Recruitment of study subjects

To determine the sample size needed, data was used from prior studies conducted at UTMB, similar studies reported in the literature, and a predictive power analysis. Individuals

younger than 16 years old were not included in this study, as only a very small number of these patients attend UTMB family planning clinics.

Only young women who wished to use oral hormonal contraception were recruited because birth control pills are among the most effective reversible methods available to prevent unintended pregnancy when used consistently and correctly, and it is the most popular method among young patients. Birth control pills have over 99% efficacy with perfect use, [35] are female-controlled, and are safe for long-term use. Furthermore, users of injectable contraception (Depo-Provera, Pharmacia & Upjohn, Kalamazoo, Mich); the transdermal patch (Ortho Evra, Ortho-McNeil Pharmaceutical, Raritan, NJ); an intrauterine device; or the vaginal ring (NuvaRing; Organon, Inc, West Orange, NJ) were not recruited because too few of the younger women seen in the UTMB family planning clinics request these methods, and instruction in the correctness and consistency of use of these methods require qualitatively different strategies than those previously developed by the investigators for contraceptive pills.

Inclusion and exclusion criteria

Inclusion criteria

1. Sexually active females 16 to 24 years old who presented to a UTMB family planning clinic and requested to initiate oral contraception for birth control.

Exclusion criteria

1. Women who were currently pregnant.

2. Women who wished to become pregnant within the next 12 months.

3. Women with a medical contraindication to use of estrogen (eg, thromboembolic disease, acute liver disease, breast cancer, genital cancer, or undiagnosed genital bleeding).

4. Women who wanted to initiate use of a contraceptive method that is not oral, such as transdermal (the patch) or injectable (DMPA) methods, or the vaginal ring.

5. Current users of oral contraceptives or those who had previously used them for >1 month.

Randomization

After obtaining informed, written consent, patients were randomized to receive standard clinical care or one of the two interventions (C or C + P). A fully documented randomization scheme was developed by the Office of Biostatistics using the PLAN procedure in SAS (SAS Institute, Cary, NC).[36] Patients randomized to standard care received all of their contraceptive services from the practitioner at that clinic as described below (see Description of Standard Care.). Patients randomized to the clinic-based intervention (C) received these same services from the practitioner at that clinic and met with the Health Educator assigned to that clinic. Patients randomized to the clinic-based plus telephone intervention (C + P) received their contraceptive services from the practitioner at that clinic, met with the Health Educator at that site, and received phone calls by the Health Educator for the following 6 months.

All participants assigned to the C and C + P groups received the clinic-based intervention. At the time the clinic-based intervention was delivered, the Health Educator was blinded as to which subjects were randomized to C versus C + P; therefore, she did not know who would receive follow-up phone calls. This methodology minimized the potential for bias in the delivery of the clinic-based intervention. For example, the Health Educator may have unintentionally delivered the intervention differently if she was aware that a particular participant would receive follow-up telephone calls (versus not receiving phone calls). After the clinic-based session ended, the complete study group information was revealed to the Health Educator and the patient so that plans could be made to call the participants assigned to C + P. The randomized group assignment for every study patient was documented into the research database using “Group 1,” “Group 2,” and “Group 3” nomenclature that was revealed as C, C + P, or standard care only as necessary to research personnel conducting follow-up assessments. In addition, a code representing the individual delivering the clinic-based intervention was entered into the database to permit evaluation of any potential differences by the Health Educators.

Description of the Three Study Arms

1. Standard Care (Controls)

The UTMB family planning clinics follow a written protocol for new users of hormonal contraception that is based on the standard of care in the United States. New patients are scheduled for a 15-minute visit. At this visit, patients are given oral and written instructions on all contraceptive methods. The written materials include a standard brochure; this same

brochure is used for women of all ages. After the patient selects a method, they are advised of the possible side effects and warning signs of this particular method and instructed in the use of their particular method. Each patient is also advised that hormonal contraception does not protect against STIs, and they are encouraged to use condoms.

Women who choose oral contraception are given a 4-month supply at their initial visit. All patients are instructed to initiate use of their method within 7 days of starting their next menstrual cycle. A supply of 24 condoms is given to all patients free of charge. Patients are also given a phone number for the clinic that they can call between 8 AM and 5 PM to speak to someone if they have a question. If a clinic director is not available to take their call, they may leave a message and the phone call will be returned later. At check-out, an appointment is made for a follow-up appointment in 2 to 3 months. If the patient misses this initial follow-up appointment, a clinic staff member attempts to reach her by phone; if that fails, a letter is sent to the patient.

2. Clinic-based Intervention (C)

After completing their visit with the practitioner at the clinic, those participants randomized to one of the intervention groups also met one-on-one with a Health Educator. The Health Educator used educational and behavioral counseling techniques geared toward lower health literacy and specifically designed to increase adherence to medications. The different components of the clinic-based intervention we used are summarized below.

1. Hand outs were distributed with simple, concrete, written instructions for birth control pills and for condoms, including what participants should do if they miss doses or appointments.

2. Instructions were reviewed verbally using visual aids, including a pill package, in language that is easily understood by the patient.

3. The patient was asked to repeat back key portions of the instructions to insure that she understood them.

4. Each participant was asked to develop a cue, based on her daily routine that would assist her in remembering to take her pill.

5. Participants who were on their period were asked to take their first pill at the visit and label their next three packages with the date each package should be opened and started.

Participants not on their period were instructed in how to initiate their pills and label their next three pill packs.

6. The risk of pregnancy if contraception was not used correctly was discussed and the impact this would have on her life.

7. All participants were informed of the noncontraceptive benefits of birth control pills.

8. It was discussed with each participant how she would deal with the most common side effects, should they occur, and develop a specific plan for handling them. (Behavioral)

9. Participants were educated about different types of STIs, how they are transmitted, and her risk of contracting an STI as well as the potential effects that contracting an STI would have on her life and the need for dual use.

10. Participants practiced condom application on a plastic model and discussed specific condom negotiation skills that they could use with her partner.

Both educational and behavioral strategies were included in this intervention. This is in agreement with a meta-analysis of intervention studies on adherence that reported that those programs that combined educational and behavioral techniques were more effective than programs using only one of these techniques. [37] Furthermore, those programs employing two educational strategies were generally better than those using only one. Similarly, the World Health Organization reported in 2003 that all of the most promising methods of improving adherence behavior use a combination of strategies.[38]

The literature was reviewed to determine the type of educational and behavioral interventions that would most likely be effective. Studies on interventions in adolescents have found that personalized information is preferred over leaflets[39] and videotape presentations.[19] Educational sessions have been found to be most effective when they are brief, organized, and focused with repetition and specific expectations.[40] This is consistent with the observation that most patients can assimilate only two or three important pieces of information in a brief time. [41] Failure to read and understand written materials that came with the pills and not receiving adequate information or help from their health care provider have been associated with a greater than twofold increase (relative risk = 2.2) in nonadherence with oral contraceptives. [42] Thus, “user friendly” written materials were given to the patients

and reviewed with them during the face-to-face sessions using concrete examples and plain language.[43]

One of the behavioral interventions that has been shown to most consistently improve long-term adherence with oral medication is the use of cues. In fact, one study of 6,676 women demonstrated that those who did not have an established routine for pill taking were 3.3 times more likely to be noncompliant than those who did.[42] Thus, the Health Educator encouraged this technique and helped each patient identify cues based on her daily routine. For example, if the patient anticipated taking her medication after brushing her teeth in the morning, seeing the toothbrush became a cue. [44]

Another behavioral intervention that has been shown to increase adherence with oral contraceptives is use of a same day start regimen. In a study of 193 young women under 23 years old, Lara-Torre and Schroeder noted that those who were instructed to begin their pills the same day they were seen in the office were significantly more likely to be using oral contraception at their 3 month follow up than those who waited to initiate their medication.[45] Thus, those women who were on their period at the time of their clinic visit were instructed to begin their medication while they were still at the office.

Finally, the intervention included anticipation of side effects which can be an important barrier to consistent use of oral contraception. The Health Educator worked with the patient at the initial visit to anticipate potential adverse effects and discussed them in advance. Barriers to reliable use, such as running out of pills, also were discussed. Behavioral skills that are necessary for condom use include communication, negotiation, and refusal skills as well as technical condom-use skills.[11] Study participants worked with the Health Educator to develop these skills. In addition, they were given an opportunity to practice their technical skills at the clinic by learning how to apply a condom properly using a model available in the clinic. Participants practiced negotiation skills through the use of role-play scenarios.

3. Clinic-based plus Telephone Intervention (C + P)

Those subjects randomized to the clinic-based plus telephone intervention group received the same treatment at their clinic visit as those randomized to the C group. In addition, they were contacted regularly by the Health Educator for 6 months following their baseline clinic visits. Patients were contacted at a time during the day they designated as most convenient. Those who requested that they be called during the late afternoon or evening hours due to their work or school schedule were accommodated. These phone interactions are summarized below.

1. Before they left the clinic, participants were given a toll-free number that they could call 24 hours a day if they needed assistance or had questions regarding their medication. They were encouraged to use this number if they were uncertain about how to take their pills.

2. One week after the baseline clinic visit, participants were contacted by phone to determine if they have begun their period. If a participant had started her period, the educator asked whether she has begun her medication. If the participant had started her period and not started her medication, she was instructed to take her pill while on the phone.

3. Participants who had not started their periods within 1 week of their clinic visit were called weekly until they stared their menstrual cycle. Once a participant began her cycle, the instructions outlined in Step 2 were followed.

4. During this phone call, all participants were instructed to label their next three packages with the date each package should be opened and started.

5. During this phone call, the date that each participant would run out of medication was calculated, and the next appointment made—making certain that it occurred before she ran out of medication.

6. Health Educators called participants in 4-week intervals following this first phone call (5, 9, 13, 17, 21, and 25 weeks after they started their pills) to deliver the telephone intervention component. During these phone calls, the Health Educator reviewed how to use their pills correctly, what to do about incorrect use of the pill to "get back on track," side effects, and the importance of dual use of condoms.

7. If, during any intervention phone call, a patient stated that she wished to switch pill type or switch to a different contraceptive method, the Health Educator stressed the importance of continuous contraception and encouraged the patient to see a provider *before* stopping her pills.

These telephone calls after the clinic encounter provided an opportunity for the Health Educator to reinforce certain messages. Telephone-delivered interventions have been shown to be effective in a number of prior studies.[46] For example, they have been effective in encouraging behavior change in patients with chronic disease when used in conjunction

with other techniques, such as face-to-face counseling, video or slide presentations, or family support materials. These efforts were sustained during the time that the telephone intervention was in effect. [47]

The telephone intervention component was developed after a comprehensive review of the literature. First, both proactive and reactive approaches were used, as recommended by McBride and Rimer in a review of 74 randomized studies; they observed that this combination may be needed to reach underserved target groups.[46] In the proposed study, the telephone intervention consisted of women being called every 4 weeks by a Health Educator (proactive) and being provided with an 800 number that they could call as needed (reactive).

Second, the telephone intervention was only one component of the clinic-based plus telephone intervention. This was critical because telephone-based interventions that have relied almost entirely on the telephone have had limited success when used to encourage behavior change. In fact, the absence of the other components may have been the reason why one study of 63 adolescents failed to find a difference in contraceptive use after 15 months between those who received 2 to 6 phone calls over a 4- to 6-week interval and those who did not.[48] In contrast, this study included a telephone intervention component that augmented the receipt of patient education, written materials, and practical demonstrations of contraceptive and condom use delivered one-on-one in the clinic setting.

Furthermore, programs with longer durations have been shown to be more effective. In a review of behavioral interventions to reduce sexual risk behaviors among young women, Robin and colleagues noted that the duration of programs played a role in their effectiveness.[49] Rotheram-Borus also noted a relationship between the program's duration and its effectiveness.[50] In their study, a reduction in sexual risk behaviors was observed when the intervention consisted of seven sessions, but not when it had only three sessions. Based on this review of the literature, an intervention was designed with a minimum of seven telephone calls delivered over a 6-month interval. The first 6 months of use were targeted, as this is the time period during which women are learning to use the method properly, establishing good habits, and allowing their bodies and self-concept to accommodate use of hormonal contraception. This is also the time of greatest discontinuation and is therefore a critical time to intervene.

Finally, telephone-delivered interventions can effectively improve patient adherence to treatment regimens while minimizing logistical barriers and cost.[46] All participants were provided with a toll-free number to contact the Health Educator, if needed. In addition, the

patient's time preference for receiving a phone call was documented, in the event she will not be at that number all day or would prefer to speak to study personnel only at certain times during the day or evening. An intervention study by Chewning et al[51] examining hormonal contraceptive use among adolescent patients demonstrated that adolescents were receptive to telephone contact. Similar to the calling methodology used in published research,[51] calling procedures were negotiated with each participant at her initial visit to minimize inconvenience, maximize retention, and protect confidentiality. Specifically, multiple phone numbers were obtained and acceptable and unacceptable times to call.

Pilot Testing

Pilot testing was conducted among 18 clinic patients who met all inclusion and exclusion criteria. A randomization scheme was used that assigned pilot subjects into one of two (C or C + P) groups. All pilot subjects met with the Health Educator (following their regular clinic visit) who then delivered the clinic-based intervention. Pilot subjects in the C + P group received two follow-up phone calls in addition to the clinic-based intervention. The first phone call was made 1 week after their clinic visit and continued weekly until they had started their period and started their first pill pack. The second call occurred the following month to reinforce the intervention. For the purposes of expediency, telephone calls were limited to these two time points. Pilot subjects in the C + P group were asked to evaluate the intervention they received following their last phone call.

Approximately 2 weeks after the clinic-based intervention (for C subjects) or the last phone call (for C + P subjects), each pilot subject was contacted to assess the subject's experience, including her opinions and perceptions of the relevance of the intervention material and her ability to apply the information. Information was also obtained on the overall intrusiveness of the intervention, its acceptability, its strengths and weaknesses, and the perceived impact of the intervention on the individual's contraceptive and sexual behavior. Conducting these assessments by telephone mirrored the methodology used in the main study and provided insight regarding the ability to reach participants by phone. Each participant in the pilot study was reimbursed $40 for her time and scientific contribution, similar to the methodology for reimbursement that was planned for use in the full study ($20 each for the clinic visit and the assessment phone call).

Blinding of Study Personnel

A recognized problem among complex interventions is that subjects usually can determine their assignment.[52] Given the intensity of the C and C + P interventions and the descriptions that had to be provided during the informed consent process, it is not possible to blind participants in this study to their group assignment.

The Clinical Research Coordinator who performed the assessment phone calls was not informed of the patient's group assignment, although information provided by the participant may have revealed her group assignment. In addition, blinding of the study group during the first stages of data analysis was maintained by using general nomenclature to disguise the study group to reduce the potential for bias in the interpretation of the findings.

Description of Recruitment Sites

The UTMB Regional and Maternal Child Health Program (RMCHP) was used for recruitment for this study because the demographic characteristics of the RMCHP clinic patients closely mirror risk factors for poor contraceptive adherence. Contraceptive failure rates have been demonstrated to be highest in cohabitating and other unmarried women, those with family incomes below 200% of the federal poverty level, black and Hispanic women, and adolescents and women in their 20s.[20] A substantial percentage of women seen in the UTMB RMCHP clinics have incomes below 200% of the federal poverty level and the majority of those 23 years old or younger are unmarried. UTMB's family planning clinic population is approximately 18% black, 45% white, and 33% Hispanic. Hispanic patients were an important group to include because from 1990 to 1996, the pregnancy rate among young Latinas declined only 6% compared with 20% among black and 16% among white adolescents.[53] Furthermore, this clinic population includes school drop-outs, another at-risk population. The diversity of this clinic population helped ensure the generalizability of the sample to young women at high risk for an unintended pregnancy.[54]

Assessment of Outcomes

Outcomes were assessed among women assigned to both of the intervention groups and the standard care group at 3, 6, and 12 months because most discontinuation occurs within the first year of use.[55] In fact, most women who stop using oral contraceptive pills do so in the first 6 months. For instance, Rosenberg et al observed that 15% of their total sample stopped using their pills after 2 months and 28% discontinued after 6 months.[8]

Similarly, a previous study on adolescent mothers demonstrated that 47% of those who initiated birth control pills immediately after delivery were no longer using this method 6 months later.[6] Thus, it was critical to perform evaluations at 3 and 6 months when the risk of discontinuation was the highest. However, an assessment at 12 months was also needed to assess the number of young women who experienced an unintended pregnancy or contracted a STI as a result of inconsistent use of contraception or failure to use condoms. Research participants were reimbursed $20 for the baseline visit and each assessment phone call for a total of $80.

Baseline measures

Demographic information and sexual history. At the initial visit, patients were asked to report their age, race/ethnicity, marital status, employment, education level, and if any grade levels at school were repeated. Sexual activity data and reproductive health indicators included number of sexual partners in the past year, lifetime number of sexual partners, parity, history of an STI and condom use at last intercourse. Participants were also queried about what pill they were prescribed or received that day (the day of study enrollment) in the clinic and both the brand name and formulation of the prescribed pill were documented for each study subject.

Health literacy. Women who do not read or understand the dosing instructions for oral contraceptives are at high risk for poor adherence.[37] This is a particular problem for young women because patient package information for many oral contraceptives is written at a tenth- to twelfth-grade reading level.[56] Furthermore, women with low health literacy are likely to have difficulty processing and implementing the instructions into a routine that results in perfect compliance. The association between functional literacy and medication adherence, particularly contraceptive adherence, is understudied.[57] In fact, intervention studies have been criticized for failing to stratify outcomes by literacy level, and the Agency for Healthcare Research and Quality has identified the importance of this analytic step.[58]

Thus, it was important to assess health literacy in this sample. Several assessments of functional health literacy have been developed, each with strengths and weaknesses.[59] A brief measure was selected to use that evaluates comprehension of prose passages and numerical information. Specifically, the short Test of Functional Health Literacy in Adults (S-TOFHLA) was administered.[60] The S-TOFLA presents four numeracy items (eg, prescription bottles, appointment slips) and two prose passages (eg, basic written facts) and takes about

12 minutes to complete. The instrument was derived from the longer, well-established TOFHLA and is available in English and Spanish. [61,62] The prose passages on the S-TOFHLA are written at a fourth- and tenth-grade level; the numeracy items reflect important or frequent tasks in the health care setting including understanding dosing information on a prescription label, reading an appointment slip, and timing medication doses.

Pregnancy attitudes and intentions. Some participants may have had ambivalence regarding pregnancy even though they were seeking contraception. Little is known about how pregnancy attitudes relate to patterns of contraceptive use,[63] with one cross-sectional study showing that the most common reason for nonuse of contraception among adolescents was absence of a negative attitude toward having a baby. [64] Data from the National Longitudinal Study of Adolescent Health suggest that ambivalent attitudes toward pregnancy are associated with reduced odds of using contraception[65] and are predictive of pregnancy 1 year later. [66] At baseline and the 3-, 6-, and 12-month assessments, participants were asked to respond (yes/no) to the question: "I know you said that you do not intend to become pregnant any time soon, but do you really intend to remain nonpregnant in the next 3 months?" In addition, attitudes toward pregnancy were assessed with the item: "If you were pregnant now, how would you feel about it?" using a five-point Likert-type scale with the anchors "very happy to be pregnant" and "very unhappy to be pregnant." [67] Finally, ambivalence about pregnancy at baseline was assessed using a five-point visual analog scale with the anchors "very much" to "not at all," as ambivalence is associated with infrequent use of contraception and condoms among adolescents. [68,69] Using this scale, ambivalence was considered as any response other than "not at all."

Perceived severity and susceptibility. Participants were asked to indicate their agreement with the following two items addressing perceived severity of pregnancy from the Add Health project that were predictive of pregnancy 1 year later [66,70]: "Getting pregnant at this time in my life is one of the worst things that could happen to me," and "It would not be all that bad if I got pregnant at this time in my life." A "strongly disagree" (1) to "strongly agree" (5) rating scale was used. Perceived susceptibility to pregnancy was assessed with multiple items. The first item derives from the Add Health study[70] "Imagine that you were to have sexual intercourse with someone just once, but were unable to use any method of birth control for some reason. What is the chance that you would get pregnant?" The response options included the following: "almost no chance," "some chance, but prowere asked to

indicate their perceived risk of becoming pregnant using a five-point “strongly disagree” to “strongly agree” rating scale.

Outcome measures

Contraceptive adherence.

Each subject was asked whether or not she was still using birth control pills. Women who reported they were no longer on their method were queried about when they stopped taking their pills and if there was a particular reason for stopping. Those who stopped using oral contraception over the course of the study were offered instruction on how to re-initiate use of their pills if they expressed the desire to do so.

Those reporting that they were still taking their pills were asked to describe when and how they took their pills to determine correctness. This was determined by asking specific questions about the number of missed pills (how many left in the pack at the end of the month) and incorrect starting (ie, delayed) of the initial or subsequent pill packs during the time period being assessed (baseline to 3 months, 3–6 months, and 9–12 months). Whether pills were taken out of order was assessed (incorrect day or inert vs active pills) and whether correct procedures were followed to “catch up” when pills were missed. These questions reflect published criteria for effective use of oral contraceptives.[71] Participants were asked, “Have you missed any pills in the past week?” Additional questions assessed forgotten pills such as, “How many days in the last month (30 days) did you forget to take a pill?” and “How many times in the last month (30 days) have you forgotten to take two or more pills?” Participants were also asked “How many times since you started taking your pills did you forget to take two or more pills?” at the 3-month assessment, and “How many times since the last assessment did you forget to take two or more pills?” for the 6- and 12-month follow-up assessments. These questions were followed by the response options: none, once, twice, three or more times. Women’s reports of having missed two or more pills have been shown to be accurate using electronic monitoring systems. For instance, data reported by Potter et al showed that for 92% of months in which women self-reported that two or more pills had been missed, electronic data were consistent with their report.[72] Regardless of whether one or more pills were reportedly forgotten, all participants were asked, “What do you do when you miss taking the pill one day?” with the following response options: take two pills the next day (correct option), skip that day and take one pill the next day, stop taking pills for that month, or something else (provide verbal explanation). These data were then used to determine adherence.

Dual method use. Use of condoms in addition to oral contraception will be measured at the 3-, 6-, and 12-month telephone assessments. Across the 3-month assessment interval, participants were asked to estimate the percentage of times they had sexual intercourse that a condom was used. This will be done by providing an example that if they had sex about 10 times, and about 7 times a condom was used, this would be 70%. Consistent condom use was documented for individuals who reported that a condom was used every time they had sex (100%). In addition, an item from the Add Health study was used to assess frequency of condom use more generally (ie, without the use of percentages). This item was: "Thinking about all of the times you have had sexual intercourse (in the last ___ months), about what proportion of the time has a partner of yours used a condom?" Five response options were given: "none of the time," "some of the time," "half of the time," "most of the time," and "all of the time." Those who reported inconsistent use for either question were asked "The last time you had sexual intercourse, did your partner use a condom?" All participants who reported using condoms within the past 3 months were asked to report the type of condom used. Specifically, they were asked, "When condoms were used, were they: always a latex condom, sometimes a latex condom, or always a nonlatex condom?" Finally, participants who reported using condoms within the past 3 months were asked about condom application, such as the timing of when the condom was put on relative to any penile/vaginal contact (before or after), and whether or not the condom ever slipped off during intercourse (yes, ever/no, never).

Pregnancy rates and STIs. Pregnancy and STI rates were assessed by self-report at 3, 6, and 12 months. During the phone assessments, each subject was asked whether she has become pregnant or received treatment for a STI. Appropriate referrals were made for women who indicated they were pregnant, and they were discontinued from the study.

Follow-up measures at 3, 6, and 12 months

Satisfaction with method. Participants' satisfaction with their pills after 3, 6, and 12 months of use was assessed by using questions from a previously published study I conducted in the UTMB family planning clinics.[33] Specifically, it asks, "Overall, how satisfied are you with your current method of birth control?" to which subjects will respond using a Likert-type scale with the words "very dissatisfied," "somewhat dissatisfied," "somewhat satisfied," and "very satisfied." In addition, participants were asked to describe the

characteristics they like the most and least about their pills, and whether they would recommend using birth control pills to a friend.

Sexual activity. Consistent contraceptive use over time may vary with the existence of a sexual partner and the particular activities engaged in with the current partner. At baseline, and after 3, 6, and 12 months, it was assessed whether the participant has one or more current sexual partners, and whether she has had sexual intercourse (penile-vaginal penetration) in the last 30 days. Additionally, among those reporting intercourse in the last 30 days, the frequency of intercourse was assessed, as infrequent intercourse is associated with less consistent contraceptive use.[73]

Continuity of hormonal contraception. Over the 12-month duration of this study, some study patients decided to switch contraceptive methods. Although few data are available on method switching, data from the 1995 National Survey of Family Growth show that the 2-year switching rate for unmarried women using the pill is 52%.[21]

Although the primary aim of this study was to educate and support initiators of oral contraception to use the pill correctly and consistently for the duration of the study, a broader goal of this research program was to encourage sexually active young women who seek contraception to use reliable, effective, and safe methods correctly and continuously. Therefore, study participants who discontinued their pills and did not switch to another hormonal method were offered instruction on how to re-initiate use of the pill if they chose. If not, they were encouraged to see a provider when they wished to initiate a new hormonal method so they could begin a new method in a timely fashion.

Patient follow-up

Excellent tracking of all participants over the 12-month study period was a high priority to maximize retention. At the baseline clinic visit, participants were asked for primary and secondary phone numbers at which they could be reached for follow-up assessments. In addition, cell phone numbers were obtained as well as beeper numbers and mailing address. Each participant was asked to provide the names, addresses, and telephone numbers of three individuals who would know of her whereabouts in the event of a move. Finally, UTMB's electronic medical record system was used to facilitate tracking as it includes the most recently recorded address and phone number for the patient as well as patient-specified contacts or alternative telephone numbers (eg, work, relative's house).

Sample Size Justification and Projected Attrition

Prior to the initiation of the study, a power analysis was conducted. Calculations were based on the ability to detect differences in adherence rates after 12 months, which is the primary outcome of this study. Specifically, the study was designed to detect an odds ratio (OR) of 2.0, or that women in the C + P group would be twice as likely to still be using contraceptive pills after 12 months compared with women in the standard care (S) group. This was considered what would be a clinically meaningful difference. We then increased the sample size estimates obtained from these calculations to enable us to have adequate power to detect meaningful differences between study groups by age strata (Specific Aim 3), since a larger sample size is needed to detect a statistical interaction (age group × study group).

To estimate the expected rates of adherence among women assigned to the C+P group, data were used from a prior study conducted on bone mineral density at UTMB in these same clinics, in which components of the planned C+P intervention were delivered. Adherence rates for pill users in that study were approximately 87% at 3 months, 76% at 6 months, and 63% at 12 months.

The table below shows the required sample sizes needed to detect an OR of at least 2.0 between the C + P group and the other two intervention groups at 3, 6, and 12 months with 90% power, using a chi-square test of equal proportions with a 0.05 2-sided significance level.

Table I. Sample size needed per study group at 3, 6, and 12 months

	Time Period		
	3 Months	**6 Months**	**12 Months**
Standard care/C	0.74	0.60	0.46
C + P	0.87	0.76	0.63
Odds ratio	2.4	2.1	2.0
Power	90%	90%	90%
N per group	**209**	**189**	**190**

C = clinic-based intervention, C + P = clinic-based intervention with phone calls intervention

This study had a final sample size in each group of over 200 women after 12 months. Thus, we had adequate power to examine the primary outcomes.

An additional aim of this study was to compare the effect of the intervention on adolescents 16–19 years of age as compared to those 20–24 years of age. This is

essentially testing for the (age group × study group) interaction described above. Using the anticipated adherence rate of 63% at 12 months shown in the above table for the C+P group, we hypothesized that adolescents (16–19 years of age) would respond more favorably to the interventions relative to the young adult group (20–24 years of age). We also assumed that the groups C and Standard Care would have a similar effect within age groups. The figures in Table II show a large effect in the younger age group (74% vs 52% vs 52%) and a much smaller effect in the older age group (65% vs 61% vs 61%). Calculations from power software based on applications of GEE[74] indicate that to detect this interaction with 80% power at $\alpha = 0.05$, a sample size of 210 subjects per cell would be needed. Sample size calculations were made using nQuery Advisor 5.0 (Statistical Solutions, Los Angeles, Calif),[75] the PLAN procedure in SAS,[36] and SAS macros by Rochon.[76]

Table II. Effect sizes for adherence rates for assessing the (age group × intervention) interaction among C + P versus C or C + P versus standard care

N per Cell	16–19 years			20–24 years		
	C + P	C only	Standard Care	C + P	C only	Standard Care
210	74%	52%	52%	65%	61%	61%

C = clinic-based intervention, C + P = clinic-based intervention with phone reinforcement

Our final sample size, however, was not large enough to stratify by these two age groups. To address this, a Bonferroni correction was performed to determine the appropriate level of significance for analysis of the two separate age groups with the equation .05/20 as there were 20 different outcomes examined. As a result, a P value <.0025 was considered significant for all analyses stratified by age (16-19 y and 20-24 y).

Data Analyses

Data analysis began with summary tables and descriptive analyses, including sets of descriptive bivariate analyses (eg, chi-square and t-tests). The primary end point for the study was at 12 months. Secondary end points were 3 and 6 months. The longitudinal models were designed to compare the overall or “average” experience of subjects across all three time points. Potential confounders and modifiers were noted for consideration in the models.

In addition, models were developed across the 3, 6, and 12-month outcomes to assess changes in these binary outcomes over time. We used General Estimating Equations to estimate parameters for these models. These models have the advantage of accommodating some missing data, which, for this study, was missing data at 3, 6, or 12 months but not missing data at all three time points. In addition, these models allowed us to obtain odds ratios for the exposure variables while adjusting for the estimated errors for the repeated measurements. The data set easily met the sample size requirement of GEE models, which is dependent upon having a large number of clusters (ie, subjects with correlated data at 3, 6, and 12 months). The large sample size also allowed us to include as many covariates as needed. Furthermore, we used clinic location as a categorical variable to adjust for the variation of outcome variable by clinic location.

A total of 1,155 subjects were randomized to the three study groups (C, C + P, standard care) resulting in six subsamples (three study groups × two age strata). Because there was randomization to study groups, there was little concern for confounding. However, we

compared distributions of potential confounders and modifying variables such as age, race or ethnicity, health literacy, and pregnancy attitude. Any variables found to be unevenly distributed across study groups were controlled for in the usual ways including stratification and inclusion of variables, such as ethnicity, as covariates in statistical models.

Chapter 5: Results for Specific Aim 1 – Pilot study to assess interventions

Pilot testing of the planned interventions was conducted at 2 clinics (Galveston and Angleton). A total of 23 participants were recruited. Of these 15 were between 16 and 19 years of age and 8 were 2-24 yo. Audio tapes were made of the interventions to ensure consistency across sites.

Participants completed written evaluations to assess how well the intervention was received. Analysis was performed using a Fischer's exact test to determine if responses differed by clinic site.

Table III. Evaluation of pilot study

1: How interesting would you rate the information you received about using your pills?

	Not at all interesting	Slightly Interesting	Quite Interesting	Extremely Interesting	P
PCP			2 (18%)	9 (82%)	.640
Angleton			4 (34%)	8 (66%)	

2: How interesting would you rate the information you received about using condoms?

	Not at all interesting	Slightly Interesting	Quite Interesting	Extremely Interesting	P
PCP			4 (36%)	7 (64%)	.537
Angleton		1 (8%)	6(50%)	5 (42%)	

3: How much of the information you received from the HE about birth control pills was new to you?

	None of it	Some of it	Half of it	Most of it	All of it	P
PCP		1 (9%)	1 (9%)	6 (55%)	3 (27%)	.804
Angleton		3 (25%)	1 (8%)	4 (33%)	4 (34%)	

4: How much of the information you received from the HE about condoms was new to you?

	None of it	Some of it	Half of it	Most of it	All of it	P
PCP	2 (18%)	3 (27%)	2 (18%)	3 (27%)	1 (10%)	.714
Angleton	1 (8%)	5 (43%)	4 (33%)	2 (16%)		

5: How would you rate the length of time you spent with the HE?

	Too long	Somewhat long	Just about right	Not long enough	P
PCP			11 (100%)		1.00
Angleton			11 (92%)	1 (8%)	

6: Based on what the educator said, how important is it to use condoms in addition to taking your pill?

	Not at all important	Somewhat Important	Very Important	Extremely Important	P
PCP			1 (10%)	10 (90%)	1.00
Angleton		1 (9%)	2 (16%)	9 (75%)	

7: How clear were the instructions about when to start taking your BCPs?

	Not at all clear	Somewhat clear	Extremely clear	P
PCP			11 (100%)	.217
Angleton		3 (25%)	9 (75%)	

8: How clear were the instructions about what to do if you miss a pill?

	Not at all clear	Somewhat clear	Extremely clear	P
PCP		1 (10%)	10 (90%)	.478
Angleton			12 (100%)	

9: How likable (personable) was the educator that you met with?

	Not at all	Somewhat	Quite	Extremely	P
PCP				11 (100%)	
Angleton				12 (100%)	

10: How trustworthy did the educator seem to you?

	Not at all	Somewhat	Quite	Extremely	P
PCP			1 (10%)	10 (90%)	1.00
Angleton			1 (8%)	11 (92%)	

11. How concerned did the educator seem about you learning how to take BCPs?

	Not at all	Slightly	Quite	Extremely	P
PCP			1 (10%)	10 (90%)	.478
Angleton				12 (100%)	

12. How helpful did the role playing seem when the educator talked with you about negotiating condom use?

	Not at all	A little bit	Quite	Extremely	P
PCP			2 (18%)	9 (82%)	1.00
Angleton			3(25%)	9 (75%)	

13. How helpful was it for you, personally, to practice putting a condom on the model with the health educator present?

	Not at all	A little bit	Quite	Extremely	P
PCP	1 (9%)	1(9%)	1 (9%)	8 (73%)	.155
Angleton			5 (42%)	7 (58%)	

14. How do you feel about the time you have spent in the clinic today with the HE talking about your pills?

	Definitely a waste of time	Probably a waste of time	Probably a good use of my time	Definitely a good use of my time	P
PCP			1 (10%)	11 (90%)	1.00
Angleton			2 (16%)	10 (84%)	

15: How likely is it that you will share any of the information you got today with a friend or someone else you know who uses BCPs?

	Not at all likely	Somewhat Likely	Very Likely	Extremely Likely	P
PCP		1 (9%)	2 (18%)	8 (73%)	1.00
Angleton			2 (16%)	10 (84%)	

Analysis of responses by clinic site did not show any significant differences between the two clinics. Overall, the intervention was rated highly at both sites. All participants found the material interesting (questions 1 and 2) and at least some of the information about birth control pills new (question 3). Over 80% at each site also found at least some of the information new about condoms (question 4). The length of time that was spent with the health educator was rated as just about right by all but one of the subjects (question 5). Eighty-seven percent stated that the instructions were extremely clear about when to start their pills (question 7) and 96% stated that the instructions were clear about what to do if they missed a pill (question 8). In addition, almost all participants found the health educator to be personable, trustworthy, concerned and helpful (questions 9-13). All participants felt that the visit was a good use of their time (question 14).

Due to large percentage of women who responded positively, it was determined that the intervention was ready for implementation and recruitment for the main study began.

Chapter 6: Results for Specific Aim 2 – Effects of interventions on oral contraceptive and condom use

A. Sample characteristics at baseline

Following the pilot study, we approached 20,263 sexually active, low income women seeking contraceptive care at one of five federally funded family planning clinics for possible inclusion in the study. Of these 18,625 women were not eligible. The most common reasons for ineligibility were that they did not want to use oral contraception (N=10,654 or 57.2%), were already using oral contraception (9.3%), had used OC in the past for >1 month (22.7%) or planned to become pregnant within 12 months (3.2%). (See exclusion criteria in Chapter 4, Methods.)

This left 1638 women who met all criteria and were eligible to participate. However, 483 (30%) refused participation. Thus, 1155 women met criteria and agree to be enrolled in the study. No differences were observed between those who refused and those who enrolled with regard to the desire for a pregnancy within the next 12 months ($p = 0.26$) or having ever had sex ($p = 0.09$). However, those who refused participation were significantly older (mean age of those who refused 20.2 ± 2.4 compared to the age of those enrolled 19.9 ± 2.4; $p<.001$). Although statistically significant, this age difference was felt to be too small to be clinically meaningful. Additionally, Hispanic women were significantly less likely to agree to participate as compared to White and African-American women (35% of Hispanic women refused participation as compared to approximately 20% of White and African-American women; $p< 0.001$).

Among the 1155 participants, 644 (56%) were between 16 and 19 years of age and 511 (44%) were 20-24 yo. Distribution among racial/ethnic groups was representative of the clinics' patient bases: Hispanic = 626 (54%); black = 215 (19%); white = 287 (25%); and other = 27 (2%). Most of the women were single/never married (78%), and about a quarter of them worked more than 20 hours per week. Analyses of baseline characteristics revealed no significant differences between the three study groups with regard to mean age, race, marital status, education, employment, or school performance (Table IV).

Table IV. Demographic characteristics of the entire sample at baseline by assigned intervention group (N=1155)

	C N = 383	C+P N = 384	S N = 388	P value±
Age (mean ± SD)	19.8±2.3	19.9±2.4	20.0±2.4	0.47
Race (%)				0.76
White	105 (27.4)	86 (22.4)	96 (24.7)	
Black	68 (17.8)	74 (19.3)	73 (18.8)	
Hispanic	200 (52.2)	214 (55.7)	212 (54.6)	
Other	10 (2.6)	10 (2.6)	7 (1.8)	
Marital Status (%)				0.61
Never married	302 (79.1)	306 (80.1)	298 (77.2)	
Married, divorced, or separated	80 (20.9)	76 (19.9)	88 (22.8)	
Education (%)				0.31
Did not complete HS or get GED	198 (51.7)	188 (49.0)	173 (44.6)	
HS graduate	179 (46.7)	192 (50.0)	211 (54.4)	
College degree†	2 (0.5)	1 (0.3)	1 (0.3)	
Employment Status (%)				0.32
Does not work	243 (63.4)	227 (59.1)	238 (61.3)	
Employed ≤ 20 h/wk	38 (9.9)	51 (13.3)	35 (9.0)	
Employed > 20 h/wk	102 (26.6)	104 (27.1)	113 (29.1)	
Ever repeated a grade in school (%)	72 (18.8)	88 (23)	84 (21.9)	0.35

Numbers vary in some categories due to missing data; † No comparison among groups

Furthermore, there were no significant differences between the study groups in history of sexually transmitted infections, condom use at last intercourse, number of sexual partners in the last year or their lifetime or mean number of prior pregnancies (Table V).

Table V. Reproductive characteristics of the entire sample at baseline by assigned intervention group (N=1155)

	C N = 383	C+P N = 384	S N = 388	P value
No. sexual partners in the last year (mean ±SD)	1.63 ± 1.3	1.59 ± 1.1	1.64 ± 1.4	0.76
No. lifetime sexual partners (mean ±SD)	3.9 ± 5.1	3.6 ± 3.3	3.9 ± 5.8	0.52
Mean number of prior pregnancies (mean ±SD)	1.6 ± 0.8	1.6 ± 0.8	1.4 (0.7)	0.12
History of STI (%)	72 (18.9)	76 (19.9)	71 (18.4)	0.80
Condom use at last intercourse (%)	155 (44.5)	177 (50.0)	168 (46.3)	0.33

Numbers vary in some categories due to missing data.

Standardized measures of health literacy, pregnancy attitudes, perceived severity and susceptibility were also assessed at baseline as these could possibly affect contraceptive adherence. No differences were observed between groups as shown below in Table VI.

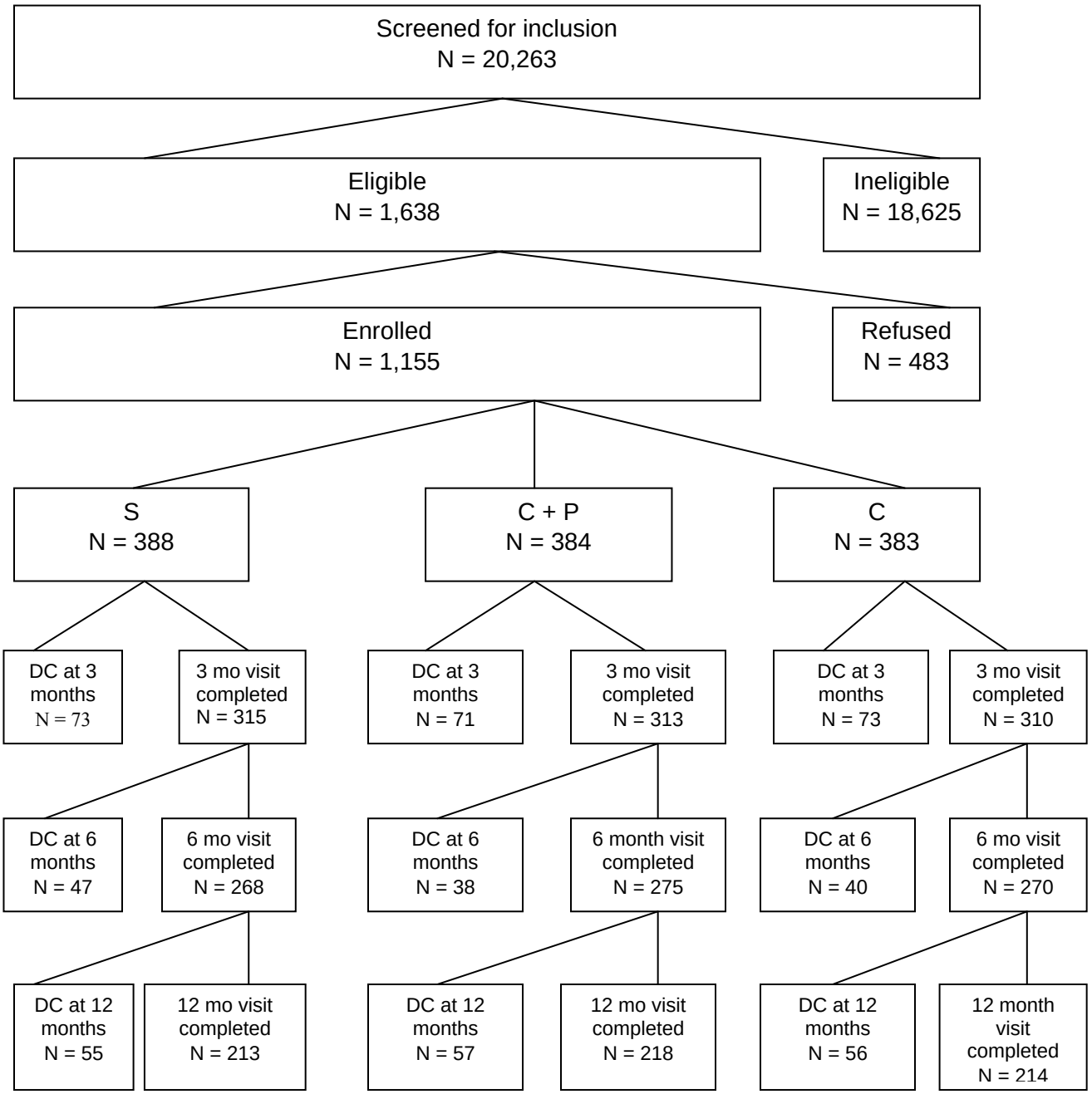
Table VI. Measures of pregnancy attitudes, health literacy, and perceived severity and susceptibility of the entire sample at baseline by intervention group (N=1155)

	C N = 383	C+P N = 384	S N = 388	P value
Positive attitude toward pregnancy	2.81 ± 0.6	2.85 ± 0.6	2.86 ± 0.6	0.48
Perceived risk for pregnancy	2.95 ± 0.8	2.98 ± 0.8	2.95 ± 0.8	0.86
Susceptibility for pregnancy	3.68 ± 1.1	3.75 ± 1.1	3.75 ± 1.1	0.56
Health literacy	33.4 ± 3.6	33.8 ± 3.4	33.2 ± 4.6	0.15

B. Follow up rate at 3, 6, and 12 months

Follow up data were obtained from assessment calls conducted at 3, 6, and 12 months. Assessment calls were successfully conducted on 81.2% (938/1155) of women at 3 months, 70.4% (813/1155) at 6 months and 55.8% (645/1155) at 12 months, as shown below in Figure 1. No differences in follow up rates were observed by intervention group.

Figure 1. Total number of women recruited and followed at 3, 6, and 12 months by intervention group



To assure the validity of the data collected for the study, analyses of those lost to follow-up as compared to those completing follow-up were conducted (Table VII). The only differences observed were that White women were less likely to remain in the study than non Whites and that those who remained in the study had a slightly higher parity than those

who discontinued. This difference in parity was too small to be clinically meaningful (1.6 vs. 1.5). Final GEE analysis adjusted for race.

Table VII. Demographic and reproductive differences in baseline characteristics among those who discontinued early vs. those who remained in study all 12 months

	Remained in study N = 645	Discontinued study N = 510	P value
Intervention groups (%)			0.86
C Intervention group (N =383)	214 (55.9)	169 (44.1)	
C + P Intervention group (N = 384)	218 (56.8)	166 (43.2)	
S Intervention group (N = 388)	213 (54.9)	175 (45.1)	
Race (%)			0.006*
White (N = 287)	139 (48.4)	148 (51.6)	
Black (N = 215)	131 (60.9)	84 (39.1)	
Hispanic (N = 626)	364(58.1)	262 (41.9)	
Other† (N = 27)	11 (40.8)	16 (59.3)	
Age (%)			0.11
16 to 19 (N = 643)	347 (54.0)	296 (46.0)	
20 to 24 (N = 512)	298 (58.2)	214 (41.8)	
Marital Status (%)‡			0.09
Never married (N = 906)	494 (54.5)	412 (45.5)	
Married, divorced, or separated (N=244)	148 (60.7)	96 (39.3)	
No. sexual partners in the last year (N = 1146)‡	1.60 ± 1.3	1.64 ± 1.2	0.54
No. lifetime sexual partners (N = 1133)‡	3.79 ± 5.0	3.82 ± 4.7	0.93
Education (%)‡			0.72
Did not complete HS or get GED (N = 559)	311 (55.6)	248 (44.4)	
HS graduate (N = 582)	327 (56.2)	255 (43.8)	
College degree† (N = 4)	2 (50.0)	2 (50.0)	
Employment Status (%)‡			0.65
Does not work (N = 708)	396 (55.9)	312 (44.1)	
Employed ≤ 20 h/wk (N = 124)	67 (54.0)	57 (46.0)	
Employed > 20 h/wk (N = 319)	179 (56.1)	140 (43.0)	
Ever repeated a grade in school (%)‡			0.10
No (N = 905)	516 (57.0)	389 (43.0)	
Yes (N = 244)	126 (51.6)	118 (48.4)	
Mean number of prior pregnancies (N = 602; N = 549 who had never been pregnant)	1.6± 0.8	1.5 ± 0.7	0.04
History of STD (%)‡			0.52
No (N = 929)	513 (55.2)	416 (44.8)	
Yes (N = 219)	126 (57.5)	93 (42.5)	
Condom use at last intercourse (%)			0.83
No (N = 593)	333 (56.2)	260 (43.8)	
Yes (N = 562)	312 (55.5)	250 (44.5)	

† Comparison not made
‡ Numbers vary due to missing data
*Hispanic > White (P<.01) and Black > White (P<.01)

C. Outcomes

The first outcome examined was duration of OCP use by intervention group. This included those who remained on their original brand prescribed and those who switched to a different brand of OCPs. Those who did not take any OCPs were coded as 0 months of use. No difference was observed between the three groups, as shown below in Table VIII.

Table VIII. Mean number of pill packs taken correctly by intervention group*

	C (n=310)	C+P (n=313)	S (n=315)	P value
Mean number of pill packs used correctly	5.2	5.9	5.3	.064

* Participants were excluded who could not be reached for any follow-up phone calls

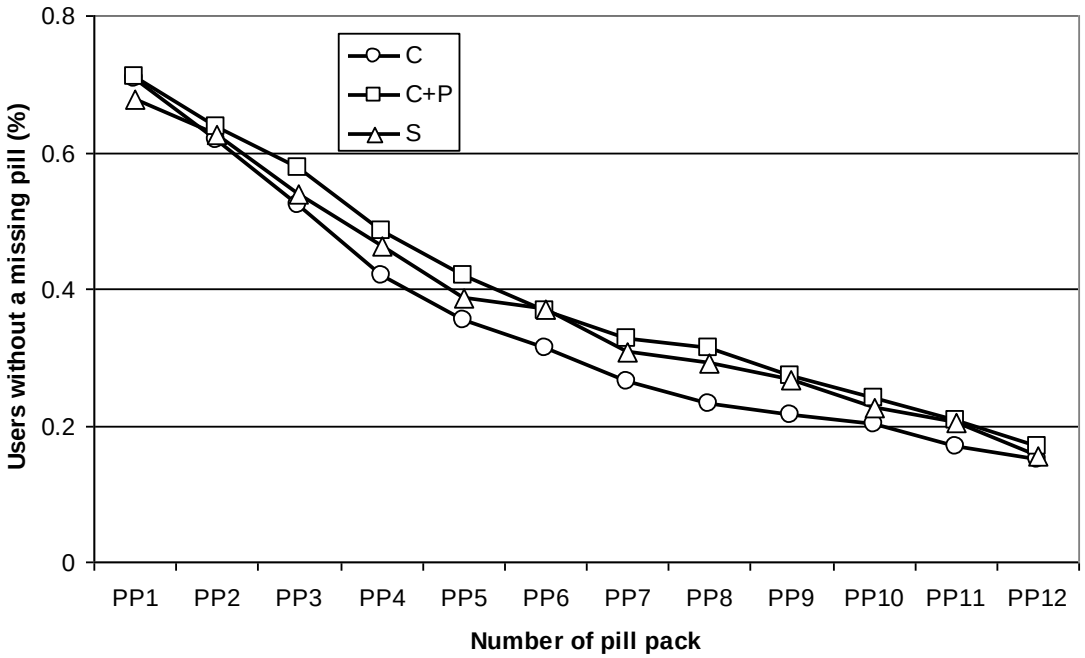
Next, the percentage of women who continued to use oral contraceptives was examined. As shown below in Table IX, there were few differences between groups. Overall, the percentage who reported that they were still using OCPs at 3, 6, and 12 months did not differ by intervention group. However, women in the C group were significantly less likely than those in the S group (p=.012) and those in the C+P group (p=.030) to report they were still using the same brand as originally prescribed at the 3 month phone call. At 12 months, those in the C group were less likely than those in the C+P group to be using their original brand (p=.031). More importantly, those in the C group were more likely than those in the C+P group to report that they were not using any contraceptive at the 3 month follow up (p=.004). This finding suggests that the C intervention was not effective in helping women stay on their oral contraceptives. Furthermore, the most intensive intervention (C+P) was not more effective than standard care for any of the outcomes examined.

Table IX. Duration of oral contraceptive pill use by assigned intervention group

	C	C+P	S	*P* value
Continued to use oral contraceptive pills	N (%)	N (%)	N (%)	
3 mo	192 (64.4)	224 (73.2)	215 (71.0)	.052
6 mo	122 (46.4)	151 (55.5)	144 (55.0)	.062
12 mo	69 (32.6)	76 (35.4)	77 (36.8)	.643
Continued to use same brand prescribed				
3 mo	173 (90.1)	214 (95.5)	209 (96.3)	.016
6 mo	103 (84.4)	139 (92.1)	133 (92.4)	.056
12 mo	55 (79.7)	70 (92.1)	70 (90.9)	.044
Switched to contraceptive method other than pill				
3 mo	62 (24.5)	59 (20.9)	52 (19.6)	.364
6 mo	76 (38.4)	70 (31.7)	64 (30.6)	.199
12 mo	66 (48.9)	78 (50.7)	66 (46.2)	.739
Not using any contraception				
3 mo	54 (17.6)	30 (9.6)	45 (14.5)	.014
6 mo	71 (26.4)	52 (19.1)	58 (21.8)	.116
12 mo	76 (36.0)	61 (28.4)	70 (32.9)	.237
Lost to follow-up				
3 mo	73 (19.1)	71 (18.5)	73 (18.8)	.980
6 mo	113 (29.5)	109 (28.4)	120 (30.9)	.740
12 mo	169 (44.1)	166 (43.2)	175 (45.1)	.872

In addition to examining duration of use, we examined whether either intervention helped women take their medication as directed (Figure 2). First, we compared perfect use (defined as starting each pack on time and not missing any pills) by intervention group. Each pill pack was considered separately and many women demonstrated perfect use in some months but not others. On first examination, it appeared that those who were randomized to C+P did the best during most months while those randomized to C did the worst. This was not anticipated as C patients received much more education in the clinic than those randomized to S. However, a statistically significant difference was noted between groups in only one of the 12 cycles (cycle 8) and this difference was between those in the C and C + P groups (P=.01). No significant difference was observed in any cycle between women in either intervention group and those randomized to S, suggesting that neither intervention increased perfect use of OCPs over standard care.

Figure 2. Percentage of women who reported perfect use of OCPs by intervention

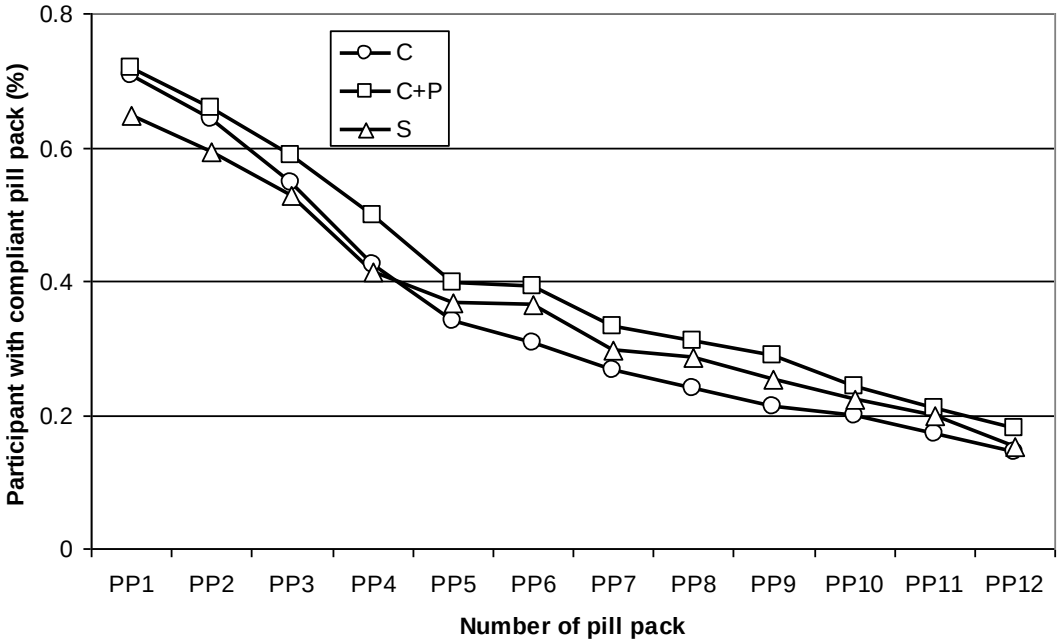


	C (N=383)	C+P (N=384)	S (N=388)	P value
PP1	0.707572	0.710938	0.677835	.544
PP2	0.618799	0.638021	0.626289	.857
PP3	0.522193	0.578125	0.53866	.244
PP4	0.420366	0.484375	0.463918	.171
PP5	0.355091	0.419271	0.386598	.165
PP6	0.313316	0.367188	0.371134	.160
PP7	0.263708	0.325521	0.306701	.140
PP8	0.232376	0.31250	0.291237	.032*
PP9	0.214099	0.270833	0.265464	.056
PP10	0.201044	0.239583	0.226804	.385
PP11	0.169713	0.205729	0.203608	.336
PP12	0.148825	0.169271	0.154639	.661

Next, we assessed whether the interventions had an effect on correct use of oral contraceptives (defined as starting each pack on time and correctly making up any pills missed). Significant differences were observed during three different pill packs (4, 6, and 9). For pill pack 4, a greater percentage of C+P women correctly used their OCPs as compared to those in C (P=.046) and S (P=.021). In months 6 and 9, the only differences were between women in C and C+P groups (P = .017 and .013 respectively). In both cases, those in C actually performed less well than those in C + P. It appeared that those in C were less likely to take their pills correctly than those in S at several points, but this comparison did not reach significance. Thus, those in C did not adhere to the medications any better

than those in the S group. Furthermore, those in the C+P group demonstrated correct use more often than those in the S group for one pill pack only (pill pack 4; figure 3).

Fig 3. Percent of participants with correct oral contraceptive use by intervention



	C (N=383)	C+P (N=384)	S (N=388)	P value
PP1	0.707572	0.71875	0.646907	.067
PP2	0.642298	0.658854	0.592784	.141
PP3	0.545692	0.588542	0.528351	.224
PP4	0.425587	0.497396	0.414948	.044
PP5	0.339426	0.398438	0.368557	.238
PP6	0.308094	0.390625	0.365979	.049
PP7	0.266319	0.330729	0.296392	.149
PP8	0.240209	0.309896	0.286082	.091
PP9	0.211488	0.289063	0.252577	.046
PP10	0.198433	0.242188	0.224227	.341
PP11	0.172324	0.208333	0.198454	.426
PP12	0.143603	0.179688	0.152062	.359

Since women fluctuated in perfect and correct use over the 12 pill packs, we also examined compliance using data collected at 3, 6, and 12 months without considering the month that pills were missed. This was done by looking at the percentage who reported missing one or more OCPs 3, 6, and 12 months after randomization (Table IX). The only difference was that women in the C+P group were more likely to report missing 3 active pills and restarting them in the past 90 days than those in C (p=.011) and S (p=.031). Since those in C+P had received the most intensive intervention, it was not clear why they would report missing more pills. One possibility was that women randomized to C+P were more

likely to restart their pills while those in the other groups may have discontinued their medication when they missed multiple pills. Overall, neither the C nor the C+P intervention decreased the number of times that women missed taking their OCPs. Furthermore, it did not appear to help women restart their pills unless they had missed multiple pills.

Table X. Counts and percentage of women who missed taking pills by intervention

	C	C+P	S	*P* value
Pill pack compliant				
3 mo	95 (30.7)	93 (29.7)	84 (26.7)	.517
6 mo	37 (13.3)	55 (19.2)	47 (17.0)	.167
12 mo	24 (9.5)	32 (12.1)	24 (9.6)	.555
Missed ≥1 active pill(s) in past 7d				
3 mo	25 (8.1)	27 (8.6)	21 (6.7)	.640
6 mo	12 (4.4)	10 (3.6)	11 (4.1)	.891
12 mo	7 (3.3)	5 (3.3)	4 (1.9)	.636
Missed ≥1 active pill(s) in past 30d				
3 mo	55 (17.7)	59 (18.9)	52 (16.5)	.744
6 mo	32 (11.9)	39 (14.2)	29 (10.8)	.473
12 mo	25 (11.7)	15 (6.9)	19 (8.9)	.221
Missed 1 active pill and restarted in past 30d*				
3 mo	43 (13.9)	54 (17.3)	43 (13.7)	.366
6 mo	27 (10.0)	26 (9.5)	23 (8.6)	.850
12 mo	20 (9.4)	10 (4.6)	13 (6.1)	.129
Missed 2 active pills and restarted in past 30d*				
3 mo	12 (3.9)	13 (4.15)	14 (4.4)	.938
6 mo	7 (2.6)	8 (2.9)	10 (3.7)	.732
12 mo	3 (1.4)	4 (1.8)	4 (1.9)	.915
Missed 3 active pills and restarted in past 30d*				
3 mo	16 (5.2)	10 (3.2)	17 (5.4)	.351
6 mo	7 (2.6)	11 (4.0)	6 (2.2)	.438
12 mo	6 (2.8)	3 (1.4)	5 (2.4)	.582
Missed an active pill and restarted in past 90d*				
3 mo	92 (29.7)	95 (30.4)	104 (33.0)	.634
6 mo	47 (17.4)	50 (18.2)	50 (18.7)	.930
12 mo	26 (12.2)	19 (8.7)	25 (11.7)	.455
Missed 2 active pills and restarted in past 90d*				
3 mo	23 (7.4)	22 (7.0)	37 (11.8)	.067
6 mo	12 (4.4)	18 (6.6)	20 (7.5)	.327
12 mo	9 (4.2)	9 (4.1)	5 (2.4)	.503
Missed 3 active pills and restarted in past 90d*				
3 mo	31 (10.0)	33 (10.5)	43 (13.7)	.300
6 mo	15 (5.6)	32 (11.6)	17 (6.3)	.016╫
12 mo	13 (6.1)	10 (4.6)	11 (5.2)	.784

* One or more times; ╫ Significance difference was found between C+P and C (p=.011), and C+P and S (.031) groups using chi square analysis

During both interventions, women were instructed in the importance of developing and using a cue. A cue was an object or action which the woman would identify with taking her oral contraceptive pill, such as brushing her teeth or turning off her alarm clock in the morning. It was recommended that she keep her pill pack near the object and always take her medication when she performed this action. The following tables demonstrate that

women in the C+P intervention were most likely to identify a cue and those in the S group were least likely (Table XI-XIII). However, there was no difference between intervention groups in the effectiveness of the cue as a reminder to take their oral contraceptive pills.

Table XI. Frequency of developing a cue and using it as a reminder at 3 months

	C N = 298	C+P N = 306	S N = 303	P value
Identified a cue (%)	226 (75.8)	275 (89.9)	186 (61.4)	0.00*
Cue served as reminder for pill taking (%)	212 (95.1)	263 (96.0)	176 (95.1)	0.86

*C>S (P<.01); C+P>S (P<.01); C+P>C (P<.01)

Table XII. Frequency of developing a cue and using it as a reminder at 6 months

	C N = 263	C+P N = 272	S N = 262	P value
Identified a cue (%)	202 (76.8)	239 (87.9)	156 (59.5)	0.00*
Cue served as reminder for pill taking (%)	185 (92.0)	227 (95.4)	151 (96.8)	0.11

*C>S (P<.01); C+P>S (P<.01); C+P>C (P<.01)

Table XIII. Frequency of developing a cue and using it as a reminder at 12 months

	C N = 212	C+P N = 215	S N = 209	P value
Identified a cue (%)	162 (76.4)	185 (86.0)	125 (59.8)	0.00*
Cue served as reminder for pill taking (%)	150 (93.2)	171 (92.4)	117 (93.6)	0.92

*C>S (P<.01); C+P>S (P<.01); C+P>C (P=.01)

A large number of reasons were cited by participants for stopping OCP use. For most reasons, the numbers were too small to do meaningful comparisons (Table XIV). Thus, the three most common reasons were compared by intervention group (Table XV). The only significant difference observed was that women in the C group were more likely than those in the C+P group at the 6th month visit to report that they discontinued OCPs because they could not remember to take their medication (p=.03). No differences were observed between women in either intervention group and those randomized to standard care at any follow up visit.

Table XIV. Descriptive table showing reasons given for stopping oral contraceptives after initiating use

	S group			C group			C+P group		
	3 mo N=115	6 mo N=79	12 mo N=74	3 mo N=122	6 mo N=81	12 mo N=58	3 mo N=104	6 mo N=87	12 mo N=72
Side effects	32	14	11	34	21	7	29	9	13
Decided to get pregnant	2	3	0	4	4	0	3	2	2
Ran out of pills	17	26	28	17	20	21	12	25	22
Negative family pressure	0	0	1	1	0	0	1	1	0
Waiting for period to start	2	3	2	0	3	1	5	9	2
Cost	1	2	2	3	2	2	1	0	2
Can't remember to take pills	24	8	9	23	18	6	23	7	9
Had difficulty restarting after missing pills	9	6	6	8	4	1	8	4	6
Too much trouble	2	3	5	3	3	1	1	1	1
Not having sex	0	4	1	1	0	1	0	4	0
Pills left at different location	11	1	4	6	5	3	7	5	5
Pregnant	5	4	4	10	6	8	3	5	5

Table XV. Evaluation of most common reasons for stopping oral contraceptives by intervention group*

	C	C+P	S	*P* value
Side effects	N (%)	N (%)	N (%)	
3 mo	34/310 (11.0)	29/313 (9.3)	32/315 (10.2)	0.78
6 mo	21/270 (7.8)	9/275 (3.3)	14/268 (5.2)	0.07
12 mo	7/214 (3.3)	13/218 (6.0)	11/213 (5.2)	0.41
Ran out of pills				
3 mo	17/310 (5.5)	12/313 (3.8)	17/315 (5.4)	0.56
6 mo	20/270 (7.4)	25/275 (9.1)	26/268 (9.7)	0.62
12 mo	21/214 (9.8)	22/218 (10.1)	28/213 (13.1)	0.47
Can't remember to take pills				
3 mo	23/310 (7.4)	23/313 (7.3)	24/315 (7.6)	0.99
6 mo	18/270 (6.7)	7/275 (2.5)	8/268 (3.0)	0.03
12 mo	6/214 (2.8)	9/218 (4.1)	9/213 (4.2)	0.69

*Based on available data at each follow up visit

Questions at 3, 6, and 12 months also inquired about satisfaction with their method and whether they would recommend it to a friend. At 3 months, those in the C group were less likely than those in the C+P and S groups to recommend their method to a friend (Table XVI). However, this difference was no longer present by 6 months. Furthermore, there were no differences between intervention groups in reported satisfaction at 3, 6, and 12 months (Tables XVII-XVIII).

With regards to condom use, no differences were observed between the three groups in overall condom use at last sex or in dual use during the last 3 months at any of the follow up phone calls.

Table XVI. Satisfaction with method and condom use at 3 months by intervention group

	C	C + P	S	*P* value
Satisfaction with method	3.50 ± 0.70	3.61 ± 0.70	3.51 ± 0.71	0.14
Recommend BCP to a friend (%)	216 (90.8)	241 (95.6)	237 (96.3)	0.02*
Partner used condom at last sex (%)	120 (51.3)	147 (58.91)	124 (51.0)	0.20
Dual method use in the last 3 months (%)	57 (25.6)	72 (30.6)	67 (29.0)	0.47

*C<C+P (P=.031); C<S (P=.012)

Table XVII. Satisfaction with method and condom use at 6 months by intervention

	C	C + P	S	*P* value
Satisfaction with method	3.37 ± 0.80	3.52 ± 0.77	3.50 ± 0.75	0.09
Recommend BCP to a friend (%)	220 (92.4)	244 (95.7)	223 (94.1)	0.31
Partner used condom at last sex (%)	120 (49.8)	127 (50.2)	107 (44.8)	0.41
Dual method use in the last 3 months (%)	63 (29.9)	69 (30.1)	54 (25.6)	0.51

Table XVIII. Satisfaction with method and condom use at 12 months by intervention

	C	C + P	S	*P* value
Satisfaction with method	3.30 ± 0.90	3.48 ± 0.76	3.38 ± 0.84	0.09
Recommend BCP to a friend (%)	198 (93.8)	205 (95.3)	200 (95.7)	0.65
Partner used condom at last sex (%)	100 (46.9)	101 (46.3)	82 (38.5)	0.15
Dual method use in the last 3 months (%)	55 (30.1)	54 (27.8)	52 (27.8)	0.86

Furthermore, no differences were observed by intervention group in the number of women who kept their follow up appointment 3-4 months after their initial visit (Table XIX). When rates of sexually transmitted infections and pregnancy were examined, it was noted that women randomized to C were actually more likely to report a pregnancy than those randomized to standard care (17.5% vs. 9.5%, P = .001). There was also marginal significance in the pregnancy rate between those in the C and C+P groups (P=.053). No differences were observed between groups in the number who were treated for a STI (Table XX).

Table XIX. Number and percentage (in parenthesis) who attended clinic 3-4 months following the initial visit by intervention group

	C N=383	C+P N=384	S N=388	*P* value
Kept clinic appointment in 3-4 mo	175 (45.7)	199 (51.8)	185 (47.7)	.222

Table XX. Number and percentage (in parenthesis) that were treated for sexually transmitted infections (STI) or became pregnant within 12 months by intervention group

	C N=383	C+P N=384	S N=388	*P* value
Treated for STI	29 (7.6)	39 (10.2)	27 (7.0)	.230
Became pregnant	67 (17.5)	48(12.5)	37(9.5)	.004*

C vs. S (P=.001); C vs. C+P (P=.053)

Chapter 7: Specific Aim 3 – Results for effect of interventions stratified by age group (16-19 yo vs. 20-24 yo)

The final specific aim of this study was to determine if there were differences in outcomes by age, when subjects were stratified into two groups (16-19 yo and 20-24 yo). This would allow us to determine if the intervention was effective in one age group, but not the other. Due to the lack of power and large number of comparisons, a Bonferroni correction was performed. This indicated that P values less than .0025 should be considered significant, which are indicated in red type.

I started the analyses for Specific Aim 3 by examining those randomized to each arm by age (Figure 4) and follow up rates by age (Table XXI). There were no significant differences between the two age groups in follow up rates.

Figure 4. Recruitment and intervention assignment by age group

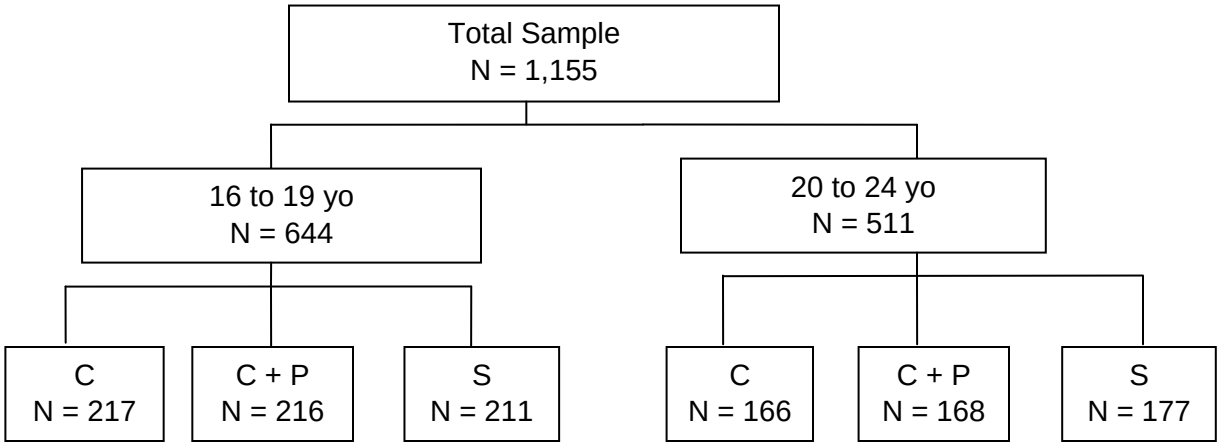


Table XXI. Overall follow-up rates at 3, 6, and 12 months by age group

	16 – 19yo	20 – 24yo	P value
Completed the 3-month visit (%)	516 (80.2)	422 (82.5)	0.36
Completed the 6-month visit (%)	438 (84.9)	375 (88.9)	0.07
Completed the 12-month visit (%)	347 (79.2)	298 (79.5)	0.93

Demographic characteristics and standardized measures of health literacy, pregnancy attitudes, perceived severity and susceptibility assessed at baseline were then stratified by age. There were no differences by intervention group when stratified by age (Table XXII) Furthermore, there were no differences between study groups in scores obtained for health

literacy, attitudes toward pregnancy, perceived susceptibility and perceived risk (Table XXIII).

Table XXII. Demographic characteristics by intervention group within age category

	16 to 19 yo			P value	20 to 24 yo			P value
	C	C + P	S		C	C + P	S	
Race (%)				0.55				0.78
White	72 (43.1)	53 (33.1)	68 (41.7)		33 (23.9)	33 (23.6)	28 (19.3)	
Black	44 (31.7)	51 (32.3)	43 (31.2)		24 (18.6)	23 (17.7)	30 (20.4)	
Hispanic	95 (68.3)	107 (67.7)	95 (68.8)		105 (81.4)	107 (82.3)	117 (79.6)	
Other†	6 (2.8)	5 (2.3)	5 (2.4)		4 (2.4)	5 (3.0)	2 (1.1)	
Marital Status (%)				0.74				0.86
Never married	199 (91.7)	199 (93.0)	191 (91.0)		103 (62.4)	107 (63.7)	107 (60.8)	
Married, divorced, or separated	18 (8.3)	15 (7.0)	19 (9.0)		62 (37.6)	61 (36.3)	69 (39.2)	
Education (%)				0.32				0.32
Did not complete HS or get GED	135 (63.1)	135 (62.8)	118 (56.7)		63 (38.2)	53 (31.9)	55 (31.1)	
HS graduate	79 (36.9)	80 (37.2)	90 (43.3)		100 (60.6)	112 (67.5)	121 (68.4)	
College degree†	0 (0.0)	0 (0.0)	0 (0.0)		2 (1.2)	1 (0.6)	1 (0.6)	
Employment Status (%)				0.85				0.06
Does not work	139 (84.8)	132 (82.0)	139 (84.8)		104 (88.9)	95 (81.2)	99 (90.8)	
Employed ≤ 20 h/wk	25 (15.2)	29 (18.0)	25 (15.2)		13 (11.1)	22 (18.8)	10 (9.2)	
Employed > 20 h/wk	53 (27.6)	53 (28.6)	45 (24.5)		49 (32.0)	51 (34.9)	68 (40.7)	
Ever repeated a grade in school (%)	39 (18.1)	56 (26.0)	52 (24.9)	0.10	33 (19.9)	32 (19.0)	32 (18.3)	0.93

Numbers vary in some categories due to missing data
† No comparison among groups

Table XXIII. Measures of pregnancy attitudes, health literacy, and perceived severity and susceptibility of the entire sample at baseline by intervention within age groups (N=1155)

	16 to 19 yo				20 to 24 yo			
	C	C + P	S	P value	C	C + P	S	P value
Positive attitude toward pregnancy	2.81 ± 0.62	2.92 ± 0.54	2.91 ± 0.61	0.11	2.81 ± 0.68	2.76 ± 0.62	2.81 ± 0.59	0.70
Perceived risk for pregnancy	295 ± 0.77	2.98 ± 0.75	2.97 ± 0.81	0.91	2.95 ± 0.82	2.98 ± 0.78	2.92 ± 081	0. 83
Suscepti-bility for pregnancy	3.62 ± 1.04	3.66 ± 1.08	3.71 ± 1.08	0.64	3.76 ± 1.14	3.86 ± 1.03	3.80 ± 1.08	0.67
Health literacy	33.6 ± 3.4	33.6 ± 3.7	33.6 ± 3.74	0.99	33.2 ± 3.9	34.0 ± 3.12	32.8 ± 5.5	0.04

Outcomes were then examined within each age group. For duration of OCP use, it was observed that younger women randomized to the C+P group used more pill packs, on average, than those randomized to the C or S groups (Table XXIV). However, this was not significant at the value of P<.0025.

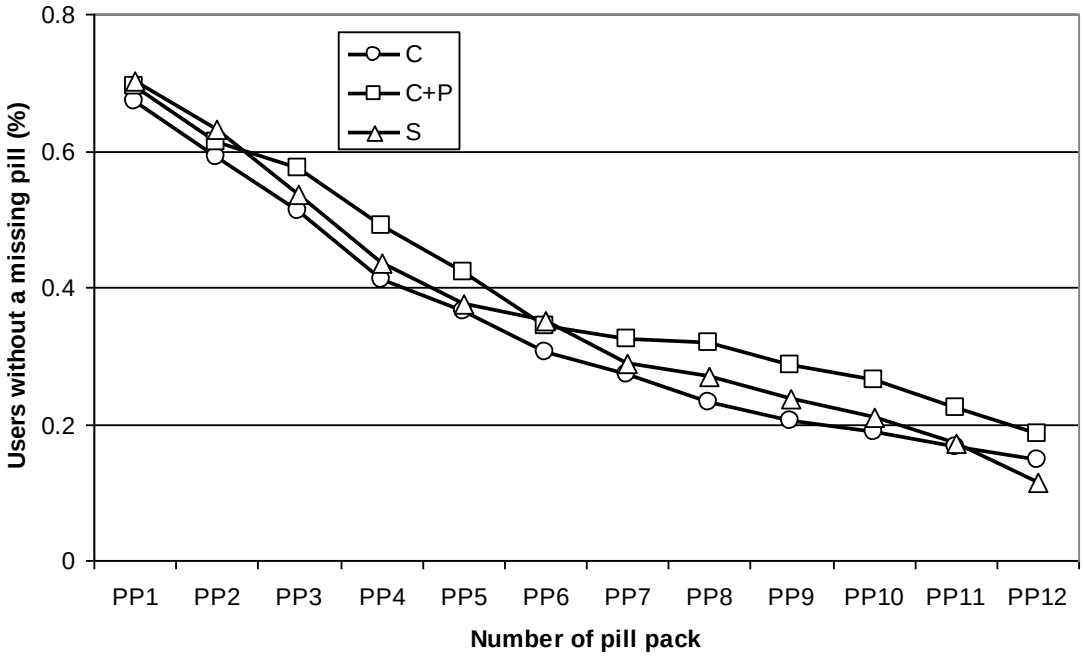
Table XXIV. Mean number of pill packs taken correctly by intervention group and age

	C (n=310)	C+P (n=313)	S (n=315)	
Total	5.2	5.9	5.3	.064
16-19 yrs	5.2	6.1	5.0	.027*
20-24 yrs	5.2	5.7	5.7	.578

Excluded participants who could not be reached for any follow-up phone calls
* C+P > S (P=.04)

Perfect use and correct use were also examined within each age group. There were no differences in perfect use (never missing a pill) for either age group (Figure 5-6). With regards to correct use, there was only a significant difference at the .05 level during one out of 12 months which was observed only among women in the 16-19 year old group. This was due to fewer women in the C group using their OCPs correctly than those in the C+P group. However, this difference was not significant at the .0025 level (Figure 7-8).

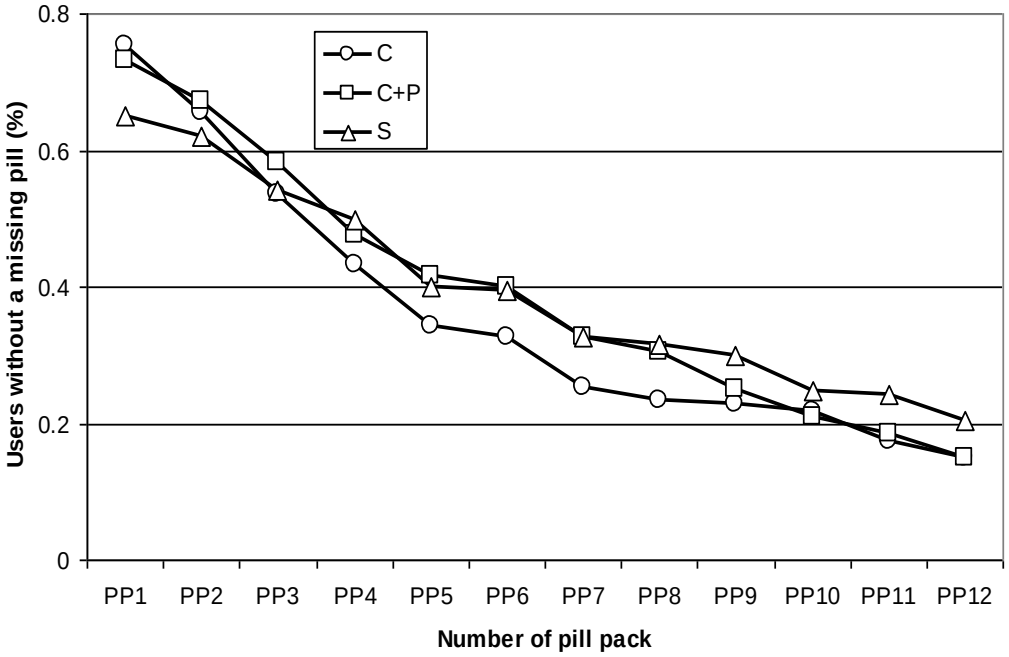
Fig 5. Perfect use of oral contraceptives by intervention group among 16-19 year old participants



Based on initial number of participants in each intervention group
C = Clinic-based intervention (n=217)
C+P = Clinic-based intervention with phone reinforcement (n=216)
S = Standard clinic practice (n=211)

	C	C+P	S	P value
PP1	0.672811	0.694444	0.701422	.800
PP2	0.589862	0.611111	0.630332	.692
PP3	0.511521	0.574074	0.535545	.420
PP4	0.410138	0.490741	0.436019	.227
PP5	0.364055	0.421296	0.374408	.429
PP6	0.304147	0.342593	0.350711	.549
PP7	0.271889	0.324074	0.2891	.479
PP8	0.230415	0.319444	0.270142	.114
PP9	0.202765	0.287037	0.236967	.120
PP10	0.18894	0.263889	0.208531	.150
PP11	0.165899	0.222222	0.170616	.250
PP12	0.147465	0.185185	0.113744	.116

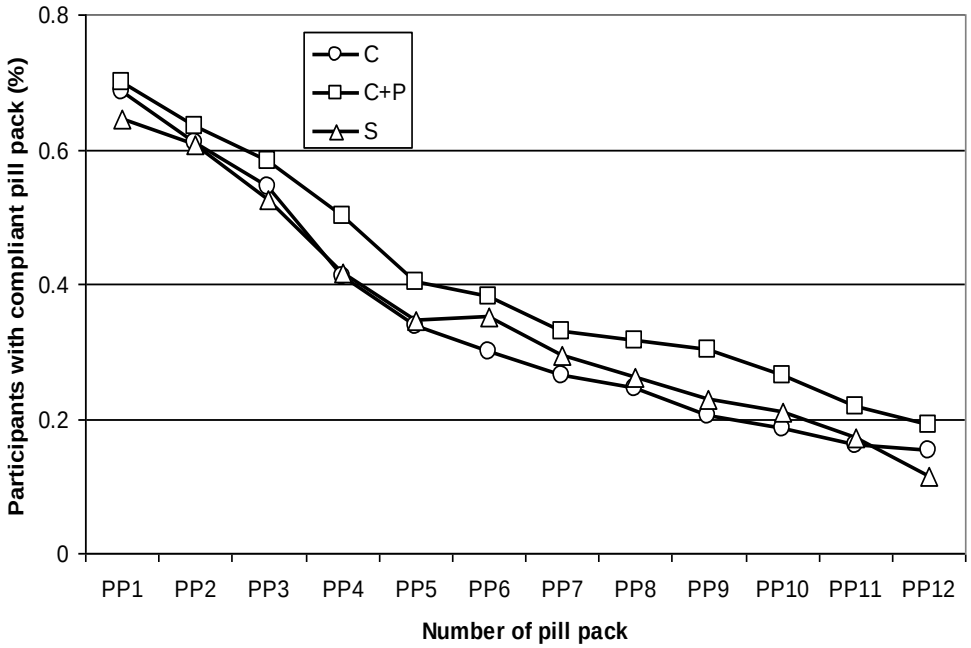
Fig 6. Perfect use of pill by intervention methods among 20-24 year old participants



Based on initial number of participants in each intervention group
C = Clinic-based intervention (n=166)
C+P = Clinic-based intervention with phone reinforcement (n=168)
S = Standard clinic practice (n=177)

	C	C+P	S	P value
PP1	0.753012	0.732143	0.649718	.081
PP2	0.656627	0.672619	0.621469	.594
PP3	0.536145	0.583333	0.542373	.639
PP4	0.433735	0.47619	0.497175	.490
PP5	0.343373	0.416667	0.40113	.359
PP6	0.325301	0.39881	0.39548	.290
PP7	0.253012	0.327381	0.327684	.229
PP8	0.23494	0.303571	0.316384	.204
PP9	0.228916	0.25	0.299435	.309
PP10	0.216867	0.208333	0.248588	.639
PP11	0.174699	0.184524	0.242938	.231
PP12	0.150602	0.14881	0.20339	.304

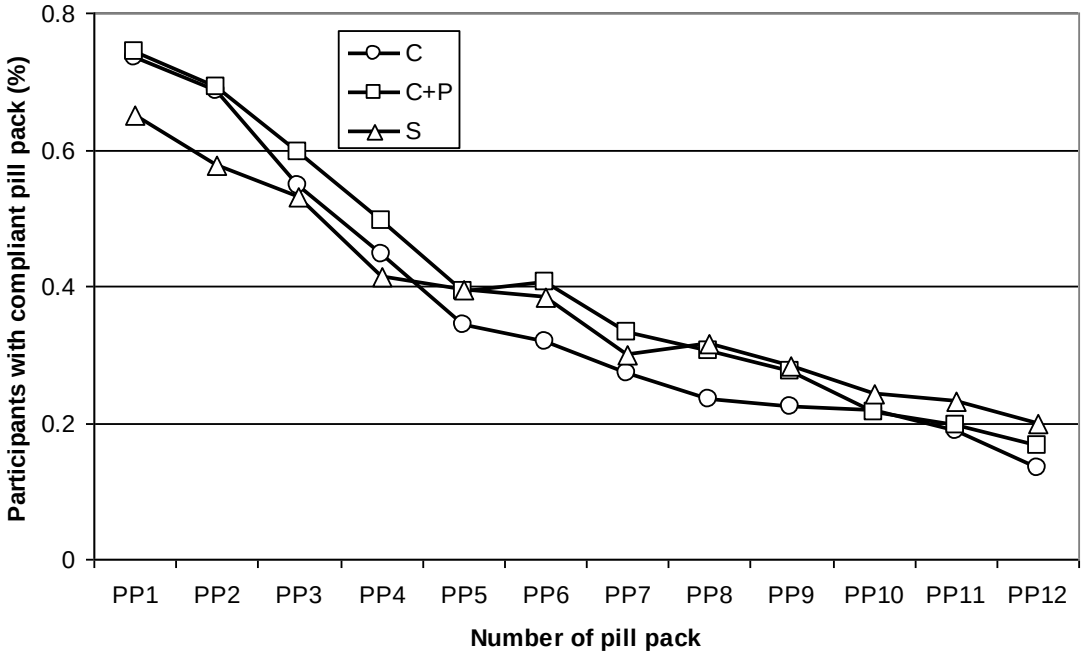
Fig 7. Participants with correct oral contraceptive pill use by intervention group among 16-19 year old participants



Based on initial number of participants in each intervention group
C = Clinic-based intervention (n=217)
C+P = Clinic-based intervention with phone reinforcement (n=216)
S = Standard clinic practice (n=211)

	C	C+P	S	P value
PP1	0.686636	0.699074	0.64455	.452
PP2	0.608295	0.634259	0.606635	.804
PP3	0.543779	0.583333	0.526066	.475
PP4	0.410138	0.5	0.417062	.113
PP5	0.336406	0.402778	0.345972	.300
PP6	0.299539	0.37963	0.350711	.206
PP7	0.262673	0.328704	0.293839	.321
PP8	0.24424	0.314815	0.260664	.227
PP9	0.202765	0.300926	0.227488	.047
PP10	0.184332	0.263889	0.208531	.122
PP11	0.16129	0.217593	0.170616	.269
PP12	0.152074	0.189815	0.113744	.091

Fig 8. Participants with correct oral contraceptive pill use by intervention among 20-24 year old participants



Based on initial number of participants in each intervention group
C = Clinic-based intervention (n=166)
C+P = Clinic-based intervention with phone reinforcement (n=168)
S = Standard clinic practice (n=177)

	C	C+P	S	P value
PP1	0.73494	0.744048	0.649718	.103
PP2	0.686747	0.690476	0.576271	.040
PP3	0.548193	0.595238	0.531073	.466
PP4	0.445783	0.494048	0.412429	.311
PP5	0.343373	0.392857	0.39548	.539
PP6	0.319277	0.404762	0.384181	.240
PP7	0.271084	0.333333	0.299435	.463
PP8	0.23494	0.303571	0.316384	.204
PP9	0.222892	0.27381	0.282486	.403
PP10	0.216867	0.214286	0.242938	.779
PP11	0.186747	0.196429	0.231638	.553
PP12	0.13253	0.166667	0.19774	.269

Next, we examined the frequency of developing a cue and using it to remember to take their oral contraceptives by intervention group. Overall, these results within each group closely resembled those seen for the overall group. Development of a cue was significantly more common among women assigned to the C+P arm than S in both age groups (Tables XXIII-XXV). Among women 20-24 years of age, a significant difference at the .0025 level

was also seen between those in the C and S groups as well as those in the C and C+P groups. Development of a cue was the only finding in which the intensity of the intervention mirrored the outcome (C+P > C > S).

Table XXV. Frequency of identifying a cue by intervention group and age at 3 months

	16 – 19yo			*P* value	20 – 24yo			*P* value
	C	C + P	S		C	C + P	S	
Identified a cue (%)	125 (76.2)	147 (88.6)	110 (67.1)	<0.001*	101 (75.4)	128 (91.4)	76 (54.7)	<0.0001**
Cue served as reminder for pill taking (%)	115 (92.7)	142 (97.3)	103 (94.5)	0.23	97 (98.0)	121 (94.5)	73 (96.1)	0.42

*C+P>S (P<.0001); C>S (P=.07); C+P>C (P=.003)
** C+P>S (P<.0001); C>S (P<.0001); C+P>C (P<.0001)

Table XXVI. Frequency of identifying a cue by intervention group and age at 6 months

	16 – 19yo			P value	20 – 24yo			P value
	C	C + P	S		C	C + P	S	
Identified a cue (%)	109 (76.2)	131 (90.3)	86 (62.8)	<0.001*	93 (77.5)	108 (85)	70 (56.0)	<0.001**
Cue served as reminder for pill taking (%)	96 (88.9)	126 (96.2)	84 (97.7)	0.02***	89 (95.7)	101 (94.4)	67 (95.7)	0.89

*C+P>S (P=.000); C>S (P=.014); C+P>C (P=.001)
**C+P>S (P=.000); C>S (P=.000);
*** C<S (P=.02); C+P>C (P=.03)

Table XXVII. Frequency of identifying a cue by intervention group and age at 12 months

	16 – 19yo			P value	20 – 24yo			P value
	C	C + P	S		C	C + P	S	
Identified a cue	90 (76.9)	101 (88.6)	69 (62.7)	<0.001*	72 (75.8)	84 (83.2)	56 (56.6)	<0.001**
Cue served as reminder for pill taking (%)	81 (91.0)	93 (92.1)	66 (95.7)	0.52	69 (95.8)	78 (92.9)	51 (91.1)	0.54

*C+P>S (P=.000); C>S (P=.02); C+P>C (P=.02)
**C+P>S (P=.000); C>S (P=.005)

Satisfaction rates and condom use were also examined for each age group. Only one difference was noted at the .0025 level; those randomized to C were actually less likely to recommend their method to a friend than those randomized to S. No differences were observed in condom use or dual use of condoms and oral contraceptives at 3, 6, or 12 months.

Table XXVIII. Satisfaction with method and condom use at 3 months by age

	16 – 19yo			P value	20 – 24yo			P value
	C	C + P	S		C	C + P	S	
Satisfaction with method	3.47 ± 0.77	3.65 ± 0.68	3.48 ± 0.73	0.08	3.54 ± 0.61	3.58 ± 0.64	3.55 ± 0.67	0.88
Recommend BCP to a friend	120 (89.6)	132 (96.4)	138 (98.6)	0.004*	96 (92.3)	109 (94.8)	99 (93.4)	0.62
Partner used condom at last sex	71 (55.0)	83 (59.7)	82 (57.7)	0.74	49 (46.7)	64 (56.1)	42 (41.6)	0.08
Dual method use in the last 3 months	31 (25.4)	43 (35.2)	43 (33.1)	0.25	26 (25.7)	29 (25.7)	24 (23.8)	0.93

*S>C (p=0.001); C+P>C (p= 0.03)

Table XXIX. Satisfaction with method and condom use at 6 months by age

	16 – 19yo			P value	20 – 24yo			P value
	C	C + P	S		C	C + P	S	
Satisfaction with method	3.41 ± 0.77	3.54 ± 0.80	3.58 ± 0.71	0.27	3.32 ± 0.83	3.49 ± 073	3.41 ± 0.79	0.23
Recommend BCP to a friend	118 (91.5)	130 (97.0)	118 (96.7)	0.12	102 (93.6)	114 (94.2)	105 (91.3)	0.70
Partner used condom at last sex	75 (56.8)	76 (57.6)	61 (48.8)	0.33	45 (41.3)	51 (42.1)	46 (40.4)	0.94
Dual method use in the last 3 months	38 (34.2)	40 (33.9)	29 (26.4)	0.36	25 (25.0)	28 (25.9)	25 (24.8)	0.96

Table XXX. Satisfaction with method and condom use at 12 months by age

	16 – 19yo			P value	20 – 24yo			P value
	C	C + P	S		C	C + P	S	
Satisfaction with method	3.31 ± 0.91	3.58 ±0.73	3.35 ± 0.85	0.03*	3.29 ± 0.88	3.37 ± 0.78	3.42 ± 0.82	0.47
Recommend BCP to a friend	109 (92.4)	110 (97.3)	103 (93.6)	0.30	89 (95.7)	95 (93.1)	97 (98.0)	0.25
Partner used condom at last sex	60 (50.8)	60 (52.2)	48 (42.1)	0.26	40 (42.1)	41 (39.8)	34 (34.3)	0.54
Dual method use in the last 3 months	27 (27.6)	32 (31.7)	28 (27.7)	0.81	28 (32.9)	22 (23.7)	24 (27.9)	0.44

*C+P>S (P=.03); C+P>C (P=.014)

Next, we examined rates of clinic follow up which were recommended for 3-4 months after the initial visit (Table XXXI). No differences were observed between the three study groups in those who kept their appointment at three months, regardless of whether they were still taking their oral contraceptives.

Table XXXI. Counts and percentages (in parentheses) for clinic follow up at 3-4 months by intervention and age groups

	16 – 19yo			P value	20 – 24yo			P value
	C	C + P	S		C	C + P	S	
Kept appt to refill BCP (%)†	101 (46.5)	119 (56.1)	97 (46.2)	0.07	74 (44.6)	80 (47.6)	88 (50.0)	0.60
Still taking OCP at FU appt	92 (87.6)	117 (91.4)	95 (91.3)	0.56	67 (83.8)	81 (90.0)	86 (91.5)	0.24

† "No" category includes patients who obtained prescription refills without completing an appt (N = 45)

Finally, we assessed rates of sexually transmitted infections and pregnancy within each age group. No significant differences were observed for either outcome after 12 months (Table XXXII).

Table XXXII. Counts and percentages (in parentheses) of sexually transmitted infections (STI) and pregnancy diagnosis within 12 months by intervention and age groups

	16-19 yo			*P*	20-24 yo			*P*
	C (n=217)	C+P (n=216)	S (n=211)		C (n=166)	C+P (n=168)	S (n=177)	
Positive test for STI	16 (7.4)	32 (14.8)	21 (10.0)	.040	13 (7.8)	7 (4.2)	6 (3.4)	.140
Became pregnant during FU	38 (17.5)	24 (11.1)	20 (9.5)	.030	29 (17.5)	24 (14.3)	17 (9.6)	.103

Chapter 8: General Estimating Equation Models (GEE), Multiple Regression Analysis, and Mantel-Haenszel test

GEE models were used to control for the effects of age, race, and timing of the follow up visit on the outcomes of interest. GEE models were selected as they allowed accommodation for missing data at 3, 6, or 12 months. Clinic location was also included as a categorical variable to adjust for variation in outcomes which may have been attributable to clinic location. The results of the GEE are shown below.

Table XXXIII. Association of type of intervention with contraceptive adherence characteristics and satisfaction: Generalized Estimating Equations Model Results

Contraceptive adherence characteristics	Standard care [OR (95% CI)]	Clinic-based intervention with educational information and counseling [OR (95% CI)]	Clinic-based intervention with phone reinforcement [OR (95% CI)]
Discontinued study	1.00	0.91 (0.72-1.16)	0.94 (0.74-1.19)
Not using any contraception	1.00	1.31 (0.96-1.78)	0.79 (0.57-1.09)
Switched to different brand pills	1.00	2.34 (1.29-4.24)	1.14 (0.59-2.18)
Correctly used OCPs	1.00	1.06 (0.79-1.41)	1.21 (0.91-1.61)
Would recommend it to friends	1.00	0.57(0.33-0.997)	1.03 (0.56-1.92)
Satisfaction with the method	1.00	0.89 (0.58-1.36)	1.19 (0.76-1.86)

A separate GEE model was used for each of the adherence variables listed above. Adjusted by race (non-Hispanic whites, non-Hispanic black, Hispanics) age (16–19 yr vs. 20–24 yr) and follow-up visit as a categorical variable (0, 3, 6, 12 month)

Two significant findings were observed. Those randomized to the clinic based intervention (C) were more likely to switch brands of oral contraceptives than those in the standard care arm (S). Furthermore, those in the C group were less likely to recommend their method to friends. No differences were observed in adherence, switching, correctness of use, or satisfaction with their method between women randomized to the more intensive intervention (C+P) and standard care (S).

Next, we examined the effect of each intervention on missing doses, controlling for age, race, and timing of the follow up visit (Table XXXIV). No significant differences were found between women in the standard care group and those in either intervention.

Table XXXIV. Association of invention type with missed pill variables: Generalized Estimating Equations Model Results

Contraceptive adherence characteristics	S [OR (95% CI)]	C [OR (95% CI)]	C+P [OR (95% CI)]
Missed active pill(s) in the past week	1.00	1.27 (0.79-2.01)	1.20 (0.74-1.93)
Missed active pill(s) in the past month	1.00	1.14 (0.83-1.58)	1.17 (0.85-1.62)
Missed an active pill and restarted in the past month*	1.00	1.14 (08.0-1.64)	1.19 (0.84-1.70)
Missed 2 active pills and restarted in the past month*	1.00	0.76 (0.41-1.44)	0.89 (0.48-1.62)
Missed 3 active pills and restarted in the past month*	1.00	1.08 (0.63-1.65)	0.85 (0.48-1.50)
Missed an active pill and restarted in the past 3 months*	1.00	0.90 (0.68-1.19)	0.91 (0.69-1.20)
Missed 2 active pills and restarted in the past 3 months*	1.00	0.69 (0.49-1.08)	.077 (0.50-1.18)
Missed 3 active pills and restarted in the past 3 months*	1.00	0.86 (0.59-1.25)	1.05 (0.73-1.50)

* One or more time
A separate GEE model was used for each of the adherence variables listed above.
Adjusted by race (non-Hispanic whites, non-Hispanic black, Hispanics) age (16–19 yr vs. 20–24 yr) and follow-up visit as a categorical variable (0, 3, 6, 12 month)

Also, we examined condom use and STI rates. One finding was significant. Those who were randomized to the C+P intervention were more likely to report condom use at last sexual intercourse, but not dual use. No difference was observed in STI rate or dual use between those in the standard care group and either intervention (Table XXXV).

Table XXXV. Association of type of contraceptive use enforcement methods with STI rate and condom use at last sexual intercourse: Generalized Estimating Equations Model Results

	S [OR (95% CI)]	C [OR (95% CI)]	C+P [OR (95% CI)]
STI	1.00	1.10 (0.60-2.01)	1.38 (0.78-2.44)
Condom use at last sexual intercourse	1.00	1.08 (0.87-1.35)	1.25 (1.01-1.57)
Dual use (contraceptive plus condom) at last sexual intercourse	1.00	1.08 (0.79-1.47)	1.20 (0.88-1.63)

A separate GEE model was used for each of the adherence variables listed above.
Adjusted by race (non-Hispanic whites, non-Hispanic black, Hispanics) age (16–19 yr vs. 20–24 yr) and follow-up visit as a categorical variable (0, 3, 6, 12 month)
*P<.05

Overall, GEE analysis showed that women in C and C+P did not differ from standard care after 12 months in the likelihood that they would still be using contraception, correctly

use their contraception or be satisfied with their method. Furthermore, there were no differences between standard care and those women in the two intervention groups in the likelihood that they would miss taking doses of their medication or that they would restart them in a correct fashion if they missed doses of their medication. Finally, we failed to observe a difference between the intervention groups and standard care in STI rates or dual use. Women I the C group were more likely to switch brands of birth control and less likely to recommend their method to their friends than those in the S group. The one positive effect observed was that women in the C=P group were more likely to report condom use at last intercourse than those in the S group.

In addition, multiple regression analyses were performed to control for age and race on duration of using oral contraceptives correctly. These analyses also considered the effect of using a cue on correct use. Differences between S and C [-0.40 (-1.02, 0.23), P=0.214] and between S and C+P [0.17(-0.047, 0.80), P=0.610] with regard to mean number of pill packs taken correctly were not significant. Overall, those who identified a cue, irrespective of interventions, reported taking two more pill packs correctly than those who did not (2.04 (1.36-2.73); P<.001).

Finally, the effects of these two interventions on pregnancy rates were examined using a Mantel-Haenszel test which controlled for clinic location and age. This test is similar to the log rank test which is used in survival analysis, except that it is restricted to two curves. Using this test, we observed no significant difference in pregnancy rates between women in the C and C+P groups as compared to standard care. The rate ratio for “C” compared to “S” was 1.347 (95% CI, 0.932-1.947) and for “C+P” was 1.022 (95% CI, 0.693-1.509). Thus, neither intervention was effective in reducing unintended pregnancies.

Table XXXVI. Rate ratio for pregnancy in “C” and “C+P” groups in comparison with “S” group

	S [RR (95% CI)]	C [RR (95% CI)]	C+P [RR (95% CI)]
Pregnancy	1.00	1.35 (0.93-1.95)	1.02 (0.69-1.51)

Chapter 9: Discussion and conclusion

In this study, we observed that women who received additional education in the clinic on how to take their birth control pills were no more likely than those randomized to standard care to take them correctly or to remain on this method. We also did not observe any effect of these interventions on the number of women who attended their first follow up clinic visit, level of satisfaction with their method, or on pregnancy rates. One puzzling finding was that women in the C group were less likely than those in the S group to report they were still using the same brand as originally prescribed at the 3 month phone call. Also, those in the C group were less likely than those in the S group to recommend their method to a friend after 3 months. This difference, however, was no longer present by 6 months. Overall, there were few differences between the C and S groups, demonstrating that additional education in the clinic is not sufficient to increase adherence with oral contraceptives. In addition, almost no differences were observed between those who received phone support for several months after the initial clinic visit (C+P) and the standard care group.

Although disappointing, these findings are in agreement with two recently published studies[16,19] on this topic, one which employed very similar methodology to the current investigation. [19] In that study, 805 adolescents 14-18 years of age, who attended a reproductive health clinic in San Francisco, were randomized to receive standard care or standard care plus nine follow up phone calls over 12 months. Follow up data were collected at 6, 12, and 18 months. Similar to our study, the investigators found no difference between the standard care group and those who received phone calls in levels of contraceptive use or pregnancy rates. Furthermore, the authors noted that clinic counselors were only able to complete 2.7 calls per patient and had to make 7.8 attempts for every completed call. Thus, this intervention was very time consuming. The current investigation confirms the findings of this earlier study that calling patients after their visit is not an effective method to improve compliance with oral contraceptives among young women.

Furthermore, there was no difference between those who received an intervention and standard care in the percentage of women who took their medication every day. One of the most common reasons for missing pills was an inability to remember taking them. To address this problem, all women in the C and C+P groups were taught to identify a cue, such as brushing their teeth, which they would associate with taking their medication. Multiple regression analysis did demonstrate a relationship between development of a cue and the length of time that women took their oral contraceptives correctly. It has been proposed that modern technology could be used as a reminder as well. This idea was tested

by Hou and associates[16] who conducted a study on 82 women using text messaging to remind women to take their birth control pills. No beneficial effect of this intervention was observed which may have been due to their small sample size. Additional research needs to be conducted using modern technology to determine whether it may be beneficial in helping women take oral contraception correctly.

One concerning finding from this study is that almost 20% of women reported missing at least 1 active pill during the last month when interviewed 3 months after receiving their prescription. It is likely that this number is actually an underestimate of the number of missed pills. A prior study noted that under reporting of missed birth control pills was common when compared to recordings made by an electronic monitoring device[16] that study showed that women actually missed on average more than 4 pills per cycle. This high rate of missed doses places users at a significant risk of unintended pregnancy and accounts for the discrepancy between theoretical and actual user effectiveness of oral contraceptives.

The high rate of missed doses and failure to switch to a method with which they could adhere were very likely factors in the high pregnancy rate we observed. Overall, 10-18% of women in this study became pregnant within 12 months of their baseline clinic visit, even though all had been prescribed effective birth control and stated that they did not wish to become pregnant during the following 12 months. This high pregnancy rate, which occurred even among those who received one of the interventions, demonstrates the frequent inability of young women to adhere to the daily regimen required to use birth control pills. This was demonstrated in a recent study of 5,087 women between 14 and 25 years of age which showed that those who used oral contraception had a much higher discontinuation rate after 12 months than those who selected an intrauterine device (IUD) for birth control. Satisfaction was also higher among users of IUDs (80%) than OCPs (41%).[77] Based on their findings, the authors suggested that long acting contraception may be more suited for young women because they are not user dependent and thus, adherence levels are high.

Furthermore, these interventions did not increase the percentage of women who practiced dual use (use of condoms plus oral contraceptives). This is unfortunate as dual use not only offers protection against STIs, but also acts as a back-up method when oral contraceptives are not taken correctly. In fact, it has been estimated that if half of all women who used hormonal methods alone also used condoms, 40% of unplanned pregnancies among this population could be prevented. [78] Furthermore, those who use both condoms and a hormonal method report high sexual satisfaction scores, probably because they feel more protected against unwanted pregnancies and STIs. [79] Interventions which have been

successful in increasing dual rates were far more intensive than the two interventions tested in this investigation. For example, one required African American males 9-15 years of age to attend seven 1.5-hour sessions and one all-day session focused on decision making.[27] Another assigned girls 13-17 years of age to case management services and peer leadership groups.[80] However, these interventions are unlikely to be instituted in a clinical setting due to their high cost and long time commitment.

The only beneficial effect of either intervention that we observed using GEE analysis was that more women in the C+P group reported using condoms at last intercourse than those in the S group. This finding may have been driven by a higher likelihood to use condoms within the first 3 months after beginning the study. The 3 month follow up interview was the closest time point to the actual intervention, when subjects practiced placing condoms on models and negotiating condom use with a partner. Thus, it is logical that they would be most comfortable when their training was more recent. However, no difference was observed in STI rates over the year of follow up so it is not clear that this resulted in better health.

This study has several limitations. A number of instruments were subjective self-reports and may have biased our findings. Also, a possibility exists that the assessment calls to members of the S group acted as an intervention, thus causing data to more resemble that of the intervention groups. In addition, the number of women lost to follow-up was greater than anticipated. One reason for this was that many women lived in the region affected by Hurricane Ike which made landfall while the study was in progress. Many participants were relocated to other areas of Texas and could not be contacted.

Furthermore, additional analysis could be performed using these data. For example, it would be beneficial to perform a log rank test on several additional outcomes, such as rates of OCP continuation, and STIs. Each of these outcomes is amenable to survival analysis as there is a single time point at which the outcome occurs. This type of analysis would not be appropriate for correctness of OCP use as women often used pills incorrectly one month, correctly the next and then incorrectly again.

This randomized, longitudinal study adds to the literature by demonstrating that many women have a very difficult time adhering to oral contraceptives, even when extensive assistance is offered. This is concerning as this is still the most common method prescribed to women residing in the US, even though many other types are now available. When oral contraceptives are prescribed, it is critical that health care providers assess their patients to determine if they can adhere to a regimen which requires medication to be taken on a daily

basis for an extended period of time. Women who do not feel that they would be good candidates should be offered longer acting methods, such as an intrauterine device.

Appendix A -- Birth control pill information sheet

You have chosen a very effective method of birth control, if taken about the same time every day. Going on the pill means going on a schedule: one pill every day of the month. This is what protects you from pregnancy – not any single pill – but the day by day action of the whole series (28 day packs). The steady high level of the hormone estrogen keeps your body from releasing its monthly egg cell. No egg – no baby. Once you stop the pill, your body will go back to making eggs normally.

1. Take your first pill on the first SUNDAY after your period begins. If your period starts on a Sunday, take your first pill on that day.

Monday	Tuesday	Wednesday	Thurs	Friday	Saturday	Sunday
		Period begins				Take first pill

2. Swallow one pill every day until you finish the pack. Pills work best when taken at the SAME time every day. Try to associate taking your pill with some daily activity like brushing your teeth or going to bed. If the pills make you feel sick to your stomach, try taking them at bedtime.

3. While you are taking the last row of pills (week #4), your period should begin. It may be shorter than usual and the flow lighter. If you have no period for two months in a row, check with your Healthcare Provider.

4. **REMEMBER**: Birth control pills only prevent pregnancy. They do not protect you from sexually-transmitted diseases or the AIDS virus. Always have your partner use a condom.

5. During your first month of taking the pills, you have to use extra protection (foam and condoms),
or just don't have sex at all. After the first month, you will be safe from pregnancy while taking the pills.

MISSING PILLS

If you forget to take one pill, take it as soon as you remember. Then take the **next** pill at your regular time.

If you don't notice that you have forgotten to take your pill until it is time to take your next pill, take them both at your regularly scheduled time.
If you miss two pills, then take two pills each day for two days, then continue as usual. **IMPORTANT!** Be sure to use condoms or abstinence for the rest of that month.

If you miss three pills, **STOP** taking the pills. You could become pregnant, so you must use condoms or abstinence for the rest of that month. Wait for your next period, and start a new pill pack as explained in 1-5 above. .

MINOR SIDE EFFECTS

Women who use the pill sometimes experience minor side effects, such as nausea, breast tenderness, depression, headaches, spotting between your periods or bloating. Here are some suggestions on what you can do:

Nausea – try taking your pills at night when you go to bed, or try taking them with a little food such as crackers.
Breast tenderness – continue to take your pills at the same time every day. This usually goes away after the first 3 months of taking the pill.
Depression – sometimes you may feel a "little blue" while taking the pill. You should never feel like you want to harm yourself or someone else. If you feel like this, please ask for help or call 911 immediately.
Headaches – take Tylenol and see if this helps.
Spotting between your period – spotting usually goes away after a few months if you take your pill at the same time each day, although missing pills may still make you spot. This is not dangerous. It is a nuisance so you will need to remember to keep some mini pads at school or work in case you need them in the middle of the day.
Bloating – some women may feel bloated or worry they have gained weight. You should not gain more than 1 or 2 pounds from using the pill. Studies show the pill does not cause overall weight gain, so if you are gaining weight, be sure to look at your overall food intake. Determine if you have been eating fast food more, eating bigger portions, or look at your exercise patterns to determine if you have been exercising less or have been less active.

Side effects like these are unpleasant but not dangerous. They usually go away as your body gets use to the pill. If you have any of these problems and they are really bothering you or they do not go away after a few months, call the clinic. We can help you figure out what to do, or we will change you to a different pill. This usually takes care of the problem.

IT IS YOUR RESPONSIBILITY TO LEARN THE PILL WARNING SIGNS

If you experience any of the following signals, do not ignore them. Contact your Healthcare Provider.

A – Abdominal pain (severe)
C – Chest pain or shortness of breath
H – Headaches (severe)
E – Eye problems like blurred vision, flashing of bright light, or blindness
S – Severe leg pains (calf or thigh)

LONG TERM HEALTH BENEFITS FROM BIRTH CONTROL PILL USE

- Improves acne in most young women
- Lighter and more regular periods

- Less premenstrual tension (PMS) and cramps
- Less iron-deficiency anemia
- Less cases of ovarian and uterine cancer

IF YOU ARE TAKING ANTIBIOTICS:

Taking antibiotics like: penicillin, amoxicillin, erythromycin, tetracycline, etc., while on birth control pills may cause an unwanted pregnancy, and/or spotting. While you are taking antibiotics, continue to take your birth control pills and be sure to use a condom or abstinence

REMEMBER:

* Take your pill at the same time every day.
* Reduce the risk of side effects by getting 30 minutes of vigorous leg exercise (jogging, fast walking, biking, aerobics) 3-4 times every week.
* While taking birth control pills, **DO NOT SMOKE** cigarettes.
* Have a complete physical exam and Pap smear once a year.

THE PILL DOES NOT PREVENT SEXUALLY-TRANSMITTED DISEASES. ALWAYS HAVE YOUR PARTNER USE A CONDOM.

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Vita for Abbey Berenson, MD

Professor, Departments of Obstetrics/Gynecology and Pediatrics
Director, UTMB Center for Interdisciplinary Research in Women's Health
The University of Texas Medical Branch
Galveston, Texas 77555-0587
(409) 772-2417

EDUCATION:

Undergraduate: Sept. 1976 May 1980	The University of Texas - B.A. Austin, Texas Major: Plan II Honors Program
Medical School: June 1980 May 1984	Baylor College of Medicine - M.D. Houston, Texas
Residency: July 1984 June 1988	Baylor College of Medicine Department Ob/Gyn Houston, Texas
Fellowship: 1991	Queen Charlotte's and Chelsea Hospital London, England
2002-03	University of Houston Certificate in Business Administration

PROFESSIONAL WORK HISTORY AND TEACHING EXPERIENCE:

1989-93	Assistant Professor, University of Texas Medical Branch
1993-98	Associate Professor, University of Texas Medical Branch
1993-2008	Chief of Pediatric and Adolescent Gynecology, University of Texas Medical Branch
1998-present	Director of Family Planning, University of Texas Medical Branch
1998-present 2002-present	Professor, University of Texas Medical Branch Director, Center for Interdisciplinary Research in Women's Health

RESEARCH ACTIVITIES:

A. Principal Areas of Research

1. Appearance of the external genitalia in prepubertal girls
2. Contraception
3. Risk behaviors in adolescents

B. Current Funding

1. Principal Investigator and Program Director, $2,500,000
"UTMB Women's health research scholars' program"
K12 Institutional Research Career Development Award (BIRCWH)
National Institutes of Child Health and Human Development
August 29, 2005 – June 30, 2015 (Renewal)

2. Principal Investigator, $789,740
"Midcareer investigator award in patient-oriented research"
K24 Individual Research Career Development Award
National Institute of Child Health and Human Development
March 15, 2003 - February 28, 2013 (Renewal)

3. Principal Investigator, $1,837,800
"Interdisciplinary women's reproductive health fellowship"
Ruth L. Kirschstein National Research Service Award (NRSA)
T32 Institutional Research Training Grant
National Institute of Child Health and Human Development
May 1, 2008 - April 30, 2013

4. Principal Investigator, $120,000
"Contemporary intrauterine contraception use among adolescents: Examination of a national health claims database"
Society of Family Planning
October 1, 2010 - September 30, 2012
Score 1.1

C. Prior Grant Support as PI:

1. Principal Investigator, $1,000
"Appearance of the hymen in children: A longitudinal study"
William and Mary McGanity Research Fund
September 1, 1990 - August 31, 1991

2. Principal Investigator, $12,500
"Effect of physical assault in pregnancy on neonatal outcome"
John Sealy Memorial Endowment Fund
April 1, 1992 - March 31, 1993

3. Principal Investigator, $946,539 (25% effort)
"Hymenal changes in prepubertal girls due to sexual abuse"
National Institute of Mental Health
August 1, 1994 – January 31, 2000
Score 2.3 percentile

4. Principal Investigator, $791,215 (15% effort)
"Comparison of norethindrone-containing oral contraceptive pills to desogestrel-containing pills and Depo-Provera in a military and civilian population"
Defense Women's Health Initiative
U.S. Army Medical Research and Materiel Command
October 1, 1996 - July 31, 2001
Score 6.5 percentile

5. Principal Investigator, $20,000 (15% effort)
"Normal hymenal development from 6 to 12 years of age"
UTMB John Sealy Memorial Endowment Fund
September 1, 1998 - February 28, 2001

6. Subproject Principal Investigator, $11,060,406
"Hymenal configuration in children"
UTMB General Clinical Research Center Grant
National Center for Research Resources,
General Clinical Research Center Program
December 1, 1998 - November 30, 2003

7. Principal Investigator, $10,000
"A multi-center, open label study to assess satisfaction and experience with Alesse® in adult women"
Wyeth-Ayerst Laboratories
June 1, 1999 - December 31, 1999

8. Principal Investigator, $40,000 (10% effort)
"A prospective study of the effects of method of contraception on bone density in young premenopausal women"
National Osteoporosis Foundation
September 1, 1999 - August 31, 2000

9. Principal Investigator, $20,500
"A randomized double-blind parallel multi-center study to evaluate the effects on cycle control of three trimegestone/ethinyl estradiol regimens use. An open label Mircette® treatment arm"
Wyeth-Ayerst Laboratories
November 1, 1999 - November 30, 2000

10. Principal Investigator, $81,081
Diversity supplement to "Effect of hormonal contraception on bone mineral density" to support Laura Romo, Ph.D.
National Institute of Child Health and Human Development
November 1, 2002 - August 31, 2003

11. Principal Investigator, $250,432
Diversity supplement to above grant to support Kevin McKinney, M.D.
National Institute of Child Health and Human Development
March 1, 2004 - August 31, 2006

12. Subproject Principal Investigator, $2,383,544
"Effect of hormonal contraception on bone mineral density"
UTMB General Clinical Research Center Grant
National Center for Research Resources,
General Clinical Research Center Program
April 1, 2005 - March 31, 2006

13. Principal Investigator, $2,091,496 direct cost
"Effect of hormonal contraception on bone mineral density"
National Institute of Child Health and Human Development
September 1, 2001 - August 31, 2008

14. Principal Investigator, $1,169,551
"Improving adolescent adherence to hormonal contraception"
Health Resources and Services Administration
Janauary 1, 2006 – January 31, 2011

D. Prior Grant Support as Co-investigator

1. Director of Clinical Research Core, $1,846,588 direct cost
UTMB Women's reproductive health research career development center of excellence
K12 Institutional Research Career Development Award (WRHR)
Gary Hankins, M.D., PI
National Institute of Child Health and Human Development
March 1, 2004 - February 28, 2009

2. Co-Investigator, $1,000,000 (2% effort)
"Effect of stressors on substance use in young, poor women"

Helen Wu, Ph.D., PI
National Institute on Drug Abuse

3. April 1, 2006 – October 31, 2010 Co-investigator, $1,125,000 (2% effort)
Intervention to improve follow-up of abnormal Pap tests"
Carmen Radecki Breitkopf, Ph.D., PI
National Cancer Institute
Sept 1, 2005 - May 31, 2010

4. Consultant, $211,140
Jan Paradise, M.D., P.I.
"Agreement and possible bias in sexual abuse examinations"
National Institute of Mental Health
July 1, 1992 - December 31, 1994

5. Mentor and Co-Investigator, $149,000
Carmen Radecki, Ph.D., P.I.
"Predicting adherence to follow up of abnormal Pap smears"
National Cancer Institute
April 1, 2001 - March 31, 2003

6. Mentor and Co-Investigator, $147,089
Z. Helen Wu, Ph.D., P.I.
"Club drug use in young, low income women"
National Institute of Drug Abuse
September 30, 2001 - May 31, 2003

7. Co-Investigator, $350,000
Constance Wiemann, Ph.D., P.I.
"Epidemiology of drug abuse among adolescent mothers"
National Institute of Drug Abuse (score 3.9 percentile)
March 1, 1995 - February 28, 2000

8. Co-Investigator, $149,500
Constance Wiemann, Ph.D., P.I.
"Drug use patterns of adolescent mothers after delivery"
National Institute on Drug Abuse (score 123; percentile 0.6)
August 1, 1993 - July 31, 1995

9. Co-Investigator, $30,629
Constance Wiemann, Ph.D., P.I.
(supplemental funding to grant above)
"Drug use patterns of adolescent mothers after delivery"
Hogg Foundation for Mental Health
October 1, 1993 - September 31, 1995

10. Co-Investigator, $148,480
Marinel Ammenheuser, Ph.D., P.I.
"Mutant T cells in pregnant abusers of drugs and tobacco"
National Institute of Drug Abuse
July 1, 1993 - June 30, 1995

11. Co-Investigator, $23,558
Vaughn I. Rickert, PsyD., P.I.
"Mental health correlates of Rohypnol use"
Hogg Foundation for Mental Health
February 1, 1997 - January 31, 1998

12. Co-Investigator, $12,500
Marinel Ammenheuser, Ph.D., P.I.
"In vivo frequencies of mutant placental lymphocytes from newborns of mothers who smoke cigarettes"
UTMB Small Grant Program
April 1, 1991 - March 31, 1992

BOARD CERTIFICATION: American College of Obstetricians and Gynecologists
Board Certified 1990

HONORS: Undergraduate:

1. Graduated summa cum laude
2. Graduated with special honors in major
(Plan II Honors Program)
3. Phi Beta Kappa (Elected 1980)
4. Alpha Lambda Delta Honor Society (Elected 1976)
5. Beta Beta Beta Science Society (Elected 1977)

Medical School:

1. James and Minnie Edmondson Scholarship Award

Faculty:

1. Second Place Prize Paper. (Contraceptive use among adolescent mothers at 6 months postpartum by AB Berenson and CM Wiemann)
The American College of Obstetricians and Gynecologists Annual Meeting. Denver, CO. April 27 - May 1, 1996.
2. Certificate of Merit Award. (Inadequate weight gain among pregnant adolescents: Risk factors and relationship to infant birth weight by AB Berenson et al) The Central Association of Obstetricians and Gynecologists Annual Meeting. Houston, TX. October 18, 1996.
3. Best Poster Award. (Use of Video Eyeglasses to Decrease Anxiety Among Children Undergoing Genital Examinations by AB Berenson et al.) The Central Association of Obstetricians and Gynecologists Annual Meeting. Scottsdale, AZ. October 29 - November 1, 1997.

POSTDOCTORAL FELLOWS AND FACULTY MENTORED (Years mentored):

Carmen Radecki Breitkopf, PhD, Assistant Professor	(1999 - 2005)
Z. Helen Wu, PhD, Assistant Professor	(2001 - 2005)
Laura Romo, PhD, Assistant Professor,	(2002 - 2003)
Ruth Levine, MD, Associate Professor	(2002 - 2003)
Kevin McKinney, MD, Assistant Professor	(2004 - 2006)
Heather Littleton, PhD, Postdoctoral Fellow	(2004 - 2006)
Susan Odom, PhD, Postdoctoral Fellow	(2006 - 2007)
Monic Behnken, JD, PhD, Postdoctoral Fellow	(2008 - 2009)
Yen-Chi Le, PhD, Postdoctoral Fellow	(2008 - 2009)
Kristen Chambliss, PhD, Postdoctoral Fellow	(2008 - 2009)
Mahbubur Rahman, PhD, MBBS, MPH Assistant Professor	(2007 - 2010)
Jeffrey Temple, PhD, Assistant Professor	(2007 - 2010)
Patricia van den Berg, PhD, MPH, Assistant Professor	(2008 - 2010)
Monawar Hosain, PhD, Postdoctoral Fellow	(2008 - 2010)
Kristy Ward, MD, Postdoctoral Fellow	(2009 - 2010)
Angelica Roncancio, PhD, Postdoctoral Fellow	(2009 - 2010)
Humera Mohammed MD, Postdoctoral Fellow	(2010 - 2011)
Tabassum Laz, MBBS, PhD, Postdoctoral Fellow	(2010 - present)
Ophra Leyser, PhD, Postdoctoral Fellow	(2010 - present)
Jacqueline Hirth, PhD, Postdoctoral Fellow	(2010 - present)
Sarah Tom, PhD, Assistant Professor	(2010 - present)
Andrea DeMaria, Postdoctoral Fellow	(2011 – present)

AWARDS TO STUDENTS AND FELLOWS DURING PRECEPTORSHIPS:

1. First place, Roche Laboratories award for excellence in clinical research and first place, AMA overall excellence in research. (A survey of cesarean section rates in adolescents under 17 years old) Presented by Diana Smigaj. National Student Research Forum, 1990.
2. Trainee Travel Award. (The decision to breastfeed: Cultural determinants among adolescent mothers by J DuBois, CM Wiemann, and AB Berenson.) Presented by J. DuBois. Southern Society for Pediatric Research. New Orleans, LA. February 6, 1997.

3. Young Investigator Award (An evaluation of health care providers' sexual violence screening practices) Presented by Heather Littleton, Ph.D. Central Association of Obstetricians and Gynecologists. Las Vegas, NV. October 18-21, 2006.
4. Trainee Travel Award. (Early weight gain predicts excessive weight gain in DMPA users by YL Le, M Rahman, AB Berenson) Presented by Yen-Chi L. Le. Association of Clinical Research Training. Washington, DC. April 14-15, 2009.
5. Best Overall Clinical Sciences Poster. (Rouhani M, Leyser-Whalen O, Rahman M, Berenson AB. Risk Factors for Failure to Place Transcervical Sterilization Coils in the Tubal Ostia.) UTMB Medical Student Summer Research Program. June 24, 2011.

INVITED PANELS/STUDY SECTIONS:

1. Panel Member. Research Guidelines for Standardizing the Measurement of Violence Occurring Around the Time of Pregnancy, Sponsored by Centers for Disease Control and Prevention (CDC), Atlanta, GA. May 8-9, 1997.
2. Presenter. "Normal Anogenital Anatomy", Consensus Conference sponsored by Packard Foundation on Establishing a Medical Research Agenda for Child Sexual Abuse, Salt Lake City, UT. May 16-17, 1997.
3. Member. Advisory group to Packard Foundation on research related to diagnosis and management of sexual abuse, 1994-1997.
4. Grant Reviewer. Medical Research Council meeting on sexual health and HIV research strategy committee, United Kingdom, 2003
5. Member. Data Safety Monitoring Board for NIH Vaginal Ring Study (CCN006), 2007-08
6. Consultant. FDA expert advisory panel on Reproductive Health Drugs, Washington DC, December 16, 2003 and January 23-24, 2007.
7. Grant reviewer for Society of Family Planning; June 3-4, 2009.
8. Invited Panel Member. Centers for Disease Control and Prevention (CDC) Meeting on "Establishing US Guidelines for Contraceptive Management", Atlanta, GA; February 17-19, 2009.
9. Invited Panel Member. Centers for Disease Control and Prevention (CDC) Meeting on "Adaptation of WHO Selected Practice Recommendations for Contraceptive Use in the US", October 2010.
10. Member, Scientific Review Group. ZHD1 DSR-K (02) - National Institute Child Health and Development (NICHD) Contraceptive Trials Network. Reproductive Health Branch, January 12, 2010.
11. Member, Scientific Review Group. 2011/05 ZRG1 F16-B (20) L - Fellowships: Health and Health Related Behavior of Individuals and Populations. San Francisco. March 9, 2011.
12. Member, Data Safety Monitoring Board for Contraceptive Levonorgestrel Patch Study, National Institute Child Health and Development (NICHD) Reproductive Health Branch, March 2011-present.

EDITORIAL BOARDS:

Journal of Aggression, Maltreatment and Trauma 1997-present

Precis: An Update in Obstetrics and Gynecology, 2nd Edition of Reproductive Endocrinology and Infertility	2000-2002
Journal of Pediatric and Adolescent Gynecology	2001-2004
OB GYN News	2002-2005
Precis: An update in Obstetrics and Gynecology, 3rd edition of Gynecology	2004-2005
The Female Patient, Editorial Advisory Board	2005-2006
Precis: An update in Obstetrics and Gynecology, 4th edition of Gynecology	2009-2010

JOURNAL REVIEWER:

Journal of the American Medical Association
Obstetrics and Gynecology
American Journal of Obstetrics and Gynecology
Pediatrics
Archives of Pediatrics and Adolescent Medicine
Journal of Reproductive Medicine
American Journal of Epidemiology
Journal of Adolescent Health
Journal of Bone and Mineral Research
Journal of Pediatrics
Obesity

INVITED LECTURES, SEMINARS, SYMPOSIA:

1. Dysfunctional uterine bleeding in adolescents. North American Society of Pediatric and Adolescent Gynecology, September 30, 1988.
2. Medical liabilities of teen pregnancies. The obstetrical approach to teen pregnancies. Conference on Teenage Pregnancy. Longview, TX. September 15, 1989.
3. Vulvovaginal disorders in children. Cooke Society, Galveston, TX. October 6, 1989.
4. Overview of pediatric gynecology. The 24th Annual Family Practice Review. April 9-13, 1990.
5. Dysfunctional uterine bleeding. Gynecology update: 1991 Centennial Postgraduate course. October 3, 1991.
6. Birth control in the teenage patient. Pelham P. Staples Educational Symposium. Fort Worth, TX. September 18, 1992.
7. Developmental changes in the hymen. Conference on Responding to Child Maltreatment. San Diego, CA. January 29, 1993.
8. Overview of pediatric gynecology. Ray A. Kroc Visiting Professorship. St. Louis University. February 15-19, 1993.
9. The genital exam in non-abused, prepubertal children. North American Society of Pediatric and Adolescent Gynecology. April 16-18, 1993.
10. Hymenal anatomy: normal variations. The 42nd Annual Pediatric Review and Update. June 17-19, 1993.

11. Menstrual irregularities in adolescents. The 28th Annual Family Practice Review. April 28, 1994.
12. Conference on Responding to Child Maltreatment. San Diego, CA. January 26-27, 1995.
    - Normal genitalia, birth to puberty
    - Doctrine and disagreement: Physical findings, prepubertal aged children (Panel discussion)
13. Update on Mullerian anomalies. Grand Rounds. Case Western Reserve University. Cleveland, OH. April 19, 1995.
14. Contraception and the adolescent patient. American College of Obstetricians and Gynecologists, San Francisco, CA. May 6-10, 1995.
15. Appearance of the external genitalia in children. Sexual assault forensic examination (SAFE) training workshop. Columbia, MO. October 6, 1995.
    - Development of the hymen
    - Conditions which mimic sexual abuse
17. Examining children and adolescents. American College of Obstetricians and Gynecologists Annual Meeting. Denver, CO. April 29, 1996.
18. Moderator of scientific session. American College of Obstetricians and Gynecologists Annual Meeting. Denver, CO. April 29, 1996.
19. Pediatric Gynecology. American College of Obstetricians and Gynecologists Annual Meeting. Denver, CO. April 30, 1996.
20. Osler Institute Obstetrics and Gynecology Board Review Course. Dallas, TX. August 23, 1996.
    - Pediatric Gynecology
    - Sexual Assault
21. Dysfunctional uterine bleeding in adolescents. The 6th National Conference on Women's Health Care. Las Vegas, NV. September 17, 1996.
22. The 4th National Conference on Obstetrics & Gynecology - Issues in women's health in the '90s. St. Thomas, VI. November 20 - 23, 1996.
    - Vulvar Disorders in Children and Adolescents
    - The Adolescent Gynecologic Exam
    - Dysfunctional Uterine Bleeding in Adolescents
    - Identification/Management of Congenital Anomalies of the Vagina
23. Conference on responding to child maltreatment. San Diego, CA. January 27-31, 1997.
    - What to do about Controversial Findings in Sexual Abuse Cases (Panel Discussion)
    - Vulvar Conditions Which Mimic Sexual Assault (Workshop)
24. The pelvic exam in children and adolescents. (Luncheon Conference) Presented at the American College of Obstetricians and Gynecologists Annual Meeting. Las Vegas, NV. April 28, 1997.
25. Diagnosis and treatment of sexual assault in the pediatric patient. (Clinical Seminar) Presented at the American College of Obstetricians and Gynecologists Annual Meeting. Las Vegas, NV. April 28, 1997.
26. Domestic violence, sexual assault and drug dependency. (Course Director of 060 course) Presented at the American College of

Obstetricians and Gynecologists Annual Meeting. Las Vegas, NV. April 29-30, 1997.

27. Visiting Professorship, Departments of Pediatrics and Ob/Gyn. Santa Clara Valley Medical Center. San Jose, CA. May 15, 1997.
    - Vulvar Disorders in Children
    - Abnormal Uterine Bleeding in Adolescents
    - Gynecologic Evaluation of the Pediatric Patient
28. Pediatric and adolescent gynecology postgraduate course (Course Director). Presented at the Central Association of Obstetricians and Gynecologists. Scottsdale, AZ. October 30-November 1, 1997.
29. Moderator, poster session on contraception. Society of Adolescent Medicine Annual Meeting. Atlanta, GA. March 4-8, 1998.
30. Postgraduate course on adolescent gynecology (Course Director of 060 course). Presented at American College of Obstetricians and Gynecologists Annual Meeting. New Orleans, LA. May 12–13, 1998.
31. Sammelweis - Waters OB/GYN conference. Sponsored by New Jersey Medical School. March 28-30, 1998.
    - Gynecologic Evaluation of the Adolescent Patient
    - Dysfunctional Uterine Bleeding in Adolescents
    - Evaluation of the Sexually Abused Child
32. Workshop on sexual abuse. (Chair) World Congress of Pediatric and Adolescent Gynecology. Helsinki, Finland. June 2, 1998.
    - Sexual Assault and the Adolescent Patient
33. Psychosomatic problems (Luncheon Conference). World Congress of Pediatric and Adolescent Gynecology. Helsinki, Finland. June 2, 1998.
34. Pediatric and adolescent gynecology (Course Director). Half-day symposium presented at the District VII Annual Meeting of the American College of Obstetricians and Gynecologists. Birmingham, AL. October 26, 1998.
35. Gynecologic development of the pediatric patient. Presented at the Intensive Refresher Course in Obstetrics and Gynecology, sponsored by RUSH-Presbyterian-St. Lukes Medical Center. Houston, TX. April 29, 1999.
36. Postgraduate course on adolescent gynecology (Course Director of 060 course). Presented at the American College of Obstetricians & Gynecologists Annual Clinical Meeting. Philadelphia, PA. May 18-19, 1999.
37. Dysfunctional uterine bleeding. Presented at Grand Rounds, Yale University. New Haven, CT. May 20, 1999.
38. Risk taking, relationship to intimate partner violence, and sexual risk behaviors among adolescents. Presented at the National Conference on Violence and Reproductive Health sponsored by Centers for Disease Control and Prevention (CDC). Atlanta, GA. June 14, 1999.
39. Dysfunctional uterine bleeding and the adolescent patient. Presented at Grand Rounds, University of Washington. Seattle, WA. November 17, 1999.
40. Evaluation and management of vaginal anomalies. Presented at the Seattle Gynecological Society, Seattle. WA. November 17, 1999.

41. Date rape for teen health: strengths, risks and strategies (CME course). Seattle, WA. November 18, 1999.
42. A Comprehensive Update in Obstetrics and Gynecology. Sundance, UT. February 21-26, 2000.
    - Domestic Violence Against Women-The Gynecologist's Role
    - Dysfunctional Uterine Bleeding in Adolescence
    - Vulvar Disorders-A Common Complaint of Adolescents
    - Vaginal Anomalies-Early Recognition and Treatment
43. Child sexual abuse. Presented at the Women's Health Research Exhibit on NIH funded projects. Washington, DC. April 4, 2000.
44. The medical evaluation of the sexually abused child: an introduction. Presented at the Annual Clinical Meeting of Pediatric and Adolescent Gynecology. Atlanta, GA. April 15, 2000.
45. The pelvic exam in children and adolescents. (Luncheon Conference) Presented at the American College of Obstetricians and Gynecologists Annual Meeting. San Francisco, CA. May 22, 2000.
46. Common problems in pediatric and adolescent gynecology. (Luncheon conference) Presented at the American College of Obstetricians and Gynecologists Annual Meeting. San Francisco, CA. May 23, 2000.
47. Postgraduate course on adolescent gynecology (Course Director of 060 course). Presented at the American College of Obstetricians & Gynecologists Annual Clinical Meeting. San Francisco, CA. May 24, 2000.
48. Fall Assembly of the Seattle Gynecologic Society. Seattle, WA. September 22-23, 2000.
    - Dysfunctional Uterine Bleeding
    - Sexual Assault in Adolescents
49. Date Rape. Presented at the Mini-Medical School Program for Founder's Day. University of Texas Medical Branch. Galveston, TX. October 14, 2000.
50. Anatomical changes associated with sexual assault. Presented at the Conference on Responding to Child Maltreatment. San Diego, CA. January 24, 2001.
51. Ask the Expert. Conference on Responding to Child Maltreatment. San Diego, CA. January 24, 2001.
52. Teleconference on the diagnosis of sexual abuse in prepubertal girls. Presented for the Child Advocacy Outreach Project. February 26, 2001.
53. Postgraduate course (060) on adolescent gynecology. Presented at American College of Obstetricians and Gynecologists Annual Clinical Meeting. Chicago, IL. April 30 - May 2, 2001.
    - Dysfunctional uterine bleeding
    - Sexual assault
    - Controversies in contraception
54. Diagnosis of sexual abuse in the prepubertal child. (Clinical seminar). Presented at the American College of Obstetricians and Gynecologists Annual Clinical Meeting. Chicago, IL. April 30, 2001.
55. Tips for performing a pelvic examination on pediatric and adolescent patients. (Luncheon conference). Presented at the American College of Obstetricians and Gynecologists Annual Clinical Meeting. Chicago, IL. May 1, 2001.

56. The David Feld Memorial Lecture, Wayne State University. June 12, 2001.
    - Genital findings in abused vs. non-abused prepubertal females
57. Genital findings associated with sexual assault in children. Presented at Ground Rounds, St. Louis University. St. Louis, MO. August 2, 2001.
58. A study of hymenal characteristics and measurements in abused and non-abused girls: With new research including posterior hymen findings. Presented at San Diego Conference on Child and Family Maltreatment. San Diego, CA. January 25, 2002.
59. Course director of freestanding postgraduate course, American College of Obstetricians and Gynecologists, "Adolescent Gynecology", Banff, Alberta Canada, February 6-8, 2003.
    - Development of the female genitalia from birth to puberty
    - Contraception for adolescents
    - Acquaintance/date rape
60. Controversies in hormonal contraceptive use during adolescence. Presented at the Texas Association of Obstetricians and Gynecologists Annual Meeting. Galveston, TX. April 3-5, 2003.
61. Contraceptive use during adolescence. Presented at Grand Rounds, Cook Children's Medical Center, Fort Worth Texas, August 3, 2004.
62. Dysfunctional uterine bleeding. Presented at The American College of Obstetricians and Gynecologists Annual District meeting. Manhattan, NY. October 29, 2004.
63. Dysfunctional uterine bleeding in adolescence. Presented at Albert Einstein School of Medicine Grand Rounds for Obstetrics and Gynecology. March 8, 2005.
64. Treatment of dysfunctional uterine bleeding in adolescents. Presented at the 77th Annual Joint Meeting of ACOG Texas Section. San Antonio, TX. March 31, 2006.
65. Pediatric vulvovaginitis. Presented at the Herman L. Gardner Memorial Lecture at the 18th Biennial Conference on Diseases of the Vulva and Vagina. Houston, TX. February 9, 2007.
66. Effects of depot medroxyprogesterone acetate on bone mineral density. Presented at Ob/Gyn Grand Rounds, Harvard Medical School. February 11, 2009.
67. Effects of depot medroxyprogesterone acetate on weight and body composition. Presented at Ob/Gyn Grand Rounds at University of Texas Health Science Center, April 7, 2009.

BIBLIOGRAPHY:

PUBLISHED:

A. ARTICLES IN PEER-REVIEWED JOURNALS:

1. **Berenson AB**, Pokorny SF, Dutton R. The autoamputated ovary - a rare cause of abdominal calcification. Adolesc Pediatr Gynecol 1989;2:99-102.
2. **Berenson AB**, Hammill HA, Martens MG, Faro S. Bacteriologic findings of post-cesarean endometritis in adolescents. Obstet Gynecol 1990;75:627-9.

3. **Berenson AB**, Stansberry SD. Diagnosis of hematometrosalpinx and ipsilateral renal agenesis with magnetic resonance imaging. Adolesc Pediatr Gynecol 1990;3:207-9.
4. **Berenson AB**, Hammill HA, Martens MG, Faro S. Bacteriologic findings with ectopic pregnancy. J Reprod Med 1991;36:118-20.
5. **Berenson AB**, Heger AH, Andrews SA. Appearance of the hymen in newborns. Pediatrics 1991;87:458-65.
6. **Berenson AB,** Stiglich NJ, Wilkinson GS, Anderson GD. Drug abuse and other risk factors for physical abuse in pregnancy among white non-Hispanic, black, and Hispanic women. Am J Obstet Gynecol 1991;164:1491-6; discussion 1496-9.
7. **Berenson AB**, Heger AH, Andrews SA. Morphology of the hymen in twins. Adolesc Pediatr Gynecol 1991;4:82-4.
8. **Berenson AB**, Heger AH, Hayes JM, Bailey RK, Emans SJ. Appearance of the hymen in prepubertal girls. Pediatrics 1992;89:387-94.
9. Morris DL, **Berenson AB**, Lawson J, Baker JL, Lester JW. A comparison of pregnant Hispanic adolescents ≤ 17 years old with those of Black and Anglo ethnicity. Adolesc Pediatr Gynecol 1992;5:32-8.
10. **Berenson AB**, San Miguel V, Wilkinson GS. Violence and its relationship to substance use in adolescent pregnancy. J Adolesc Health 1992;13:470-4.
11. **Berenson AB**, San Miguel V, Wilkinson GS. Prevalence of physical and sexual assault in pregnant adolescents. J Adolesc Health 1992;13:466-9.
12. **Berenson AB**, Edmonds DK, Pryse-Davies J. Seromucinous cystadenoma in a true hermaphrodite: a case report. Adolesc Pediatr Gynecol 1993;6:36-8.
13. **Berenson AB.** Appearance of the hymen at birth and one year of age: a longitudinal study. Pediatrics 1993;91:820-5.
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SUBMITTED:

1. *Asem H, Zhang DD, Semper-Ternent RA, Kuo Y, Hatch SS, Freeman J, **Berenson AB**. The effect of postoperative beam, implant, and combination radiation therapy on GI and bladder toxicities in women with Stage I uterine cancer. Submitted to Geriatric Oncology, August 22, 2011.

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B. OTHER:

BOOKS:

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INVITED CHAPTERS/ARTICLES:

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TAPES:

1. Moderator, ACOG Update Continuing Education Series. Adolescent Gynecology, Vol 27, October 2001.

POSTER AND ORAL RESEARCH PRESENTATIONS:

1. **Berenson AB,** Findley W, Gibbons W. Effect of delta-9 tetrahydrocannabinol on mouse embryo growth. Oral presentation; International Embryo Transfer Society, January 24, 1984.
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20. **Berenson AB**, Wiemann CM, Wilkinson, GS, Jones, WA. Effects of physical violence experienced by pregnant adolescents on perinatal outcome. Poster presentation; Annual Meeting of the Society of Adolescent Medicine, March 19, 1993.
21. Ammenheuser MM, **Berenson AB**, Stiglich NJ, Whorton EB Jr, Ward JB Jr. A dose-related increase in the frequency of HPRT mutant lymphocytes in smoking mothers and their newborns. Poster presentation; Environmental Mutagen Society Annual Meeting, April 17-22, 1993.
22. **Berenson AB,** Garcia AS, Barnett S. Perianal findings in infants ≤18 months of age. Oral presentation; Annual Meeting of the North American Society of Pediatric and Adolescent Gynecology, April 16-18, 1993.

23. **Berenson AB**. Appearance of the hymen at birth and one year of age: a longitudinal study. Oral presentation; Annual Meeting of the North American Society of Pediatric and Adolescent Gynecology, April 16-18, 1993.
24. Wiemann CM, **Berenson AB,** Wagner KD, Vreeke S, Landwehr BM. Prevalence and correlates of psychopathology among pregnant adolescents. Poster presentation; North American Society of Pediatric and Adolescent Gynecology, April 16-18, 1993.
25. **Berenson AB**, Wiemann CM, Wilkinson GS, Jones WA. Perinatal morbidity associated with violence experienced by pregnant women. Oral presentation; Annual Meeting of The Central Association of Obstetricians and Gynecologists, October 28, 1993.
26. Ammenheuser MM, **Berenson AB**, Babiak AE, Whorton EB Jr., Ward JB Jr. Elevated frequencies of HPRT mutant lymphocytes in pregnant women who smoke marijuana. Poster presentation; Environmental Mutagen Society, February, 1994.
27. Paradise JE, Finkel M, Beiser A, **Berenson AB**, Emans J, McCann J, Greenberg D. Variability and bias in physicians' interpretations of photographs of girls' genitalia. Oral presentation; Annual Meeting of the Ambulatory Pediatric Association, May 3, 1994.
28. Wagner KD, **Berenson AB**. Major depression and panic disorder associated with Norplant. Poster presentation; Annual Meeting of the American Psychiatric Association, May 24, 1994.
29. **Berenson AB**, Wiemann CM. Use of Norplant vs oral contraceptives in adolescence: A case control study. Oral presentation; Annual Meeting of the American Gynecologic and Obstetric Society (AGOS), September 8, 1994.
30. **Berenson AB**, Wiemann CM, Somma-Garcia A. Barriers to Norplant use among indigent women of Southeast Texas. Poster presentation; Annual Meeting of the Central Association of Obstetricians and Gynecologists, October 14-16, 1994.
31. Wiemann CM, **Berenson AB**, Garcia-Del Pino L, McCombs SL. Entry into prenatal care at < 20 weeks gestation: Adolescents at risk. Poster presentation; Annual Meeting of the Society for Gynecologic Investigation, March 15-18, 1995.
32. **Berenson AB**. A longitudinal study of hymenal morphology in the first three years of life. Poster presentation; Annual Meeting of the Society for Gynecologic Investigation, March 15-18, 1995.
33. **Berenson AB**, Wiemann CM. Risk of an adverse perinatal outcome among adolescents ≤15 years of age. Poster presentation; Annual Meeting of the American College of Obstetricians and Gynecologists, May 10, 1995.
34. **Berenson AB**, Wiemann CM. Contraceptive use among adolescent mothers at 6 months postpartum. Oral presentation; Annual Meeting of the American College of Obstetricians and Gynecologists, April 30, 1996.
35. **Berenson AB**, Wiemann CM, McCombs SL. A longitudinal prospective evaluation of Norplant use by adolescents during the first 12 months of use. Poster presentation; Annual Meeting of the American College of Obstetricians and Gynecologists, April 30, 1996.
36. Rickert VI, Wiemann CM, **Berenson AB**. Health risk behaviors among pregnant adolescents with older partners. Poster presentation; Annual Meeting of the American College of Obstetricians and Gynecologists, April 30, 1996.
37. Paradise JE, Finkel M, Beiser A, **Berenson AB**, Greenberg D, Winter M. Physicians' conformity to standards in assessing girls' genital findings. Oral presentation;

Ambulatory Pediatric Association, May 7, 1996. (Arch Ped Adol Med. 1996;150, supp 80.)

38. Paradise JE, Finkel M, Beiser, Winter M, **Berenson AB**, Greenberg D. Conformity of skilled physicians' assessments of girls' genital findings to standards. Oral presentation; Society for Pediatric Research, May 9, 1996. (Ped Res. 1996;39-138a).
39. Wiemann CM, **Berenson AB**. Factors associated with continued alcohol use in adolescent pregnancy. Oral presentation; Annual Meeting of the North American Society for Pediatric and Adolescent Gynecology, May 16-17, 1996. (J Ped Adol Gynecol. 1996;9:151).
40. Wiemann CM, **Berenson AB**. Patterns of violence experienced by adolescent mothers in the early postpartum period. Oral presentation; Annual Meeting of the North American Society of Pediatric and Adolescent Gynecology, May 16-17, 1996.
41. Rickert VI, **Berenson AB**, Wiemann CM. Employment and the Pregnant Adolescent: A Health Risk? Oral presentation; Annual Meeting of the North American Society of Pediatric and Adolescent Gynecology, May 16-17, 1996. (J Ped Adol Gynecol. 1996;9:149).
42. **Berenson AB**, Wiemann CM, Rowe TF, Rickert VI. Inadequate weight gain among pregnant adolescents: risk factors and relationship to infant birth weight. Oral presentation; Annual Meeting; Central Association of Obstetricians and Gynecologists, October 18, 1996.
43. Wiemann CM, *DuBois J, **Berenson AB**. The decision to breastfeed: cultural determinants among adolescent mothers. Oral presentation; Annual Meeting of the Society for Adolescent Medicine, March 5-9, 1997.
44. **Berenson AB** and Wiemann CM. Exposure to violence and associated health behaviors among sexually active adolescent women. Oral presentation; 7th European Congress on Pediatric and Adolescent Gynecology, Vienna, Austria. March 15, 1997.
45. Ammenheuser MM, Hastings DA, **Berenson AB**, Singleton CR, Whorton Jr. EB. Elevated frequencies of HPRT mutant lymphocytes in newborns of women who smoke marijuana. Poster presentation; Environmental Mutagen Society Annual Meeting, April 19, 1997.
46. Wiemann CM, **Berenson AB**, DuBois J. Identifying adolescents at highest risk for early breastfeeding cessation. Poster presentation; Annual Meeting of the American College of Obstetricians and Gynecologists, April 26-30, 1997.
47. Ammenheuser MM, **Berenson AB**, Singleton CR, Hastings DA, Whorton Jr. EB, and Ward Jr. JB. Frequencies of HPRT mutant lymphocytes in marijuana smokers and multi-drug users. Poster presentation; 7th International Conference on Environmental Mutagens, Toulouse, France. September, 1997.
48. **Berenson AB**, Wiemann CM, Rickert VI. Use of video eyeglasses to decrease anxiety among children undergoing genital examinations. Poster presentation; Central Association of Obstetricians & Gynecologists, October 29–November 1, 1997.
49. Rickert VI, Wiemann CM, Hankins GDV, McKee JM, **Berenson AB**. Prevalence and risk factors of chorioamnionitis among adolescents. Poster presentation; Annual Meeting of the Society of Perinatal Obstetricians, February 7, 1998.
50. Agurcia CA, Wiemann CM, Rickert VI, Volk RJ, **Berenson AB**. Adolescent pregnancy: Effects of weekly marijuana use by a male partner. Poster presentation; Annual Meeting

of the Society for Adolescent Medicine, March 5, 1998. (J Adol Health. 1998;22:174).

51. Rickert VI, Wiemann CM, **Berenson AB**. Rohypnol: More than a date rape drug. Oral presentation; Society for Pediatric Research, New Orleans, LA. May 3, 1998. (Pediatric Research. 1998;43:5A).
52. Paradise JE, Winter M, Finkel M, **Berenson AB**, Beiser A. Influence of history on physicians' interpretation of girls' genital findings with respect to sexual abuse. Society for Pediatric Research, New Orleans, LA. May 1998.
53. **Berenson AB**, Chacko MR, Wiemann CM. Influence of weight and height on hymenal measurements. Poster Presentation; World Congress of Pediatric and Adolescent Gynecology, Helsinki, Finland. June 3, 1998.
54. Wiemann CM, **Berenson AB**, Rickert VI, Agurcia CA, Volk RJ. Adolescent pregnancy: factors associated with partner directed violence. Poster Presentation; XII World Congress of Pediatric and Adolescent Gynecology, Helsinki, Finland. June 3, 1998.
55. Rickert VI, Wiemann CM, **Berenson AB**. Prevalence, patterns, and correlates of voluntary rohypnol use among sexually active female adolescents. Poster Presentation; World Congress of Pediatric and Adolescent Gynecology, Helsinki, Finland. June 8, 1998.
56. Rickert VI, **Berenson AB**, Williamson A, Wiemann CM. Immediate recall of oral contraceptive instructions: implications for providers. Oral Presentation; Annual Meeting of the Central Association of Obstetricians and Gynecologists, October 15, 1998. (Am J Obstet Gynecol. 1999;180:1399-406).
57. Wiemann CM, Volk RJ, **Berenson AB.** Drug use patterns of adolescent mothers: prepregnancy to 24 months post partum. Poster presentation; Annual meeting of the College on Problems of Drug Dependence, Acapulco, Mexico. June 17, 1999. (NIDA Research Monograph, 1999).
58. Wiemann CM, Volk RJ, **Berenson AB**. Prevalence and patterns of drug use among adolescent mothers. Poster Presentation; Annual Meeting of the Society for Adolescent Medicine, March 17, 1999. (J Adol Health. 1999;24:105).
59. Wiemann CM, Rickert VI, Volk RJ, **Berenson AB**. Are adolescents stigmatized by pregnancy? Oral Presentation; Annual Meeting of the Society for Adolescent Medicine, March 17, 1999. (J Adol Health. 1999;24:88).
60. Agurcia CA, Rickert VI, **Berenson AB**, Volk RJ, Wiemann CM. Postpartum adolescent mothers: health and pregnancy risks of involvement with an older adult partner. Oral Presentation; Annual Meeting of the Society for Adolescent Medicine, March 18, 1999. (J Adol Health. 1999;24:80).
61. Rickert VI, Wiemann CM, **Berenson AB.** Race, ethnicity differences in the prevalence and correlates of depressive symptomology. Poster presentation; Annual Meeting of the Society for Adolescent Medicine, March 17, 1999. (J Adol Health. 1999;24:109).
62. Rickert VI, Wiemann CM, **Berenson AB.** Frequency of intimate partner violence: effects of age, race and relationship length. Oral presentation; Annual Clinical meeting of the American College of Obstetricians and Gynecologists, May 15-19, 1999. (Obstet Gynecol. 1999;93:125).
63. **Berenson AB,** Chacko MR, Wiemann CM, Mishaw CO, Friedrich WN, Grady JJ. A case control study of anatomic changes which result from sexual abuse. Oral presentation;

Annual Meeting of the American Gynecologic and Obstetric Society (AGOS), September 16-18, 1999.

64. Wiemann DM, Agurcia CA, Rickert VI, **Berenson AB.** Support for adolescent mothers: Should absent fathers be pushed to provide it? Poster presentation; Annual Meeting of the Society of Adolescent Medicine, March 22, 1999. (J Adol Health. 2000;26:121).
65. Wiemann DM, Rickert VI, Agurcia CA, Volk RJ, **Berenson AB.** Violence experienced by pregnant adolescents: victim and perpetrator characteristics. Poster presentation; Annual Meeting of the Society of Adolescent Medicine, March 22, 1999. (J Adol Health. 2000;26:121).
66. Rickert VI, Neal WP, Wiemann CM, **Berenson AB.** Prevalence and predictors of low sexual assertiveness. Oral presentation; Annual Meeting of the North American Society for Pediatric and Adolescent Gynecology. April 14, 2000. (J Pediatr Adolesc Gynecol. 2000;13:88-9).
67. **Berenson AB,** Rickert VI, Grady JJ. A prospective study of the effects of oral and injectable contraception on bone mineral density. Oral presentation; American College of Obstetricians and Gynecologists, May 22, 2000. (Obstet Gynecol. 2000;95:S6.).
68. **Berenson AB**, Radecki CM, Rickert VI, Grady JJ, Thomas A. Condom practices prior to and after initiation of hormonal contraception. Poster presentation; Central Association of Obstetricians and Gynecologists, October 18-21, 2000.
69. Desai A, Wiemann CM, **Berenson AB**. Ethnic differences in rates of contraceptive and repeat pregnancy among adolescent mothers at 12 and 24 months postpartum. Oral presentation; Society of Adolescent Medicine, March 2001. (J Adol Health. 2001;28:100).
70. Wu ZH, **Berenson AB**, Wiemann CM. A profile of adolescent females with a history of sexual abuse by race/ethnicity and relationship to perpetrator: environment, risk behaviors and health outcomes. Poster presentation; Congress of Epidemiology, June 14, 2001. (Am J Epidemiol. 2001;11:153).
71. Levine R, **Berenson AB.** Anxiety disorders during pregnancy and the post-partum period. Oral presentation; Anxiety Disorders Association National Conference, March 21-24, 2002, Austin, TX.
72. Radecki Breitkopf C, **Berenson AB.** Theory-based qualitative examination of adherence to follow-up for abnormal Papanicolaou smears. Poster presentation; Society of Behavioral Medicine's Annual Meeting and Scientific Sessions, April 3-6, 2002, Washington, DC.
73. Wu ZH, **Berenson AB**, Wiemann CM, Grady JJ. Risk factors of sexually transmitted infections among sexually active adolescent girls: Implications to reduce future reinfections. Poster presentation; Society of Epidemiological Research, June 11-14, 2002. (Am J Epidem. 2002;155:403 Suppl).
74. Radecki Breitkopf C, **Berenson AB.** Nonprescription diet pill use among low-income women. Poster presentation; Annual Meeting; Society of Behavioral Medicine, March 19-22, 2003, Salt Lake City, UT. (Ann Behav Med. 25:S024 Suppl).
75. Wu ZH, **Berenson AB,** Grady JJ, Breitkopf CM. Ecstasy use by young, low income women. Invited and presented at the National Institute of Drug Abuse REACT meeting, April 9-10, 2003, Rockville, Maryland.

76. Wu ZH, **Berenson AB**, Grady JJ, and Radecki Breitkopf C. Determinants of ecstasy use in young, low-income women. Oral presentation; Annual Scientific Meeting of the College on Problems of Drug Dependence, June 14-19, 2003, Bal Harbour, FL.
77. **Berenson AB,** Radecki Breitkopf C, Grady JJ, Rickert VI, Thomas A. Effects of hormonal contraception on bone mineral density after 24 months of use. Oral presentation; Society of Gynecologic Investigation, March 25, 2004, Houston, TX. (J Soc Gynecol Investig. 2004;11:175A, Suppl).
78. Radecki Breitkopf C, **Berenson AB.** Knowledge regarding the Pap test among women undergoing annual screening. Poster session; Annual meeting of the Central Association of Obstetricians and Gynecologists, October 14-16, 2004, Washington DC.
79. Olson G, Radecki Breitkopf C, Grady J, **Berenson AB.** Acceptability of a targeted vaccine during pregnancy. Poster session; Annual meeting of the Central Association of Obstetricians and Gynecologists, October 14-16, 2004, Washington DC.
80. Wu ZH, Holzer C, **Berenson AB**. Stress, sex, and use of ecstasy and other drugs among young disadvantaged women: An untangled triangle. Oral presentation: Annual Meeting of American Public Health Association, November 6-10, 2004, Washington, DC.
81. Slomovitz B, Sun C, Frumovitz M, Soliman P, Pearson H, **Berenson AB,** Bodurka D. Are women ready for the cervical cancer vaccine? Oral presentation; Annual Meeting on Women's Cancer, March 19-23, 2005, Miami Beach, FL.
82. *****Littleton H, Radecki Breitkopf C, **Berenson A**. Body consciousness and risky sexual behaviors. Oral presentation; Annual Meeting & Scientific Sessions of the Society of Behavioral Medicine, April 13-16, 2005, Boston, MA.
83. *Littleton H, Radecki Breitkopf C, **Berenson A**. A meta-analysis of correlates of anxiety symptoms during pregnancy and the association of anxiety with neonatal outcomes. Oral presentation; Annual Convention of the American Psychological Association, August 10-13, 2006, New Orleans, LA.
84. *Littleton H, Radecki Breitkopf C, **Berenson A**. An Evaluation of Health Care Providers Sexual Violence Screening Practices. Oral presentation; Annual Meeting; Central Association of Obstetricians and Gynecologists, October 18-21, 2006, Las Vegas, Nevada.
85. *Newman JL, Radecki Breitkopf C, **Berenson AB**. Consistency between face-to-face interview and self-administered questionnaire reports of sensitive health-related behaviors among female adolescents. Poster presentation; Annual Meeting; Society for Adolescent Medicine, Denver, Colorado, March 2007. (J Adolesc Health 2007;40:S22-S23)
86. *Newman JL, Radecki Breitkopf C, **Berenson AB**. Relationship between bone mineral density and parity in a multiethnic sample of healthy reproductive-aged women. Poster presentation; Scientific Annual Meeting; Society for Gynecologic Investigation, Reno, Nevada, March 2007.
87. Temple J, **Berenson A**, Radecki Breitkopf C. The relative importance of preventative health behaviors among women of lower socioeconomic status. Poster presentation: 16th Annual Meeting; Society for Prevention Research, San Francisco, California, May 2008.
88. Temple J, Marshall LL, **Berenson A**. Effects of Partner Abuse on Women's Mental Health: A Longitudinal Study. Poster presentation: American College of Obstetricians and Gynecologists 55th Annual Clinical Meeting, San Diego, California, May 2008. (Obstet Gynecol 2008;111:15S)

89. Wu H, Holzer C, Grady JJ, **Berenson AB**. Stress, health related quality of life and DSM-IV substance abuse and dependence in young, low-income women. Poster presentation: 70th Annual Meeting of the College on Problems of Drug Dependence, San Juan, Puerto Rico, June 2008.
90. **Berenson AB**, *Odom S, Radecki CR, Rahman M. Physiologic and psychological symptoms associated with injectable and oral contraceptive use. Poster presentation; Scientific Annual Meeting of the Society for Gynecologic Investigation, San Diego, CA, March 2008.
91. **Berenson AB**, Rahman M. Changes in weight, total fat, percent body fat, and central-to-peripheral fat ratio associated with injectable & oral contraceptive use. Oral presentation; Central Association of Obstetricians and Gynecologists 75th Annual Meeting, New Orleans, LA, October 2008.
92. *Chambliss KH, van den Berg P, **Berenson AB**. Physical activity and depressive symptoms in a tri-ethnic sample. Poster presentation; Society of Behavioral Medicine's 30th Annual Meeting and Scientific Sessions, Montreal, Quebec, Canada, April 2009.
93. *Le YL. Rahman M, **Berenson AB**. Early weight gain predicts excessive weight gain in DMPA users. Poster presentation; National Clinical and Translational Research Education Annual Meeting, Washington, DC, April 2009.
94. *Hosain GM, Rahman M, **Berenson A**. Racial/ethnic differences in association between body fat distribution and serum lipid profiles among reproductive aged women. Poster presentation; Society Epidemiologic Research Annual Meeting, Anaheim, CA, June 2009.
95. Rahman M, **Berenson A**. Predictors of higher bone mineral density loss among depot medroxyprogesterone acetate users. Poster presentation; Society Epidemiologic Research Annual Meeting, Anaheim, CA, June 2009.
96. Rahman M, Temple J, Breitkopf C, **Berenson A**. Racial differences in body fat distribution among reproductive-aged women. Oral presentation; Society Epidemiologic Research Annual Meeting, Anaheim, CA, June 2009.
97. *Hosain GM, **Berenson AB**, Wu ZH. High risk sexual behavior among women with attention deficit disorder. Poster presentation; American Public Health Association Annual Meeting, Philadelphia, PA, November 2009.
98. *Ward KK, **Berenson AB**, Radecki Breitkopf CM. Passive smoke exposure and cervical cytology in a largely Hispanic population. Poster presentation; Society of Gynecologic Oncologists, San Francisco, CA, March 14-17, 2010.
99. *Ward KK, *Roncancio AM, **Berenson AB**. Acculturation among Hispanic women as related to awareness of emergency contraception and intention to use. Poster presentation: Society for Gynecologic Investigation Annual Meeting, Orlando, FL, March 24-28, 2010.
100. *Roncancio AM, **Berenson AB**, Rahman M. The mediating role of acculturation in health-related internet use among Latinas. Poster presentation: Society of Behavioral Medicine, Seattle, WA, April 2010.
101. Temple JR, *Behnken M, **Berenson AB**, Wu H. Effect of specific abuse types on women's mental health and substance use. Poster presentation; Association for Behavioral and Cognitive Therapy, San Francisco, CA. November 18-21, 2010.
102. *Mohammed H, Zhang DD, Samper Ternent RA, Kuo Y, Hatch S, Freeman J, **Berenson, AB**. The effect of beam, implant, and combination radiation therapy on GI and bladder

toxicities in women with uterine cancer. Poster presentation: Society of Gynecologic Investigation Annual Meeting, Miami, Fl. March 2011.

103. *Laz TH, Rahman M, **Berenson AB**. Trends in serum lipids, hypertension, physician advice, and compliance among reproductive age women. Poster presentation: Society of American Hypertension Annual Meeting, NYC, NY, May 21-24, 2011.
104. Rahman M, *Laz TH, **Berenson AB**. Association of weight misperception with abnormal lipid levels and hypertension among overweight and obese reproductive age women. Poster presentation: Society of American Hypertension, NYC, NY, May 21-24, 2011.
105. *Mohammed H, Tan A, Wilkinson G, **Berenson AB**. Complications of intrauterine contraceptives in women with bipolar disorder. To be presented as poster presentation at the North American Forum on Family Planning, Washington DC, October 22-24, 2011.
106. Tom SE, **Berenson AB**. Sleep quality, perceived stress, and obesity among low income, reproductive-aged women. To be presented at the Gulf Coast Women's Health Research Forum, September 30, 2011.

*Postdoctoral Fellow

Permanent address:
2014 Port Royal
Nassau Bay, Texas

This dissertation was typed by Abbey Berenson, MD.