

## **ABSTRACT**

**Objective:** To identify whether group family planning counseling is as effective as individual family planning counseling in Ghana, using a randomized, noninferiority study design.

**Methods:** Female gynecology patients were enrolled from two teaching hospitals in Ghana. Patients were randomized to receive either group or individual family planning counseling. The margin of noninferiority was set at 10%. The primary outcome in this study was change in contraceptive use intention before and after the intervention. Changes in family planning knowledge and intended method type were also explored.

**Results:** Comparisons between the two study arms suggests that randomization was successful. Before the intervention, 84% of the individual study arm (n=325) and 87% of the group study arm (n=306) intended to use contraception. After family planning counseling, intention to use contraception increased by 4.6% in the individual counseling study arm and 5.2% in the group study arm, the difference between the two study arms, adjusted for study site, is 0.1%, (95% CI: -6.42 to 6.62).

**Conclusion:** Group family planning counseling is as effective as individual family planning counseling in increasing intention to use contraception among female gynecology patients in Ghana.

## INTRODUCTION

The 80 million unplanned pregnancies worldwide each year demonstrates the depth of global need for family planning services (UNFPA 1997). According to the Ghana Demographic and Health Survey (GDHS) only 21% of women were using any method of family planning, and just 15% were using a modern method in 2003 (GSS, NMIMR, and ORC Macro 2004). Unmet need, i.e., not using a contraceptive method while wanting to delay or avoid pregnancy (Casterline and Sinding 2000; Westoff 1988), was 34% during this same time period in Ghana (GSS et al. 2004). Compared to other sub-Saharan African nations, only Rwanda has a higher unmet need for family planning at 38% (Macro 2009).

Despite low rates of modern contraceptive use and high unmet need, awareness of modern contraception is quite high in Ghana—98% of women knew of a modern contraceptive method in 2003. Intention to use family planning in the next year was 54% among currently married women who were not using contraception in 2003 (GSS et al. 2004). This level of intention to use family planning in the next year was only surpassed in West Africa by Burkina Faso at 58% (Macro 2009). Among non-users of contraception in Ghana, 26% of women cited fear of side effects as the main reason for non-use of contraception—among the highest rates on the continent (Macro 2009).

At the same time, the total wanted fertility was 3.7 children per woman, yet, on average, women have 4.4 children per women in Ghana—one of the lowest total fertility rates in sub-Saharan Africa (GSS et al. 2004). In order to accomplish this low fertility rate, women must either under report contraceptive use, abstain from sexual intercourse, or terminate unwanted pregnancies (Blanc and Grey 2002). In Ghana, abortion is legal yet some women who seek to terminate pregnancies instead resort to unsafe abortions because safe abortion services are neither publically available nor advertised (R. Adanu, personal communication, June 2008; Morhe, Morhe, and Danso 2007). When complications occur from an unsafe abortion, the woman may be rushed to the hospital for emergency treatment. A study of gynecology admissions at the Korle Bu Teaching Hospital in Accra found that 18% of gynecology admissions were related to complications of unsafe abortion in 2000 (Srofenyoh and Lassey 2003).

Postabortion care is the term used for the clinical and preventive services women with abortion complications optimally receive when presenting as emergency cases at health institutions. It is comprised of three elements, (1) emergency treatment, (2) family planning counseling and services, and (3) reproductive health service referrals (Corbett and Turner 2003; Greenslade et al. 1994). The second aspect of postabortion care, family planning counseling and services, has been shown to increase intention to use, or actual use, of contraceptives in Egypt (Abdel-Tawab et al. 1999; Huntington et al. 1995), Tanzania (Rasch et al. 2004, 2005, 2008), Malawi (Lema and Mpanga 2000), Kenya (Solo et al. 1999), Zimbabwe (Johnson et al. 2002), and Latin America (Billings et al.

2003, 2005; Farfan et al. 1997). Researchers have also examined the effect of contraceptive counseling prior to the abortion – results have been mixed (Bender and Gerisson 2004; Ortayli, Bulut, Nalbant 2001; Yassin and Cordwell 2005), possibly due to limitations in the study design in the one study with negative results.

In Ghana, hospital patients admitted to the gynecology ward are admitted for a range of issues including abortion complications. The standard of care in Ghana following an abortion (spontaneous or induced) includes a one-on-one session with a highly trained and experienced family planning nurse. However, other women in the ward who have experienced a problematic pregnancy, or other gynecological problem, may also have an unmet need for contraception given the high unmet need nationally.

One-on-one family planning counseling is time consuming for nurses and potentially stigmatizing for patients (as women are singled out from the ward). Group family planning counseling has the potential to increase the family planning knowledge and use among a greater proportion of women with unmet need for family planning as compared to individual family planning counseling, primarily through more efficient use of limited human resources.

The objective of this study was to determine whether group family planning counseling was as effective as individual family planning counseling in increasing women's intention to use family planning. The null hypothesis was that the individual and group counseling differed, more specifically; group counseling was less likely to increase contraceptive use intention as compared to individual family planning counseling. The alternative hypothesis was that individual and group family planning counseling were equally effective in increasing intentions to use family planning.

## **METHODS**

### Study population

Participants in the trial were female patients from the two teaching hospitals in Ghana, the Komfo Anokye Teaching Hospital in Kumasi and the Korle Bu Teaching Hospital in Accra. The participants were recruited from the gynecology wards at each hospital.

The inclusion criteria were as follows: (1) indicated a desire to wait at least 12 months before the next pregnancy, (2) not sterile, and (3) at least 18 years of age. Initially, we planned to restrict the study sample to women who were admitted to the hospital for induced abortion complications; however, during the formative research phase of this study the researchers found that the local abortion terminology differed. Women and providers used the word “abortion” to mean spontaneous abortion while induced abortions were referred to as “illegal abortion.” In addition, due to the stigma associated with induced abortions in Ghana, women were not always willing to disclose the reason they were admitted to the gynecology ward. Given the extremely sensitive nature of

induced abortion in Ghana, and the nearly universal need for family planning among this population, the researchers decided to expand the study sample to all patients who met the three aforementioned criteria without asking patients to specify the reason or type of pregnancy termination during the screening process. It was expected that the inclusion criteria would capture all gynecological patients with unmet need.

This trial was approved by the local institutional review boards at the Komfo Anokye Teaching Hospital and Korle Bu Teaching Hospital, as well as the Johns Hopkins Bloomberg School of Public Health Committee on Human Subjects Research. This trial has been registered with ClinicalTrials.gov and the trial number is NCT00814411. This manuscript follows the guidelines delineated by Piaggio et al. (2006) in regard to noninferiority trials.

### Intervention

Patients were recruited for this study while they were recovering on the gynecology ward and preparing for hospital discharge. To assess study eligibility, the all-female research team screened the patients on the gynecology wards. If a woman was eligible for the study, and indicated that she would like to participate, then the consent form was read aloud to her. Once she consented, she was interviewed face to face. First the baseline survey was administered. After the baseline interview form was completed, she received family planning counseling with a trained, experienced family planning nurse either individually or in a group depending on the randomization schedule. Study participants did not know whether they would receive individual or group family planning counseling during recruitment, consent, or the baseline interview.

The family planning counseling intervention in both arms included three main components: (1) introduction to the basic physiology of reproduction, (2) an overview of family planning and the different methods available, and (3) messages tailored to the individual patient to help her determine the correct method for her and the potential side effects with that method. The majority of family planning counseling sessions in this setting are learning opportunities, where the family planning counselor educates the patients on reproduction generally and contraceptive method types. During the discussion of method types the counselor periodically interacts with the patients to judge their comprehension, or the patients ask questions about common misconceptions or concerns, to which the counselor responds. To ensure the intervention was the same for all study participants at each study site, the student investigator provided training to the family planning nurses at both study sites using the counseling guide developed for this study.

Following family planning counseling, each study participant was interviewed a second time with a follow-up face to face interview to measure the effect of the intervention on intention to use family planning and family planning knowledge among the study participants (see Figure 5.1). All study participants received compensation for participating in the study.

### Primary Outcome

The primary outcome in this study is women's intention to use contraception, comparing intention before and after family planning counseling. Two questions regarding intention to use contraception were included sequentially in the baseline questionnaire. The first question asked whether the participant intended to use contraception at any time, "Do you think you will use a contraceptive method to delay or avoid pregnancy at any time in the future?" and the second question enquired into immediate intention, "Do you think you will start using a contraceptive method to delay or avoid pregnancy immediately after this hospital visit?"

Those study participants responding 'no' to the first question were not asked the second question, and they were recorded as 'no' in the intention variable. Those study participants responding 'no' to either question were asked why they did not plan to use contraception in the future or immediately. If the study participant said 'yes' to the future intention question and did not respond to the second question, she was recoded as 'yes' on the second question if she did not give a reason for non use and a 'no' if she did give a reason for non use. If the respondent gave a 'don't know' response to the first question about future intentions then she was coded as a 'no' for the intention variable if she gave a reason for non use.

Intention to use family planning was again asked in the follow-up questionnaire administered after the family planning counseling intervention. If the respondent did not respond to the question or gave a 'don't know' response then the variable was recoded as 'no'. The primary outcome is the difference in contraceptive use intention comparing reported intention at baseline and follow-up.

### Secondary Outcomes

We explored intended method choice as a secondary outcome to determine whether there were differences by study arm in the type of contraceptive method women intended to adopt. In the follow-up questionnaire participants were asked to name the type of contraceptive method they intended to use immediately following the question that inquired about intention to use family planning.

We also examined the difference by study arm in spontaneous recall of modern family planning methods before and after the intervention. At baseline, study participants were asked to name all of the family planning methods that they knew. Every spontaneous response was identified on the questionnaire by the interviewer. The knowledge score created for this analysis was based on only spontaneous mention of modern contraceptive methods. A simple additive scale was created to count the number of methods mentioned without prompting. Spontaneous recall of methods was asked again in the follow-up interview. Women were asked to indicate all family planning methods they knew. The post counseling modern method knowledge score was created by adding all of the spontaneously mentioned modern methods. In this study, modern methods include female sterilization, male sterilization, pill, IUD, injectables, implant, male condom, female condom, diaphragm, foam or jelly, and emergency contraception.

### Sample Size

This study is a noninferiority trial; therefore, a predetermined acceptable margin of noninferiority had to be established. For this study the margin of noninferiority was set at 10%. The Type I error was set at 0.05 and the Type II error at 0.10. The change in contraception use intention pre and post family planning intervention was estimated a priori to be 18%. In order to estimate the sample size, a sample size formula specifically designed for testing the equivalency of interventions was used (Friedman, Furberg, and DeMets 1998). Using this equation, it was determined that a total sample size of 621 was needed. A priori we did not assume there would be any loss to follow-up as all activities occurred on the same day at one location. However, during data collection it became apparent that loss to follow-up would be an issue, given this nuance we oversampled to ensure the target sample size would be reached.

### Randomization

Randomization occurred by clinic day. A random number table, stratified by study center, was utilized to determine study arm allocation. All participants recruited on an individual family planning counseling day, determined by the randomization schedule, received family planning counseling, one-on-one, with a trained family planning nurse. In contrast, all study participants recruited on a group family planning counseling day received family planning counseling with a trained family planning nurse in a group with other female gynecology patients. The size of the group family planning counseling sessions varied from between two to five study participants. The study procedures were the same at both study sites.

Randomization was checked by testing for differences between the participants in the two study arms on the following characteristics: mean age, number of live children, literacy, number of years of education, wealth quintile, religion, ethnicity, marital status, gynecological condition, and ever use of modern family planning.

### Statistical Methods

Data were entered initially into Microsoft Excel version 3.0. The data were then transferred to STATA version 9.0 for analysis (StataCorp 2009). First, we determined whether randomization was successful by comparing the characteristics of the women in the two study arms (individual vs. group counseling). Second, we assessed whether the study participants at the two study sites differed (Kumasi vs. Accra). Next, we compared intention to use family planning by study arm and pre-post changes in family planning intention by study arm were also examined. We compare the overall rates of intention to use contraception by study arm, as well as within-study arm. Finally, we use a difference in difference model to assess noninferiority. All models included a control for study site due to differences in the characteristics of women admitted to the two gynecology wards.

As secondary outcomes we considered the method women intended to use as well as the change in spontaneous recall of modern contraceptive methods pre and post intervention.

Chi-square tests were used to test the differences between categorical variables and Student's t-tests were used to check the differences between continuous variables. McNemar's test was used to test the categorical paired differences within study arms, and the paired t-test was used to test the differences within study arm for the continuous variables. Due to differences in the study sample by study site, final estimates were adjusted for study site. Analyses were conducted by both intent-to-treat and per-protocol. Per protocol analysis is useful in generating confidence about the results when the results are consistent between intent-to-treat analysis and per protocol analysis, because with noninferiority trials there is an increased risk of a Type I error with intent-to-treat analysis (Piaggio et al. 2006).

## RESULTS

Data collection, recruitment and follow-up, began in June and ended in July 2008. During this time, 942 female gynecology patients were screened for eligibility. Among the 216 women deemed ineligible for study participation through the screening process, the most common reason for ineligibility was women desiring a pregnancy in less than 12 months, 56% (120/216). Other reasons for ineligibility included being less than 18 years of age at the time of recruitment, 7% (14/216), and self-reported infertility, 38% (82/216). Out of the 726 women eligible for the study, 11% (78/726), refused to participate in the study (see Figure 5.2).

Nearly equal proportions of the 648 study participants were randomized to receive individual family planning counseling, 51% (332/648), and group family planning counseling, 49% (316/648). In the individual arm, 2% (7/332), were lost to follow-up, while in the group arm, 3% (10/316) were lost to follow-up. In this study, lost to follow-up means the patient consented, was interviewed at baseline, but was not interviewed at follow-up. When planning this study we had not anticipated any losses would occur since all activities occurred at a single location on the same day. Nevertheless, there were some losses experienced. Seventeen of those enrolled were lost to follow-up, or 3% (17/648). Therefore, there were 631 participants with complete data, 325 in the individual arm and 306 in the group counseling study arm (see Figure 5.2).

### *Background Characteristics*

There were no statistically significant differences in background characteristics by study arm, suggesting randomization was successful (see Table 1). Over 80% of the sample was admitted to the gynecology wards due to complications of abortion, and approximately 20% of those were abortion complications due to induced abortion.

Some characteristics of the women participating in the study varied by the Kumasi and Accra study sites. Mean age, mean years of education, proportion Christian, proportion in a monogamous marriage, and type of gynecological condition did not differ between the two study sites. In contrast, the mean number of live children was significantly higher in Kumasi as was illiteracy. Fewer people in Accra were in the lowest wealth quintile, while Kumasi had more ethnic Akans. Despite Accra being the capital and largest city in Ghana – ever used modern contraception was lower in Accra (31.9%) than in Kumasi (58.3%) (see Table 2).

#### *Primary outcome: Change in contraceptive use intentions*

##### Pre-Post Comparisons

At baseline, 84% in the individual study arm and 87% in the group study arm intended to use contraception, a non-significant difference between study arms (see Table 3). The proportion of the sample intending to use contraception after family planning counseling by study arm was 88% and 93% in the individual and group study arms, respectively. This was borderline significant ( $p = 0.08$ ), favoring group counseling, but this effect is attenuated after adjusting for site ( $p = 0.16$ ).

##### Within-Arm, Pre-Post Comparisons

The pre-post difference within the group study arm, before counseling (87%) and after counseling (93%) is significantly different ( $p = 0.01$ ) using McNemar's Test to test the difference in paired outcomes. Again this result suggests a larger increase in intention to use in the group counseling arm. However, this pre-post difference is not statistically significant when the model is adjusted for site.

##### Test of Noninferiority

To test our main hypothesis of noninferiority of group counseling, we compare the difference of the differences in intention to use contraception before and after counseling by study arm. The difference in intention to use contraception before and after family planning counseling was 4.6% in the individual arm. In the group arm, the difference in intention to use contraception before and after the intervention was 5.2%. The difference in the change between the two study arms, adjusted for study site, is 0.1%, (95% CI: -6.4 to 6.6). The 95% confidence interval includes zero and the lower bound (-6.4) is greater than our a priori margin of noninferiority (-10), thus, demonstrating that group family planning counseling is noninferior to individual family planning counseling (see Figure 5.3).

In the per protocol analysis, similar conclusions can be drawn to the intent-to-treat analysis conclusions generating additional confidence in the study findings. There is a greater increase in intention to use family planning in the group counseling study arm, but this difference is not statistically significant in comparison to the individual study arm (see Table 3).



*Secondary outcomes: Knowledge of contraceptive methods and method choice*

At baseline, the mean number of modern contraceptive methods known in the total sample was 2 prior to the family planning counseling intervention. In each randomized study arm, the mean number of modern methods known at baseline was also 2, suggesting no difference by study arm in knowledge of modern methods at baseline by study arm. The mean number of modern contraceptive methods known at follow-up was 6 for the total study sample, as well as for each study arm.

The data show that the intervention increased knowledge for women who received either individual or group counseling. The increase in modern contraceptive methods known from baseline to follow-up in the individual study arm is 4.07 methods (95% CI: 3.82 to 4.33). In the group study arm, the increase in modern methods known is 3.86 methods (95% CI: 3.60 to 4.13). The difference between the two study arms (group – individual), adjusted for study site, is -0.21, (95% CI: -0.42 to 0.17). This difference is not significantly different from zero, indicating that group counseling is just as good (noninferior) to individual family planning counseling in increasing knowledge of modern contraceptive methods (see Table 4).

Similar findings in regards to the modern method knowledge occur in the per protocol analysis as did in the intent-to-treat analysis. There is no statistical difference between the two study arms in the change in modern family planning methods known comparing the period before and after the family planning intervention using either intent-to-treat or per protocol analyses (see Table 4).

Among the study participants indicating they intend to use a family planning method at follow-up (n=566), 51% (286/566) were in the individual study arm and 50%, (280/566) were in the group study arm. Nearly two-thirds of the sample intended to use pills or injectables. Oral contraceptive pills were the most common method chosen in both study arms, 32% and 35%, in the individual and group study arms, respectively. The second most common method chosen was injectables, 28% in the individual study arm and 29% in the group study arm. In the GDHS, oral contraceptive pills, injectables, and male condoms were the most commonly currently used contraceptive methods by all women (4%). In fact, implants were more frequently chosen than male condoms in this study, in contrast to the GDHS results (GSS et al. 2004). Female sterilization was the intended choice for more women in the group study arm, 4%, than in the individual arm, 2%. However, both implants (17% and 10%) and IUD (7% and 5%) were chosen with a greater frequency in the individual study arm as compared to the group arm. In fact, intention to use implant is the only method intention that significantly differed by study arm (as compared to all other methods). Implant and IUD current use in the GDHS was less than 1% for both methods; therefore, both implants and IUDs were intended for use at a higher rate in this study than were reported as currently used by the GHDS in the general population (GSS et al. 2004). Overall, only 7% of the study participants chose a traditional method, i.e., either periodic abstinence or withdrawal, slightly higher than the traditional method current use rate reported in the GDHS (GSS et al. 2004) (see Table 5).

## **DISCUSSION**

Our findings indicate that group family planning counseling is not inferior to individual family planning counseling within the margin of -10%. Gynecology patients in the group study arm and the individual study arm did not differ in change in intention to use contraception after family planning counseling. In both study arms, more women intended to use contraception after family planning counseling than had intended prior to family planning counseling. The increase in intention was not large; the ability to increase the proportion intending to use contraception was hampered by the high intention to use family planning at baseline. The intention to use family planning at baseline in this study was much higher than the intention reported in the 2003 GDHS, 85% vs. 54% (GSS et al. 2004). This difference is not surprising given the fact that the majority of women in our sample had a traumatic pregnancy experience, have an unmet need for family planning, and are highly motivated to avoid a repeat unintended pregnancy as compared to a nationally representative sample of women.

We also found a significant increase in knowledge of family planning methods when comparing knowledge before and after counseling. The change in knowledge score was not significantly different by study arm. Thus, these findings provide additional support for our hypothesis, that group family planning counseling is not inferior to individual family planning counseling. The findings also demonstrate the usefulness of gynecology ward family planning counseling on increasing modern contraceptive method knowledge more broadly.

Despite family planning efforts around the world, there remains a need for effective family planning as evidenced by the number of women seeking unsafe abortions globally. Interventions that improve the efficiency of family planning counseling may increase the impact of family planning interventions. Gynecology patients are a critical target population for family planning interventions because they have a high probability of unmet need. Research in other sub-Saharan African countries has shown that postabortion patients at tertiary institutions are less likely to receive family planning information due to the high patient caseload (Kinoti, Gaffikin, and Benson 2004). This study utilizes the local resources by intervening with admitted patients at the hospital with local hospital staff, family planning nurses. This study capitalizes on the fact that many patients have similar levels of knowledge about family planning and can be counseled effectively in groups. Finally, a strength of this intervention is that it is a randomized control trial, the gold standard of study designs.

Noninferiority trials are commonly used for drug trials; they are less commonly used for behavioral interventions (Piaggio et al. 2006). Here, we chose to use a noninferiority trial design based on a multitude of factors including (1) the extreme need for family planning among gynecology patients in Ghana – not only unsafe abortion complication patients,

(2) the level of burden on family planning nurses to provide counseling to significantly more patients than they can, thereby creating a situation of ‘missed opportunities’, and (3) to conduct meaningful research that could be easily translated into practice - a sustainable solution to meet the immediate, and potentially life saving, needs among both the gynecology patients and hospital-based family planning nurses in Ghana.

The main limitation in this study was the lack of family planning service provision. In the postabortion care model, the second element of postabortion care is family planning counseling and service provision. Provision of family planning methods was not possible in this study. The family planning nurses do not provide the patients with contraception; the nurses believe the patients cannot start using contraception until they have had a few weeks to recover – ideally beginning use after their follow-up appointment two weeks following the procedure. Prior research has shown that few postabortion patients return for follow-up appointments (Grimes et al. 2004; Langer et al. 1997). The belief that contraception is not safe to start immediately after postabortion treatment is not supported in the research (WHO 1993, 2003). Specifically, IUD (Grimes et al. 2004; Moussa 2001; Stanwood, Grimes, and Schulz 2001), barrier<sup>1</sup>, or hormonal methods (WHO 1993, 2003) – can all be safely initiated immediately following treatment and prior to the woman’s departure from the health facility. Immediate family planning initiation will likely benefit postabortion patients who have a low probability of returning for services and whose fertility may return quickly -- within two weeks of the abortion<sup>2</sup>. We do not know the extent of provider misconceptions in other service areas within Ghana. Research on postabortion care provider misconceptions, and interventions designed to overcome this barrier in family planning service provision, are both urgently needed.

Intention to use family planning in this study serves as an indication of future contraceptive use. It would have been ideal to have a three month, or longer, follow-up with the study participants to determine whether patients were successful in realizing their contraceptive use intentions as has been demonstrated in other research among postabortion patients (Rasch et al. 2008). Intention to use family planning has been associated with future contraceptive use in the general population in Morocco (Curtis and Westoff 1996), and with current contraceptive use in Venezuela and Kenya (Kar and Talbot 1980). As Kar and Talbot (1980) explain, contraceptive use intentions are more likely to be realized in societies where contraceptive use is the norm. This may explain the low realization of contraceptive use based on prior intentions more than twenty years ago in Bangladesh (Bhatia 1982). In Ghana, contraceptive use is not the norm, demonstrated by the low contraceptive prevalence rate; therefore, the family planning use intentions of the women in this study are less likely to be realized than would be the intentions of women in a society where family planning use is socially accepted.

Generalizability is limited here to admitted gynecology patients. Not all women with abortion complications make it to the hospital for treatment or need care. In addition, the

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<sup>1</sup> IUD insertions after a second trimester abortion carry greater risk of expulsion. Diaphragms and cervical caps should not be fitted until six weeks after a second trimester abortion. Ovulation dependent natural family planning methods should not be used until after three cycles.

<sup>2</sup> The quick return of fertility, within two weeks, is following a first trimester abortion.

availability of legal abortion measures makes our sample less broadly generalizable to postabortion care patients in settings with restrictive abortion laws. However, it has been recognized that in any setting, regardless of the abortion law, affluent women society are able to access safe abortion services while the poor women must rely on unsafe abortion (AGI 1999).

There is a global need to improve family planning counseling and use to prevent unwanted pregnancies. The number of unwanted births every year and the number of women resorting to unsafe abortions validate the need for finding appropriate interventions capable of increasing family planning use. In particular, the need for increased family planning use in Ghana is marked. Women in this setting resort to drastic measures to terminate an unwanted pregnancy – it is a public health priority to make safe, preventive methods available to all women in Ghana, not just the wealthy, before they risk their health and survival repeatedly.

Postabortion care has been shown to have a positive effect on abortion complication patients in terms of satisfaction with services (Melkamu et al. 2005) and contraceptive use (Abdel-Tawab et al. 1999; Billings et al. 2003; Farfan et al 1997; Huntington et al. 1995; Johnson et al. 2002; Langer et al. 1997; Lema and Mpanga 2000; Rasch et al. 2004, 2005, 2008; Solo et al. 1999). Gynecology patients will benefit greatly from the opportunity to interact with family planning nurses and receive counseling from them. As it is now, in resource poor settings there is more demand for family planning counseling on gynecology wards than can be met (Kinoti et al. 2004). By using the few resources in the most efficient way possible, such as utilizing group counseling sessions, those resources can have a greater effect on reducing the number of unintended pregnancies, and the resulting negative sequelae.

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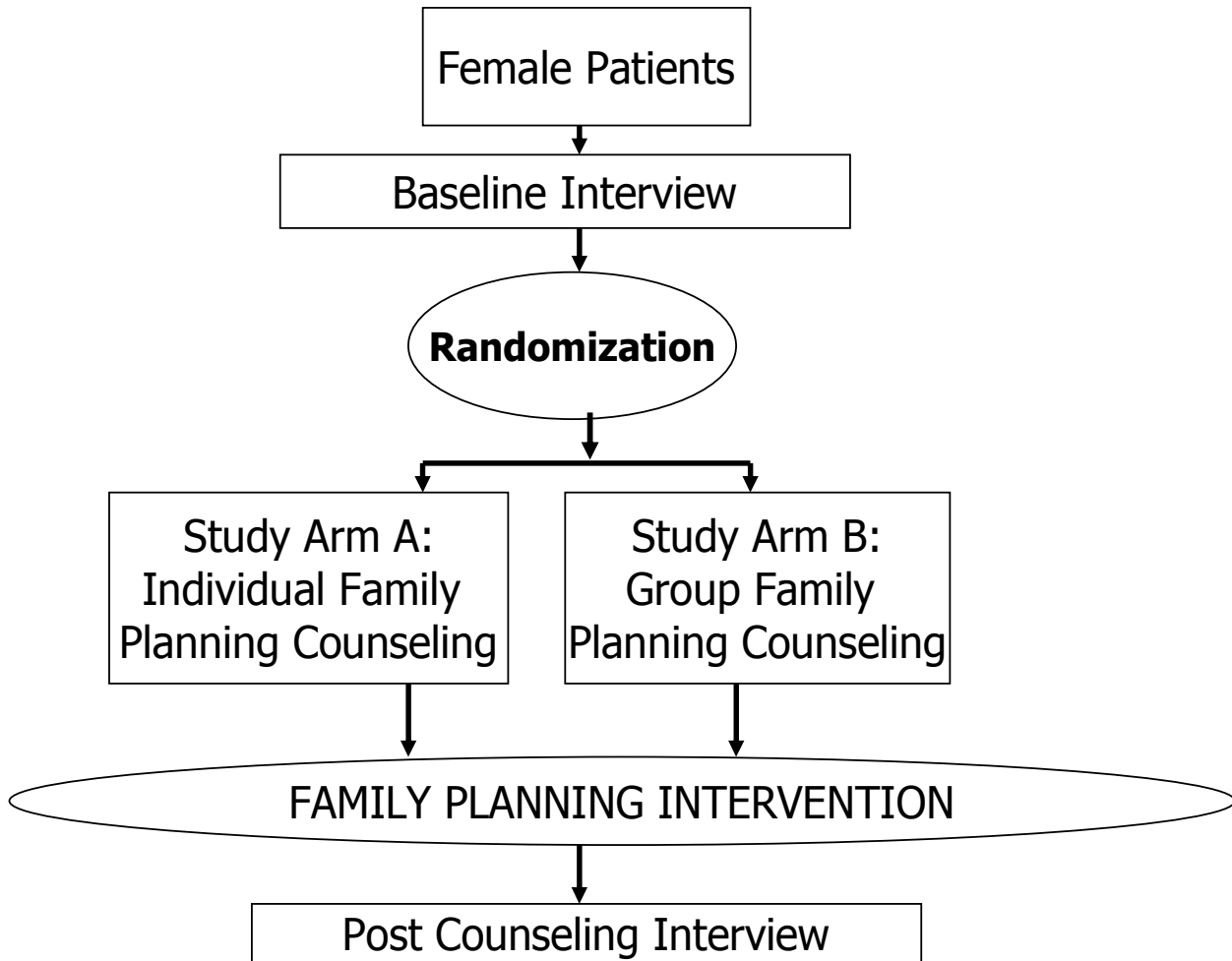
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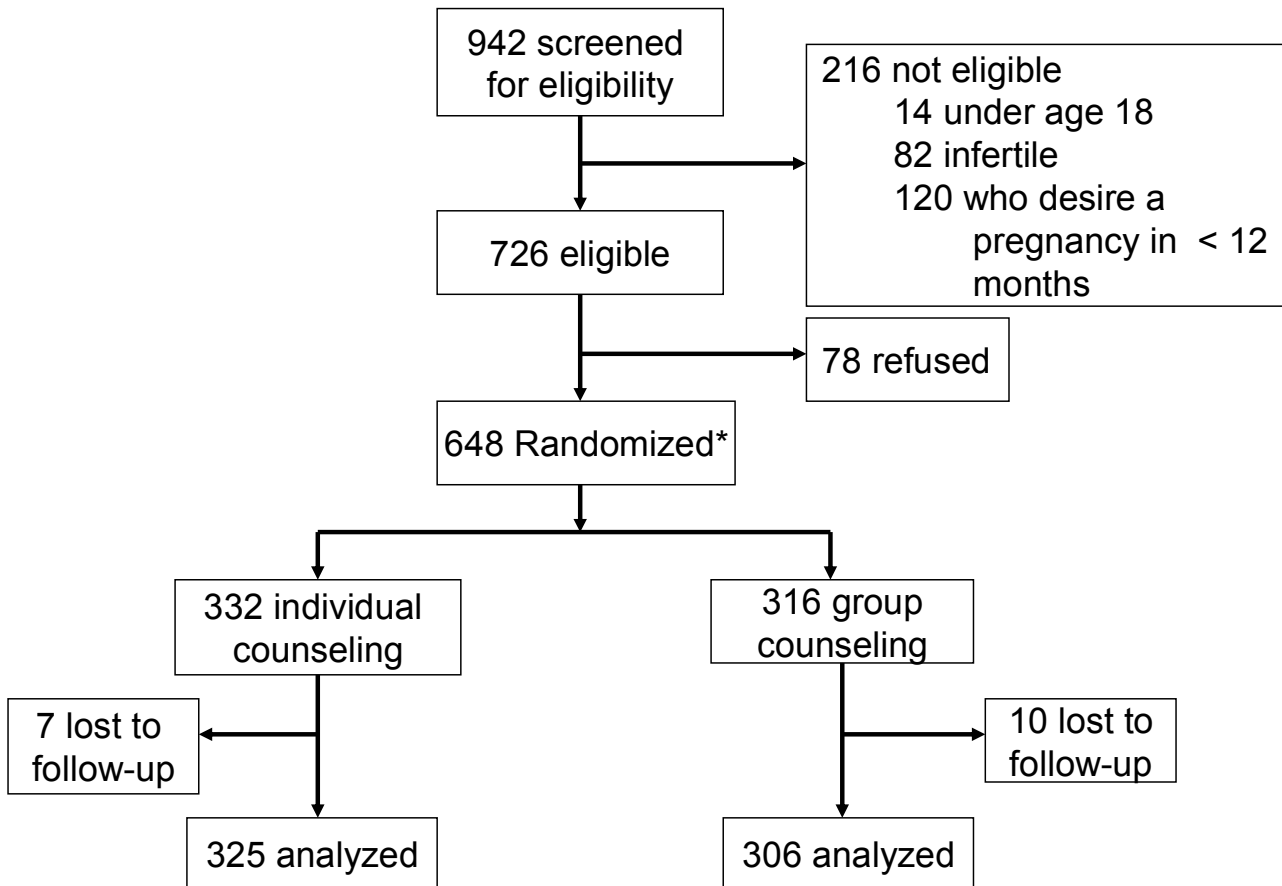
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**Figure 5.1. Group versus Individual Family Planning Counseling Randomized, Noninferiority Control Trial Study Design**



**Figure 5.2. Group versus Individual Family Planning Counseling Randomized, Noninferiority Control Trial Flow Diagram**



\*Randomization was by day

**Table 5.1. Characteristics of gynecology patients randomized to group or family planning counseling, by study arm in an experimental study at 2 teaching hospitals, Kumasi and Accra Ghana**

Characteristic	Individual (n = 325)		Group (n = 306)		Total (n = 631)	
		SD		SD		SD
Age, mean years range (18-55)	28.2	6.4	27.8	6.3	28.0	6.4
Live Children, mean number range (0-8)	1.4	1.5	1.4	1.5	1.4	1.5
% Literate	60.0		53.9		57.1	
Years of Education, mean years range (0-25)	8.0	5.1	8.2	4.8	8.1	5.0
% in Lowest Wealth Quintile	19.7		19.9		19.8	
% Christian	89.2		85.6		87.5	
% Akan	63.4		62.1		62.8	
% in Monogamous Marriage	56.0		54.6		55.3	
Type of Gynecological Condition						
% Induced Abortion	16.6		15.0		15.9	
% Spontaneous Abortion	65.2		69.9		67.5	
% Ectopic	7.4		7.2		7.3	
% Other	10.8		7.8		9.4	
% Ever used Modern Family Planning	42.5		45.1		43.7	

P-values are a test for mean or proportion differences between study arms

\*p<0.05; \*\*p<0.01; \*\*\*p<0.001

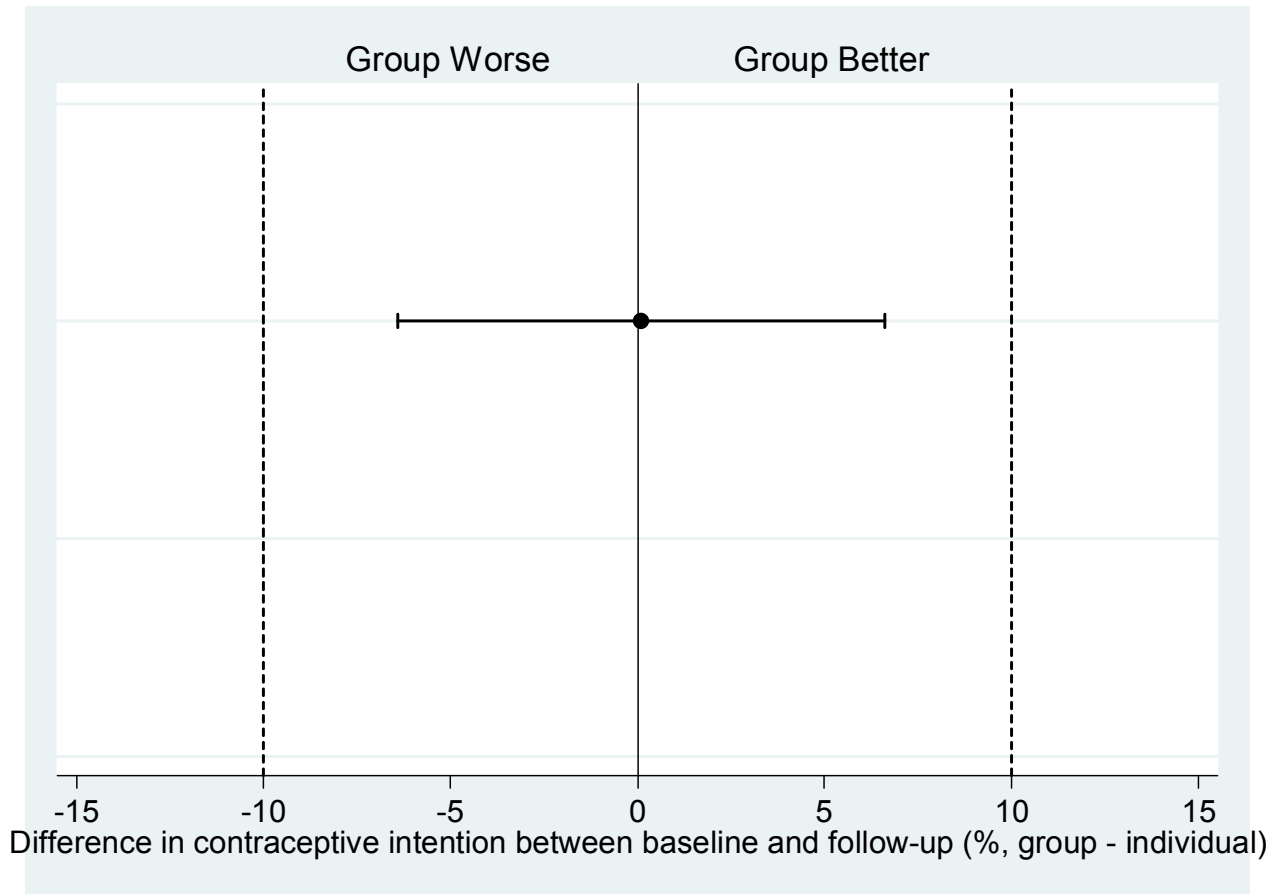
**Table 5.2. Characteristics of gynecology patients randomized to group or family planning counseling, by study site in an experimental study at 2 teaching hospitals, Kumasi and Accra Ghana**

Characteristic	Kumasi (n = 283)		Accra (n = 348)		Total (n = 631)	
		SD		SD		SD
Age, mean years range (18-55)	27.9	6.4	28.1	6.4	28.0	6.4
Live Children, mean number range (0-8)***	1.6	1.6	1.2	1.4	1.4	1.5
% Literate**	50.9		62.1		57.1	
Years of Education, mean years range (0-25)	8.0	4.3	8.2	5.5	8.1	5.0
% in Lowest Wealth Quintile***	26.9		14.1		19.8	
% Christian	86.9		87.9		87.5	
% Akan***	76.3		51.7		62.8	
% in Monogamous Marriage	56.9		54.0		55.3	
Type of Gynecological Condition						
% Induced Abortion	15.2		16.4		15.9	
% Spontaneous Abortion	70.0		65.5		67.5	
% Ectopic	7.1		7.5		7.3	
% Other	7.8		10.6		9.4	
% Ever used Modern Family Planning***	58.3		31.9		43.7	

P-values are a test for mean or proportion differences between study sites

\*p<0.05; \*\*p<0.01; \*\*\*p<0.001

**Figure 5.3**



**Table 5.3. Intention to use family planning at baseline and follow-up among gynecology patients randomized to group or individual counseling, by study arm and overall in an experimental study at 2 teaching hospitals, Kumasi and Accra Ghana**

	<b>Total</b>	<b>Individual</b>	<b>Group</b>	<b>P-value Group vs. Individual</b>	<b>P-value* Group vs. Individual</b>
<b>Intention to Use Family Planning</b>					
<b>Intent to Treat</b>					
<b>n</b>	631	325	306		
Baseline	85.4	83.7	87.3	0.205	0.251
Follow-up	90.3	88.3	92.5	0.076	0.156
<b>P-value: Follow-up vs Baseline</b>	0.003	0.071	0.011		
	4.91	4.62	5.23		
<b>Difference (95% CI)</b>	(1.68-8.14)	(-0.40-9.63)	(1.20-9.26)		
<b>Difference in the Differences (95% CI)*</b>	<b>0.10</b> <b>(-6.42-6.62)</b>				
<b>Per Protocol</b>					
<b>n</b>	574	308	266		
Baseline	86.4	84.7	88.4	0.209	0.267
Follow-up	90.6	88.0	93.6	0.021	0.057
<b>P-value: Follow-up vs Baseline</b>	0.014	0.211	0.020		
	4.18	3.25	5.26		
<b>Difference (95% CI)</b>	(0.84-7.52)	(-1.86-8.35)	(1.12-9.41)		
<b>Difference in the Differences (95% CI)*</b>	<b>1.47</b> <b>(-5.29-8.24)</b>				

\*Adjusted for site

**Table 5.4. Spontaneous knowledge of modern contraceptives at baseline and follow-up among gynecology patients randomized to group or individual counseling, by study arm and overall in an experimental study at 2 teaching hospitals, Kumasi and Accra Ghana**

	<b>Total</b>	<b>Individual</b>	<b>Group</b>	<b>P-value Group vs. Individual</b>	<b>P-value* Group vs. Individual</b>
<b>Mean number of modern methods known</b>					
<b>Intent to Treat</b>	(SD)	(SD)	(SD)		
<b>n</b>	631	325	306		
Baseline	2.12 (2.09)	2.02 (2.11)	2.23 (2.07)	0.201	0.233
Follow-up	6.09 (1.98)	6.09 (1.96)	6.09 (2.01)	0.989	0.710
<b>P-value: Follow-up vs Baseline</b>	0.000	0.000	0.000		
	3.97	4.07	3.86		
<b>Difference (95% CI)</b>	(3.79-4.16)	(3.82-4.33)	(3.60-4.13)		
<b>Difference in the Differences (95% CI)*</b>	<b>-0.12</b> <b>(-0.42-0.17)</b>				
<b>Per Protocol</b>					
<b>n</b>	574	308	266		
Baseline	2.12 (2.05)	2.01 (2.06)	2.25 (2.04)	0.159	0.157
Follow-up	6.12 (1.95)	6.13 (1.91)	6.11 (2.00)	0.899	0.649
<b>P-value: Follow-up vs Baseline</b>	0.000	0.000	0.000		
	4.00	4.12	3.86		
<b>Difference (95% CI)</b>	(3.80-4.19)	(3.86-4.38)	(3.57-4.15)		
<b>Difference in the Differences (95% CI)</b>	<b>-0.15</b> <b>(-0.45-0.16)</b>				

\*Adjusted for site

**Table 5.5. Contraceptive method type use intention at follow-up among gynecology patients randomized to group or individual counseling, by study arm and overall in an experimental study at 2 teaching hospitals, Kumasi and Accra Ghana**

	Individual (n = 286)	Group (n = 280)	Total (n = 566)
<b>Method Chosen</b>	%	%	%
Female Sterilization	1.8	4.3	3.0
Male Sterilization	0.4	0.0	0.2
Pill	32.2	35.0	33.6
IUD	7.0	5.0	6.0
Injectable	28.0	28.9	28.5
Implant*	16.8	10.4	13.6
Male Condom	5.9	7.9	6.9
Female Condom	1.4	1.1	1.2
Diaphragm	0.4	0.0	0.2
Jelly/Foam	0.0	0.4	0.2
Periodic Abstinence	5.2	5.7	5.5
Withdrawal	1.1	1.4	1.2

p-values are a test of proportion intending to use method vs. all other methods

\*p<0.05; \*\*p<0.01; \*\*\*p<0.001