

# Strategies to improve adherence and acceptability of hormonal methods for contraception (Review)

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## ABSTRACT

### Background

Worldwide, hormonal contraceptives are among the most popular reversible contraceptives in current use. Despite their high theoretical effectiveness, typical use results in much lower effectiveness. In large part, this disparity reflects difficulties in adherence to the contraceptive regimen and low rates for long-term continuation.

### Objectives

To determine the effectiveness of ancillary techniques to improve adherence to, and continuation rates of, hormonal methods of contraception.

### Search strategy

We searched computerized databases for randomized controlled trials (RCTs) comparing client-provider interventions with standard family planning counseling. Sources included CENTRAL, MEDLINE, EMBASE, POPLINE, LILACS, and PsycINFO.

### Selection criteria

Randomized controlled trials (RCTs) of an intensive counseling technique or client-provider intervention versus routine family planning counseling. Interventions included group motivation; structured, peer, or multi-component counseling; and intensive reminders of appointments. Outcome measures were discontinuation, reasons for discontinuation, number of missed pills and on-time injections, and pregnancy.

### Data collection and analysis

The primary author evaluated all titles and abstracts from the searches to determine eligibility. Two authors independently extracted data from the included studies. With RevMan 4.2, we calculated the odds ratio for all dichotomous outcomes and the weighted mean difference for continuous data. The studies were so different that we could not conduct a meta-analysis.

### Main results

We found six RCTs; only one showed a statistically significant benefit of the experimental intervention. In that trial, women who received repeated, structured information about the injectable contraceptive depo-medroxyprogesterone acetate (DMPA) were less likely to have discontinued the method by 12 months (OR 0.27; 95% CI 0.16 to 0.44) than were women who had routine counseling. The intervention group was also less likely to discontinue due to menstrual disturbances. In another study, the intervention group was less likely to discontinue due to dissatisfaction with the contraceptive method, but overall continuation was not affected.

### Authors' conclusions

Most studies to date have shown no benefit of strategies to improve adherence and continuation. These trials have important limitations, however. Two had small sample sizes, several had high losses to follow-up, and the intervention and its intensity varied across the studies. High-quality research is a priority, since adherence and continuation are fundamentally important to the successful use of hormonal contraceptives.

## PLAIN LANGUAGE SUMMARY

### Strategies to improve use of hormonal contraception

Worldwide, hormonal contraceptives are among the most popular reversible contraceptives in current use. Despite their high potential for effectiveness, typical use results in much lower effectiveness. In large part, this difference reflects problems in following the contraceptive regimen and low rates for continuing. The intent of this review was to determine if enhanced counseling improved adherence to, and continuation of, hormonal methods of contraception. Randomized controlled trials were examined for ways to help women use hormonal contraceptives. Quality varied among the six trials found. Some studies had small numbers of participants and several had high losses to follow-up. Only one trial of structured counseling found a significant benefit. Women who received repeated, structured information were more likely to continue with an injectable contraceptive one year later than the women who had routine counseling. Also, the women who had structured counselling were less likely to stop using the contraceptive due to menstrual changes.

To prevent unintended pregnancies, following and continuing the contraceptive regimen are both important. More trials of good quality and different designs are needed to judge whether enhanced counseling makes a difference in contraceptive use.

## BACKGROUND

Worldwide, hormonal contraceptives are among the most popular reversible methods of family planning. In the late 1990s, about 14% of married women in more-developed countries were using oral contraceptives. In less-developed countries, this figure was 6% (PRB 2002). An injectable depo-medroxyprogesterone acetate (DMPA) is used by an estimated 3.5 million women worldwide including more than 3% of women in the U.S (Lei 1996; Mosher 2004). This translates into tens of millions of women using hormonal contraceptives.

Despite high theoretical effectiveness of hormonal methods, typical use has less favorable results. For example, in the U.S., the first-year failure rate for typical use of oral contraceptives is about 8%, whereas it is only 0.3% for perfect use (Fu 1999; Trussell 2004). The wide gap between theoretical and actual effectiveness is attributed to human factors. Several types of hormonal contraceptives depend on adherence to the regimen, which is often called 'compliance' in the medical literature. Repetitive and correct use by the woman is critical for successful use of the combined oral contraceptives (COCs), progestin-only pills, the patch, the vaginal ring, and injectable contraceptives. In contrast, the effectiveness of other hormonal contraceptives including the levonorgestrel intrauterine system and subdermal delivery systems, depend less on remembering to use them. In those cases, continuation, rather than adherence to the regimen, determines success.

Hormonal contraceptives in general are characterized by both poor adherence and relatively high discontinuation rates. The latter is mainly due to the hormonal side effects (Davie 1996; Lei 1996). Nearly half of COC users miss one or more pills each month, and more than a fifth miss two or more (Rosenberg 1998). Difficulties in correct pill-taking may lead to discontinuation and to unintended pregnancy. An estimated 32% of new COC users discontinue the method in the first year of use (Schwartz 2002). Unintended pregnancies related to COC use are estimated to account

for 20% of the 3.5 million annual unintended pregnancies in the U.S. (Rosenberg 1995; Rosenberg 1999). The cumulative discontinuation figures for levonorgestrel subdermal implants range from 10% to 13% at one year to 28% at two years (Fleming 1998; Glasier 2002). The existing data vary greatly on discontinuation for DMPA injections, with some studies reporting discontinuation as high as 70% at six months of use (Lim 1999).

An 'ideal' contraceptive would be characterized by easy use, minimal side effects, excellent tolerability, and high continuation rates. The search for such a contraceptive led to the introduction of low-dose pills and combined injectables, as well as new contraceptive delivery systems, such as the skin patch, hormone-releasing intrauterine system, and intravaginal ring. Low-dose contraceptives were developed over a twenty-year period and have less estrogen than their predecessors. The estrogen reduction was intended to lower risk of adverse health events while combining estrogen and progesterone to maintain efficacy (Gallo 2005). Combined injectable contraceptives contain a progestin plus an estrogen. They were developed to address negative side effects of progestin-only formulations (Hatcher 2004). However, the new methods have not been associated with substantial improvement in contraceptive continuation or adherence. Indeed, COCs containing 20 µg of ethinyl estradiol had higher discontinuation rates, which were related to more irregular bleeding (Gallo 2005). Continuation for the combined injectable DMPA and estradiol cypionate at the end of the first year has been reported to be 52% (Hall 1997). About 15% of treatment cycles while using the vaginal ring were not consistent with the dosing regimen (Dieben 2002). The women had ring-free time periods that were longer, shorter, or more frequent than recommended. During the first year of use, at least 25% of women discontinue the levonorgestrel intrauterine system, which has been described as being close to an 'ideal contraceptive' (Diaz 2000).

The fact that even close to ideal methods are characterized by far from ideal adherence or continuation leads to a conclusion that

contraceptive continuation may depend on other factors besides individual characteristics of the method and willingness or ability of the woman to follow the contraceptive regimen. The quality of family planning services is an important factor that may affect contraceptive acceptability and continuation. According to Blanc 2002, within the first year of starting a method, 7% to 27% of women stop using contraception for reasons that could be addressed during family planning counseling, including side effects and health concerns related to the contraceptive method. Quality of services is defined by provider skills, quality of information provided, client-provider interactions, and continuity of care (ARHP 2004; Blanc 2002; Jain 1989). Recent reviews have emphasized an individualized approach in family planning services focused on individual needs assessment and interpersonal relations between the consumer and the provider (ARHP 2004; Rudy 2003).

An important component of family planning service is to provide the client with objective and harmonized information about contraceptive methods. Various counseling interventions are aimed to cover knowledge gaps about correct contraceptive use (Little 1998) and typical side effects (Blanc 2002), in order to improve the woman's understanding of the method and the consequences of inaccurate use. The available data demonstrate a positive impact of counseling on contraceptive knowledge and use. A Canadian survey indicated that women who had counseling also had more accurate responses on the majority of questions about OC use, benefits, and side effects (Gaudet 2004). According to Jain 1989, client-provider relations and information provided can affect contraceptive acceptability and continuation.

This systematic review examined the hypothesis that advanced counseling techniques or other client-provider interventions could increase adherence to, and continuation of, hormonal contraceptives.

## OBJECTIVES

The intent was to determine the effectiveness of ancillary counseling techniques to improve adherence to, and continuation of, client-dependent hormonal methods of contraception.

## CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW

### Types of studies

Eligible studies were all randomized controlled trials of one or more intensive counseling techniques or other client-provider interventions (any type) versus routine family planning counseling approaches for the improvement of adherence and continuation.

### Types of participants

Eligible participants were women of reproductive age without medical contraindications to hormonal methods of contraception.

### Types of intervention

Eligible interventions were client-provider interventions such as group motivation; structured, peer or multi-component counseling; and intensive reminders of follow-up appointments. These were designed to facilitate the use of hormonal methods of contraception and compared to routine methods of family planning counseling.

### Types of outcome measures

Outcome measures included discontinuation, reasons for discontinuation, number of missed pills, number of on-time injections, and pregnancy.

## SEARCH METHODS FOR IDENTIFICATION OF STUDIES

See: methods used in reviews.

We searched the following computerized databases for randomized controlled trials (RCTs) comparing client-provider interventions with standard family planning counseling: Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE using PubMed, EMBASE, POPLINE, LILACS, PsycINFO, Dissertation Abstracts Online, African Index Medicus, IMEMR, and IMSEAR.

Our CENTRAL search used the strategy: counseling AND compliance AND acceptability AND continuation AND discontinuation.

We searched MEDLINE via PubMed with the recommended Cochrane search strategy revised for PubMed searches (Robinson 2002):

((randomized controlled trial [pt] OR controlled clinical trial [pt] OR randomized controlled trials [mh] OR random allocation [mh] OR double-blind method [mh] OR single-blind method [mh] OR clinical trial [pt] OR clinical trials [mh] OR ("clinical trial" [tw]) OR ((singl\* [tw] OR doubl\* [tw] OR trebl\* [tw] OR tripl\* [tw]) AND (mask\* [tw] OR blind\* [tw])) OR ("latin square" [tw]) OR placebos [mh] OR placebo\* [tw] OR random\* [tw] OR research design [mh:noexp] OR comparative study [mh] OR evaluation studies [mh] OR follow-up studies [mh] OR prospective studies [mh] OR control\* [tw] OR prospective\* [tw] OR volunteer\* [tw]) NOT (animal [mh] NOT human [mh])) AND (counseling[title/abstract word] OR "intensive reminders"[title/abstract word] OR "peer counseling"[title/abstract word] OR "structured counseling"[title/abstract word]) AND (compliance[title/abstract word] OR discontinuation[title/abstract word] OR continuation[title/abstract word] OR acceptability[title/abstract

word]) AND ((depot medroxyprogesterone acetate[title/abstract word] OR contraceptives, oral[MeSH]) OR NORPLANT[title/abstract word] OR implants[title/abstract word] OR “contraceptives, injectable”[title/abstract word] OR “vaginal ring”[title/abstract word] OR “NET-EN”[title/abstract word] OR “Mesigyna”[title/abstract word] OR Cyclofem[title/abstract word] OR “levonorgestrel-releasing intrauterine system”[title/abstract word] OR “transdermal contraceptive patch”[title/abstract word])

Our POPLINE search used the strategy:  
counseling & (compliance/ adherence/ acceptability/ discontinuation/ continuation) & (oral contraceptives/ Depot medroxyprogesterone acetate/ NORPLANT/ implants/ injectable contraceptives/ vaginal ring/ NET-EN/ Mesigyna/ Cyclofem/ levonorgestrel-releasing intrauterine system/ transdermal contraceptive patch) & (compar\*/ clinical trials/ comparative studies/ random/ double-blind studies)

Our EMBASE, PsycINFO and Dissertation Abstracts Online searches used the strategy:  
counseling AND (compliance OR user(w)compliance OR acceptability OR acceptors OR acceptance OR discontinuation OR continuation OR adherence) AND(Norplant OR ((implant OR implants OR injectable OR injectables OR drug implant OR drug injection) AND hormonal contraception) OR oral contraceptive agent OR medroxyprogesterone(w)acetate OR vaginal(w)ring OR contraceptive(w)patch OR (levonorgestrel AND (IUD OR IUS OR intrauterine device OR intrauterine(w)system))

Our African Index Medicus search used the strategy:  
(Counseling or counselling or reminders) NOT (AIDS or HIV)

Our LILACS search used the strategy:  
Counseling OR intensive reminders OR “peer counseling” OR “structured counseling” [Words] and Compliance OR discontinuation OR continuation OR acceptability OR patient acceptance of health care [Words]

Our IMEMR search used the strategy:  
counseling or reminders.

Our IMSEAR search used the strategy:  
(counseling or intensive reminders or peer counseling or structured counseling) and (hormonal contraception or hormonal contraceptive agent).

We wrote to the first authors of identified and included studies to request additional information about the study, as well as information about published or unpublished trials not discovered in our search. We reviewed the reference lists of identified articles and wrote to the experts in the field to seek trials we might have missed. We unsuccessfully attempted to locate and contact the authors of two unpublished randomized trials for more information about their studies.

## METHODS OF THE REVIEW

The primary author evaluated all titles and abstracts located in the literature searches to determine whether they met the inclusion criteria. We assessed the methodological quality of the trials using the Cochrane guidelines (Alderson 2004). We focused on the method of randomization; the number of women randomized, excluded, or lost to follow-up; and the use of allocation concealment and blinding.

Two authors independently extracted data from the studies identified for inclusion to increase accuracy. We used RevMan 4.2 for data entry and analysis. We calculated the odds ratio (OR) for all dichotomous outcomes and the weighted mean difference (WMD) for continuous data. For all data, 95% confidence intervals (CI) were also computed. Since the studies identified were so different in both exposures and outcomes, we did not conduct a meta-analysis.

## DESCRIPTION OF STUDIES

Six RCTs were identified during the search and met the criteria for inclusion in the review (Andolsek 1982; Burnhill 1985; Canto De Cetina 2001; Gilliam 2004; Jay 1984; Keder 1998).

Andolsek 1982 examined the effect of counseling by group motivation on contraceptive choice, length of use, and reason for discontinuation at six months. From 1030 women obtaining services at a university hospital in Slovenia (former Yugoslavia), 503 women were chosen at random for the group-motivation arm. Of the original 1030 women, 600 had an induced abortion a month earlier, while 430 came primarily for contraceptive advice. Group motivation was facilitated by five specially-trained nurses. They explained in a simple 30- to 60-minute lecture, using audiovisual aids, about genital tract anatomy and physiology, the physiology of conception, and general family planning. They also explained in detail the advantages and disadvantages of the available contraceptive methods. The women in the control group received only brief information on the existing methods from their physician or nurse. Length of use was assessed with the six-month discontinuation rates, which included only women who ceased using the chosen method and not those lost to follow-up.

Burnhill 1985 investigated a peer-counseling intervention with a sample of 200 women at a university hospital in New Jersey (U.S.). These women were requesting elective abortion, and they were at high-risk of repeat unplanned pregnancy. The participants were randomly assigned to either the control or the experimental group. The experimental group had five counseling sessions, which included an individual 45-minute session at intake, a one-hour private contraceptive-education session before the pre-admission physical exam, supportive counseling during the hospital stay, a telephone call one week after the procedure, and an hour-

long counseling session at the two-week follow-up appointment. Counselors were women from 22 to 32 years of age, who had some peer-counseling experience and who had undergone elective abortion themselves. The control intervention consisted of three brief contacts for data collection purposes without extended participant counseling. These contacts were at the pre-abortion visit for the physical exam, during a brief post-operative visit to discharge the participant from the hospital, and at the two-week follow-up exam. After the two-week follow-up visit, both groups were contacted every three months for data collection. The authors evaluated the choice of more effective method of contraception, early initiation of the use of oral contraceptives following abortion, pregnancy, and continuation of contraceptive use 15 months after abortion.

Canto De Cetina 2001 compared structured counseling with routine counseling to improve adherence in women receiving DMPA for contraception. The study enrolled 350 women at a family planning clinic in Merida, Yucatan (Mexico), who voluntarily chose DMPA for contraception. The participants were randomized to receive either structured or routine counseling (175 women per group). Structured pre-treatment counseling was provided through a uniform set of audiovisual messages on risks, benefits, and overall characteristics of the injectable contraceptive. The information included the mode of action of DMPA and common side effects, such as the irregular menstrual periods, heavy bleeding, spotting, and amenorrhea. The counseling emphasized that the potential side effects would not be detrimental to the participant's health. These indications were repeated at each follow-up visit. Women were encouraged to return to the clinic for any DMPA-related concerns. Participants in the control group received routine information on the expected side effects of DMPA. The timing of follow-up visits coincided with the injection time, which was every three months for one year. The study assessed side effects, discontinuation at 12 months, and reasons for discontinuation. The cumulative discontinuation at 12 months included those lost to follow-up.

Gilliam 2004 studied an antepartum, multi-component intervention that included counseling, a videotape about oral contraceptives (OCs), and written material. It was compared with resident-physician counseling and aimed to increase adherence to OCs and to decrease repeat unplanned pregnancies in young women. Prior to hospital discharge, all participants received resident-physician counseling, which was typical postpartum care for this hospital in Chicago, Illinois (U.S.). Residents discussed how to take the pill and what to do if a pill is missed, as well as side effects and risks and benefits of OCs. All participants received three labeled pill packets with pill-taking instructions and phone numbers for 24-hour access to a physician if they had contraceptive questions. These procedures were identical for both the intervention and control group. In addition, women in the intervention group received one-on-one counseling by a nurse, watched a ten-minute videotape about OCs, and received six informational sheets about taking OCs. The information included how to take OCs, what to do if

a pill is missed, how OCs work, emergency contraception, risks and benefits of OCs, myths about OCs, and contact information for a nurse or physician if a question should arise. The nurse also reviewed all written educational material in detail. The study enrolled 43 women during their antepartum visits, but not all used OCs. There were 33 women who were randomized into one of the study groups, with 18 women to the intervention group and 15 to the control group. The study assessed adherence to OCs at one year through the following variables: still using OCs, switched to a different method, not using contraception, and pregnancy. Data were collected at the time of enrollment (between 34 weeks and term); immediately following the intervention (or resident-physician counseling); and at 6 weeks, 6 months, and 12 months postpartum. The follow-up visits were intended to complement routine clinical visits when possible.

Jay 1984 compared peer counseling with nurse counseling to improve adolescent adherence to COCs. From an adolescent gynecology clinic in Georgia (U.S.), there were 57 females who wanted to use COCs and agreed to participate in the study. They were randomly assigned to the peer-counselor or nurse-counselor group. All participants were followed up at one, two, and four months. Non-adherence was measured with a four-factor Guttman scale that consisted of whether the participant 1) became pregnant during the previous month, 2) missed her appointment, 3) reported missing three or more COCs during the month, and 4) had absence of urinary fluorescence at the follow-up. The latter is a method for monitoring the use of the prescribed COC and riboflavin pill (Silberstein 1966). The four-month loss rate included failing to keep the second rescheduled broken appointment or discontinuing the COC regimen.

In Keder 1998, a system of intensive reminders was compared to the regular written appointment cards to improve adherence to DMPA. The trial enrolled 250 women who selected DMPA for contraception while attending a hospital clinic in Pittsburgh, Pennsylvania (U.S.). All women were given a written appointment card for their next injection, which was scheduled for 12 weeks. The participants were randomized to either a no-reminder group that only got the standard written appointment card or to a reminder group that received mail and telephone reminders as well as the written appointment card. Women from the reminder group were sent a letter two weeks before each scheduled injection. Those who failed to keep their appointments were contacted by phone. This process was continued until they changed methods of contraception, were lost to follow-up, or the study ended. Women were followed for one year or a total of four additional injections after the initial selection of DMPA treatment. The trial evaluated the discontinuation at 12 months, degree of satisfaction among the groups, side effects, reasons for discontinuation, and the number of on-time injections. We combined those lost to follow-up and the discontinued participants to analyze discontinuation rates at 12 months. Participants who received their DMPA injections within 14 weeks of the prior injection were classified as 'on-time.'



## METHODOLOGICAL QUALITY

The results of four single-center RCTs of moderate quality were published in peer-review journals (Canto De Cetina 2001; Gilliam 2004; Jay 1984, Keder 1998). Randomization methods were specified in three of the trials. Keder 1998 used a computer-generated randomization list. Both Jay 1984 and Gilliam 2004 used computer-generated random numbers tables. Only Gilliam 2004 reported the method of allocation concealment.

Blinding of the participants was not feasible in three of the trials. Research team members were blinded to group participation in Gilliam 2004. The investigators and research team members of the Keder 1998 trial were not blinded. The urine samples for fluorescence in Jay 1984 were evaluated in a double-blind fashion by a panel of three independent observers. Whether blinding of investigators and evaluators of the study outcomes was maintained in Canto De Cetina 2001 is unclear.

Other quality issues were inclusion criteria, sample size, and clarity of interventions and outcomes. Two studies had small sample sizes (Gilliam 2004; Jay 1984). All four studies included data from all randomized participants in the analysis. The study interventions were clearly defined in all four trials. Inclusion/exclusion criteria were not specified in Jay 1984. Outcomes of all studies were clearly determined; the main outcome for all trials but one (Jay 1984) was discontinuation. Jay 1984 used a Guttman-type scale for non-adherence, which included pregnancy and reported use of contraceptives. Gilliam 2004 was the only trial with pregnancy as a specific outcome. However, Andolsek 1982 listed pregnancy as one of several reasons for discontinuation.

Loss to follow-up was the lowest in Canto De Cetina 2001 at 1% and 2% of the structured-counseling and routine-counseling groups, respectively. The reported loss to follow-up in Keder 1998 for the year-end interview was high, with 34% in the reminder group and 38% in the no-reminder group. Jay 1984 reported losses of 42% and 23% in the nurse-counselor and peer-counselor groups, respectively. The losses reportedly included both discontinuation and loss to follow-up. Gilliam 2004 had 11% lost to follow-up in the intervention group and 40% in the control group.

Jay 1984 reported that the participants were tested prior to randomization to ensure that the groups did not differ in the correlates with non-adherence or teen pregnancy. The authors also did not mention steps taken to conceal the allocation process. Thus, the quality of random assignment in the trial is unclear. The use of a biomarker to assess pill use strengthened the results of the trial, given the well-documented limitations of self-reported data to measure adherence among OC users (Potter 1996). However, this objective outcome was reported as part of a scale which included self-reported missed pills. Jay 1984 used regression to account for number of sexual partners, frequency of sexual activity, worry, and hopelessness. By controlling for these covariates, the estimates would no longer be based on randomized groups. How-

ever, the outcomes reported (and used in this review) appeared to be crude rather than adjusted measures, although the authors did not clearly specify.

Reports of two unpublished RCTs were also assessed for quality. One was conducted in Slovenia (former Yugoslavia) (Andolsek 1982) and the other was from New Jersey (U.S.) (Burnhill 1985). While Andolsek 1982 did not provide details on the method of randomization or allocation concealment, the study intervention and admission criteria were clearly defined. The authors did not report excluding participants after randomization or losing any participants to follow-up. The study evaluated the effect of group-motivation counseling on choice and continuation of oral contraceptives and non-hormonal methods of contraception, such as IUD and barrier methods. The results of the RCT conducted in New Jersey (Burnhill 1985) were obtained from an abstract in POPLINE and an unpublished report. No information was provided on the method of randomization or allocation concealment. Although the study attempted to evaluate pregnancy rates, its interpretation is limited since the total number of participants assessed for pregnancy was unclear. Also, the trial had high losses of about 83%. Thus, we did not include any quantitative results from the trial in this review.

## RESULTS

Canto De Cetina 2001 showed a statistically significant difference in discontinuation rates between the participants who received structured counseling and those who were given routine information about DMPA. The odds ratio for discontinuation at six months was 0.36 (95% CI 0.20 to 0.64), and at 12 months it was 0.27 (95% CI 0.16 to 0.44). Women in the structured-counseling group were less likely to discontinue the method due to menstrual disturbances (amenorrhea and irregular and heavy bleeding) than women in the routine-counseling group (OR 0.20; 95% CI 0.11 to 0.37). The two groups were similar for discontinuation rates due to other medical problems (pregnancy, weight gain, vomiting, dizziness, depression, and loss of libido). Loss to follow-up was low and similar for the two groups as well.

Gilliam 2004 did not find any significant differences between those in the multi-component intervention and the control group. The groups did not differ in the proportions that continued OC use at one year or those who switched the type of contraceptive used. Pregnancies were similar in the two groups. However, the power to detect differences was limited since the sample size was small. Loss to follow-up was lower in the intervention group (OR 0.19; 95% CI 0.03 to 1.13).

Jay 1984 showed no difference at four months between the adherence scores of the peer-counseling and nurse-counseling groups (for using oral contraceptives). The weighted mean difference was near zero. These appeared to be crude results (unadjusted for other

factors), although the report was not clear on this point. The losses at four months were similar for the two groups.

Keder 1998 found no statistically significant differences in method discontinuation at one year between the reminder and control groups. There were also no substantial differences between the two groups in on-time injections for those who continued DMPA or for the participants overall. Loss to follow-up was similar for the two groups.

The unpublished report of Andolsek 1982 showed no difference between the motivation and control groups in contraceptive-method discontinuation at six months. The authors did not report separately for those with and without hormonal contraceptives. Those in the motivation group were less likely to discontinue use due to dissatisfaction with the selected method (OR 0.61; 95% CI 0.38 to 0.98). The group-motivation and control groups did not differ in discontinuation due to side effects, unintended pregnancy, or other reasons that included physician advice, induced abortion preferred, no contraception needed, or failure to obtain the selected method.

## DISCUSSION

The few RCTs on this topic provided limited evidence on whether different counseling strategies improved adherence to, or continuation of, hormonal contraceptives. Only one trial showed that the experimental intervention improved overall continuation (Canto De Cetina 2001). The study also indicated the intervention group was less likely to discontinue due to menstrual disturbances. This suggests a benefit of pre-emptive counseling about contraceptive side effects, which often dominate women's decisions about family planning. In another trial (Andolsek 1982), the intervention group was less likely to discontinue due to dissatisfaction with the contraceptive method. This did not affect overall continuation, which was no different among the study groups. These results suggest that enhanced counseling, while having limited effect on contraceptive continuation, may change the reasons why women stop using contraception.

This review has several serious limitations that warrant more cautious interpretation of the results. All but one study (Canto De Cetina 2001) had high losses to follow-up, ranging from 11% to 42%. After randomization, losses to follow-up that exceed 20% of participants can jeopardize trial validity (Schulz 2002). Two studies had small sample sizes (Jay 1984; Gilliam 2004), which increased the likelihood of a Type II error.

In addition, the type and intensity of the experimental interventions varied across the studies. One study had multiple contacts for each group with different counselors (Jay 1984). Two studies had an enhanced educational intervention but it was limited to one contact (Andolsek 1982; Gilliam 2004). Another study used reminders and phone calls rather than a counseling intervention

(Keder 1998). The only study that showed a difference had multiple counseling contacts for the intervention group versus a single contact on side effects for the control group (Canto De Cetina 2001). This suggests that the nature as well as the intensity of the intervention may be associated with successful use of contraception.

Ascertainment bias may have arisen in two ways. First, assessment of subjective outcomes may have been influenced by the lack of treatment blinding. If present, however, it did not produce favorable results. Another important concern is the limited value of self-reported data for measuring continuation and consistency of contraceptive use (Potter 1996). Although three studies used some objective measures in addition to self-reports (one study had pregnancy as an outcome, one used urinary riboflavin as part of an adherence scale, and a third used percentages of on-time injections), the main conclusions of this review heavily depend on the self-reported data.

All the trials included in this review had randomized participants within the center. This method can lead to some 'contamination' across study groups, due to participants sharing information. Such sharing would reduce the likelihood of finding a difference between the groups.

The unknown external validity of the results is another limitation of this review: the individual study findings may be specific to the setting and not generalizable to other situations. The content and process of counseling interventions may be appropriate only for a local population or clinic and not be relevant universally, so effects may differ across groups and sites.

## AUTHORS' CONCLUSIONS

### Implications for practice

Good personal communication between clients and providers is generally considered important for successful use of hormonal contraception. However, little evidence from randomized controlled trials supports the hypothesis that enhanced counseling improves contraceptive use. Intensive counseling interventions with multiple contacts may be needed to improve adherence and acceptability of contraceptive use.

### Implications for research

The published trials are limited in both scope and quality. Small sample sizes and high losses to follow-up undermine trial quality and the outcome measures are often self-reports of unknown validity. A high-quality RCT with adequate power and a well-designed intervention may help to answer the question whether enhanced counseling is making a difference in continued and correct use of hormonal contraceptive methods. A trial with randomization at the clinic level or a non-randomized multi-center comparative study may provide additional information on this topic.

## POTENTIAL CONFLICT OF INTEREST

Dr. Grimes has consulted with or served on a speakers bureau for Berlex Laboratories, GynoPharma, Mead Johnson, Organon, Ortho-McNeil, Parke-Davis, Schering, Searle, and Wyeth-Ayerst.

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## TABLES

### Characteristics of included studies

Study	Andolsek 1982
Methods	Methods of randomization were not reported. One site at the Obstetrics and Gynecology Department of Ljubljana University, Slovenia (former Yugoslavia). Participants were followed for six months.
Participants	1030 women attending the Human Reproduction Unit. Women with contraindications for any type of contraception were excluded from the study.
Interventions	Group motivation counseling by specially trained medical nurses versus routine counseling by physician or nurse. Lecture and audiovisual presentation; one time.
Outcomes	Choice of contraceptive method, discontinuation rate at six months, reasons for discontinuation.
Notes	Six hundred women out of 1030 had an induced abortion recently, and 430 women came primarily to get contraceptive advice.
Allocation concealment	B – Unclear

Study	Burnhill 1985
Methods	Methods of randomization were not reported. One site at Middlesex General University Hospital in New Brunswick, NJ (USA)
Participants	200 women requesting elective abortion and were at high risk of unintended pregnancy.
Interventions	Multi-contact peer counseling versus routine counseling.
Outcomes	Choice of more effective contraception, pregnancy rates, continuation of contraceptive use, continuation of OC use.
Notes	
Allocation concealment	B – Unclear

Study	Canto De Cetina 2001
Methods	Methods of randomization are not reported. One site at “Centro de Investigaciones Hideyo Noguchi,” Merida, Yucatan (Mexico). Participants were followed for 12 months.
Participants	350 women attending the Family Planning Clinic and willing to use DMPA for contraception. Inclusion criteria were: between the ages of 18 and 35 years old, living in a rural area; proven fertility; regular menstrual cycles during the previous six months; not breastfeeding; at least one child; normal PAP smear; willing to use DMPA as the only contraceptive agent during the course of the study; willing to return to the clinic every three months. Exclusion criteria were: current or history of thrombophlebitis; thromboembolic disorders; hypertension; cerebral vascular disease; active or chronic liver disease; known or suspected breast or genital organ malignancy; endocrinopathy undiagnosed; vaginal bleeding; diabetes mellitus.
Interventions	Structured pre-treatment and follow-up counseling versus routine pre-treatment counseling.
Outcomes	Cumulative life table discontinuation rate, reason for discontinuation, DMPA-induced side effects.
Notes	
Allocation concealment	B – Unclear

Study	Gilliam 2004
Methods	Computer-generated random numbers table.

## Characteristics of included studies (Continued)

	One site at Northwestern Memorial Hospital, Chicago, IL (USA). Participants were followed for one year.
Participants	33 African American low-income females attending Prentice Ambulatory Care. This resident-run clinic serves low-income women receiving public assistance. Inclusion criteria: 25 years or younger; with unplanned pregnancy; intending to use OCs postpartum.
Interventions	Antepartum, multi-component intervention consisting of counseling, a videotape about OCs, and written material versus resident-physician counseling (usual care).
Outcomes	Continuation rate at one year, switch to other contraceptives at one year, pregnancy rate at one year.
Notes	Knowledge of OCs mentioned, but data reported elsewhere. 43 women were enrolled in the Chicago study but only 33 were randomized. Reasons for study enrollment without randomization included participants changing their mind about using OCs, delivering at an outside hospital, and failure of the study team to randomize the participant prior to leaving the hospital due to miscommunication with nursing staff or leaving after a 24-hour rather than 48-hour stay.
Allocation concealment	A – Adequate

### Study Jay 1984

Methods	Computer-generated random numbers table. One site of the Title V Children and Youth Project for the State of Georgia (USA). Participants were followed for four months.
Participants	57 adolescents attending adolescent gynecology clinic and were willing to use oral contraceptives.
Interventions	Peer versus nurse counseling at three appointments for both groups
Outcomes	Noncompliance measured by a Guttman scale consisting of 1) avoidance of pregnancy, 2) appointment adherence, 3) pill count, 4) urinary fluorescence for riboflavin. Second outcome was attrition rate at four months (end of study) - defined as failing to keep the second rescheduled broken appointment or discontinuing the oral contraceptive regimen.
Notes	31 (54%) subjects were assigned to the nurse-counselor group, and 26 (46%) were assigned to the peer-counselor group. 50% (28 or 29) of the participants were expected to be assigned to each group. A sampling error of this degree was not significant with a sample size of 57.
Allocation concealment	B – Unclear

### Study Keder 1998

Methods	Computer-generated randomization list. One site at the Magee-Womens Hospital clinic in Pittsburgh, PA (USA). Participants were followed for 12 months.
Participants	250 women attending the clinic and willing to use DMPA for contraception. Inclusion criteria were access to a telephone and planning to return to the same facility for continuing care. Exclusion criteria were currently receiving depot medroxyprogesterone treatment, planning to undergo tubal ligation, immediately postpartum, unwilling to provide back up contact information.
Interventions	Mail and telephone reminders of the next injection two weeks before each scheduled injection versus written appointment card.
Outcomes	Discontinuation rate at 12 months, rate of on-time injections, reason for discontinuation, DMPA-induced side effects.
Notes	An injection received within 14 weeks of the prior injection was classified as 'on-time' injection. Women enrolled were told of their assignment.
Allocation concealment	B – Unclear

## Characteristics of excluded studies

Study	Reason for exclusion
Bender 2004	Did not evaluate any outcomes relevant to this review.
Metson 1991	Not a randomized controlled trial.

## ANALYSES

### Comparison 01. Group motivation versus routine counseling

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Discontinuation of selected contraceptive at six months	1	1030	Odds Ratio (Fixed) 95% CI	1.04 [0.80, 1.34]
02 Discontinuation due to side effects of selected contraceptive	1	1030	Odds Ratio (Fixed) 95% CI	1.34 [0.72, 2.48]
03 Discontinuation due to dissatisfaction with selected contraceptive	1	1030	Odds Ratio (Fixed) 95% CI	0.61 [0.38, 0.98]
04 Discontinuation due to pregnancy	1	1030	Odds Ratio (Fixed) 95% CI	0.67 [0.31, 1.45]
05 Discontinuation because no contraception was needed	1	1030	Odds Ratio (Fixed) 95% CI	1.03 [0.66, 1.59]
06 Discontinuation for other reason	1	1030	Odds Ratio (Fixed) 95% CI	0.71 [0.44, 1.16]

### Comparison 02. Structured counseling versus routine counseling

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Discontinuation by 6 months	1	350	Odds Ratio (Fixed) 95% CI	0.36 [0.20, 0.64]
02 Discontinuation by 12 months	1	350	Odds Ratio (Fixed) 95% CI	0.27 [0.16, 0.44]
03 Discontinuation due to menstrual disturbances	1	350	Odds Ratio (Fixed) 95% CI	0.20 [0.11, 0.37]
04 Discontinuation due to other medical reasons	1	350	Odds Ratio (Fixed) 95% CI	0.84 [0.36, 1.92]
05 Lost to follow-up	1	350	Odds Ratio (Fixed) 95% CI	0.66 [0.11, 4.02]

### Comparison 03. Multicomponent intervention versus routine counseling

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Continuation of oral contraceptives at one year	1	33	Odds Ratio (Fixed) 95% CI	1.14 [0.21, 6.16]
02 Known pregnancy by one year	1	33	Odds Ratio (Fixed) 95% CI	1.30 [0.19, 9.02]
03 Switched contraceptives by one year	1	33	Odds Ratio (Fixed) 95% CI	3.20 [0.67, 15.38]
04 Loss to follow-up	1	33	Odds Ratio (Fixed) 95% CI	0.30 [0.06, 1.51]

#### Comparison 04. Peer counseling versus nurse counseling

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Non-compliance (Guttman score) at four months	1	38	Weighted Mean Difference (Fixed) 95% CI	-0.21 [-0.88, 0.46]
02 Attrition at four months	1	57	Odds Ratio (Fixed) 95% CI	0.42 [0.13, 1.32]

#### Comparison 05. Intensive reminders versus written appointment cards

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Discontinuation at 12 months	1	250	Odds Ratio (Fixed) 95% CI	1.11 [0.67, 1.82]
02 On-time injections of those who continued DMPA	1	110	Odds Ratio (Fixed) 95% CI	0.75 [0.22, 2.63]
03 On-time injections overall	1	250	Odds Ratio (Fixed) 95% CI	0.87 [0.52, 1.44]
04 Loss to follow-up	1	250	Odds Ratio (Fixed) 95% CI	1.26 [0.75, 2.12]

### INDEX TERMS

#### Medical Subject Headings (MeSH)

Contraception [\*psychology]; Contraceptive Agents, Female [\*administration & dosage; adverse effects]; Contraceptives, Oral, Hormonal [administration & dosage; adverse effects]; Counseling; Medroxyprogesterone 17-Acetate [administration & dosage; adverse effects]; \*Patient Compliance [psychology]; Randomized Controlled Trials; \*Treatment Refusal [psychology]

#### MeSH check words

Female; Humans

### COVER SHEET

<b>Title</b>	Strategies to improve adherence and acceptability of hormonal methods for contraception
<b>Authors</b>	Halpern V, Grimes DA, Lopez L, Gallo MF
<b>Contribution of author(s)</b>	Vera Grigorieva developed the idea, did the primary data extraction, and drafted the review. Maria Gallo provided assistance with data extraction. David Grimes participated in writing the review. Laureen Lopez did the secondary data extraction and wrote parts of the review.
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<b>Date new studies sought but none found</b>	Information not supplied by author
<b>Date new studies found but not yet included/excluded</b>	Information not supplied by author



**Date new studies found and included/excluded** Information not supplied by author

**Date authors' conclusions section amended** Information not supplied by author

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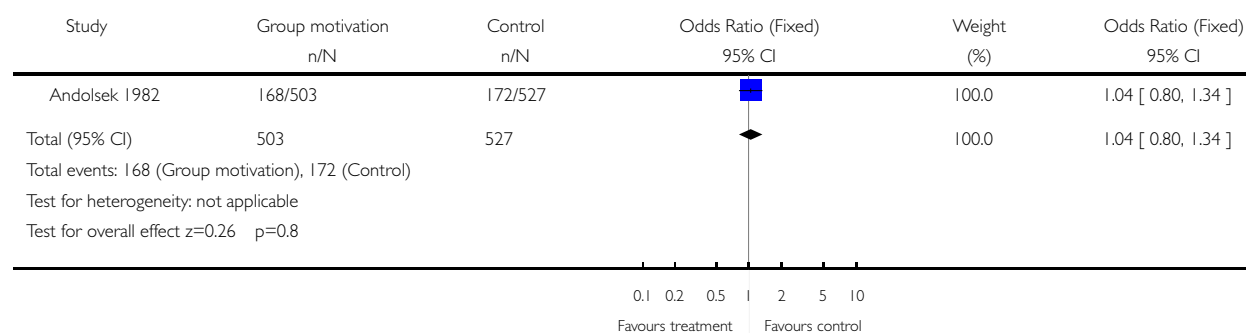
## GRAPHS AND OTHER TABLES

### Analysis 01.01. Comparison 01 Group motivation versus routine counseling, Outcome 01 Discontinuation of selected contraceptive at six months

Review: Strategies to improve adherence and acceptability of hormonal methods for contraception

Comparison: 01 Group motivation versus routine counseling

Outcome: 01 Discontinuation of selected contraceptive at six months

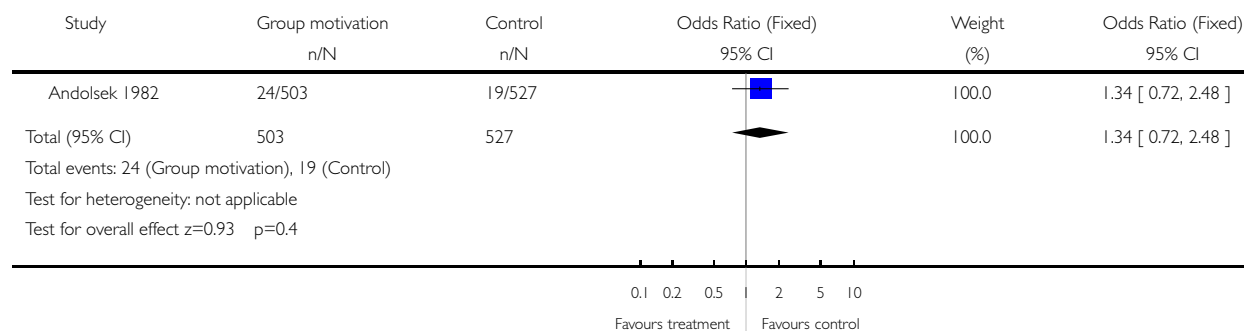


### Analysis 01.02. Comparison 01 Group motivation versus routine counseling, Outcome 02 Discontinuation due to side effects of selected contraceptive

Review: Strategies to improve adherence and acceptability of hormonal methods for contraception

Comparison: 01 Group motivation versus routine counseling

Outcome: 02 Discontinuation due to side effects of selected contraceptive

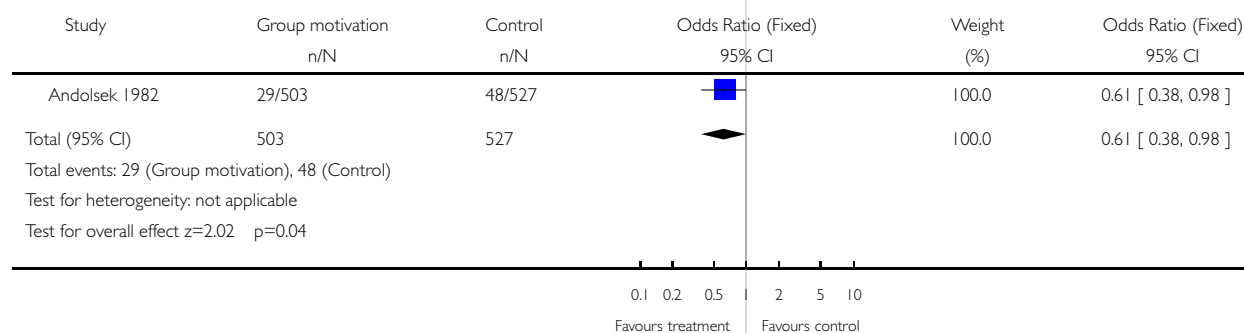


### Analysis 01.03. Comparison 01 Group motivation versus routine counseling, Outcome 03 Discontinuation due to dissatisfaction with selected contraceptive

Review: Strategies to improve adherence and acceptability of hormonal methods for contraception

Comparison: 01 Group motivation versus routine counseling

Outcome: 03 Discontinuation due to dissatisfaction with selected contraceptive

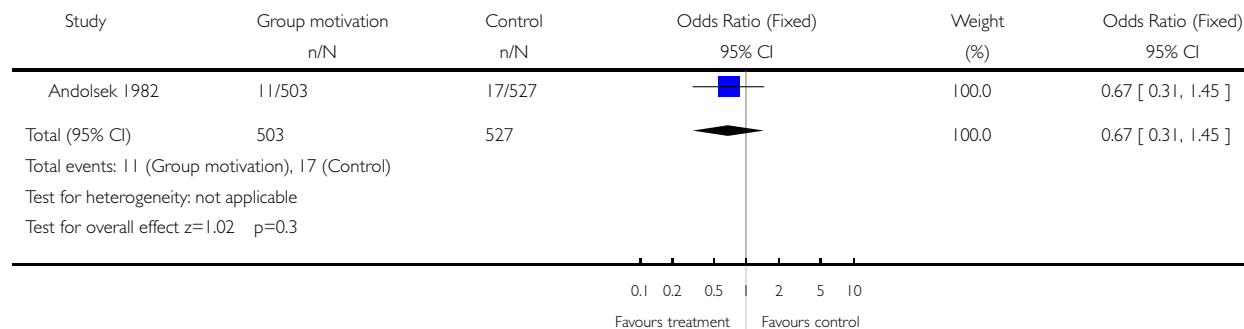


#### Analysis 01.04. Comparison 01 Group motivation versus routine counseling, Outcome 04 Discontinuation due to pregnancy

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Comparison: 01 Group motivation versus routine counseling

Outcome: 04 Discontinuation due to pregnancy

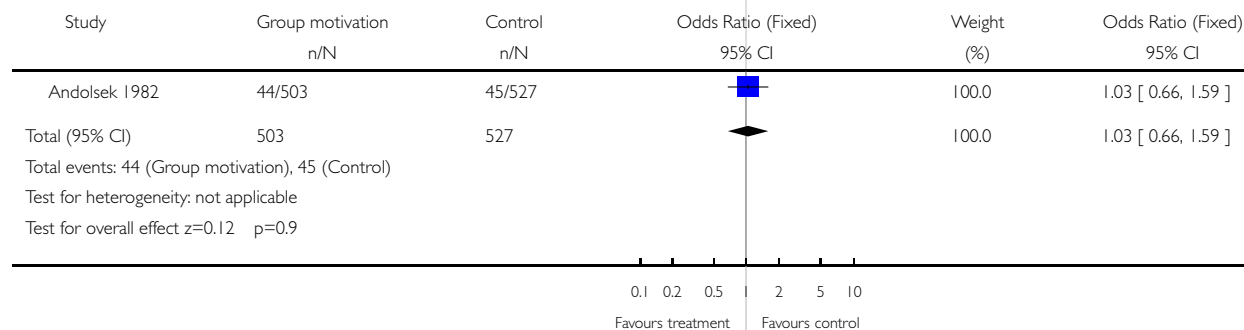


#### Analysis 01.05. Comparison 01 Group motivation versus routine counseling, Outcome 05 Discontinuation because no contraception was needed

Review: Strategies to improve adherence and acceptability of hormonal methods for contraception

Comparison: 01 Group motivation versus routine counseling

Outcome: 05 Discontinuation because no contraception was needed

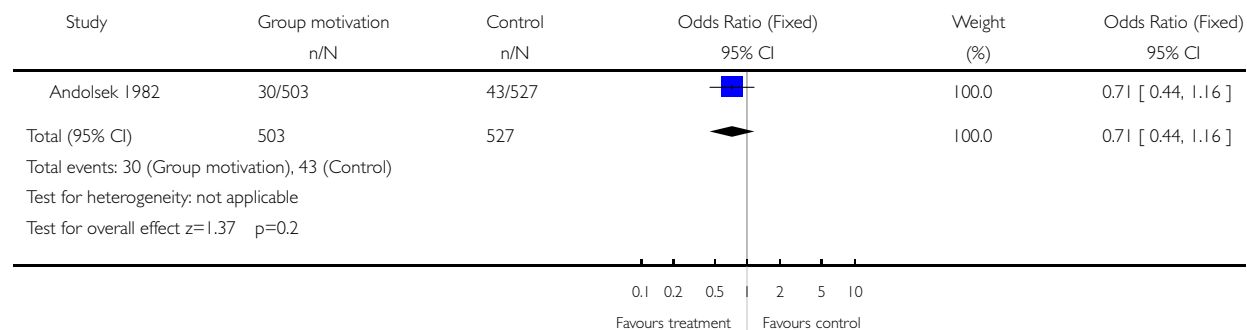


### Analysis 01.06. Comparison 01 Group motivation versus routine counseling, Outcome 06 Discontinuation for other reason

Review: Strategies to improve adherence and acceptability of hormonal methods for contraception

Comparison: 01 Group motivation versus routine counseling

Outcome: 06 Discontinuation for other reason

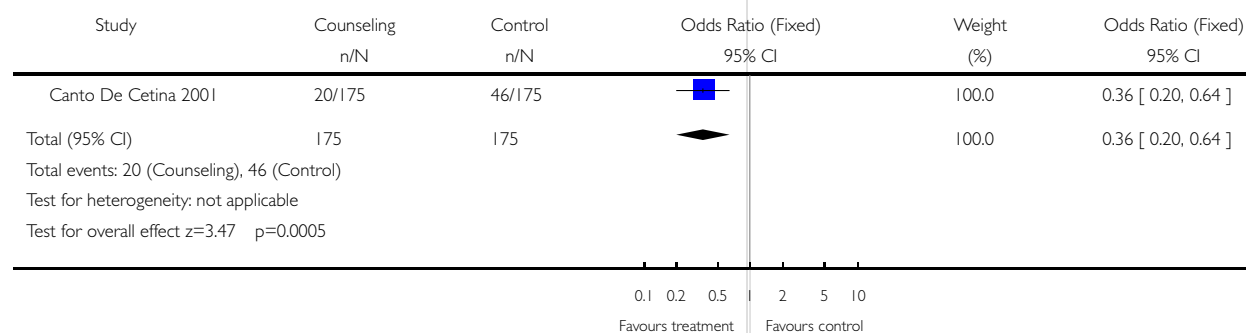


### Analysis 02.01. Comparison 02 Structured counseling versus routine counseling, Outcome 01 Discontinuation by 6 months

Review: Strategies to improve adherence and acceptability of hormonal methods for contraception

Comparison: 02 Structured counseling versus routine counseling

Outcome: 01 Discontinuation by 6 months

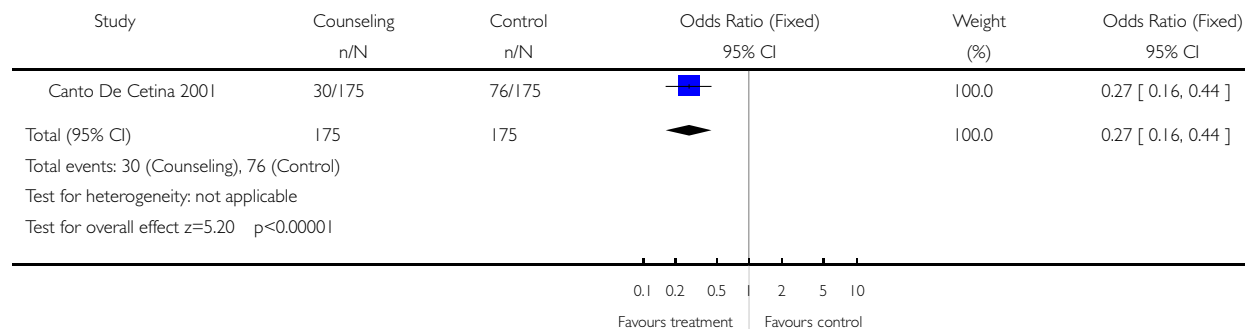


### Analysis 02.02. Comparison 02 Structured counseling versus routine counseling, Outcome 02 Discontinuation by 12 months

Review: Strategies to improve adherence and acceptability of hormonal methods for contraception

Comparison: 02 Structured counseling versus routine counseling

Outcome: 02 Discontinuation by 12 months

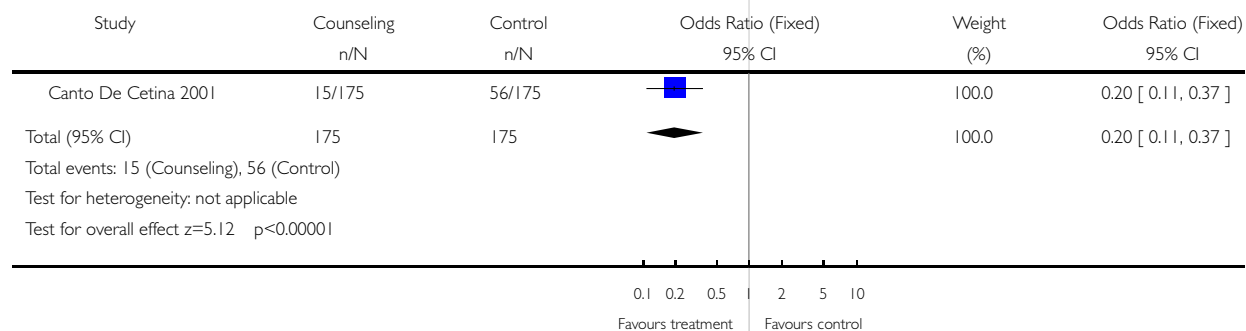


### Analysis 02.03. Comparison 02 Structured counseling versus routine counseling, Outcome 03 Discontinuation due to menstrual disturbances

Review: Strategies to improve adherence and acceptability of hormonal methods for contraception

Comparison: 02 Structured counseling versus routine counseling

Outcome: 03 Discontinuation due to menstrual disturbances

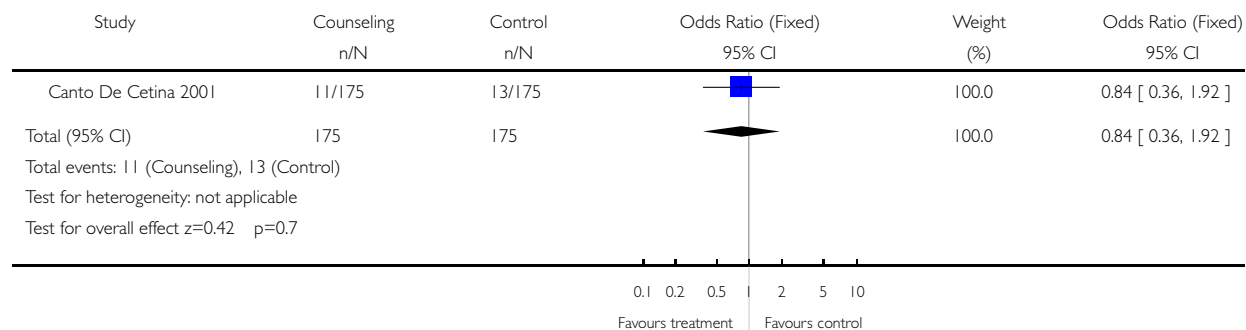


### Analysis 02.04. Comparison 02 Structured counseling versus routine counseling, Outcome 04 Discontinuation due to other medical reasons

Review: Strategies to improve adherence and acceptability of hormonal methods for contraception

Comparison: 02 Structured counseling versus routine counseling

Outcome: 04 Discontinuation due to other medical reasons

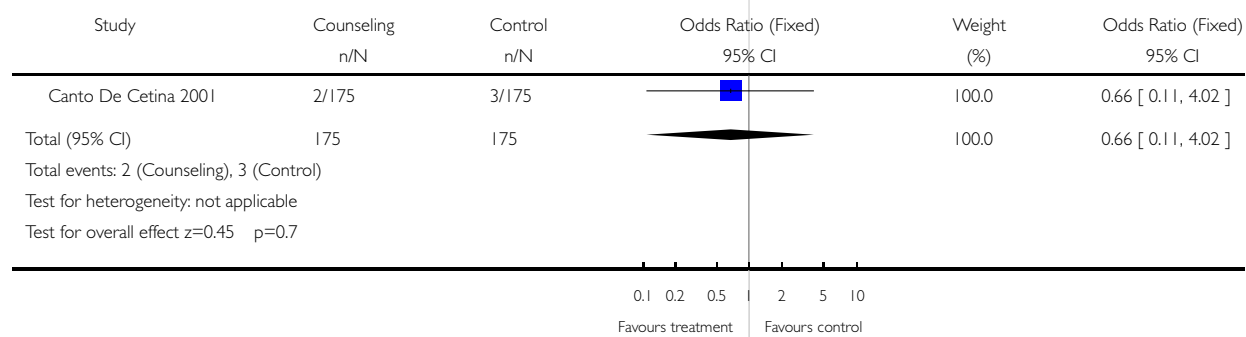


### Analysis 02.05. Comparison 02 Structured counseling versus routine counseling, Outcome 05 Lost to follow-up

Review: Strategies to improve adherence and acceptability of hormonal methods for contraception

Comparison: 02 Structured counseling versus routine counseling

Outcome: 05 Lost to follow-up

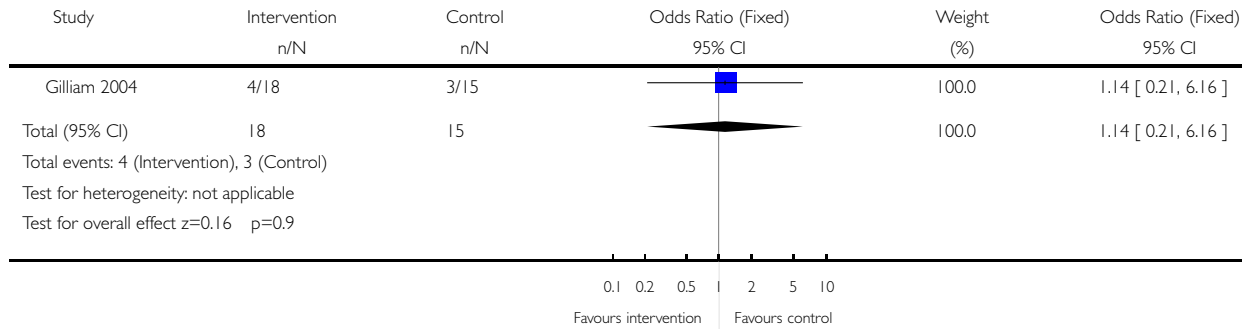


### Analysis 03.01. Comparison 03 Multicomponent intervention versus routine counseling, Outcome 01 Continuation of oral contraceptives at one year

Review: Strategies to improve adherence and acceptability of hormonal methods for contraception

Comparison: 03 Multicomponent intervention versus routine counseling

Outcome: 01 Continuation of oral contraceptives at one year

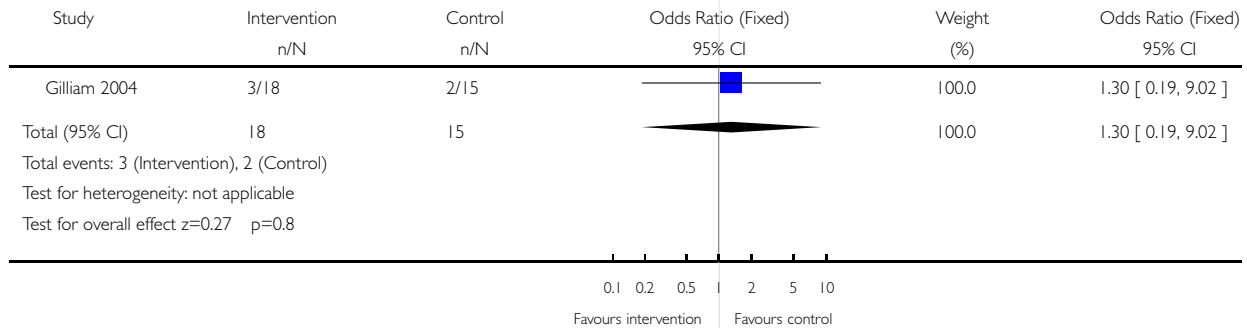


### Analysis 03.02. Comparison 03 Multicomponent intervention versus routine counseling, Outcome 02 Known pregnancy by one year

Review: Strategies to improve adherence and acceptability of hormonal methods for contraception

Comparison: 03 Multicomponent intervention versus routine counseling

Outcome: 02 Known pregnancy by one year

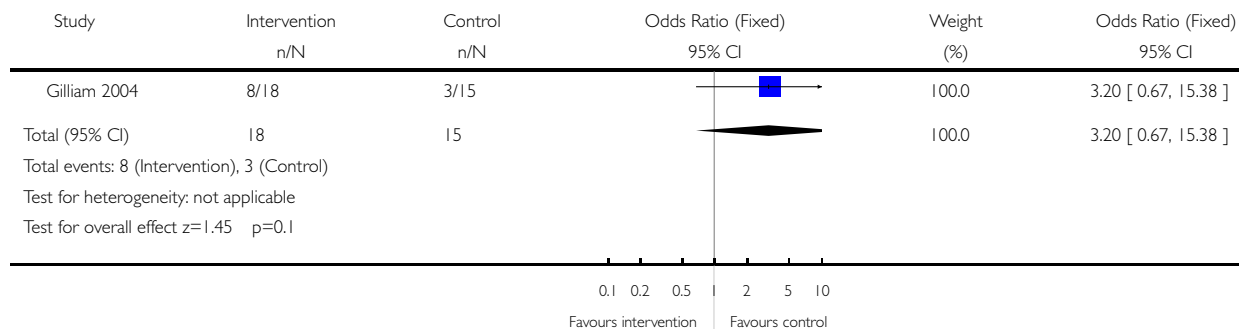


### Analysis 03.03. Comparison 03 Multicomponent intervention versus routine counseling, Outcome 03 Switched contraceptives by one year

Review: Strategies to improve adherence and acceptability of hormonal methods for contraception

Comparison: 03 Multicomponent intervention versus routine counseling

Outcome: 03 Switched contraceptives by one year

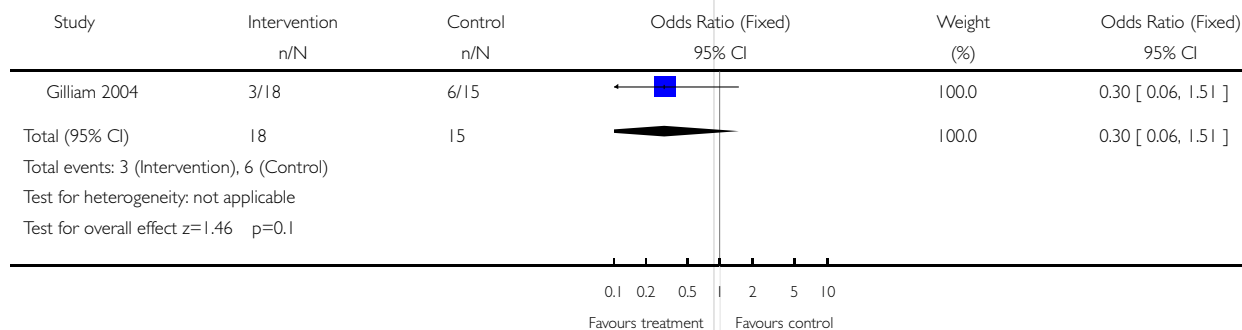


### Analysis 03.04. Comparison 03 Multicomponent intervention versus routine counseling, Outcome 04 Loss to follow-up

Review: Strategies to improve adherence and acceptability of hormonal methods for contraception

Comparison: 03 Multicomponent intervention versus routine counseling

Outcome: 04 Loss to follow-up



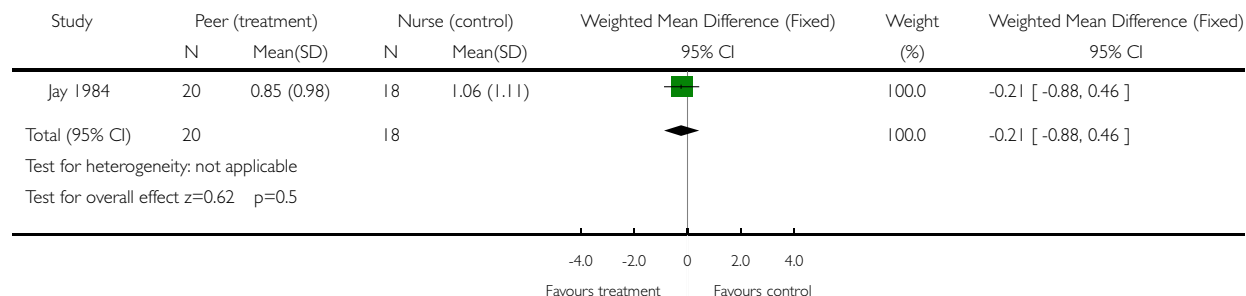


### Analysis 04.01. Comparison 04 Peer counseling versus nurse counseling, Outcome 01 Non-compliance (Guttman score) at four months

Review: Strategies to improve adherence and acceptability of hormonal methods for contraception

Comparison: 04 Peer counseling versus nurse counseling

Outcome: 01 Non-compliance (Guttman score) at four months

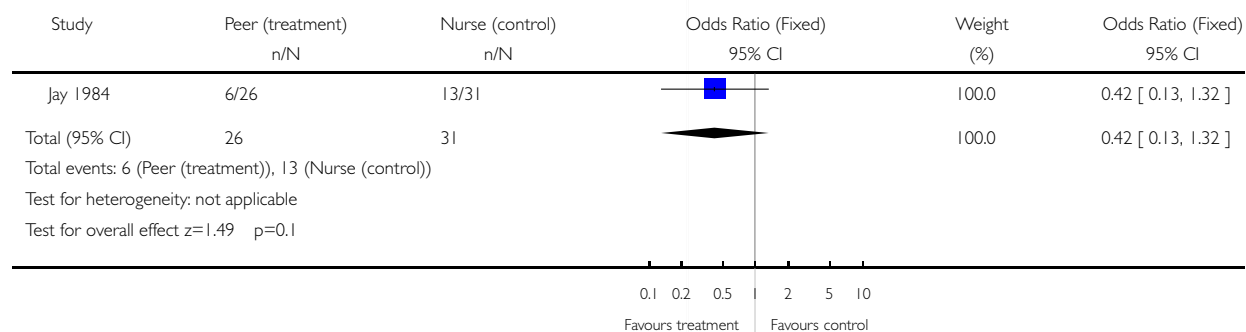


### Analysis 04.02. Comparison 04 Peer counseling versus nurse counseling, Outcome 02 Attrition at four months

Review: Strategies to improve adherence and acceptability of hormonal methods for contraception

Comparison: 04 Peer counseling versus nurse counseling

Outcome: 02 Attrition at four months

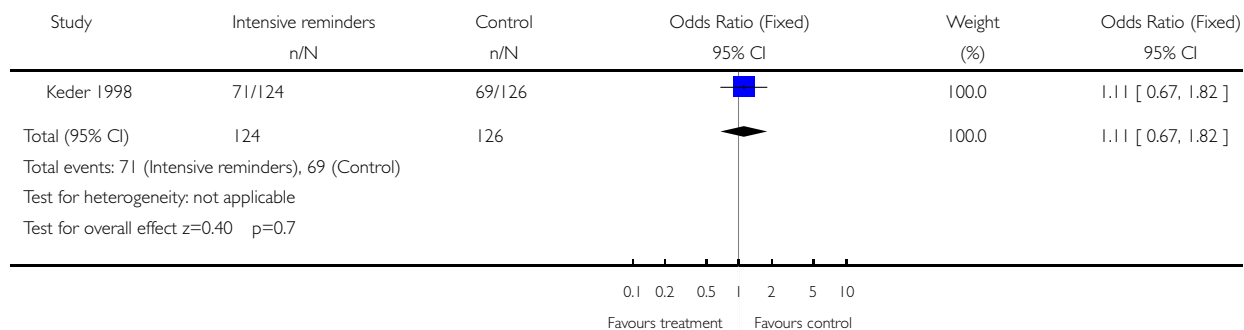


### Analysis 05.01. Comparison 05 Intensive reminders versus written appointment cards, Outcome 01 Discontinuation at 12 months

Review: Strategies to improve adherence and acceptability of hormonal methods for contraception

Comparison: 05 Intensive reminders versus written appointment cards

Outcome: 01 Discontinuation at 12 months

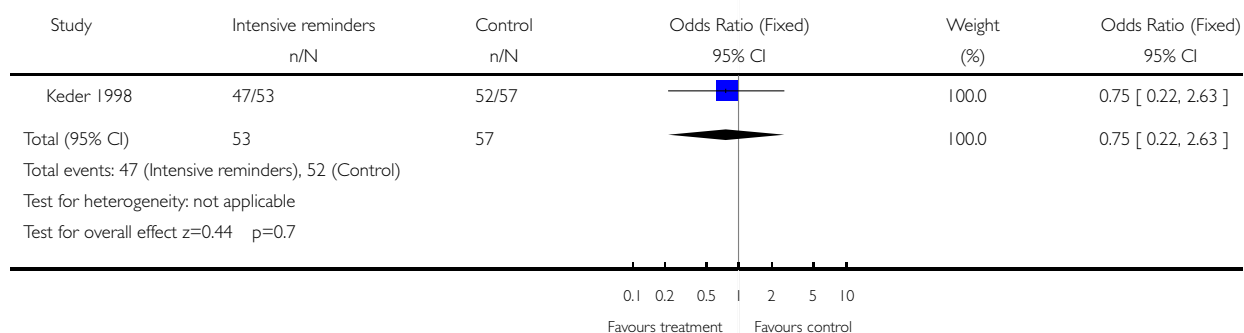


### Analysis 05.02. Comparison 05 Intensive reminders versus written appointment cards, Outcome 02 On-time injections of those who continued DMPA

Review: Strategies to improve adherence and acceptability of hormonal methods for contraception

Comparison: 05 Intensive reminders versus written appointment cards

Outcome: 02 On-time injections of those who continued DMPA

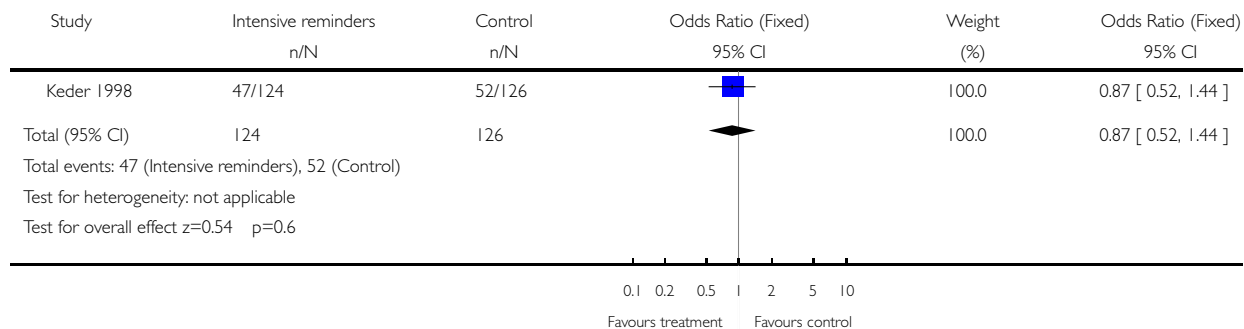


### Analysis 05.03. Comparison 05 Intensive reminders versus written appointment cards, Outcome 03 On-time injections overall

Review: Strategies to improve adherence and acceptability of hormonal methods for contraception

Comparison: 05 Intensive reminders versus written appointment cards

Outcome: 03 On-time injections overall



### Analysis 05.04. Comparison 05 Intensive reminders versus written appointment cards, Outcome 04 Loss to follow-up

Review: Strategies to improve adherence and acceptability of hormonal methods for contraception

Comparison: 05 Intensive reminders versus written appointment cards

Outcome: 04 Loss to follow-up

