A randomized clinical trial of the effect of intensive versus non-intensive counselling on discontinuation rates due to bleeding disturbances of three long-acting reversible contraceptives

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STUDY QUESTION: Does intensive counselling before insertion and throughout the first year of use have any influence on discontinuation rates due to unpredictable menstrual bleeding in users of three long-acting reversible contraceptives (LARCs)?)

SUMMARY ANSWER: Intensive counselling had a similar effect to routine counselling in terms of discontinuation rates due to unpredictable menstrual bleeding in new users of the contraceptives.

WHAT IS KNOWN ALREADY: Contraceptive efficacy and satisfaction rates are very high with LARCs, including the etonogestrel (ENG)-releasing implant, the levonorgestrel-releasing intrauterine system (LNG-IUS) and the TCu380A intrauterine device (IUD). However, unpredictable menstrual bleeding constitutes the principal reason for premature discontinuation, particularly in the cases of the ENG-implant and the LNG-IUS.

STUDY DESIGN, SIZE, DURATION: A randomized clinical trial was conducted between 2011 and 2013, and involved 297 women: 98 ENG-implant users, 99 LNG-IUS users and 100 TCu380A IUD users.

PARTICIPANTS, SETTING, METHODS: Women accepting each contraceptive method were randomized into two groups after the women chose their contraceptive method. Group I received routine counselling at the clinic, including information on safety, efficacy and side effects, as well as what to expect regarding bleeding disturbances. Group II received ‘intensive counselling’. In addition to the information provided to those in Group I, these women also received leaflets on their chosen method and were seen by the same three professionals, the most experienced at the clinic, throughout the year of follow-up. These three professionals went over all the information provided at each consultation. Women in both groups were instructed to return to the clinic after 45 (+7) days and at 6 and 12 (+1) months after insertion. They were instructed to record all bleeding episodes on a menstrual calendar specifically provided for this purpose. Additionally, satisfaction with the method was evaluated by a questionnaire completed by the women after 12 months of use of the contraceptive method.

MAIN RESULTS AND THE ROLE OF CHANCE: There were no significant differences between the intensive and routine counselling groups on the discontinuation rates due to unpredictable menstrual bleeding of the three contraceptives under evaluation. The 1-year cumulative discontinuation rates due to menstrual bleeding irregularities were 2.1, 2.7 and 4.0% and the continuation rates were 82.6, 81.0 and 73.2%, for the ENG-implant, the LNG-IUS or the TCu380A IUD users, respectively. The main reasons for discontinuation of the methods were weight gain in users of the ENG-implant and expulsion of the TCu380A.

LIMITATIONS, REASONS FOR CAUTION: The main limitations are that we cannot assure generalization of the results to another settings and that the routine counselling provided by our counsellors may already be appropriate for the women attending the clinic and so consequently intensive counselling including written leaflets was unable to influence the premature discontinuation rate due to unpredictable menstrual bleeding. Additionally, counselling could discourage some women from using the LARC methods offered in the study and consequently those women may have decided on other contraceptives.
**WIDER IMPLICATIONS OF THE FINDINGS:** Routine counselling may be sufficient for many women to help reduce premature discontinuation rates and improve continuation rates and user satisfaction among new users of LARC methods.

**TRIAL REGISTRATION NUMBER:** The trial was registered at clinicaltrials.gov (NCT01392157).

**STUDY FUNDING/COMPETING INTEREST(S):** The study was partially funded by the Fundação de Apoio a Pesquisa do Estado de São Paulo (FAPESP) grant # 2012/01379-0, the Brazilian National Research Council (CNPq) grant #573747/2008-3 and by Merck (MSD), Brazil under an unrestricted grant. The LNG-IUS were donated by the International Contraceptive Access Foundation (ICA) and the copper IUD by Injeflex, São Paulo, Brazil. L.B. has occasionally served on the Board of MSD, Bayer and Vifor.

**Key words:** counselling / long-acting contraceptive methods / copper intrauterine device / implant / levonorgestrel-releasing intrauterine system

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### Introduction

The long-acting reversible contraceptives (LARCs) include the copper-intrauterine device (IUD), the levonorgestrel-releasing intrauterine system (LNG-IUS) and the levonorgestrel (LNG)- and the etonogestrel (ENG)-releasing subdermal implants (Peterson and Curtis, 2005). Contraceptive efficacy and continuation rate with these methods are high with the advantage that they are convenient and their efficacy depends on one single or, at most, two simple injections. In Brazil, some observers have called for a concerted effort to expand the use of LARCs (Peterson and Curtis, 2005).

In Brazil, the only copper IUD available is the TCu380A and the only implant is the ENG-implant (Implanon®, Merck, Oss, The Netherlands). Despite its high contraceptive efficacy and minor (though many) side effects (Croxatto 2000, 2002), the ENG-implant is not widely used in Brazil. The reasons for this could be due to its lack of availability in the public sector, the lack of trained health care professionals (HCPs) in insertions and removals, and probably the lack of studies about women’s opinions regarding its side effects, particularly those associated with bleeding disturbances. Regarding the LNG-IUS, similar local studies of bleeding disturbances have been conducted in Brazil (Díaz et al., 2000; Hidalgo et al., 2002). The main side effect of the ENG-implant is menstrual bleeding irregularities, including infrequent or frequent and prolonged bleeding without any previous symptoms, and this is the main reason for premature discontinuation (Mansour et al., 2011). However, the possibility of the contraceptive method inducing amenorrhoea may be seen as an advantage. There is no way of predicting which women will go on to develop bleeding disturbances and there is no effective treatment prior to implant insertion to avoid menstrual bleeding irregularities. However, previous studies with other progestin-only contraceptive methods have shown that adequate and intensive counselling, in which the woman is provided with information on the bleeding profiles she can expect while using the method, may contribute towards improving the continuation rate (Mansour et al., 2011).

It is important to take into account that side effects induced by LARCs methods could lead to premature removals which in turn could influence continuation rates and user satisfaction and potentially increase unwanted pregnancies. First year continuation rates are high with LARC methods, with rates of 67–75% having been reported for the ENG-implant (Kalmuss et al., 1999; Croxatto et al., 1999; Smith and Reuter, 2002; Agrawal and Robinson, 2005; Lakha and Glasier, 2006; Harvey et al., 2009), rates of 86–90% having been described for the LNG-IUS (Andersson et al., 1994; Baldasztı et al., 2003; Suhonen et al., 2004; Sheng et al., 2009; Bahamondes et al., 2012; Ferreira et al., 2014), and a rate of 84% being reported for the TCu380A IUD (Peipert et al., 2011). Counselling is crucial and when intensive counselling has been given, 1-year continuation rates have reached 80–90% in users of the ENG-implant (Davie et al., 1996; Rubenstein et al., 2011) and 90% in users of the LNG-IUS (Baldasztı et al., 2003).

The objectives of this randomized clinical trial (RCT) were to compare the discontinuation rates due to unpredictable menstrual bleeding and the 1-year continuation rates after women were allocated to either intensive counselling or the routine counselling provided at a Brazilian public sector clinic among new acceptors of the ENG-implant, the LNG-IUS or the TCu380A IUD.

### Materials and Methods

This RCT was conducted at the Department of Obstetrics and Gynaecology, School of Medical Sciences, University of Campinas (UNICAMP), Campinas, Brazil. The Ethical Committee approved the study and all the participating women signed an informed consent form. The trial was registered at ClinicalTrials.gov: NCT01392157. The study population included women of 18–40 years of age attending the family planning clinic and requesting any LARC method. According to the current practice at the clinic, all the women provided unbiased counselling on all the contraceptive methods available at the clinic. All the contraceptive methods were offered at no cost to the women. The methods available at the time of the study were: the TCu380A IUD (Optima, Injeflex, São Paulo, Brazil), the ENG-implant (Implanon®, Merck, Oss, The Netherlands) (only for research purposes), the LNG-IUS (Mirena®, Bayer Oy, Turku, Finland), the injectable depot-medroxyprogesterone acetate, once-a-month combined injectables, oral contraceptives, the vaginal ring, and the male and female condom.

After a brief counselling session and provision of information about the available contraceptive methods at the clinic, the women who chose the ENG-implant, the LNG-IUS or the TCu380A IUD were invited to participate in the trial and were randomly allocated (1:1) to one of two groups using sealed opaque envelopes prepared according to a computerized randomization program by a person who was not directly involved in the study. The women were included sequentially until there was a maximum sample size of 100 women in each contraceptive group.

The women allocated to Group I received the routine verbal counselling given at the clinic, which includes information on anatomy (mostly for those who chose the IUD and the LNG-IUS), mechanism of action, safety, efficacy, how and when fertility can return, side effects of the chosen methods, and the non-contraceptive benefits of the method, as well as information about scheduled and non-scheduled visits. In addition, women were provided with information on what to expect with respect to unpredictable bleeding disturbances. This session of counselling lasted ~15 min. The women in this group received the counselling from the nurses on duty and
the follow-up visits were attended by a person on duty that day at the clinic, including residents in training and medical students.

The women in Group II received 'intensive counselling' in which, in addition to the information provided to those in Group I, these women were given a leaflet on the chosen method developed specifically for the study and pre-tested. The leaflet contained a drawing showing the anatomy of the pelvis, in-depth explanation of changes in bleeding patterns that could occur during the use of the chosen LARC method, the mechanism of action of bleeding irregularities and the possibilities of treatment. This additional session of counselling lasted ~15 min. The women in this group were always attended to and counselled by the same three professionals who were the most experienced at the clinic, who went over all the information provided at each consultation throughout the year of follow-up. Only the women in Group II also received telephone calls as a reminder of the next scheduled visits.

All of the women were instructed to return to the clinic at 45 days (±7 days), and 6 and 12 months (±1 month) after insertion or at any time if needed and were also instructed to record any bleeding episodes in a menstrual diary specifically provided for this purpose. Satisfaction with the method was evaluated based on a questionnaire completed by the women after 12 months of use of the contraceptive method. All the women in both groups were instructed that they have the right to remove the chosen contraceptive method at any time and to receive a different one. The women did not receive any incentive to return for the visits or to choose a particular method.

Analysis of bleeding patterns

Bleeding patterns were analysed in accordance with the terminology proposed by the World Health Organization (WHO, 1989) in 90-day reference periods: ‘amenorrhoea’ was defined as no bleeding during the reference period; ‘infrequent bleeding’ as fewer than three bleeding episodes; ‘frequent bleeding’ as more than five bleeding episodes; ‘irregular bleeding’ as between three and five episodes with less than three bleeding-free intervals of 14 days or more in length; ‘prolonged bleeding’ as one or more bleeding episodes lasting 14 days or more; and ‘none of the above’ as a ‘normal’ bleeding pattern.

Statistical analysis

Sample size was calculated based on the assumption that 20% of new contraceptive users would opt to use either the ENG-implant, the LNG-IUS or the TCu380A IUD and that the continuation rate at the end of the first year after insertion would be 80% in each group of users. For an alpha of 5% (Type I error) and a Type II error of 20%, 91 women would have to be recruited to each group. Taking into account a possible loss to follow-up of 10%, it was decided to enrol 100 women to each contraceptive method.

Statistical analysis was performed using the SPSS statistical software package for Windows, version 20. Significant differences were established at P < 0.05. Analysis of variance (ANOVA) or the Kruskal–Wallis test was used to compare the sociodemographic characteristics between the groups. The χ² test was used to compare the qualitative variables. The cumulative continuation and discontinuation rates for each reason were calculated by life-table analysis and the Wilcoxon–Gehan test was used to compare the rates between the groups.

Results

Enrolment started on 2 August 2011 and ended on 5 June 2012. During that period, 1004 women consulted at the clinic requesting a contraceptive method. A total of 300 women agreed to participate in the study; however, due to the contamination of one LNG-IUS and two ENG-implants, analysis was conducted on 98 users of the ENG-implant, 99 users of the LNG-IUS and 100 users of the TCu380A IUD (Fig. 1). The characteristics of the subjects are shown in Table I. There were no significant differences in age between the groups; however, the ENG-implant users had had fewer children and had a lower body mass index (BMI; kg/m²).

The return for each of the scheduled visits was at the same rate in both counselling groups. The continuation rates were 82.6, 81.0 and 73.2% for the ENG-implant, the LNG-IUS and the TCu380A IUD (P = 0.214), respectively (Table II). There were no significant differences in the number of women discontinuing the method due to bleeding or pain between the three contraceptive methods. However, significantly more ENG-implant users discontinued the method because of weight gain compared with the other two methods (P = 0.022), while discontinuation rates due to expulsion were higher with the TCu380A IUD when compared with the LNG-IUS users (P = 0.008) (Table II). (Women could request another insertion after expulsion but in that case, they were discontinued from this study.) There were no significant differences in the continuation rate at 12 months between the women who received intensive counselling and those who received regular counselling in any of the three groups. With respect to the ENG-implant and the LNG-IUS, over 80% of users continued using the method irrespective of whether they had received intensive or routine counselling. Of the TCu380A IUD users who received intensive counselling, 65.9% continued with the method compared with 70.0% of those who received only routine counselling. After 12 months of follow-up, the satisfaction rate among the continuing users was 90.0% with the ENG-implant, 91.0% with the LNG-IUS and 85.7% with the TCu380A IUD (P = 0.612).

Figure 2 compares the bleeding patterns for the three contraceptive methods from insertion up to 12 months of use in accordance with each 90-day evaluation period. For the ENG-implant users, the most common bleeding patterns were infrequent bleeding in the first 90-day evaluation period and amenorrhoea or infrequent bleeding in the following 90-day evaluation periods. For the LNG-IUS users, the two most common bleeding patterns were frequent or prolonged bleeding in the first 90-day evaluation period, and amenorrhoea, infrequent or normal bleeding in the fourth 90-day evaluation period. Finally, the most common bleeding pattern in users of the copper IUD was normal menstruation. In the first 90-day evaluation period, 50% of these users were menstruating normally and this proportion increased to almost 90% at 12 months. Bleeding patterns were similar in the women who had received intensive counselling and in those who had received routine counselling (data not shown).

Discussion

The main finding of our study was that the rates of premature discontinuation due to menstrual bleeding disturbances among the three groups of LARC users were very low and consequently the 1-year continuation rate ranged from 73% among copper IUD users to 83% among ENG-implant acceptors. Additionally, women randomly allocated to either intensive or routine counselling did not show any differences in the discontinuation rates due to unpredictable menstrual bleeding.

These results could be interpreted as the conundrum of whether the glass is half-empty or half-full. In one way, it could be argued that routine counselling is not an important tool to reduce premature discontinuations and to improve the continuation rate. However, in the opposite
direction it may be possible to conclude that routine counselling is enough to maintain the adherence of the women to the selected contraceptive method. Our centre is probably the largest Brazilian family planning clinic with >30 years of operation and >20 000 women attending per year, and consequently, the result that premature removals were equal in the two randomly allocated groups likely reflects that the routine counselling alone is adequate and fulfils the needs of the population who use our service. It may be speculated from our results that regarding the side effects induced by contraceptives, mainly those related to unpredictable menstrual bleeding which are unacceptable,
Counselling and long-acting reversible contraceptives

inconvenient or considered severe by the users, the women were probably influenced by either routine or intensive counselling this helps to avoid premature discontinuations.

Counselling provided to contraceptive users and potential users is a well-accepted strategy and tool to increase acceptance, adherence, continuation and user satisfaction. However, in some settings counselling is a crucial activity during contraceptive use to reduce premature discontinuations due to side effects, and to improve continuation rate and satisfaction. LARC methods are highly effective methods (Winner et al., 2012); however, premature discontinuations reduce this effectiveness and in many cases could lead women to choose less effective methods or to discontinue prematurely, both of which increase the risk of unplanned pregnancy.

We observed that the main reasons for discontinuation were expulsion in the TCu380A IUD and LNG-IUS groups and weight gain in users of the ENG-implant. An increase in weight during the use of hormonal contraceptive methods has already been reported; however, this subject is still a matter of debate (Smith and Reuter, 2002; Agrawal and Robinson, 2005; Lakha and Glasier, 2006; Wong et al., 2009). The main reasons described for discontinuation of the LNG-IUS have been weight gain (29%) (Sheng et al., 2009), headache, abdominal pain and lower back pain (7%) (Su Honen et al., 2004), and menstrual bleeding abnormalities (3–6%) (Andersson et al., 1994; Baldaszi et al., 2003; Su Honen et al., 2004). With the ENG-implant, the discontinuation rate due to menstrual bleeding irregularities has been reported as 17% at 1 year and 62% at 2 years (Croxatto et al., 1999; Smith and Reuter, 2002; Agrawal and Robinson, 2005; Lakha and Glasier, 2006; Wong et al., 2009), much higher than observed in this trial. In our study, users of the ENG-implant experienced high rates of amenorrhoea and infrequent bleeding at the end of the first year of use and it would appear that this type of bleeding pattern increases satisfaction and consequently ensures a high continuation rate.

### Table I Descriptive characteristics of the participants.

<table>
<thead>
<tr>
<th>Variables</th>
<th>Copper IUD (n = 100)</th>
<th>LNG-IUS (n = 99)</th>
<th>ENG-implant (n = 98)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>29.1 ± 6.0</td>
<td>30.8 ± 5.8</td>
<td>30.5 ± 6.1</td>
<td>0.092*</td>
</tr>
<tr>
<td>Number of children</td>
<td>1.5 ± 0.8</td>
<td>1.5 ± 0.8</td>
<td>1.1 ± 0.8</td>
<td>0.004**</td>
</tr>
<tr>
<td>Body mass index (kg/m²)</td>
<td>27.5 ± 5.3</td>
<td>27.7 ± 6.2</td>
<td>25.3 ± 4.2</td>
<td>0.022**</td>
</tr>
<tr>
<td>Years of schooling</td>
<td>10.7 ± 3.4</td>
<td>11.8 ± 3.1</td>
<td>11.7 ± 3.4</td>
<td>0.008**</td>
</tr>
<tr>
<td>Marital status, n (%)</td>
<td>79 (80.6)</td>
<td>75 (78.9)</td>
<td>70 (72.2)</td>
<td>0.331*</td>
</tr>
<tr>
<td>Ethnicity (white); n (%)</td>
<td>75 (76.5)</td>
<td>84 (86.6)</td>
<td>79 (81.4)</td>
<td>0.194*</td>
</tr>
</tbody>
</table>

| IUD, intrauterine device; LNG-IUS, levonorgestrel-releasing intrauterine system; ENG, etonogestrel. |
| Mean ± standard error of the mean.         |
| *F-test (ANOVA); **Kruskal–Wallis test; *Pearson’s χ² test. |

### Table II Cumulative continuation and discontinuation rates.

<table>
<thead>
<tr>
<th>Reasons for discontinuation</th>
<th>Method</th>
<th>Copper IUD (n = 100)</th>
<th>LNG-IUS (n = 99)</th>
<th>ENG-implant (n = 98)</th>
<th>P-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bleeding</td>
<td>Copper IUD</td>
<td>4.0 (2.3)</td>
<td>2.7 (1.9)</td>
<td>2.1 (1.5)</td>
<td>0.853</td>
</tr>
<tr>
<td></td>
<td>LNG-IUS</td>
<td>4.6 (2.3)</td>
<td>4.6 (2.3)</td>
<td>6.9 (2.7)</td>
<td>0.069</td>
</tr>
<tr>
<td></td>
<td>ENG-implant</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
<td>0.008</td>
</tr>
<tr>
<td>Weight gain</td>
<td>1.3 (1.3)</td>
<td>5.8 (2.5)</td>
<td>6.2 (2.7)</td>
<td>0.092</td>
<td></td>
</tr>
<tr>
<td>Expulsion</td>
<td>8.6 (2.8)</td>
<td>8.10 (4.2)</td>
<td>8.26 (4.0)</td>
<td>0.214</td>
<td></td>
</tr>
<tr>
<td>Continuation rate</td>
<td>73.2 (4.8)</td>
<td>81.0 (4.2)</td>
<td>82.6 (4.0)</td>
<td>0.008</td>
<td></td>
</tr>
</tbody>
</table>

| IUD, intrauterine device; LNG-IUS, levonorgestrel-releasing intrauterine system; ENG, etonogestrel. |
| *Wilcoxon–Gehan test; Standard error of the mean (SEM). |

Counselling is a crucial activity during contraceptive use to reduce premature discontinuations due to side effects, and to improve continuation rate and satisfaction. LARC methods are highly effective methods (Winner et al., 2012); however, premature discontinuations reduce this effectiveness and in many cases could lead women to choose less effective methods or to discontinue prematurely, both of which increase the risk of unplanned pregnancy.
The continuation rate of users of the ENG-implant was higher (83%) than rates reported from other studies (Kalmuss et al., 1996; Croxatto et al., 1999; Smith and Reuter, 2002; Agrawal and Robinson, 2005; Lakha and Glasier, 2006; Harvey et al., 2009); however, in the case of the LNG-IUS, the continuation rate was similar to those found in previous studies (Andersson et al., 1994; Baldaszti et al., 2003; Suhonen et al., 2004; Bahamondes et al., 2012; Ferreira et al., 2014). With respect to the TCu380A IUD, the continuation rate at the end of the first year was 73.2%, slightly lower than that of 80% found in a previous study (Peipert et al., 2011). Similarly, user satisfaction was also high with all three methods, with rates of 86% for the TCu380A IUD and 90% or over for the LNG-IUS and the ENG-implant. One explanation for these high continuation and satisfaction rates may lie in the counselling provided prior to insertion of the method. This assumption is reasonable, particularly because discontinuation rates were similar in the women who received intensive counselling and in those who were given routine counselling.

There are limitations and strengths associated with this study. The main limitation may be that information may have been exchanged between the women who received intensive counselling and those who were given only routine counselling, since they shared the same waiting room and could have discussed the information they were given during counselling. Another possible limitation is that the routine counselling provided by our counsellors is adequate for the women attending the clinic and premature discontinuation due to bleeding irregularities was already low. Consequently, intensive counselling did not, and was unlikely to, lead to further reductions in premature discontinuations due to unpredictable menstrual bleeding. Additionally, another limitation is that it may not be generalizable to less well-established and active settings.

The main strength of the study was the fact that the women were randomized to one of two counselling strategies. The message emerging from our results for low resources settings is that it is better strategies that focused on counselling about what to expect regarding bleeding disturbances and side effects is useful because it allows low rates of premature discontinuation, high rates of continuation and high user satisfaction. Furthermore, counselling potentially reduces unintended pregnancies and it is cost-effective mainly in the case of LARC methods.

In conclusion, both counselling strategies which included what to expect with respect to bleeding patterns when using an LARC method were followed by low rates of premature discontinuations and high rates of continuation and satisfaction in this cohort of Brazilian women.

**Authors’ roles**

W.M. was responsible for the collection, analysis and interpretation of the data, for writing the first version of this article and for reviewing and approving the final version of the manuscript. M.V.B. and L.B. conceived the idea for the study and were responsible for its design. They were also responsible for inserting all the devices. L.B. was also responsible for analysing and interpreting the data and for writing and revising the final version of the manuscript.

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**Figure 2** Bleeding patterns in the ENG-implant, the LNG-IUS and the TCu380A IUD users at 1 year of use. In the analysis between groups of 1–180 days, \( \chi^2 P = 0.000 \). Invalid \( \chi^2 \) test in the analysis of 181–360 days.
Access Foundation (ICA) and the copper IUD by Injeflex, São Paulo, Brazil.

**Conflict of interest**

L.B. has occasionally served on the Board of MSD, Bayer and Vifor.

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