Contraceptive uptake and compliance after structured contraceptive counseling - secondary outcomes of the LOWE trial

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Abstract
Introduction: Highly effective long-acting reversible contraceptive (LARC) methods reduce unintended pregnancy rates; however, these methods are underutilized. The LOWE trial intervention provided structured contraceptive counseling resulting in increased uptake of LARC. This longitudinal follow up of the LOWE study assessed the long-term impact of the intervention by investigating the contraceptive use at 12 months with a focus on continued use of LARC.

Material and methods: In the cluster randomized LOWE trial, abortion, youth, and maternal health clinics were randomized to provide either structured contraceptive counseling (intervention) or standard contraceptive counseling (control). The intervention consisted of an educational video on contraceptive methods, key questions asked by the health care provider, a tiered effectiveness chart and a box of contraceptive models. Women ≥ age 18, who were sexually active or planned to be in the upcoming 6 months, could participate in the study. We assessed self-reported contraceptive use at three, six and 12 months. Contraceptive choice and switches were analyzed with descriptive statistics. Contraceptive use at 12 months and continued use of LARC were analyzed using mixed logistic regressions, with clinic included as a random effect. Analysis with imputed values were performed for missing data to test the robustness of results.

Results: Overall, at 12 months, women in the intervention group were more likely to be using a LARC method (aOR 1.90, 95% CI: 1.31–2.76) and less likely to be using a short-acting reversible contraception (SARC) method (aOR 0.66, 95% CI: 0.46–0.93) compared to the control group. Women counseled at abortion (aOR 2.97, 95% CI: 1.36–6.75) and youth clinics (aOR 1.81, 95% CI: 1.08–3.03) were more likely to be using a LARC method, while no significant difference was seen in maternal health clinics (aOR 1.84, 95% CI: 0.96–3.66). Among women initiating LARC, continuation

Abbreviations: FU, follow-up; LARC, long-acting reversible contraception; LOWE, Larc fOrWard counsElng trial; SARC, short-acting reversible contraception.
rates at 12 months did not differ between study groups (63.9% vs. 63.7%). The most common reasons for contraceptive discontinuation were wish for pregnancy, followed by irregular bleeding, and mood changes.

Conclusions: The LOWE trial intervention resulted in increased LARC use also at 12 months. Strategies on how to sustain LARC use needs to be further investigated.

KEYWORDS
choice, continuation, contraception, contraceptive-counseling, LARC, long-acting reversible contraception, unintended pregnancy

1 | INTRODUCTION

Since 1990 unintended pregnancy rates have declined in Europe and the US. However, levels still remain at 35/1000 women of fertile age.1 The unmet need for family planning persists despite availability and access to contraceptive service systems and multiple effective contraceptive methods. Among Swedish women, one fifth have experienced at least one unintended pregnancy and the unmet need for family planning has increased from 9% to 17% between the years 2013 and 2021,2,3 despite easy access to and increased subsidies for contraception. Also, contraceptive counseling is part of the national sexuality education program in Sweden. The most important characteristic of a contraceptive method indicated by women is its effectiveness in preventing unintended pregnancy.2,4

Long-acting reversible contraception (LARCs), consisting of subdermal implants and intrauterine devices, are highly effective, not dependent on the user and have high continuation and satisfaction rates.5,6 LARCs are increasingly recommended as first-line choice to all women including nulliparous women and adolescents. Several studies have shown that LARCs are more effective in preventing unintended pregnancy and abortion compared to other reversible methods.7–11 However worldwide, LARCs are still underutilized and used less frequently than short-acting user dependent (SARC) methods.12

Quality of contraceptive counseling is an important factor in increasing contraceptive uptake. Health care providers have a prominent role as the informer of available options, method effectiveness, side effects and suitability, and noncontraceptive health benefits. Although there have been studies on contraceptive counseling models that clearly affect choice of method,13,14 there is no clear consensus on best practice for contraceptive counseling while meeting women’s needs and preferences, managing potential side effects, and supporting method continuation or switching while avoiding coercion.

In our previous cluster randomized controlled trial, the Larc fOrward counsEling (LOWE) trial, we evaluated the effects of structured contraceptive counseling on LARC choice and initiation (i.e., uptake) and subsequent pregnancy rates. A higher LARC uptake was seen among participants in the clinics randomized to providing the structured contraceptive counseling. In addition, pregnancy rates were lower in intervention abortion clinics at the 12month follow-up (FU).15 The secondary endpoints of contraceptive use at 3 months as well as satisfaction with the intervention and a subanalysis on effects and satisfaction in migrants have been previously published.15–17

The aim of the present study was to investigate the 12month FU on contraceptive use in both study groups (intervention and control) within the LOWE trial. In addition, continued use of contraception at 12 months post intervention with a focus on LARC and the flow of contraceptive switching was also investigated as a measure of compliance.

2 | MATERIAL AND METHODS

2.1 | Study design and study population

The LOWE trial was a cluster randomized trial including abortion, youth, and maternal health clinics in Stockholm, Sweden, conducted during 2017–2019. A detailed description of the study has been previously published.15 In brief, participating clinics were randomized to provide either structured contraceptive counseling (intervention) or to continue with their standard contraceptive counseling (control). Randomization was stratified by clinic type and clinics baseline LARC prescription (not able to collect from the four abortion clinics). For youth and maternal health clinics the proportion of migrants within the catchment areas was considered. However, due to their larger catchment areas with expected equal distribution of sociodemographic factors, no such information was collected from abortion clinics. Contraceptive methods were stratified as follows: LARC including contraceptive implants and intrauterine devices (copper and
levonorgestrel releasing), SARC (combined pill, progestin-only pill, contraceptive injectables, transdermal patch and vaginal ring), other (condom, diaphragm, smartphone application and fertility awareness methods) and no method.

Eligible women were above 18 years of age, able to understand Swedish or English either independently or with the help of an interpreter, were sexually active with a male partner or planning to be in the upcoming 6 months, and were seeking contraception for pregnancy prevention. Participants came for first-time contraceptive counseling or for renewal or switching of any contraceptive method. Before study inclusion, participants received oral and written information about the study and then signed informed consent.

The intervention took place at the clinic visit by health care providers, that is, nurse-midwives (majority) and medical doctors (mainly at abortion clinics) and consisted of four parts. (i) A 7 min long educational video on contraceptive methods to be seen by the participant prior to the counseling. (ii) Four key questions to be asked by the health care provider during the counseling visit together with (iii) a tiered effectiveness chart and (iv) a box of contraceptive models. Participants in the control clinics received routine counseling, that is, no specific structure.

The structured contraceptive counseling protocol used in the study was introduced leaving costs and other services unchanged to maintain a "real world practice". In Sweden, contraceptive counseling services, including prescriptions, are free of charge and widely available. Any prescribed method is dispensed at the pharmacy at no cost for women up to 21 years of age. SARCs are subsidized to a yearly cost of approximately 9 euros for women up to 26 years of age, while LARCs cost 9 euros for the full duration of use. Women above 26 years of age pay the full amount with cost of LARCs at approximately 90 euros for the full duration of use.

2.2 Assessments

Reports from health care providers and participants were collected using online questionnaires. At the clinic visit health care providers and participants answered the questionnaires on site, and at three, six and 12-months follow-up (FU) questionnaires were sent to participants by email. Several email attempts were made to collect the questionnaires, and if needed, additional attempts by telephone were made.

2.3 Outcomes

In this study we present secondary outcomes from the 12 months FU (i.e., the observation period of the study) including contraceptive use and continuation at 12 months with a focus on LARC, intervention effect and comparisons of the contraceptive flow during the observed study period. Initial contraceptive choice at the clinic visit was reported by the health care provider whereas contraceptive use was reported by the participant at three, six and 12-months FU.

2.4 Statistical analyses

Power calculations set at 90% power were performed on LARC choice in the initial LOWE trial including an assumed intraclass correlation of 0.05 as observed in a previous study. Power calculations were not performed for secondary outcomes. Descriptive statistics were used to analyze background characteristics.

Choice of contraceptives and switches were analyzed with descriptive statistics and visualized using Sankey diagrams. Contraceptive use at 12 months and continued use of LARC were analyzed as dependent variables in mixed logistic regressions with clinic included as a random effect. Study group, age, highest level of completed education, previous pregnancy with and without previous abortion; intended use of LARC; and clinic type were included as independent variables. Estimates are presented as crude and adjusted odds ratios (OR and aOR) respectively with 95% confidence interval (CI).

Descriptive statistics were used to compare subjects lost to follow-up with those that were nonmissing at 12 months. Tables included present nonimputed values; however, a sensitivity analysis was performed to test the robustness of results, where the analyses were repeated with imputed values using the method of "last observation carried forward". For subjects with two consecutive missing follow-up times the choice of contraceptive for the latter missing value was assumed to be "no contraceptive". Analyses were performed in R version 4.1.1 by an independent statistician.

3 RESULTS

The LOWE trial enrolled 1364 participants. Here we report contraceptive use at 12 months FU for 1338 participants presented in Figure 1 (flow chart).

An overview of baseline characteristics by study group allocation is shown in Table 1.

No baseline characteristics differed between study groups. At inclusion close to half of the participants (49%) n = 654 (both groups combined) did not use any current method of contraception. SARC methods were the most common methods and were used by 32% (n = 425), followed by other methods, that is, barrier or fertility awareness methods 13.5% (n = 180), and LARCs at a mere total of 5.3% (n = 71). Among those using a contraceptive method at baseline, the use of LARC was 30/325 (9.2%) within the intervention group and 41/351 (11.7%) within the control group.

Data on contraceptive use at 12-months FU was available for 1123/1338 women (83.9%). In the intervention group, 431/552 (78.1%) of women reported using a contraceptive method at 12 months, similar to 438/571 (76.7%) in the control group (Table 2).

Among individuals utilizing a contraceptive method, the predominant method was SARC both at initiation (3 months) and during the 12-month FU period. This was the case despite a minor decrease in usage, from 269/489 (55.0%) to 221/431 (51.3%) in the intervention group, and from 329/493 (66.7%) to 268/438 (61.2%) in the control group.
Regarding LARC, there was a slight increase in its utilization at the 12-month mark within the intervention group, rising from 213/489 (43.5%) at initiation (3 months) to 193/431 (44.8%) at 12 months. A slight increase could also be observed in the control group, where LARC use rose from 153/493 (31.0%) to 153/438 (34.9%) at 12 months compared to initiation. A summary of contraceptive use (including data missing at each timepoint) is presented in Table S1.

At 12 months FU, women in the intervention group were more likely to be using a LARC method (aOR 1.90, 95% CI: 1.31–2.76) and less likely to be using a SARC method (aOR 0.66, 95% CI: 0.46–0.93) compared to initiation.
than women in the control group. No significant difference was seen for "other methods" or "no method". A total of 254/1123 (22.6%) (both groups combined) were not using any contraception (Table 2).

Women counseled at abortion and youth clinics randomized to intervention, were more likely to use LARC at 12 months FU, compared to control (aOR 2.97, 95% CI: 1.36–6.75 and aOR 1.81, 95% CI: 1.01–3.28).

TABLE 1 Baseline characteristics of the study participants by group allocation.

<table>
<thead>
<tr>
<th>Sociodemographic characteristics</th>
<th>Intervention (n = 658)</th>
<th>Control (n = 680)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age (years) (n = 1338)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median (IQR)</td>
<td>24 (20–29)</td>
<td>24 (20–30)</td>
</tr>
<tr>
<td><strong>Reproductive and contraceptive history</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current or previous pregnancy (n = 1335)</td>
<td>223 (34.0%)</td>
<td>257 (37.8%)</td>
</tr>
<tr>
<td>Nulliparous (n = 1332)</td>
<td>538 (82.3%)</td>
<td>531 (78.3%)</td>
</tr>
<tr>
<td>Medical abortion (n = 1333)</td>
<td>137 (20.9%)</td>
<td>152 (22.4%)</td>
</tr>
<tr>
<td>Surgical abortion (n = 1332)</td>
<td>44 (6.7%)</td>
<td>48 (7.1%)</td>
</tr>
<tr>
<td>Birth (n = 1333)</td>
<td>127 (19.3%)</td>
<td>173 (25.4%)</td>
</tr>
<tr>
<td><strong>Highest completed education (n = 1295)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary school</td>
<td>71 (11.1%)</td>
<td>77 (11.7%)</td>
</tr>
<tr>
<td>Secondary school</td>
<td>328 (51.3%)</td>
<td>365 (55.6%)</td>
</tr>
<tr>
<td>College/university</td>
<td>239 (37.4%)</td>
<td>214 (32.6%)</td>
</tr>
<tr>
<td>Unknown</td>
<td>1 (0.2%)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td><strong>Current contraception (n = 1330)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LARC a</td>
<td>30 (4.6%)</td>
<td>41 (6.1%)</td>
</tr>
<tr>
<td>SARC b</td>
<td>209 (32.0%)</td>
<td>216 (32.0%)</td>
</tr>
<tr>
<td>Other c</td>
<td>86 (13.1%)</td>
<td>94 (13.9%)</td>
</tr>
<tr>
<td>No method</td>
<td>329 (50.3%)</td>
<td>325 (48.0%)</td>
</tr>
<tr>
<td>Intended LARC use prior to counseling (n = 1320)</td>
<td>128 (19.7%)</td>
<td>156 (23.3%)</td>
</tr>
<tr>
<td>Number of clusters (n = 28)</td>
<td>14 (50%)</td>
<td>14 (50%)</td>
</tr>
</tbody>
</table>

Note: Data are n (%). Extracted from the LOWE trial. Current contraception noted at study entrance.

Abbreviations: IQR, interquartile range; LARC, long-acting reversible contraception; SARC, short-acting reversible contraception.

aLARC: Intrauterine device or subdermal implant.
bSARC: Combined pill, progestin-only pill, contraceptive injection, transdermal patch, or vaginal ring.
cOther: Condom, diaphragm, smartphone application, fertility awareness methods.

TABLE 2 Logistic mixed model for use of contraception at 12 months.

<table>
<thead>
<tr>
<th>FU12</th>
<th>Contraceptive use</th>
<th>Intervention effect</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>LARC a</td>
<td>SARC b</td>
</tr>
<tr>
<td></td>
<td>Unadjusted OR (95% CI)</td>
<td>Adjusted OR (95% CI)</td>
</tr>
<tr>
<td></td>
<td>193/552 (35.0%)</td>
<td>153/571 (26.8%)</td>
</tr>
<tr>
<td></td>
<td>1.51 (1.08–2.10)</td>
<td>1.90 (1.31–2.76)</td>
</tr>
<tr>
<td></td>
<td>0.72 (0.40–1.28)</td>
<td>0.66 (0.46–0.93)</td>
</tr>
<tr>
<td></td>
<td>0.0169</td>
<td>0.8330</td>
</tr>
</tbody>
</table>

Abbreviations: CI, confidence interval; LARC, long-acting reversible contraception; OR, odds ratio; SARC, short-acting reversible contraception.

Note: Data are n (%) and odds ratio (95% confidence interval). All models include a random intercept for clinic. Model adjusted for: Age, highest level of completed education, previous pregnancy with and without previous abortion; intended use of LARC; and clinic type.

aLARC: Intrauterine device or subdermal implant.
bSARC: Combined pill, progestin-only pill, contraceptive injection, transdermal patch, or vaginal ring.
cOther: Condom, diaphragm, smartphone application, fertility awareness methods.
95% CI: 1.08–3.03, respectively), while no significant difference was seen in maternal health clinics (aOR 1.84, 95% CI: 0.96–3.66) (Table S2).

Table 3 shows the proportion of users who continued over time per chosen method group at the clinic visit. At 12 months FU, LARC users continued use at approximately 64% in both intervention and control groups. Continued use of SARC methods was slightly higher (Table 3).

The continuation rate of LARC was method dependent and did not result from allocation to intervention or control (aOR 1.04, 95% CI: 0.60–1.82). Age, highest completed education level, pregnancy with and without previous abortion and clinic type also did not show any significant effect on LARC continuation. However, intended use of LARC had a significant impact on LARC continuation rates where those not intending to use a LARC method were continuing users to a lesser extent in comparison to those who intended to use a LARC (aOR 0.50, 95% CI: 0.32–0.80) (Table S3).

Contraceptive flow over 12 months for each contraceptive method group, including intended contraceptive use, is shown in Figure 2A, B.

The flow of each contraceptive method from the clinic visit until 12 months FU is presented in Figure 3A, B.

The most common specified reason for participants to discontinue their latest method was wish for pregnancy, followed by bleeding complaints and mood changes (Table 4).

A drop out analysis at 12 months FU showed that more women who intended to use a LARC method were nonmissing (Table S4). Sensitivity analysis where robust and did not change results except in maternal health clinics randomized to intervention where a notable difference was seen in LARC utilization at 12 months FU, compared to control (aOR 1.83, 95% CI: 1.06–3.24). Also, compared to abortion clinics, maternal health clinics were more likely to continue a LARC method (aOR 2.80, 95% CI: 1.17–6.70).

4 | DISCUSSION

This current longitudinal study reports the contraceptive use and continuation in both study groups (intervention and control) with a focus on LARC at 12 months FU. LARC use at 12 months FU was significantly higher in the intervention group. Approximately three out of four participants in both study groups were using an effective (LARC or SARC) method of contraception at 12 months post intervention. Continued use of LARC was method dependent and did not depend on allocation to intervention or control group. The most common reason for contraceptive discontinuation were wish for pregnancy followed by irregular bleeding and mood changes.

Women who had received their counseling at an abortion or youth clinic were significantly more likely to be using a LARC method, while no significant difference was seen in maternal health clinics at 12 months FU.

Although there was no significant difference in continued use of LARC between intervention and control groups, the findings of a higher LARC use at 12 months in the intervention group can most probably be contributed by the initial intervention effect on LARC uptake at baseline (i.e., choice + initiation). Notably, no differential effects were found for age, education, pregnancy with and without previous abortion, or clinic type on continuation of LARC. However, participants intending to use a LARC prior to counseling had a significantly increased likelihood of continuing a LARC method during the entire study period, stressing the importance of motivation.

In comparison to another prospective trial continuation rates of LARC were lower in our cohort. In contrast to the US CHOICE study in which the long term LARC continuation rates were 86% at 12 months and 67% at 3 years, our findings showed a LARC continuation of approximately 64% (both study groups) at 12 months. The CHOICE study specifically targeted women with risk factors for unintended pregnancy such as age below 25, low socioeconomic status and minority racial or ethnic background while our study had a more heterogenous population which may explain the difference. In addition, the CHOICE study provided no cost contraception in a setting where costs of LARCs are high. In our study, cost and access aspects could not influence results as this study was conducted in a real life setting.

Factors associated with participants decision to discontinue a method are multifactorial and complex. In a study on Swedish speaking women seeking abortion, few had used effective methods, and many had discontinued contraception during the last year. Around conception over 60% relied on withdrawal or used no method indicating a high unmet need for contraception. The most common reasons of nonuse and failure were an underestimated risk for pregnancy and experiences of negative contraceptive side effects. Reasons for avoiding hormonal contraception specifically were mood swings followed by depressive symptoms.

At 12 months FU we found that 22.6% of women used no method of contraception with a majority discontinuing their previous method somewhere between six to 12 months.

Hence, continuation rates and use of effective contraception (LARC and SARC) during the first half of the study period were considerably higher in comparison to the second half. Wish for pregnancy was the most common reason for discontinuing a method at 12 months stressing the importance of reversible methods with easy access to removal of LARC methods. Since the importance of counseling on irregular bleeding patterns with different methods is well known to health care providers, we believe that participants were well informed. Despite this, consistent with other studies, irregular bleeding patterns and mood changes were other main reasons for discontinuing a method.

This highlights the importance of more focus on the art of counseling, and continued development of highly effective methods with fewer side effects and more tolerable bleeding patterns.
### TABLE 3  Continued use over time per contraceptive method group chosen at the clinic visit.

<table>
<thead>
<tr>
<th>Time</th>
<th>Category</th>
<th>LARC&lt;sup&gt;d&lt;/sup&gt;</th>
<th>SARC&lt;sup&gt;e&lt;/sup&gt;</th>
<th>Other&lt;sup&gt;f&lt;/sup&gt;</th>
<th>No method</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Intervention (N=267)</td>
<td>Control (N=206)</td>
<td>Intervention (N=342)</td>
<td>Control (N=412)</td>
<td>Intervention (N=27)</td>
</tr>
<tr>
<td>FU3</td>
<td>Continued&lt;sup&gt;a&lt;/sup&gt;</td>
<td>188 (84.7%)</td>
<td>138 (80.2%)</td>
<td>246 (91.1%)</td>
<td>306 (95.9%)</td>
</tr>
<tr>
<td></td>
<td>Switched&lt;sup&gt;b&lt;/sup&gt;</td>
<td>34 (15.3%)</td>
<td>34 (19.8%)</td>
<td>24 (8.9%)</td>
<td>13 (4.1%)</td>
</tr>
<tr>
<td></td>
<td>Returned&lt;sup&gt;c&lt;/sup&gt;</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td></td>
<td>Missing</td>
<td>45</td>
<td>34</td>
<td>72</td>
<td>93</td>
</tr>
<tr>
<td>FU6</td>
<td>Continued&lt;sup&gt;a&lt;/sup&gt;</td>
<td>186 (79.5%)</td>
<td>140 (78.2%)</td>
<td>249 (90.2%)</td>
<td>315 (93.8%)</td>
</tr>
<tr>
<td></td>
<td>Switched&lt;sup&gt;b&lt;/sup&gt;</td>
<td>44 (18.8%)</td>
<td>37 (20.7%)</td>
<td>23 (8.3%)</td>
<td>16 (4.8%)</td>
</tr>
<tr>
<td></td>
<td>Returned&lt;sup&gt;c&lt;/sup&gt;</td>
<td>4 (1.7%)</td>
<td>2 (1.1%)</td>
<td>4 (1.4%)</td>
<td>5 (1.5%)</td>
</tr>
<tr>
<td></td>
<td>Missing</td>
<td>33</td>
<td>27</td>
<td>66</td>
<td>76</td>
</tr>
<tr>
<td>FU12</td>
<td>Continued&lt;sup&gt;a&lt;/sup&gt;</td>
<td>149 (63.9%)</td>
<td>114 (63.7%)</td>
<td>182 (65.2%)</td>
<td>236 (69.0%)</td>
</tr>
<tr>
<td></td>
<td>Switched&lt;sup&gt;b&lt;/sup&gt;</td>
<td>75 (32.2%)</td>
<td>58 (32.4%)</td>
<td>91 (32.6%)</td>
<td>99 (28.9%)</td>
</tr>
<tr>
<td></td>
<td>Returned&lt;sup&gt;c&lt;/sup&gt;</td>
<td>9 (3.9%)</td>
<td>7 (3.9%)</td>
<td>6 (2.2%)</td>
<td>7 (2.0%)</td>
</tr>
<tr>
<td></td>
<td>Missing</td>
<td>34</td>
<td>27</td>
<td>63</td>
<td>70</td>
</tr>
</tbody>
</table>

Abbreviations: LARC, long-acting reversible contraception; SARC, short-acting reversible contraception.

<sup>a</sup>Continued user defined as continued use of contraceptive method “within” a group (i.e., continued use of a LARC, SARC, other, no method) chosen at the clinic visit, up until each follow up time.

<sup>b</sup>Switched from contraceptive method group (LARC, SARC, other, no method) chosen at the clinic visit to another method group (including no method), up until each follow up time.

<sup>c</sup>Returned user defined as returning to the contraceptive method group (LARC, SARC, other, no method) chosen at the clinic visit after a previous switch to another method group (including no method), up until each follow up time.

<sup>d</sup>LARC: Intrauterine device or subdermal implant.

<sup>e</sup>SARC: Short-acting reversible contraception: combined pill, progestin-only pill, contraceptive injection, transdermal patch, or vaginal ring.

<sup>f</sup>Other: Condom, diaphragm, smartphone application, fertility awareness methods.
SARC methods had the highest proportion of discontinuers with approximately 25% of women discontinuing a SARC at 12 months. Removal of LARC methods requires seeking care and may add costs. In our setting, access to removal is without additional costs which may have impacted continuation rates compared with previous studies. 18

The strength of our study includes its prospective design and relatively large sample size. The cluster randomization of clinics limits potential spillover effects between clinics and providers. Participants could be included for start of a new method, switching, stopping or continuing a current method at the study start and during the whole study period, which increases generalizability. Additionally, the design of the structured counseling without incurring costs and using a real life setting, has to our knowledge not been examined in any previous randomized trials.

Figure 2 (A) Sankey flow diagram, illustrating contraceptive use over time, in the intervention group. (B) Sankey flow diagram, illustrating contraceptive use over time, in the control group.

T0=intended contraceptive use prior to clinic visit, T1= contraceptive choice at clinic visit, T2= contraceptive use at 3 months FU, T3= contraceptive use at 6 months FU T4= contraceptive use at 12 months FU
The height of the bars represent the number of subjects within each contraceptive method group
For T0, T2, T3 and T4 those loss to follow-up are not included, hence the lower total bar hights.
The number of respondents discontinuing a method due to a wish for pregnancy at T2: were 3/3528 (0.4%), T3: 7/552 (1.3%), and T4: 15/552 (2.7%).
LARC, long-acting reversible contraception: intrauterine device or subdermal implant.
SARC, short-acting reversible contraception: combined pill, progestin-only pill, contraceptive injection, transdermal patch or vaginal ring.
Other: Condom, diaphragm, smartphone application, fertility awareness methods.
The main limitations include self-reported data and loss to FU. Self-reported data could have led to different forms of reporting bias. Furthermore, choice of contraception at the clinic visit was reported by the healthcare provider and actual collection of prescriptions were not controlled for other than at self-reported FU. When analyzing missing and nonmissing data more women who intended to use a LARC method were nonmissing which might slightly overestimate results of LARC use.

**CONCLUSION**

The LOWE trial intervention involved structured contraceptive counseling with a strong focus on method effectiveness, which resulted in a notable increase in the utilization of long-acting reversible contraceptives (LARC) at the 12-month follow-up. Women who received counseling at intervention clinics exhibited a higher prevalence of LARC usage compared to those counseled at control clinics. Notably, the
most significant impact of the intervention on LARC utilization at the 12-month mark was observed in abortion and youth clinics, with no significant difference noted in maternal health clinics.

However, it is essential to highlight that the intervention did not have a significant influence on LARC continuation. The primary reason for not using contraception at the 12-month mark was a wish for pregnancy. Additionally, it is imperative to underscore the need for further research to explore strategies for sustaining LARC utilization. Equally important is the investigation of strategies to manage irregular bleeding and mood changes, which emerged as the second most prevalent reasons for discontinuation.

**AUTHOR CONTRIBUTIONS**
Kristina Gemzell-Danielsson was responsible for the study concept, trial protocol, regulatory approvals and overall responsibility for the study conduct and funding. Helena Kopp Kallner, Niklas Envall, Karin Emtell Iwarsson contributed to study design, protocol development and in securing funding as well as in conduct of the study. Fabian Söderdahl was responsible for the study data analysis plan. All authors except Isabella Bizjak were involved in the development of study tools and recruitment of participating clinics. Isabella Bizjak, Karin Emtell Iwarsson and Niklas Envall acquired the data. Isabella Bizjak was responsible for data analyses. All authors contributed to the interpretation of the data and manuscript writing. Women of fertile age responded to a pretrial survey on contraceptive use and experiences and thus contributed to study design.

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**CONFLICT OF INTEREST STATEMENT**
KEI reports nonfinancial support from Bayer AG, nonfinancial support from RemovAid AS, outside the submitted work. NE reports personal fees from Bayer AG, outside the submitted work. HKK reports personal fees and other from Bayer, personal fees from MSD, personal fees from Exeltis, personal fees from Mithra, personal fees from Natural Cycles, personal fees from Gedeon Richter, personal fees from Preglem, outside the submitted work; Gemzell-Danielsson reports other from RemovAid; personal fees and other from MSD/Merck, Bayer AG, Gedeon Richter, Exeltis, Natural Cycles, Mithra, MedinCell, and Myovant, outside the submitted work. IB has nothing to disclose.

**ETHICS STATEMENT**
Ethical approval was obtained by the regional ethics committee in Stockholm (Dnr 2017/525–31/4) on March 29, 2017. The trial reported according to the Consort Statement Extended Guidelines and was registered at clinical trials.gov (NCT03269357).

### Table 4: Reasons for discontinuing a method among those not using any contraception at 12 months (n=254).

<table>
<thead>
<tr>
<th>Reason</th>
<th>Frequency (n)</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wish for pregnancy</td>
<td>33</td>
<td>15.6</td>
</tr>
<tr>
<td>Bleeding complaints/irregular bleeding patterns</td>
<td>29</td>
<td>13.7</td>
</tr>
<tr>
<td>Mood changes/PMS</td>
<td>22</td>
<td>10.4</td>
</tr>
<tr>
<td>No partner</td>
<td>18</td>
<td>8.5</td>
</tr>
<tr>
<td>Afraid of side effects</td>
<td>9</td>
<td>4.3</td>
</tr>
<tr>
<td>Hard to remember to take</td>
<td>9</td>
<td>4.3</td>
</tr>
<tr>
<td>Weight gain</td>
<td>7</td>
<td>3.3</td>
</tr>
<tr>
<td>Loss of sex drive</td>
<td>7</td>
<td>3.3</td>
</tr>
<tr>
<td>Contraindication</td>
<td>6</td>
<td>2.8</td>
</tr>
<tr>
<td>Acne</td>
<td>4</td>
<td>1.9</td>
</tr>
<tr>
<td>Unintended pregnancy</td>
<td>4</td>
<td>1.9</td>
</tr>
<tr>
<td>Did not plan to have sex</td>
<td>4</td>
<td>1.9</td>
</tr>
<tr>
<td>Headache</td>
<td>3</td>
<td>1.4</td>
</tr>
<tr>
<td>Too expensive</td>
<td>1</td>
<td>0.5</td>
</tr>
<tr>
<td>Other</td>
<td>55</td>
<td>26.1</td>
</tr>
<tr>
<td>Total</td>
<td>211</td>
<td>100.0</td>
</tr>
<tr>
<td>Missing</td>
<td>43</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>254</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviation: PMS, premenstrual syndrome.
REFERENCES


SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.