The efficacy, safety and acceptability of medical termination of pregnancy provided by standard care by doctors or by nurse-midwives: a randomised controlled equivalence trial

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Objective To assess nurse-midwife provision of early medical termination of pregnancy (TOP) in a high-resource setting where ultrasound examination for dating of pregnancy is part of the protocol.

Design Randomised controlled equivalence trial.

Setting Out-patient family planning unit at a university hospital.

Population Women seeking early medical TOP.

Methods A total of 1180 women were randomised, without any prior examination, to counselling, examination, and treatment by either nurse-midwife or gynaecologist. Ultrasound was performed in all cases by the allocated provider.

Main outcome measures The primary outcome was efficacy, defined as the successful completion of TOP without need for vacuum aspiration. Secondary outcomes were safety, defined as need for hospitalisation or blood transfusion, and acceptability, defined as preferred provider were the women to have a medical TOP in the future.

Results A total of 481 women in the nurse-midwife group and 457 women in the doctor group were available for the final analysis. The effectiveness of provision of medical TOP by nurse-midwife providers was superior to that provided by doctors (risk difference 1.6%, 95% confidence interval 0.2–3.0%, which was within the set margin of equivalence). There were no significant differences in safety parameters. Women examined and counselled by a nurse-midwife were significantly more likely (P < 0.001, 95% confidence interval 0.308–0.394) to prefer seeing a nurse-midwife for the consultation were they to have another medical TOP in the future.

Conclusions These findings show that nurse-midwife provision of early medical TOP in a high-resource setting, where ultrasound is part of the protocol, is effective, and can be safely implemented with high acceptability among women.

Keywords Abortion, medical abortion, midlevel provision.

Introduction

According to the World Health Organization (WHO) and the Guttmacher Institute, approximately 47 000 women die every year as a result of unsafe termination of pregnancy (TOP). Almost all these deaths occur in developing countries where access to safe TOP services is limited.1 In addition to legal limitations, access to providers may be a limiting factor in gaining access to safe TOP. Task shifting is defined as a process of delegating appropriate tasks from doctors to specialised providers, and has been found to increase productivity within healthcare systems.2 Studies from Africa show that the training of specialised non-doctor healthcare providers to perform tasks traditionally
reserved for doctors can help build sustainable, cost effective, and equitable healthcare services in both maternal healthcare and post-TOP services.3–5 In developing countries TOP services may or may not include pregnancy tests and/or ultrasound examination. Midlevel provision of medical TOP in Nepal, where ultrasound is not routine, has recently been shown to be effective and acceptable.6 The midlevel provision of surgical TOP has been shown to be equally safe and effective as that performed by doctors.7

In high-resource settings where TOP is legal it is generally a safe procedure; however, access to TOP may be limited by the scarcity of doctors willing to perform TOPs. In the USA, midlevel provision of medical TOP is becoming increasingly common. A wide variety of healthcare provider categories are involved in this care.8 The physical and pelvic examination before a TOP is traditionally performed by a doctor, and an ultrasound for dating of pregnancy is usually part of the protocol. Also, increased access to induced TOP in high-resource settings could thus be achieved by task sharing/shifting in TOP care.

The primary objective of this trial was to show that nurse-midwives can provide early medical TOP as effectively as doctors in a high-resource setting where TOP services are provided by doctors and ultrasound dating of pregnancy is part of the protocol. To show this the trial was designed as a randomised equivalence trial. Secondary objectives were to assess the safety and acceptability of nurse-midwife provision of medical TOP.

We could show that task shifting in medical TOP in high-resource settings, where vaginal ultrasound dating of pregnancy is part of the protocol, is highly effective. The results will be important for healthcare systems and the provision of safe TOP in many settings.

Methods

In Sweden, TOP is legal upon request by the woman up to 18 weeks and 0 days of gestation, and must be performed by a doctor. Permission was granted by the National Board of Health and Welfare and by the Ethical Review Board of Stockholm to allow midwives to independently provide medical TOP according to the study protocol. Nurse-midwives in Sweden may prescribe doxycycline for *Chlamydia trachomatis* infection but not antibiotics for bacterial vaginosis.

The study was registered at Clinicaltrials.gov, NCT01612923, and followed the modified CONSORT (Consolidated Standards of Reporting Trials) reporting guidelines for equivalence trials.

The trial was conducted at the out-patient family planning clinic of the Karolinska University Hospital, Sweden. Women made an appointment by calling the clinic by telephone, and were informed about the study at that time and asked if they would be willing to participate. If they were healthy, had a pregnancy of 63 days or less according to their last menstrual period, and wanted a medical TOP they were further informed of the study at the first visit to the clinic. Women were eligible to participate if they were 18 years or older, had no contraindication for medical TOP, and were in good general health with no continuing medication for chronic disease. If the women were eligible after interviewing and accepted participation they signed informed consent before they were randomised and prior to any examination had been performed. Women were allocated to the nurse-midwife arm or to the standard-care arm. In the nurse-midwife arm the examination, including the ultrasound dating of pregnancy and contraceptive counselling, was performed by the nurse-midwife. In the standard-care arm the examination, including the ultrasound dating of pregnancy and contraceptive counselling, was performed by a doctor, and further information and dispensation of medication was performed by a nurse-midwife. The gestational length was determined by measurement of gestational sac diameter or crown–rump length of the fetus, in all cases. The ultrasound was performed by the allocated provider. All women were screened for *Chlamydia trachomatis* and bacterial vaginosis according to Swedish clinical practice.

Women were excluded from both groups after examination if the ultrasound showed predefined exclusion criteria, such as a gestational length of over 63 days, evidence of pathological pregnancy, or an adnexal mass.

Two nurse-midwives experienced in medical TOP and contraceptive counselling received theoretical and practical training in vaginal ultrasound examination of early pregnancy. These nurse midwives were the sole providers in the nurse-midwife arm. There were a total of 34 doctors in the standard-care arm, reflecting the number of doctors involved in TOP care in the clinic. These doctors had varying training and experience. Some had only a few months of training, whereas others were senior consultants with long experience. The recruitment for the study began on 28 February 2011 and ended on 25 July 2012.

Randomisation was achieved through the consecutive opening of numbered opaque and sealed envelopes containing a computer-generated randomisation allocation code, in blocks of ten women, at a ratio of 1 : 1. The study was not blinded.

A woman randomised to the nurse-midwife group (intervention) was examined, counselled, informed, and treated by one single nurse-midwife. Women allocated to the standard-care group (control) were examined and counselled by a doctor, and then received additional information about the practical details and medication from a nurse-midwife, according to clinical routine. Participating nurse-midwives did not perform any regular nurse-midwife
tasks during the study period, to avoid possible bias. Medical TOP was performed according to the WHO recommended protocol, and did not differ between the groups.

All women received mifepristone 200 mg (Mifegyne®; Nordic Drugs, Limhamn, Sweden) given in the clinic according to Swedish law. The women had a free choice to administer 800 μg of misoprostol (Cytotec®; Pfizer, Sollentuna, Sweden) vaginally at home or in the clinic 24–48 hours after mifepristone administration. If no bleeding occurred within 3 hours, women were instructed to take an additional dose of 400 μg of misoprostol orally. Women were advised to take prophylactic pain treatment consisting of acetaminophen (paracetamol) 1 g (Alvedon®; Astra Zeneca, Södertälje, Sweden) and Diclofenac 100 mg (Voltaren®; Novartis, Täby, Sweden) at the time of vaginal misoprostol administration.

Contraceptive counselling and prescription was performed by a nurse-midwife or by a doctor, according to allocation. Follow-up in all cases was by low-sensitivity urinary human chorionic gonadotropin (hCG) test (cut-off 500 IU/ml; ANL-produkter AB, Alvsjo, Sweden), performed by a nurse-midwife not involved in the study, according to clinical routine, after approximately 3 weeks. Two attempts to contact women were made if women did not attend for follow-up, after which they were considered lost to follow-up.

If the urinary hCG test was positive, a serum hCG test was performed and the patient was referred for evaluation with vaginal ultrasound to rule out continuing pregnancy. The primary outcome measure was efficacy, assessed through the successful completion of TOP without the need for vacuum aspiration. Secondary outcome measures were safety, defined as the need for hospitalisation or blood transfusion, and acceptability of the procedure. The efficacy and safety were assessed by self-administered questionnaires and electronic patient records, which were completed after the initial examination and counselling, and also at the follow-up visit. Records were also checked if the patient was lost to follow-up. Complication was defined as the need for causal treatment at an unscheduled visit up to 6 weeks after the TOP, such as treatment with misoprostol, antibiotics, or treatment for anaemia. Acceptability was assessed in self-administered questionnaires by women stating whether they would prefer standard treatment by a gynaecologist or a nurse-midwife were they ever to have another medical TOP.10,11

In addition, the need for a second opinion from a doctor for nurse-midwives, or from another doctor in the case of the standard-care arm, and the reasons for this were recorded. Second-opinion consultations were performed immediately by other doctors in the clinic to avoid any delay of the TOP. The contraceptive method prior to the TOP and the prescribed method intended to start after the TOP were reported, as well as the actual method started (e.g. intrauterine contraception/implants inserted).

This study was designed as a two-sided equivalence trial with the overall efficacy of medical TOP assumed to be 95% in both groups. A clinically significant margin of equivalence was set to 5% based on what was believed to be of clinical importance to the patients. To demonstrate two-sided equivalence within a margin of 5%, with 80% power, and a confidence interval of 95% (α = 0.05), 400 women in each group would be sufficient. To compensate for loss to follow-up and patients not completing the medical TOP, 1180 patients were randomised. All statistical calculations except the generalised estimating equation were made using SPSS 20 (IBM Corporation, Somers, NY, USA). For comparison of groups with regard to skewed data the Mann–Whitney U-test was used. For variables with a normal distribution the Student’s t-test was used. For categorical variables, comparison between groups were made using the chi-square test. The equivalence between nurse-midwife providers and doctors was assessed using a generalised estimating equation. The generalised estimating equation allows for treatment as a fixed factor and provider as a random factor, and thereby enables adjustment for the difference in providers’ enthusiasm and competence. This analysis was performed in the PROC GENMOD procedure of SAS 9.3 (SAS Institute, Cary, NC, USA). In addition, the risk ratio (risk of failure in the standard group divided by risk of failure in the nurse-midwife group) for the primary outcome was added. Results were regarded as statistically significant for P < 0.05. Analysis was per protocol, according to recommendation, and followed the CONSORT guidelines for equivalence trials.

Results

A total of 1180 women were randomised, with no prior physical examination, to examination and counselling by a nurse-midwife (n = 597) or by a doctor (n = 583). A total of 105 women in both groups were excluded after examination but prior to mifepristone intake, for predefined reasons, with the numbers and reasons not differing between the groups (Table S1). Seven women in the standard-care group did not receive the allocated treatment because of sudden illness of the allocated provider. Unfortunately, these women were not followed-up and no results are available. Thus, 1068 women received and completed the allocated intervention. In the nurse-midwife group 54 women were lost to follow-up, compared with 76 women in the standard-care group (130 women in total, P = 0.038). The flow of patients is presented in Figure 1. Analysis was performed per protocol. There were no significant demographical differences between the groups (Table 1).
An overview of primary and secondary outcome measures is given in Table 2. Reasons for surgery are given in Table S2. The risk difference for efficacy was 1.6%, with a 95% confidence interval (95% CI) of 0.2–3.0% ($P = 0.027$). Although the trial was designed to show equivalence, the results show superiority for the nurse-midwife group, with a risk ratio for the primary outcome of 2.5 (95% CI 1.4–4.3) for the doctor group.

The overall complication rate was 4.1% for the women randomised to a nurse-midwife (20/493, 41 missing), and 6.1% for women randomised to a doctor (29/472, 61 missing, 95% CI 0.7 to 5%, $P = 0.14$). Reasons for complications are given in Table S3. There were no serious complications and no blood transfusions were given.

The percentage of unscheduled visits was 9% among women randomised to nurse-midwives (44/489, 45 missing), and 9.7% for women randomised to doctors (46/473, 60 missing, 95% CI –3 to 4.5%, $P = 0.7$). One patient had a continuing pregnancy at an unscheduled visit. She was successfully treated with a repeat medical TOP, according to her choice.

No significant differences existed between the groups in satisfaction with information, contraceptive counselling, feeling of calm and safety before, during, or after the TOP, with high satisfaction rates above 92% for all variables in both groups. There were no significant differences in perceived bleeding or worse pain experience on day of expulsion, or in the experience of the procedure, as compared with expectation (data not shown).

Women randomised to doctors were significantly more likely to choose home administration of misoprostol (310/1000, 31% (275/882)) than those randomised to a nurse-midwife (256/630, 41%, $P = 0.001$).

### Table 1. Demographic characteristics of women

<table>
<thead>
<tr>
<th></th>
<th>Allocated to nurse-midwife ($n = 535$)</th>
<th>Median (range)</th>
<th>Allocated to doctor ($n = 533$)</th>
<th>Median (range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>27 (18–47)</td>
<td></td>
<td>27 (18–46)</td>
<td></td>
</tr>
<tr>
<td>Gestational age at ultrasound (days)</td>
<td>45 (30–63)</td>
<td></td>
<td>45 (28–62)</td>
<td></td>
</tr>
<tr>
<td>Gravidity</td>
<td>2 (0–13)</td>
<td></td>
<td>2 (0–14)</td>
<td></td>
</tr>
<tr>
<td>Parity</td>
<td>0 (0–5)</td>
<td></td>
<td>0 (0–6)</td>
<td></td>
</tr>
<tr>
<td>Miscarriage</td>
<td>0 (0–4)</td>
<td></td>
<td>0 (0–5)</td>
<td></td>
</tr>
<tr>
<td>TOP, surgical</td>
<td>0 (0–3)</td>
<td></td>
<td>0 (0–5)</td>
<td></td>
</tr>
<tr>
<td>TOP, medical</td>
<td>0 (0–4)</td>
<td></td>
<td>0 (0–5)</td>
<td></td>
</tr>
<tr>
<td>Vaginal deliveries</td>
<td>0 (0–5)</td>
<td></td>
<td>0 (0–6)</td>
<td></td>
</tr>
<tr>
<td>Caesarian section</td>
<td>0 (0–3)</td>
<td></td>
<td>0 (0–3)</td>
<td></td>
</tr>
</tbody>
</table>

There were no statistically significant differences between the groups.
533) compared with women randomised to nurse-midwives (266/535, 95% CI 2.5–14.3%, \( P = 0.006 \)).

Doctors needed a second opinion in 4% of cases (21/533) compared with 26% of cases (139/535) for nurse-midwives (95% CI 18–26%, \( P < 0.001 \)); however, the frequency of ultrasound consultations for nurse-midwives went down as the study progressed, indicating a learning curve. Reasons for consultations are given in Table 3. The women allocated to nurse-midwives spent significantly shorter time in the family planning unit during the first visit (mean 42 minutes, SD 18.3 minutes), compared with the doctor group (mean 60 minutes, SD 24.1 minutes, \( P < 0.001 \)). Women randomised to nurse-midwives were significantly more likely (95% CI 11.8–22.5%, \( P < 0.001 \)) to prefer seeing a nurse-midwife again were they to have another TOP, although the majority were indifferent (Table 4). Patients randomised to nurse-midwives were more likely (200/535 women, 37.4%) to prefer their allocated provider than women randomised to doctors (12/533 women, 2.3%, 95% CI 30.8–39.4%, \( P < 0.0001 \)).

Women who were examined and counselled by nurse-midwives had long-acting reversible contraceptives (LARCs) inserted within 3 weeks of the TOP (intrauterine contraception and implant, 290/532, three missing), significantly more often than women examined and coun-

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**Table 2. Overview of primary and secondary outcome measures**

<table>
<thead>
<tr>
<th>Outcome measure</th>
<th>Allocated to nurse-midwife (%)</th>
<th>Allocated to doctor (%)</th>
<th>Total (%)</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Efficacy</td>
<td>476/481 (99)</td>
<td>445/457 (97.4)</td>
<td>923/940 (98.2)</td>
<td>–0.002 to 0.036</td>
</tr>
<tr>
<td>Safety</td>
<td>453/473 (95.8)</td>
<td>414/443 (93.5)</td>
<td>867/916 (94.7)</td>
<td>–0.006 to 0.054</td>
</tr>
<tr>
<td>Acceptability</td>
<td>200/535 (37.4)</td>
<td>12/533 (2.3)</td>
<td>212/1068 (19.9)</td>
<td>0.308–0.394</td>
</tr>
</tbody>
</table>

Efficacy defined as no need for surgical intervention, safety defined as no complication, and acceptability defined as women preferring their allocated provider.

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**Table 3. Reason for second opinion consultation**

<table>
<thead>
<tr>
<th>Reason for consultation</th>
<th>Allocated to nurse-midwife ( n ) (%)</th>
<th>Allocated to doctor ( n ) (%)</th>
<th>Total ( n ) (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multiple pregnancy</td>
<td>7 (1.3)</td>
<td>1 (0.2)</td>
<td>8 (0.7)</td>
</tr>
<tr>
<td>High serum hCG*</td>
<td>0 (0)</td>
<td>1 (0.2)</td>
<td>1 (0.9)</td>
</tr>
<tr>
<td>Information</td>
<td>3 (0.6)</td>
<td>1 (0.2)</td>
<td>4 (0.4)</td>
</tr>
<tr>
<td>Medical reasons</td>
<td>13 (2.4)</td>
<td>4 (0.8)</td>
<td>17 (1.6)</td>
</tr>
<tr>
<td>Ultrasound</td>
<td>59 (11)</td>
<td>8 (1.5)</td>
<td>67 (6.3)</td>
</tr>
<tr>
<td>Unknown</td>
<td>3 (0.6)</td>
<td>4 (0.8)</td>
<td>7 (0.7)</td>
</tr>
<tr>
<td>Prescription/second opinion for suspected bacterial vaginosis</td>
<td>54 (10)</td>
<td>4 (0.8)</td>
<td>58 (5.4)</td>
</tr>
<tr>
<td>Total</td>
<td>535</td>
<td>533</td>
<td>1068</td>
</tr>
</tbody>
</table>

*hCG, human chorionic gonadotropin.

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**Table 4. Preference in case of future TOP**

<table>
<thead>
<tr>
<th>Future preference</th>
<th>Allocated to nurse-midwife ( n = 534 ) (%)</th>
<th>Allocated to physician ( n = 533 ) (%)</th>
<th>95% CI</th>
<th>( P )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Midwife</td>
<td>200 (37.5)</td>
<td>108 (20.3)</td>
<td>0.118–0.225</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Physician</td>
<td>5 (0.9)</td>
<td>12 (2.3)</td>
<td>–0.003 to 0.030</td>
<td>0.06</td>
</tr>
<tr>
<td>Indifferent</td>
<td>271 (50.7)</td>
<td>320 (60)</td>
<td>0.033–0.152</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Missing</td>
<td>58 (10.9)</td>
<td>93 (17.4)</td>
<td>0.024–0.108</td>
<td>0.002</td>
</tr>
</tbody>
</table>

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selled by doctors (241/528, five missing, 95% CI 3.2–15.2%, \( P = 0.004 \)).

**Discussion**

**Main findings**

In this equivalence trial we showed the superior efficacy of nurse-midwife provision of early medical TOP in healthy women, when compared with standard doctor provision, in a setting where vaginal ultrasound examination for the dating of pregnancy is part of the protocol. We also found that nurse-midwives were significantly more likely to prescribe LARCs as post-TOP contraception.

**Strengths and limitations**

One strength of this study is that women were randomised after standard telephone screening without any prior examination. An additional strength is that the results can be generalised to high-resource settings, as ultrasound dating of the pregnancy was part of the protocol to confirm gestational length. Furthermore, women were able to choose home administration of misoprostol. To help women avoid another unwanted pregnancy, the provision of post-TOP contraception is crucial. The LARCs (intrauterine contraception and implants) have been shown to decrease the rate of repeat TOPs.\(^{14}\) Therefore, the prescribed contraceptive method was studied.

This study also has limitations. As this is the first study on task shifting to the midlevel provision of induced TOP, including ultrasound dating of pregnancy, we limited participation to healthy women. The study was not blinded. It is possible that acceptability was influenced by the involvement of highly motivated nurse-midwives, but blinding of the provider did not seem feasible. The deeper involvement in family planning may also have influenced these midwives to prescribe more LARCs to women, compared with the doctors who only performed TOP as part of their training or rotations. The results our study also show that at follow-up, a larger proportion of women in the nurse-midwife group had returned to the clinic to have the LARCs inserted. The rate of patients lost to follow-up is comparable with a recent study from Scotland,\(^{15}\) and is comparable with most studies in TOP practice.

**Interpretation**

Previous studies have shown that task shifting has a place in caesarean section provision, and in the provision of surgical TOP,\(^ {3,4,7}\) however, task shifting has so far been limited to low-resource settings. A recent study from Nepal investigated the midlevel provision of medical TOP,\(^ {6}\) however, in the Nepal study randomisation was undertaken after bimanual pelvic examination to estimate uterine size. Thus, women were already examined before the randomisation. It is well known that midlevel providers can provide the TOP drugs and the counselling. In our present study, women were self-referred and randomised before any part of the consultation had been performed. Furthermore, vaginal ultrasound dating of pregnancy was part of the routine protocol. This is another important difference to the study from Nepal, in which ultrasound examination for dating of pregnancy was not part of the protocol.\(^ {6}\) It is well documented that medical TOPs can be performed without any ultrasound examination;\(^ {16–18}\) however, ultrasound dating of the pregnancy is part of the protocol in many high-resource settings, and the results of the Nepal study may therefore not be applicable. In contrast to other studies on task shifting in TOP care, we also studied the provision of post-TOP contraception. The equivalence trial model was purposely chosen instead of the approach of inferiority trial, as midlevel provision of medical TOP may have profound advantages for women, such as being able to access TOP services where there are none available today, and shorter waiting periods to receive an appointment. A lower efficacy could therefore be tolerated; however, the study showed superiority for the nurse-midwife group.

This study showed that although a majority of patients were indifferent to the provider being a nurse-midwife or doctor, the women who expressed a preference preferred nurse-midwives to a larger extent in both randomisation groups. A possible explanation of this result may be that an uncomplicated TOP is not necessarily viewed as a medical condition that warrants the attention of a doctor. It is likely therefore that women prefer a nurse-midwife to a doctor for the examination and counselling; however, nurse-midwives do not prescribe contraceptives to women with intercurrent disease, and nor do they oversee complicated pregnancies or deliveries. In this study, women with complications or women who made unscheduled visits for fear of complications were therefore examined by doctors. The doctor on call also performed any necessary surgery. Women in the nurse-midwife group received significantly shorter consultations, but this did not reflect in lower satisfaction rates among women concerning the information received. In the nurse-midwife group the nurse-midwife was the sole provider of information and also handed out all medication. It may be that the group allocated to standard care received duplicate information or had waiting times between seeing the nurse-midwife and the doctor. More women allocated to doctors chose home administration of misoprostol, which may have impacted on the time allocated for counselling. Decreasing the time patients spend in the family planning clinic must be seen as something that is beneficial to the patient and to the healthcare system. As midwives have lower salaries than doctors, the results also have economic implications.
Conclusion

This study shows that task shifting in medical TOP in high-resource settings, where vaginal ultrasound dating of pregnancy is part of the protocol, is highly effective. In addition, nurse-midwives spent shorter time on the consultation, which has potential economic impact on the healthcare system. Furthermore, women examined and counselled by nurse-midwives received LARCs to a greater extent than women examined and counselled by doctors. This may have an impact on repeat TOP rates. Task shifting in medical TOP may therefore have a positive impact on TOP care in low- as well as in high-resource settings. The increased involvement and responsibilities of nurse-midwives in medical TOP should be encouraged. Further studies should include an extended gestational range.

Disclosure of interests

All authors declare that they have no conflicts of interest to report.

Contribution to authorship

The study was initiated by KGD, who had overall responsibility for the study. KGD, LM, RG, ES, and MJ were responsible for the project plan and planning, and KGD and LM were responsible for the training programme. HKK and KGD were responsible for conducting the study, the database design, analysis, and writing of the article. All authors assisted with writing the article.

Details of ethics approval

Permission was granted by the National Board of Health and Welfare and by the Ethical Review Board of Stockholm (permission number 2010/1828-31/3, 23 December 2010) to allow midwives to independently provide medical TOP, according to the study protocol. The study protocol was submitted with the ethics application on 11 November 2010, and was approved on 23 December 2010. Patient recruitment started in April 2011. No amendments were made to the protocol following ethics approval. Once approved by the regional ethics committee at Karolinska Institutet, all applications are publicly available. In addition, the protocol was also made available prior to and at a meeting convened by the WHO, Geneva, which was a consultation on the midlevel provision of medical abortion, with relevant material being circulated and shared before beginning the recruitment of patients for the trial. The trial was also registered at ClinicalTrials.gov after starting the study, but before recruitment had been completed (NCT01612923).

Funding

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Supporting Information

Additional Supporting Information may be found in the online version of this article:

- Table S1. Reasons for not completing treatment.
- Table S2. Reasons for surgery.
- Table S3. Reason for complication, defined as an unplanned visit for symptoms that led to further treatment.

References


