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Community-based doula support for migrant women during labour and birth: study protocol for a randomised controlled trial in Stockholm, Sweden (NCT03461640)

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ABSTRACT

Introduction Migrant women consistently rate their care during labour and birth more negatively than non-migrant women, due to communication difficulties, lack of familiarity with how care is provided, and discrimination and prejudicial staff attitudes. They also report being left alone, feeling fearful, unsafe and unsupported, and have poorer birth outcomes than non-migrant women. Community-based doulas (CBDs) are bilingual women from migrant communities who are trained in childbirth and labour support, and who facilitate communication between woman-partner-staff during childbirth. This study protocol describes the design, rationale and methods of a randomised controlled trial that aims to evaluate the effectiveness of CBD support for improving the intrapartum care experiences and postnatal well-being of migrant women giving birth in Sweden.

Methods and analysis A randomised controlled trial. From six antenatal care clinics in Stockholm, Sweden, we aim to recruit 200 pregnant Somali, Arabic, Polish, Russian and Tigrinya-speaking women who cannot communicate fluently in Swedish, are 18 years or older and with no contraindications for vaginal birth. In addition to standard labour support, women are randomised to CBD support (n=100) or no such support during labour (n=100). Trained CBDs meet with women once or twice before the birth, provide emotional, physical and communication support to women throughout labour and birth in hospital, and then meet with women once or twice after the birth. Women's ratings of the intrapartum care experiences and postnatal well-being are assessed at 6–8 weeks after the birth using selected questions from the Migrant Friendly Maternity Care Questionnaire and by the Edinburgh Postnatal Depression Scale. The intervention group will be compared with the control group using intention-to-treat analyses. ORs and 95% CIs will be estimated and adjustments made if key participant characteristics differ between trial arms.

Ethics and dissemination The study was approved by the Regional Ethical Review Board in Stockholm (approval number: 2018/12 - 31/2).

Trial registration number NCT03461640; Pre-results.

Strengths and limitations of this study

- This is a pragmatic randomised controlled trial of doula support for migrant women that fills an important gap in knowledge.
- For representativeness, the sample includes pregnant migrant women from countries that contribute the highest number of births or highest risk of perinatal morbidity and mortality in Sweden.
- Trained bilingual research assistants collect data in the women's own languages.
- A process evaluation will capture doulas' and caregivers' experiences of this complex intervention and suggest adjustments to the intervention and implementation process.
- The study is powered to evaluate the effectiveness of the intervention on maternal experiences of care, but not on maternal physical health or neonatal outcomes.

INTRODUCTION

The proportion of births to migrant women in Sweden has more than doubled over the last four decades, from 10% in 1973 to 28% in 2015.[1] Migrant women's increased risk of adverse pregnancy outcomes is well known and meta-analyses and systematic reviews show maternal and neonatal morbidity and mortality, and also obstetric interventions, such as caesarean section, are more common in migrant women than in non-migrants,.[2–4] Migrant women from low-income countries are also at increased risk of 'near miss' morbidity[5] and of excess mortality attributable to pregnancy.[6]

A systematic review of migrant women's experiences of maternity care in a number of countries (including Sweden) has shown that migrant women consistently rate their care more negatively than non-migrant women,

largely due to communication difficulties, language barriers, lack of familiarity with how care is provided, and discrimination and prejudicial staff attitudes. Migrant women also reported being left alone in labour, and feeling fearful, unsafe and unsupported.[7] Previous studies suggest that factors to be targeted to improve experiences of care and outcomes for migrant women in Sweden include: breaking down language barriers and building cultural understanding, increasing familiarity with and understanding of Swedish maternity care, and increasing women's sense of safety and confidence in giving birth.[7 8] Yet, despite the higher risk of adverse pregnancy outcomes and known inequities in Swedish maternity care,[9] few measures have been taken to meet migrant women's specific needs and reduce barriers to high quality maternal healthcare.[7]

In Sweden, migration of women of childbearing age (13–44 years) has increased most rapidly from Somalia (from 5803 to 18 798 women between 2005 and 2013) and from a number of Arabic-speaking countries (such as Iraq, Syria, Eritrea).[10] Somali women are the population group known to be at highest risk of perinatal morbidity and mortality in Sweden.[11 12] They face barriers engaging with Swedish antenatal care[13] and they have poorer experiences of care for labour and birth due to language difficulties and experiences of suboptimal care.[11 12 14] Like Somali-women, many Arabic-speaking women have arrived in Sweden after traumatic experiences of war and conflict.[15] Somali-speaking and Arabic-speaking women constitute a growing group of women giving birth in Sweden with little knowledge of how Swedish maternity care operates and they face major communication barriers, with no or very little knowledge of Swedish. Other migrant groups who have arrived in Sweden in increasing numbers in recent times, include Polish, Russian and Tigrinya speaking women who all face language barriers and lack familiarity with maternity care in Sweden.[1] For women born in Eastern Europe or the former Soviet Union, there is also an increased risk of self-reported poor health, compared with the Swedish-born population.[16]

Innovative models of care that respond to the challenges migrant and refugee families face after migration are needed to improve care and health outcomes. One Swedish initiative that has attempted to address problems with communication, women feeling unsupported by caregivers and being left alone during labour,[7] is the community-based doula (CBD) project in Gothenburg, Sweden. Since 2008, a community association, Födelsehuset/Mammaforum ('Childbirth House/Mother forum'), has provided CBDs for language assistance and support to migrant women not fluent in Swedish during labour and birth. Bilingual women from migrant communities trained in childbirth and labour support meet once or twice with women prior to the birth, provide a continuous presence and emotional and physical support and communication assistance during labour, and meet again with the women after the birth. Two very small qualitative evaluations, conducted in the early years of the programme, indicated high levels of satisfaction among supported women[17] and midwives.[18] Improved communication and information sharing, and enhanced emotional and physical support were the most important outcomes reported. Since then around 1400 women have received CBD support through Födelsehuset/Mammaforum; however, the programme has not yet been robustly evaluated.

Previous research supports the potential for CBDs to play an important role in improving continuity for migrant women during labour and birth, enhancing their experiences of birth and of care and improving their pregnancy outcomes.[7 19] Continuous physical and emotional support in labour is known to improve a range of outcomes. The 2017 Cochrane systematic review of 26 trials evaluating continuous support for women during childbirth by Bohren *et al*[19] found improved outcomes for women and their babies, including increased spontaneous vaginal births; shorter duration of labour; decreased caesarean births; fewer instrumental vaginal births; less use of regional analgesia; a reduction in low Apgar scores and also fewer negative feelings about childbirth. They found no adverse effects for women or infants. The review concluded that 'continuous support from a person who is present solely to provide support, is not a member of the woman's own network, is experienced in providing labour support, and has at least a modest amount of training (such as a doula), appears beneficial' (Bohren, p3).[19]

Two US descriptive studies investigated doula support among migrant women. One evaluated a hospital-based doula service provided to 123 of 348 Somali women giving birth in the study period. Lower rates of caesarean section (17% vs 26%) and greater satisfaction with care were found among the doula-supported Somali women.[20] Staff also felt more confident to care for Somali women when an English-speaking Somali doula was present. A second retrospective cohort study (n=11 471) evaluated a CBD programme in an urban, culturally diverse setting and found a small reduction in caesarean section among women cared for by a midwife and a doula, compared with a midwife alone (15% vs 18%).[21] To date, however, no randomised controlled trials of CBD support during childbirth for migrant women have been reported anywhere in the world.

There is mixed evidence from midwives and obstetricians about collaboration with doulas during labour and birth.[18 22] Positive aspects included the doula providing skilled physical and emotional support that is woman-centred, her continuous presence and ensuring mothers understand and are understood. Improved communication and information-sharing were reported by both women and midwives, and enhanced emotional and physical support were the most important outcomes reported by the women. However, some midwives reported uncertainty about the doula's role as an advocate for women, communicating and defending women's choices and

promoting respectful care.[18 22] Neither of these studies focused on migrant women. In the UK, a mixed-method evaluation study of volunteer doula services for migrant women was conducted in 2017. The women were positive about the service, although the doulas found it stressful to be available on a voluntary basis and to deal with ongoing requests for support from the mothers after the childbirth.[23]

A high-quality and rigorous randomised controlled trial including several migrant groups is needed to confirm previous findings and to provide a clearer view of the potential impact (positive and negative) of CBD support on migrant women's experiences of labour and birth. This study protocol describes the design, rationale and methods for a randomised controlled trial with the primary objective to evaluate the effectiveness of CBD support for improving the intrapartum care experiences and postnatal well-being of migrant women giving birth in Sweden. We hypothesise that migrant women randomised to receive CBD support in labour will (1) rate their care for labour and birth more highly and (2) experience better emotional well-being (lower mean scores on the Edinburgh Postnatal Depression Scale, EPDS) 2 months after the birth than migrant women allocated to standard care.

METHODS AND ANALYSIS

The study is designed as a two-armed randomised controlled trial, with a one-to-one allocation ratio, testing the superiority of CBD support for migrant women in addition to usual care for labour and birth over usual care alone. The trial follows the Standard Protocol Items: Recommendations for Interventional Trials statement.[24]

The programme theory is described in table 1, which includes the problem statement, conceptual framework

Table 1 Logic model of CBD support for migrant women including; problem statements, conceptual framework and rationale, hypothesised mechanisms of effect and desired outcomes

Problem statement[2 3 7–9 11]	Conceptual framework and rationale[8 19 25]	Intervention	Hypothesised mechanisms of effect	Desired outcomes
Current in-labour care in Sweden may not provide equitable care for migrant women: ► **Poorer birth outcomes** ► **Communication difficulties** ► **No routinely provided interpretation** ► **Lack of familiarity with Swedish in-labour care structures** ► **Negative attitudes from caregivers and suboptimal care**	**Core values for quality intrapartum care: respect, communication, support** **Communication and advocacy** to improve birth experience and safety **Evidence-based information** to improve birth outcomes **Person-centred care** to address women's individual needs **Continuity of care and presence** for positive care experiences and health outcomes **Emotional support** to improve birth experience **Instrumental support** to facilitate the process of normal labour **Doula support for migrant women a promising initiative**: ► Sustainable model of care operating in Gothenburg ► Positive perception of care from women ► Positive views from midwives in the provision of care ► No randomised controlled trial	**Community-based doula support, involving** ► Bilingual—bicultural doulas educated to facilitate communication and provide support during labour and birth ► Two meetings with doula during pregnancy to connect and discuss expectations and wishes ► Continuous support by CBD throughout labour and birth ► One follow-up meeting with doula to reflect on labour and birth	**Doula support will result in:** **Improved communication and information support** → Mutual understandings about desires and needs during childbirth → strategies for improved care → Timely apprehension about signs and symptoms → strategies for safe childbirth → Understanding about progress and necessary interventions → avoid anxiety → safe childbirth and positive birth experience → Women's empowerment and rights **Common background** → Cross-language/culture interactions → understanding and empower women to raise voices in having needs addressed → better suited care **Emotional support** → Reduced anxiety → increased probability for a normal birth **Instrumental support** → Hands-on comfort measures/ physical techniques → women managing pain → Hands-on comfort measures/ physical techniques → oxytocin release → Appropriate positions during labour → normal progression → Energy and fluid intake → promotes progress of labour	**Improved outcomes** **Women:** **Primary outcomes** ► Overall experience of intrapartum care (MFMCQ) ► Well-being (EPDS) Secondary outcomes ► Experience of birth overall ► Labour support overall ► Specific aspects of intrapartum care and support (MFMCQ) ► Epidural analgesia ► Length of labour ► Mode of birth ► Maternal and neonatal health

CBD, community-based doula; EPDS, Edinburgh Postnatal Depression Scale; MFMCQ, Migrant Friendly Maternity Care Questionnaire.

and rational, the components of the CBD intervention, hypothesised mechanisms of effect and desired outcomes. Underpinning central principles for the intervention are; communication and advocacy to improve birth experience and safety,[8] evidenced-based information to improve birth outcomes, person-centred care to address women's individual needs,[25] and instrumental and emotional support to facilitate the process of normal labour and birth and to improve women's experience of intrapartum care and childbirth.[19]

Patient and public involvement

Midwives and obstetricians in the Stockholm hospitals had been stressing the need for extra labour support for migrant women. A political decision to introduce CBDs, replicating the model designed and implemented by midwives in Gothenburg, was made by Stockholm County Council (Stockholms Läns Landsting, SLL) in 2016. SLL funding was first made available to the community organisation Mira to begin to implement the CBD programme in a Södertälje, a city south of Stockholm. At that time, we approached SSL to discuss the need for robust evaluation and it was agreed to use an RCT design to introduce and evaluate the programme in areas of Stockholm where the programme was not yet available. As the CBD model to be tested replicated the model previously developed, refined and successfully implemented over several years in Gothenburg, further testing the feasibility of the model was not considered necessary. Furthermore, no funding was made available to conduct an initial pilot as evaluation outcomes were required by the funders within a restricted time frame before the eventual roll-out of the model for all migrant women in need of support.

A number of antenatal clinics were approached for their high density of migrant women giving birth according to the Swedish Maternal Health Care Register.[26] Five antenatal clinics in Stockholm were chosen initially as study sites for recruiting women to the trial, and a sixth was added after 6 months when the recruitment rate was fairly low. Since recruitment commenced, women outside the study sites may now also contact the research team if they are interested in participating. Simultaneously, the CBD programme was rolled out in the remaining antenatal clinics in Stockholm. The non-profit organisation Mira is responsible for the organisation and management of CBDs, including their training, and the research team is responsible for the evaluation. The SLL finances Mira as well as the research project.

Women speaking the five languages of the participants have been involved in different aspects of the study design as a researcher (AE) or research assistants (NT and others) and have commented on the outcome measures and questionnaires, have taken part in the recruitment procedures and data collection, and continuously informed migrant communities and stakeholders about the study. Women's and staff's positive and negative experiences of the intervention are being assessed.

Table 2 Education provided to the CBDs

Content	Amount
Knowledge and understanding	
Explain the role of the CBD during pregnancy, labour and birth	
Describe the physiological processes of pregnancy, labour and birth	
Describe how caesarean section and vacuum extraction are performed	
Explain the benefits of skin-to-skin contact in the first few hours	
Explain the benefits of breastfeeding	
Describe how antenatal and childbirth care work in Sweden	
Describe normal physical and emotional problems around childbearing and how to relieve them	8 days of theoretical and practical training in classes
Skills and abilities	
Relaxation techniques and breathing techniques	
Massage techniques and physiological pain relief	
Different positions during labour	
Breastfeeding positions and techniques (basics)	
Self-reflection and attitudes	
Ability to reflect on causes of fear of childbirth and experiences of pain	
Ability to reflect on the doula's role and attitudes to the woman, her partner and staff	
Practical training	
Prepartum and postpartum meetings and support during labour and birth	CBD support to three women

CBD, community-based doula.

Community-based doulas

Female CBDs are recruited, trained and employed by Mira, using well-established processes.[17] Based on experiences from the programme in Gothenburg and Södertälje, a total of 23 CBDs are employed for the five migrant groups included in the trial, ensuring the possibility of back-up when needed. Education is provided by the same midwife overseeing all training and includes eight full days of theoretical and practical training that covers topics; such as anatomy and physiology, strategies for providing effective continuous labour support, comfort measures (breathing and relaxing techniques, providing massage, suggesting positions during labour and birth), obstetric interventions, practical strategies for facilitating communication/interpreting to enhance understanding between women and midwives and the CBDs roles and boundaries (table 2). As part of her training, a CBD to be assists three women during labour and birth before

being authorised and assigned to study participants. An experienced midwife provides supervision of CBDs during the practical training. The CBDs are employed on an hourly basis to enable flexibility in timely provision of support to women in labour. The CBDs also have additional employment duties for Mira and provide labour and birth support to women not included in the study; however, they give priority to the study participants.

Participants, inclusion criteria and recruitment

Recruitment to the study commenced on 28 February 2018 and data collection is expected to be finalised by mid-2020. Inclusion criteria are nulliparous or multiparous pregnant Somali, Arabic, Polish, Russian and Tigrinya-speaking women, who are not able to communicate fluently in Swedish, are 18 years or more, in gestational week 25–35, and with no contraindications for vaginal birth. Exclusion criteria are a planned caesarean birth and not giving consent for access to the birth records.

Midwives at six antenatal clinics identify eligible women and inform them briefly about the study, if necessary with the assistance of interpreters, and ask them whether they would be interested to receive further information about what participation would mean. If the woman is interested, the midwife fills in a logbook with inclusion criteria and the woman's contact details. Thereafter, trained bilingual research assistants collect the logbooks and contact each woman by telephone to provide more detailed study information and collect informed consent for participation. They also conduct a baseline interview, and then open the next envelope in a prenumbered sequence, with the allocation code (see under Randomisation and blinding) and inform the woman about which group she has been allocated to.

The comparison: usual intrapartum care

Regardless of their trial allocation, all women receive usual intrapartum care as provided at their chosen hospital of birth. This includes the support from a midwife and usually from one auxiliary nurse working in the labour ward. The midwife and the auxiliary nurse are responsible for between one and three women in labour. All women are encouraged to bring their partners and/or other support person to accompany them in labour, and language interpreting is offered according to the routines of the hospital. Most interpreting is provided over the phone rather than in person.

The intervention:CBD support

Women allocated to receive CBD support, in addition to usual care, are contacted by a CBD speaking their language, and arrangements are made for them to meet twice prior to the birth to get to know each other and discuss the woman's wishes regarding support during labour and birth, and what the CBD can offer. Each woman then contacts her CBD when she goes into the first stage of labour, and the CBD meets up with her at the hospital and stays with her throughout labour and birth, in addition to any other support people she may have, such as her partner. The CBD is trained to provide continuous support (emotional, physical and information support) throughout labour and birth, and to facilitate interpretation and mediate communication between the woman and her companion and the caregivers. For instance, to prevent anxiety, she is continuously present by the woman's side creating a calm atmosphere, providing reassurance and helping the woman to focus on managing contractions one at a time; physical support is provided by means of massage or assisting the woman to find a comfortable position; and information support includes helping the woman to understand the labour process and assist her in communicating with the caregiver. In addition to the CBD intervention, women receive the usual intrapartum care as provided at their chosen hospital of birth. After the birth, the CBD meets with the woman to follow up on any questions or concerns the woman has regarding the birth and postpartum period. Each woman is offered a maximum of 25 hours of CBD time, which includes the two meetings prior to the birth, support during the active phase of labour and birth and a follow-up visit postpartum. If a caesarean is necessary, the CBD accompanies the woman to the operating theatre if possible and supports her throughout the surgery. Women who are in extra need of support during additional consultations, such as regarding female genital mutilation or severe psychological trauma, may be offered additional hours with the CBD.

Randomisation and blinding

Women are randomly allocated to the intervention or control group, using a computerised randomisation schedule. The randomisation ratio is 1:1, CBD support to usual care, with block sizes of 4 or 6 randomly distributed, and with block size chosen to prevent predictability of allocation without jeopardising equal final numbers in trial groups. Allocations are prepared in sealed, opaque envelopes in a central location accessible for the bilingual research assistants. The bilingual researcher and research assistants are responsible for opening the envelopes with the allocation of participants after the baseline questionnaire has been completed by the women. Participants and data collectors cannot be blinded in this study; however, analysis will be undertaken blinded to group allocation.

Primary outcomes

Women's overall rating of labour care is measured by a single item question taken from the Migrant Friendly Maternity Care Questionnaire (MFMCQ, see under Development of questionnaires)[27]: In general, were you happy with the healthcare you received? with response alternatives: Yes, very happy; quite happy; not very happy; no, not happy at all. These will be dichotomised as: 'yes, very happy with care' and all other alternatives merged into 'less than very happy'.

Women's emotional well-being is measured using the EPDS.[28 29] The EPDS is a 10-item self-report scale widely used in research and screening for depressive symptoms postpartum. Each item is scored on a 4-point scale (0–3 points for each question) with a total score ranging from 0 to 30. Mean values on the EPDS will be compared between the groups.[29] The EPDS is widely used in all the languages included in this study, except for Somali. In Sweden, Somali women are offered screening for depressive symptoms using a Swedish version of the EPDS, which is translated on site by an interpreter. Early in the data collection we experienced that the Somali women found some of the EPDS questions difficult to understand. Therefore, parallel to this RCT, we also conduct think-aloud interviews with a different group of Somali women in order to understand how the EPDS questions are interpreted and how women come up with a response.[30 31] The results from the think-aloud interviews will contribute to the interpretation of the results for the Somali subsample.

Secondary outcomes

Overall experience of birth is measured by a single-item question on a five-point scale widely used in research[32 33]: What was your overall experience of giving birth? with a five-response scale from Very positive to very negative. Overall satisfaction with labour support is measured by Overall, what do you think about all the support you received during childbirth? with a five-response scale from very happy to not so happy. More specific assessments of intrapartum care and support are measured by a selection of relevant questions from the MFMCQ. Other secondary outcomes are: epidural analgesia, length of labour from admission and mode of birth (spontaneous vaginal, instrumental vaginal or caesarean section). Data will be retrieved from hospital patient records to enable assessment of birth outcomes.

Development of questionnaires

The study questionnaires were developed in English, translated into Swedish and the five study languages by bilingual professionals or researchers in the team, and then independently back-translated into each respective language to ensure accuracy of the translation. Survey questions, sources and response alternatives at baseline and follow-up are described in table 3. Some questions were retrieved from the MFMCQ,[27] which is a collection of questions created for studies on migrant women's experience of maternity care by members of the Reproductive Outcome and Migration collaboration. From the MFMCQ, we selected questions on background characteristics and more detailed questions on perceptions of care. Other questions were developed and tested by team members ES and RS for the Hooyo project (Group Antenatal Care for Somali women in Sweden)[34 35] and used when appropriate also in this study. The baseline and follow-up questionnaires were read and evaluated by researchers and research assistants, who could speak the relevant languages, to ensure the clarity of questions and piloted with two women. Several questions were slightly modified in response to advice from language speakers or from piloting to avoid any risk of misunderstanding.

Data collection

In order to address some of the known challenges of recruiting and retaining migrant women in clinical trials, trained bilingual research assistants collect data on women's experiences of care in their language of choice, by telephone or in face-to-face interviews as appropriate, in gestational week 25–36. Every effort is made to make the respondent feel comfortable and at ease. The same research assistant contacts the woman again by telephone at 2 months after the birth and initially asks her how she and her baby are going, before the interview starts. If women are identified with severe prenatal or postnatal physical or emotional problems, the research assistant checks that the woman is receiving appropriate care, and if not, assist her to access care.

The questionnaires are administered by the bilingual research assistants at recruitment (Q1) and 2 months after the birth (Q2). Q1 asks about sociodemographic characteristics (parity, language, knowledge of English/Swedish, family situation, reason for migration, length of residency in Sweden, education, occupation), expectations about the upcoming birth (planned support person, feelings and concerns about the upcoming birth), emotional well-being (EPDS) and health (physical health problems, medications, self-rated health). Q2 asks about self-rated health, emotional well-being, support received during labour and birth, information and cultural aspects of care. Specific questions about doula support were stated to the women in the intervention group only.

High quality prospectively collected information on pregnancy and birth outcomes will be extracted from patient records: obstetric history (parity, previous mode of birth, maternal and neonatal mortality and morbidity), pregnancy (complications, anaemia, chronic diseases and mental health problems), labour and birth (gestational week, induction/spontaneous start of labour, pain relief, mode of birth, maternal morbidity such as haemorrhage or severe injuries) and infant data (Apgar score, need of resuscitation, transferral to neonatal intensive care unit (NICU), birth weighte expansion of 'NICU, stillbirth or intrapartum death).

Process measures

A process evaluation is being performed continuously, informed by a framework suggested by Moore *et al*.[36] Different aspects of the study context, implementation of the intervention, feasibility, acceptability, fidelity and mechanisms of impact of the intervention as well as of the trial (such as the ability to recruit and retain women in the study) are assessed by means of questionnaires to the women, field notes and logbooks kept by the researchers and research assistants, as well as through qualitative studies. eCBDs, midwives and obstetricians will participate in qualitative interviews with the researchers and bilingual

Table 3 Concept/survey questions, response alternatives and questionnaire

Concept/question	Response alternative	Questionnaire Q1 (baseline)/Q2 (follow-up)
Background		
Country of birth, first language	Specify the country. Specify the language: Somali/Arabic/Tigrinya/Russian/Polish/Other	Q1
Knowledge of English and Swedish (understand/speak)	Not at all/with difficulty/well/fluent	Q1
Marital status	Married/engaged/living with a partner, but not married/widowed/separated/divorced/single/other	Q1
Who are you living with?	Husband/partner/child(ren)/mother/sister/friend/other	Q1
Reasons for migration	Refugee (asylum seeker)/family ties/job opportunity/study/other	Q1
Residence in Sweden	Years and months	Q1
Highest education attained	Secondary school/trade certificate/university/other	Q1
Education in Sweden	Yes/no/languages studies only	Q1
Current occupation	Employed/language studies/university studies/other studies/parental leave/home duties/ sick leave/unemployed or looking for job/other	Q1
In general, how would you rate your health at present?	Very good/good/neither good nor bad/bad/very bad	Q1, Q2
Expectations of labour and birth		
Who will accompany you for labour and birth?	Partner/mother/sister/friend/CBD/other	Q1
Worries about the upcoming birth	No/going to hospital/being alone/treated without respect/without kindness/not listened to/not involved in decisions/lack of understanding because of the language/not enough information/external examinations/ labour pain/genital circumcisions/giving birth/childbirth complications/something wrong with the baby/ coping with the new baby/other	Q1
Emotional well-being	Edinburgh Postnatal Depression Scale	Q1, Q2
Received support		
Support person(s) (1) when the labour started and (2) in the labour ward	Partner/mother/sister/friend/CBD/other/alone/midwife (at the labour ward)	Q2
What CBD/labour companion did that was important to you	Facilitated communication between me and midwife/me and partner (other companion)/interpreted/was by my side/supported partner (other companion)/comforted me/gave massage	Q2
CBD/labour companion helped me to	Understand what was happening/communicated my feelings/communicated my wishes/eat and drink/ feel secure/manage pain/reduce anxiety/relax/get to toilet and move around/other	Q2
Did CBD/labour companion do anything you did not like?	No/yes. If yes, what?	Q2
Information and cultural aspects of care		

Continued

Table 3 Continued

Concept/question	Response alternative	Questionnaire Q1 (baseline)/Q2 (follow-up)
Understand the information provided by midwives and doctors during the labour and birth	Always/sometimes/rarely/never/don't know	Q2
Did anyone interpret for you?*	No, but I would have liked and needed/no, I didn't need/yes. If yes, who? Husband (partner)/other family member (friend)/my child/professional interpreter/healthcare provider/doula/other	Q2
Satisfaction with the interpretation	Yes/no	Q2
Comfortable asking about things you did not understand	Always/sometimes/rarely/never	Q2
Healthcare professionals ask about preferences about care	Yes/no/no, I told them what I wanted before they asked me	Q2
Midwife/doctor ask you to do something you did not want to do	No/yes. If yes, please, specify.	Q2
Overall, were you treated differently to other people by healthcare professional	No/yes. If yes, why? Language or accent/culture/race (ethnical background)/skin colour/religion/migration status/other	Q2
Experience of other aspects of care		
Welcomed by healthcare professionals (midwives, doctors)	Always/sometimes/rarely/never	Q2
Healthcare professionals were respectful	Always/sometimes/rarely/never	Q2
Healthcare professionals made decisions without my wishes	Always/sometimes/rarely/never	Q2
They kept me informed about what was happening	Always/sometimes/rarely/never	Q2
Healthcare professionals took my worries seriously	Always/sometimes/rarely/never	Q2
Healthcare professionals were skilled in medical issues	Always/sometimes/rarely/never	Q2
Impression about the midwife who cared for you the most during the delivery, CBD/the labour companion	Absent/brusque/calm/clear/competent/condescending/considerate/encouraging/funny/incompetent/informative/rude/insensitive to your preferences/uncaring/respectful/secure/sensitive to your needs/rushed/supportive/thoughtless/unhelpful/unkind/vague/warm	Q2

Continued

Table 3 Continued

Concept/question	Response alternative	Questionnaire Q1 (baseline)/Q2 (follow-up)
Overall impression of the midwife, CBD/the labour comp.	Positive/negative	Q2
CBD/labour companion stayed as much as you wished during the labour	Yes/no	Q2
Partner/labour companion feel welcomed and involved†	Yes/no	Q2
For CBD supported only		
Describe how was the first time you met, before the labour, and after the baby was born (the second time)	Open-ended question	Q2
Overall, what do you think about all the support you received from the CBD	Yes, very positive/quite happy/not very happy/no, not happy at all	Q2
Your own experience of the labour and birth		
Feelings during labour and birth	Involved/abandoned/alert/at someone's mercy/calm/sejected/setermined/ sisappointed/focused/frightened/happy/independent/lonely/paniced/present/sad/secure/ self-confidence/strong/tense/tired/trust in my own capacity/weak/worried	Q2
What was your overall feeling during labour and birth	Good/bad	Q2
What was your overall experience of giving the birth?	Very positive/positive/both positive and negative/negative/very negative	Q2
In general, were you happy with the healthcare you received?	Yes, quite happy/quite happy/not very happy/no, not happy at all	Q2
Overall, what do you think about the support you received during the childbirth	Yes, very happy/quite happy/not very happy/no, not happy at all	Q2

(Q1 = baseline in gestational week 25–35; Q2 follow-up at 6-8 weeks post partum). Primary outcome measurements in bold.
CBD, community-based doula.

research assistants approximately halfway through and at the end of the trial. Questions to the CBDs will cover positive and negative experiences while working as a doula, experiences of communication and cooperation with women/partners/caregivers, as well as questions about doula education, and their motivations and expectations about becoming a doula. Question areas for the midwives and obstetricians include their own experiences working with CBDs and how they perceive the CBD role during childbirth. Key stakeholder interviews will also be held with labour ward managers and with key members of Mira. Interviews with women and questionnaire data in the intervention arm will explore their experiences of CBD support, such as the length and type of support received, what was most and least helpful and if the doula had helped her to understand what was happening during labour and birth and express her wishes. Questionnaire data from the women as well as monitoring data from the trial, including information about length of doula support for each woman, will also inform the process evaluation. To investigate the experiences of working as a doula, or alongside a doula, a thematic analysis will be conducted according to Braun and Clarke.[37] To investigate whether the hypothesised mechanisms of impact are apparent or not in the interviews, a deductive content analysis based on the hypothesised mechanisms of the intervention (table 1) and according to Graneheim and Lundman[38] will be performed.

Sample size

To detect an increase in women's ratings of intrapartum care from an expected 30% saying they are 'very happy' among those receiving usual care (based on estimates from studies of migrant women not fluent in the host country language[39]) to 53% in those receiving CBD support (equal to Swedish-speaking women in a national population based study[40]) with 80% power and an alpha of 0.05, 69 women in each group are needed. To have similar power to detect differences in mean scores on the EPDS (a hypothesised reduction from a mean of 8.0 in the comparison group—similar to that found in studies of migrant women, to 6.0 in the intervention group—similar to that found in Swedish population-based studies,[41] 63 women are required in each arm. Allowing for 20% lost to follow-up at the time of data collection with women 2 months post partum, we aim to recruit 174 women.

Statistical analysis

The first step of analysis will be a visual check of the comparability of the two groups. Then, the intervention group will be compared with the control group testing trial hypotheses and using intention to treat analyses that include all participants according to their trial allocation. ORs and 95% CIs will be estimated by logistic regression analysis for categorical outcomes. Comparison of means will be undertaken using t-tests where data are normally distributed, or medians compared using Mann-Whitney U tests used if not. Considerations about imputations for missing data will be made when relevant. If there are visual baseline differences on key participant characteristics (such as age, marital status, medical conditions) between trial arms, Please multivariable logistic regression analyses will be performed to adjust for any differences found.

ETHICS AND DISSEMINATION

The study has no foreseeable risks but theoretically, the CBDs might disturb the interaction between the labouring woman and her partner or the midwife and miscommunication might occur. Notably, a CBD should not replace an accredited interpreter in communication about medical interventions and important clinical decisions. The women are informed that (1) participation in the study is voluntary, (2) their decision whether or not to participate will not affect their current or future treatment, (3) if they decide to participate they are free to withdraw at any time and (4) all questionnaire data will be deidentified. Recruitment of women is mainly conducted by telephone. The bilingual research assistant reads aloud the patient information text and makes every effort to ensure that the woman understands what is expected from her if she participates in the study. Informed verbal consent to participate is then given by the women. All CBDs sign a form to abide by professional confidentiality.

DISCUSSION

The lack of equity in relation to maternity care provision and poorer outcomes for migrant women in Sweden has been known for a very long time, yet not much has been done to improve migrant women's experiences of care or their pregnancy outcomes. This trial addresses this by testing a model of care, which aims to improve intrapartum care experiences for women from Somali, Arabic, Polish, Russian and Tigrinya-speaking countries.

To date, there have been no randomised trials investigating birth outcomes for migrant women receiving bilingual labour support, such as the CBD programme offered by Födelsehuset/Mammaforum in Gothenburg for the last 10 years. A randomised controlled trial of CBD is only feasible before it becomes available to the general population of pregnant migrant women. With positive outcomes, the model is likely to be generalisable for scaling up for other groups of migrant women not fluent in Swedish and who lack familiarity with the Swedish healthcare system. This study has the potential to inform further development of the CBD model and to contribute to what is known internationally about the effectiveness of bilingual doula support in improving the care of migrant women during childbirth.

Patient and public statement

Migrant women and midwives representing the non-profit organisation Mira have been involved in the study

design, choices of study outcomes and the intervention development.

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Contributors ES and RS initiated the study and ES, HL, AE, AW and RS contributed to the planning and design of the study and developed recruitment procedures and questionnaires. ES drafted the manuscript and AW, HL, AE, RS and NT contributed to the writing, and read and approved the final version.

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REFERENCES

1 Swedish National Board of Health and Welfare. *Graviditeter, förlossningar och nyfödda barn. Medicinska födelseregistret 1973–2011. Assisterad befruktning 1991–2010*. Stockholm: Socialstyr, 2013.
2 Gagnon AJ, Zimbeck M, Zeitlin J, *et al*. Migration to Western industrialised countries and perinatal health: a systematic review. *Soc Sci Med* 2009;69:934–46.
3 Urquia ML, Glazier RH, Blondel B, *et al*. International migration and adverse birth outcomes: role of ethnicity, region of origin and destination. *J Epidemiol Community Health* 2010;64:243–51.
4 Juárez SP, Small R, Hjern A, *et al*. Caesarean birth is associated with both maternal and paternal origin in immigrants in Sweden: a population-based study. *Paediatr Perinat Epidemiol* 2017;31:509–21.
5 Wahlberg Å, Rööst M, Haglund B, *et al*. Increased risk of severe maternal morbidity (near-miss) among immigrant women in Sweden: a population register-based study. *BJOG* 2013;120:1605–12.
6 Esscher A, Haglund B, Högberg U, *et al*. Excess mortality in women of reproductive age from low-income countries: a Swedish national register study. *Eur J Public Health* 2013;23:274–9.
7 Small R, Roth C, Raval M, *et al*. Immigrant and non-immigrant women's experiences of maternity care: a systematic and comparative review of studies in five countries. *BMC Pregnancy Childbirth* 2014;14:152.
8 Binder P, Borné Y, Johnsdotter S, *et al*. Shared language is essential: communication in a multiethnic obstetric care setting. *J Health Commun* 2012;17:1171–86.
9 Swedish National Board of Health and Welfare. God vård-Vård på lika villkor. Hur jämlik är vården? In: *Hälso- och sjukvårdsrapport*, 2009: 183–204.
10 Statistics Sweden. Statistical database; 2014.
11 Essén B, Bödker B, Sjöberg NO, *et al*. Are some perinatal deaths in immigrant groups linked to suboptimal perinatal care services? *BJOG* 2002;109:677–82.
12 Esscher A, Binder-Finnema P, Bødker B, *et al*. Suboptimal care and maternal mortality among foreign-born women in Sweden: maternal death audit with application of the 'migration three delays' model. *BMC Pregnancy Childbirth* 2014;14:141.
13 Essén B, Hanson BS, Östergren P-O, *et al*. Increased perinatal mortality among sub-Saharan immigrants in a city-population in Sweden. *Acta Obstet Gynecol Scand* 2000;79:737–43.
14 Berggren V, Bergström S, Edberg A-K. Being different and vulnerable: experiences of immigrant African women who have been circumcised and sought maternity care in Sweden. *J Transcult Nurs* 2006;17:50–7.
15 Sami S, Williams HA, Krause S, *et al*. Responding to the Syrian crisis: the needs of women and girls. *Lancet* 2014;383:1179–81.
16 Sungurova Y, Johansson S-E, Sundquist J. East-west health divide and east-west migration: self-reported health of immigrants from eastern Europe and the former Soviet Union in Sweden. *Scand J Public Health* 2006;34:217–21.
17 Akhavan S, Edge D. Foreign-born women's experiences of Community-Based Doulas in Sweden--a qualitative study. *Health Care Women Int* 2012;33:833–48.
18 Akhavan S, Lundgren I. Midwives' experiences of doula support for immigrant women in Sweden--a qualitative study. *Midwifery* 2012;28:80–5.
19 Bohren MA, Hofmeyr GJ, Sakala C, *et al*. Continuous support for women during childbirth. *Cochrane Database Syst Rev* 2017;7:CD003766.
20 Dundek LH. Establishment of a Somali doula program at a large metropolitan Hospital. *J Perinat Neonatal Nurs* 2006;20:128–37.
21 Mottl-Santiago J, Walker C, Ewan J, *et al*. A hospital-based doula program and childbirth outcomes in an urban, multicultural setting. *Matern Child Health J* 2008;12:372–7.
22 Maher J. Midwife interactions with birth support people in Melbourne, Australia. *Midwifery* 2004;20:273–80.
23 Darwin Z, Green J, McLeish J, *et al*. Evaluation of trained volunteer doula services for disadvantaged women in five areas in England: women's experiences. *Health Soc Care Community* 2017;25:466–77.
24 Chan A-W, Tetzlaff JM, Altman DG, *et al*. Spirit 2013 statement: defining standard protocol items for clinical trials. *Ann Intern Med* 2013;158:200–7.
25 Ekman I, Swedberg K, Taft C, *et al*. Person-centered care--ready for prime time. *Eur J Cardiovasc Nurs* 2011;10:248–51.
26 Petersson K, Persson M, Lindkvist M, *et al*. Internal validity of the Swedish maternal health care register. *BMC Health Serv Res* 2014;14:364.
27 Gagnon AJ, DeBruyn R, Essén B, *et al*. Development of the migrant friendly maternity care questionnaire (MFMCQ) for migrants to Western societies: an international Delphi consensus process. *BMC Pregnancy Childbirth* 2014;14:200.
28 Cox J, Holden J, Henshaw C. *Perinatal mental health: the Edinburgh postnatal depression scale (EPDS) manual*. 2nd edn. London, 2012.
29 Wickberg B, Hwang CP. The Edinburgh postnatal depression scale: validation on a Swedish community sample. *Acta Psychiatr Scand* 1996;94:181–4.
30 Sudman S, Bradburn N, Schwarz N. *Thinking about answers*. 1st edn. San Francisco: Jossey-Bass Publishers, 1996.
31 Schytt E, Waldenström U, Olsson P. Self-rated health--what does it capture at 1 year after childbirth? Investigation of a survey question employing thinkaloud interviews. *Scand J Caring Sci* 2009;23:711–20.
32 Gottvall K, Waldenström U. Does a traumatic birth experience have an impact on future reproduction? *BJOG* 2002;109:254–60.
33 Waldenström U, Hildingsson I, Rubertsson C, *et al*. A negative birth experience: prevalence and risk factors in a national sample. *Birth* 2004;31:17–27.
34 Ahrne M, Schytt E, Andersson E, *et al*. Antenatal care for Somali-born women in Sweden: perspectives from mothers, fathers and midwives. *Midwifery* 2019;74:107–15.
35 Byrskog U, Ahrne M, Small R, *et al*. Rationale, development and feasibility of group antenatal care for immigrant women in Sweden: a study protocol for the Hooyo project. *BMJ Open* 2019;9:e030314.
36 Moore GF, Audrey S, Barker M, *et al*. Process evaluation of complex interventions: medical Research Council guidance. *BMJ* 2015;350:h1258.
37 Braun V, Clarke V. Using thematic analysis in psychology. *Qual Res Psychol* 2006;3:77–101.

38 Graneheim UH, Lundman B. Qualitative content analysis in nursing research: concepts, procedures and measures to achieve trustworthiness. *Nurse Educ Today* 2004;24:105–12.
39 Small R, Yelland J, Lumley J, *et al*. Immigrant women's views about care during labor and birth: an Australian study of Vietnamese, Turkish, and Filipino women. *Birth* 2002;29:266–77.
40 Waldenström U, Rudman A, Hildingsson I. Intrapartum and postpartum care in Sweden: women's opinions and risk factors for not being satisfied. *Acta Obstet Gynecol Scand* 2006;85:551–60.
41 Rubertsson C, Wickberg B, Gustavsson P, *et al*. Depressive symptoms in early pregnancy, two months and one year postpartum-prevalence and psychosocial risk factors in a national Swedish sample. *Arch Womens Ment Health* 2005;8:97–104.