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Combining one-to-one and group antenatal care: The Enhanced Antenatal Care study

Submission date
06/07/2018

Recruitment status
No longer recruiting

Registration date
19/07/2018

Overall study status
Completed

Last Edited
12/07/2018

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Many pregnant women are excited about pregnancy and parenthood, but many also feel anxious or fearful about the upcoming birth. More opportunities to talk about the birth and becoming a parent may lower fear for women and their partners. Enhanced Antenatal Care (EAC) is a new model of care aimed at reducing birth anxiety and fear, where women can both meet with their midwife one-to-one for antenatal care and take part in group antenatal care with other women and their partners expecting a baby around the same time. Each group has 4-6 women (along with their partners, who are invited to join) who meet for 90 minutes, 4 times during their pregnancy. Each group combines antenatal care with education and support.
Other countries have offered group antenatal care, with good results. However, these models offer group care for the whole pregnancy. Our model is different, as it combines one-to-one visits with their midwife and four group sessions with their midwife.
This study aims to assess women's experience with receiving antenatal care through EAC, along with their partners experience. Additionally, we also aim to look at the experience of midwives providing antenatal care through the EAC model. Furthermore, we aim to assess whether EAC is effective in lowering childbirth fear among women.

Who can participate?
Women aged over 18 who are expecting their first baby and are able to communicate in Icelandic.

What does the study involve?
There will be six healthcare centres, three of which provide standard antenatal care (comparison centres) and three of which provide Enhanced Antenatal Care (EAC) (intervention centres). In the comparison centres, participants receive one-to-one antenatal care from their midwife. In the intervention centres, EAC involves four group antenatal care meetings at weeks 25-36 and six one-to-one meetings with their midwife (3 before the group sessions and 3 after). Group sessions have between 4 and 6 women also expecting their first baby within the same month and last for 90 minutes, with each session having a discussion topic facilitated by two midwives. Partners of the women are invited to join the group sessions.
Participants in both the intervention and comparison centres will fill in online questionnaires twice during pregnancy and once after the baby is born. These questionnaires take around 10-15

minutes to complete and include questions that assess childbirth fear, childbirth intentions and attitudes towards birth and parenthood, along with questions about experience of antenatal care, interventions using during birth, methods used for coping with pain, and general experiences of childbirth. Women in EAC and their partners are invited to join a focus group 2-3 months after birth to discuss their experience participating in EAC.

What are the possible benefits and risks of participating?
A possible benefit of participating in Enhanced Antenatal Care (EAC) is that participants and their partners will receive ten hours of antenatal care, rather than the standard four hours. Additionally, they will have more opportunities to discuss pregnancy, birth and parenthood and meet other women and their partners expecting a baby around the same time as them. Therefore, EAC means that participants have the opportunity to receive increased knowledge and support during pregnancy. There are no know risks to participants taking part in this study. However, participants can choose to stop participation at any time and return to standard antenatal care.

Where is the study run from?
Trial run from: Heilsugæsla höfuðborgarsvæðisins, Álfabakka 16, 109 Reykjavik, Iceland
Trial study centres:
1. Heilsugæslan Seltjarnarnesi, 170, Suðurströnd, Seltjarnarnes, Iceland
2. Heilsugæslan Grafarvogi, Spöngin, 112 Reykjavík, Iceland
3. Heilsugæslan Hlíðum, Drápuhlíð 14-16, 105 Reykjavík, Iceland
4. Heilsugæslan Árbæ, Hraunbær 115, 110 Reykjavík, Iceland
5. Heilsugæslan Glæsibæ, Álfheimar 74, 104 Reykjavík, Iceland
6. Heilsugæslan Salahverfi, Salavegur 2, 201 Kópavogur, Iceland

When is the study starting and how long is it expected to run for?
October 2016 to December 2018

Who is funding the study?
The University of Iceland Research Fund (Rannsóknarsjóður Háskóla Íslands) (Iceland)

Who is the main contact?
Emma Marie Swift
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
VSNb2017030007/03.01

Study information

Scientific Title
Providing a combined approach of one-to-one and group antenatal care for nulliparous women to address childbirth fear and promote natural birth intentions: The Enhanced Antenatal Care study

Acronym
EAC

Study objectives
1. Is it feasible to combine group- and one-to-one antenatal care for low and moderate risk nulliparous women and their partners?
2. Is there a difference in childbirth fear and birth intentions among women in EAC compared with women in usual care?
3. Does fear of birth decrease among women in EAC from pre- to post-intervention?
4. Are women in EAC more likely to be involved in decision making in maternity care compared with women in usual care?

Ethics approval required
Old ethics approval format

Ethics approval(s)
The National Bioethics Commitee, 25/04/2017, VSNb2017030007/03.01

Study design
This is a quasi-experimental controlled trial with two arms (intervention and active comparison arm) and four assessment time points. Three healthcare clinics serve as intervention sites (H1-H3) and three clinics as comparison sites (H4-H6) providing antenatal care as usual. All six healthcare clinics (H1-H6) are similar in size, serve a similar client demographic, with two or three midwives providing antenatal care for women with low or moderate risk pregnancies living in the neighborhoods surrounding the clinics. Nulliparous women receiving antenatal care at one of the six participating healthcare clinics will be invited to participate.

Interventional quasi-experimental non-randomised two-armed controlled trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Childbirth fear

Interventions
Nulliparous women receiving antenatal care at one of the six healthcare centers (three intervention sites and three comparison sites) collaborating in our study are invited to participate in the study. The midwives providing antenatal care will provide information about informed consent and the study.
At the three intervention sites, participants are invited to join Enhanced Antenatal Care (EAC), which involves six one-to-one visits with a midwife and four midwife-led group sessions. First, there will be an hour-long one-to-one visit, followed by two further one-to-one visits lasting 20-30 minutes. Then, there will be four 90 minute midwife-led group sessions around weeks 25-36. This is then followed by one-to-one antenatal visits until the baby is born.
The group sessions within the intervention sites will consist of groups of four to six nulliparous women expecting their baby within the same calendar month. The partners of participants are also encouraged to attend. Each group session has an outline of discussion topics on pregnancy, birth and parenthood. Each group session is facilitated by two midwives; at least one is the primary midwife for the couple, providing both one-to-one care, along with facilitating groups. EAC increases contact time with the midwife from four hours in usual care to approximately ten hours. One-to-one antenatal visits occur at the same time as the group session. Women will leave the group discussion for 5-15 minutes to have their one-to-one visit with their midwife. Meanwhile, the second midwife facilitates conversation within the group session.
At the three comparison sites, participants will receive the usual antenatal care, with approximately ten one-to-one antenatal care visits with a midwife throughout pregnancy. The first visit will last approximately one hour and subsequent visits will last 20-30 minutes.
Women in both groups will be asked to complete a baseline survey to assess socio-demographic characteristics of the participants, along with sense of coherence and childbirth fear in early pregnancy. A second is sent in late pregnancy, which will include questions about childbirth fear, childbirth intentions and attitudes towards birth and parenthood, along with their experience of antenatal care (including their sense of autonomy and respectful care). A third survey, sent postpartum, collects information about interventions used during birth, methods used for coping with pain, and participants general experience of childbirth.
Furthermore, participants in the intervention group (women and their partners) will receive an

email 2-3 months postpartum with an invitation to participate in a focus group. The purpose of the focus group is to collect in-depth information about participants' experience of receiving antenatal care with EAC. Each focus group interview will be conducted by a research midwife who has not been involved with implementing or facilitating EAC.
Midwives involved in EAC will be interviewed about their experience participating in EAC once all EAC groups are complete.

Intervention Type
Other

Primary outcome measure
1. Experience with participating in EAC, to determine feasibility and acceptability:
1.1. For women, this is measured using direct questions about antenatal care in a web-based survey in late pregnancy (36-40 weeks) and a focus group interview 2-3 months postpartum.
1.2. For partners, this is measured using a focus group interview 2-3 months after the baby is born
1.3. For midwives, this is measured through an interview after all EAC groups are complete.
2. Childbirth fear is measured using the Fear of Birth Scale (FOBS) in a web-based survey early in pregnancy (12-16 weeks) and late in pregnancy (36-40 weeks)

Secondary outcome measures
The following are measured late in pregnancy (36-40 weeks) using a web-based survey:
1. Birth intentions, assessed using questions about mode of birth, pain management and other birthing preferences
2. Involvement in decision making, assessed using the Mothers Autonomy in Decision Making scale (MADM)
3. Respectful care, assessed using the Mothers on Respect Index. This is also measured 6 weeks postpartum.

Overall study start date
15/10/2016

Completion date
12/12/2018

Eligibility

Key inclusion criteria
1. Nulliparous women receiving antenatal care at one of the six participating healthcare centers
2. 18 years of age and older
3. Able to communicate in Icelandic
Partners of women in the intervention arm will also be invited to join the study.

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
96

Key exclusion criteria
Multiparous women

Date of first enrolment
16/06/2017

Date of final enrolment
01/10/2018

Locations

Countries of recruitment
Iceland

Study participating centre
Heilsugæslan Seltjarnarnesi
Suðurströnd
Seltjarnarnes
Iceland
170

Study participating centre
Heilsugæslan Grafarvogi
Spöngin
Reykjavík
Iceland
112

Study participating centre
Heilsugæslan Hlíðum
Drápuhlíð 14-16
Reykjavík
Iceland
105

Study participating centre
Heilsugæslan Árbæ
Hraunbær 115
Reykjavík
Iceland
110

Study participating centre
Heilsugæslan Glæsibæ
Álfheimar 74
Reykjavík
Iceland
104

Study participating centre
Heilsugæslan Salahverfi
Salavegur 2
Kópavogur
Iceland
201

Sponsor information

Organisation
University of Iceland

Sponsor details
Faculty of Nursing/Department of Midwifery, University of Iceland, Eirberg við Eiríksgötu, 101
Reykjavík, Iceland
Reykjavik
Iceland
101

Sponsor type
University/education

ROR
https://ror.org/01db6h964

Funder(s)

Funder type
Not defined

Funder Name
Rannsóknarsjóður Háskóla Íslands

Funder Name
Minningarsjóður Bjargar Magnúsdóttur ljósmóður og Magnúsar Jónassonar bónda

Results and Publications

Publication and dissemination plan
1. Publication as part of PhD thesis
2. Dissemination of protocol and results in scientific peer reviewed journals
3. Dissemination of results in national and international professional conferences

Intention to publish date
15/07/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Emma Marie Swift (ems23@hi.is). The anonymised raw dataset will be available Jan 2019-Jan 2025. This would be for medical professional with an interest in childbirth fear requiring data for meta-analysis, or in response to queries/requests generated from publication of results in scientific journals/presented at conferences. Data will be shared in a password protected file sent via an encrypted email service. Consent from participants was obtained via informed consent procedures and a signed informed consent document.

IPD sharing plan summary
Available on request