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Group-based antenatal birth and parent preparation for improving birth outcomes and parenting resources: Study protocol for a randomised trial

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ABSTRACT

Objectives: To examine the efficacy and cost-effectiveness of group based antenatal education for improving childbirth and parenting resources compared to auditorium based education.
Methods: Participants: 2350 Danish pregnant women and their partners ⩾18 years old, recruited before 20 + 0 gestational weeks.
Population-based individually randomised superiority trial with two parallel arms: Four sessions of birth and parent preparation in small groups (experimental group); two lectures in an auditorium (control group).
Data is collected by (1) questionnaires at baseline (≈18 weeks of gestation), 37 weeks of gestation, 9 weeks-, 6 months-, and 1 year post-partum, (2) the hospital obstetric database, (3) national registers. Primary outcome: use of epidural analgesia. Secondary outcomes: stress, parenting alliance; explorative outcomes: depressive symptoms, use of health care services, self-efficacy, well-being, family break-ups. Analyses will be intention-to-treat as well as per protocol. Process evaluation will be conducted using questionnaires and qualitative interviews. The incremental societal cost of the intervention will be computed and compared to the measured outcomes in a cost-effectiveness analysis.
Conclusion: To the best of our knowledge this is the largest well-designed randomised trial of its kind to date. The trial will bring much-needed evidence for decision makers of the content and form of antenatal education.

Introduction

The majority of prospective parents look to antenatal education to gain information on issues such as decision making about and during labour, infant and postnatal care, breastfeeding, and parenting skills [1]. However, the form and content of antenatal education has been sensitive to opinions and trends and has undergone many changes without specific evidence on its effects on relevant outcomes for parents and children.

Today, the main focus of many antenatal classes is birth and breastfeeding; while information on parent–child attachment and psychosocial aspects that relate to couple- and parenthood are generally not covered [2–5], although studies suggest that parents need this information [6]. Further, many antenatal classes are conducted in large auditoriums. It has been argued that information transfer should no longer be the focus of antenatal education. Experts suggest that educators need to become facilitators and emphasis should be shifted from the educator to the learner. Furthermore, that individuals need to interact with fellow learners and the learning environment in order to learn and obtain new competencies [7].

Previous studies of antenatal education have been difficult to interpret, mainly because of limitations in study design, high risk of bias, and small sample sizes [1]. Further, only few randomised trials have been conducted [1]. A Cochrane review of all randomised trials about individual or group antenatal education for childbirth or parenthood from 2007 concludes that the effects remain largely unknown [1]. Since then only few well-conducted randomised trials have been carried out. These suggest a positive effect of attending antenatal education, e.g. on the birth process

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[8] and on parenting self-efficacy [9]. However, the effect of antenatal education on the overall acquisition of knowledge, on parent's ability to care for infants and to making psychological and social adjustments in the transition to parenthood is still largely unknown.

Cochrane reviews of randomised trials on parent training programmes suggest that parenting programmes have a potential role to play in the promotion of mental health [10,11]; however, randomised trials on antenatal parenting programmes are scarce. Most current evidence from randomised trials addresses the use of parenting programmes, as part of secondary, high-risk approaches to prevention. However, it has been argued that they would be more effective if delivered as part of a population-based approach [11,12]; in this way they are offered to all parents to prevent problems and promote child and parent health.

To date, it is therefore unknown if: (1) antenatal preparation in small groups is superior to auditorium-based education; (2) which elements the classes should encompass to meet the parents' needs today; and (3) what the cost-effectiveness of antenatal preparation in small groups is compared to large-scale education in auditoriums.

Over the past years, Danish antenatal education has gradually moved away from large-scale auditorium-based education to antenatal birth and parent preparation classes in small groups for all expectant parents. In the Capital Region of Denmark antenatal classes are, however, still offered as lectures in hospital auditoriums with a minimum of interaction with the audience, although this region is planning to implement birth and parent preparation in small groups. The Capital Region of Denmark is therefore an ideal setting for a randomised trial of group-based versus auditorium-based antenatal education.

All healthcare systems have limited resources, and it is therefore important to develop a research-based up-to-date antenatal preparation programme and investigate its efficiency and cost-effectiveness prior to implementation.

Objective

The primary objective of the NEWBORN trial is to compare birth outcomes, parenting resources, health and thriving, and use of healthcare services in families enrolled in a research-based standardised antenatal birth and parenting programme in small groups with those allocated to auditorium-based education.

Process evaluation: As the degree of implementation of a programme is crucial to its ability to achieve any effect, we aim to ensure careful implementation of the programme. We will conduct a thorough process evaluation highlighting enabling factors and barriers to the implementation.

Cost-effectiveness analysis: Finally, the incremental societal cost of the intervention will be calculated and compared to the measured outcomes in a cost-effectiveness analysis.

Methods

Trial design

Population-based individually randomised superiority trial with two parallel arms: Four sessions of birth and parent preparation in small groups of 6–8 couples (experimental group); compared to two lectures in an auditorium on birth and breastfeeding, with participation of up to 250 people (control group).

Setting

The trial is conducted at the Department of Obstetrics and Gynaecology, Hvidovre Hospital (HH) in the Capital Region of Denmark. Denmark ensures tax-financed, free, equal access to medical health care.

Participants

Women will be enrolled from $10 - 20 + 0$ weeks of gestation. Inclusion criteria are expectant women, $\geqslant 18$ years old at enrolment, due to give birth at Hvidovre Hospital, able to speak and understand Danish, and being legally able and actually providing signed consent. The women's partners are also invited to participate.

The women will receive a written invitation to participate in the trial prior to their first visit to the birth clinic. Baseline data will be collected from the women and their partners when they accept the invitation and before randomisation. Oral and written information will be provided and the women and their partners will be randomised to the experimental group or the control group if she signs and returns the informed consent form.

Randomisation

Central randomisation will be performed using the Copenhagen Trial Unit's Online Randomisation system. A project employee will perform individual web-based randomisation according to a computer-generated allocation sequence with a varying block size concealed to the investigators. All citizens in Denmark have a unique personal identification number; the randomisation programme is set up to confirm the existence of the unique personal identification number. The allocation of participants will be 1:1 to the experimental group and the control group, respectively, stratified by vulnerability as defined by the birth site (vulnerable women: women with a previous or actual psychiatric illness, with an actual life crisis, who are victims of violence or are socially strained, versus women who are not vulnerable), and parity (nulliparous women versus multiparous women).

Intervention

The trial will have two intervention groups:

(1) The "NEWBORN" programme (experimental group). A research-based and theoretically founded birth and parenting programme developed in collaboration with midwives, health care visitors, psychologists and family therapists, parents, and leading national and international researchers and clinicians in this field (described in more detail below).
(2) Standard care (control group). The pregnant woman and her partner are offered two antenatal lectures on birth and breastfeeding in an auditorium with participation of up to 250 people.

The NEWBORN programme includes short verbal presentations from the group facilitator, individual exercises, short film presentations, time for discussions and reflection. Parents are given homework in the form of minor exercises in preparation to each session. Educational subjects are: the transition to parenthood; couple communication; birth; breastfeeding; and taking care of a newborn. A patient-network website has been created as a supplement to the sessions. The programme is focused on parenting resources important to the birth process, parenting and mental health, and that appear amenable to change, i.e.: social support, parenting alliance, cognitive coping, and parenting skills:

- *Social support:* formal and informal, emotional, informational and instrumental. Groups of 6–8 couples are offered three times 2.5 h sessions during pregnancy and one session 5 weeks postpartum. The groups are composited to enable participants establish relations with other expectant parents in their local area. Sessions are led by a midwife and the postnatal session will include a health visitor. A patient-network website enables parents to gain further information, communicate with other parents and consult online with a midwife and a health visitor.
- *Parenting alliance:* adding a component supporting the couples in the transition to parenthood and couple communication.
- *Cognitive coping:* embedding sources of self-efficacy into programme content and delivery, and by creating an environment which enables parents to discuss feelings and concerns, enhances their awareness of own resources, problem-solving strategies, and future challenges in parenting and emotional regulation
- *Parenting skills:* increasing information and exercises with feedback, e.g. on recognising signs and symptoms of thriving in the newborn, couple communication, etc.

The approach aims at strengthening relationships and improving information and problem solving skills for expectant parents in order to ease birth and the transition to parenthood.

To maximise the potential for population uptake classes have been established at three local midwifery sites. A comprehensive guide and education material for course facilitators has been developed, and facilitators, i.e. midwives and health visitors are trained at 1-day workshops. The framework for the classes is based on an estimate of adequate time allocated to each subject, and what service providers deem a sustainable service.

Session 1 (approximately 25 weeks gestation):

- The transition to parenthood – new roles and responsibilities.
- Common changes in the relationship during and after pregnancy.
- Couple communication.
- Meaning of own childhood when becoming parents.

During this session participants are introduced to one another and to the outline of the entire programme. The midwife invites the parents to think about and since discuss their expectations of the greatest joys and greatest challenges of parenthood. The midwife informs the parents about common changes and challenges in the relationship during pregnancy and after birth, and the importance of good communication. A short film is shown teaching the parents about good communication skills. The film is developed by the Danish Centre of Family Development and is inspired by PREP [13]. The film is followed by practical couple-communication exercises. Women attending the classes alone either pair up or conduct the exercise with the midwife. In short the exercise entails one person listening actively and without interrupting while the other person describes thoughts and feelings about a certain topic. Afterwards the person listening is encouraged to acknowledge what she/he has heard before changing roles. This communication exercise is used throughout the entire programme covering different topics e.g. expectations of parenthood, labour, the relationship after birth, etc. The aim is to try to understand the other person's perspective before trying to be understood. The importance of one's own childhood when becoming a parent is also a topic in this session [14]. Participants are asked to think back to their own childhood, how they were raised, their parents' parenting style (e.g. warm and affectionate, strict), traditions, etc. Afterwards they are to consider things they would like to carry forward into their own parenting as well as things they might want to do differently. Finally the couple discuss the topic using the communication technique they have been taught. The aim is to start a thought process. As there is not sufficient time for long in depth discussions participants are encouraged to carry on the discussions at home. During the first break participants who wish to do so are asked to write down their contact details so that they can be shared. Throughout all the sessions the midwife has a facilitating role helping discussions along if needed and commenting where appropriate. At the end of all sessions participants are asked to consider and write down the most important take home points of the session.

Suggested homework: seven short informational film clips (duration between 2 and 7 min) on the first signs of labour, the time at home in early labour, birth, when there is a need for obstetric intervention, and pain relief.

The films, exercises, and written information on session topics are available on the network website.

Session 2 (approximately 33 weeks gestation):

- Expectations in relation to birth.
- The normal course of labour.
- When there is a need to intervene in labour.
- Pain relief and coping strategies.
- Partner support during labour.

The aim of this session is providing participants with information, and enhancing their existing knowledge and understanding of the normal course of labour, pain-relief, and what might be expected if there is a need for obstetric intervention. After a short presentation by the midwife the couples discuss their hopes and expectations for labour and birth using the communication framework – they are asked to consider their individual resources and action competencies in relation to increasing the likelihood of obtaining their wishes. Also the couples are asked to discuss how they might support one another during labour and birth – using practical examples. For the topic on pain relief the women are asked to discuss their thoughts and previous experiences with coping with pain and physical and mental strain – what did they do, what helped them, can they use any of these strategies during labour? Next they discuss their thoughts and knowledge on various methods of pain relief. Meanwhile the men discuss their thoughts and feelings about their role during labour and birth. Plenary discussions and summing up thoughts and ideas are used so that participants can learn from and be inspired by one another. Vicarious learning and feedback are considered important in relation to self-efficacy [15].

Suggested homework: participants are encouraged to ask women in their social network about their breastfeeding experiences, and read a pamphlet that is handed out on breastfeeding [16].

Session 3 (approximately 35 weeks gestation):

- Feeding a newborn.
- Interpreting the newborn's signs, symptoms and behaviour.
- Taking care of a newborn.
- Mood swings and postnatal depressive symptomatology.

Participants discuss wishes for feeding their newborn and feeding experiences in their networks in small groups. The midwife then talks about how expectations, support, and the advice received from family and friends may affect e.g. breastfeeding intention and perseverance in the case of difficulties. Bearing the breastfeeding experiences of individuals in their social networks in mind (preparation for this session), participants are encouraged to consider who it might be most helpful to seek breastfeeding support and advice from if necessary.

Cards with a variety of breastfeeding topics are spread out on the table, and participants are asked to pick a topic that they wish

to hear more about, and tell the group why they have picked the chosen topic. Topics include e.g. how to tell that the baby is getting enough milk, positioning, importance of partner support, feeding patterns, breast engorgement, etc. There are certain topics that the midwife is told to cover regardless of whether it has been picked by a participant or not e.g. how to tell the baby is getting enough milk. The pilot study showed that participants are likely to choose a topic they already know something about in order to receive verification and feedback from the midwife and from the other participants (unpublished data) – this may help increase self-efficacy.

The midwife gives information and shows short film clips on baby cues and sleep patterns. The importance of communicating with the newborn is underlined. Information on the prevention of cot death is given. Next the initial time at home with a newborn and the importance of social networks for emotional and practical support is discussed (the group is considered a potential supportive social network). Participants are given an exercise where they are asked to fill in a list of expected daily activities after the baby is born. Afterwards they compare their list with their partner's or that of another group member before summing up in plenum. The aim of this exercise is to increase awareness of what changes life with a newborn has on a daily routine, how much time is spent on breastfeeding, etc. [14]. Participants are also asked to consider activities that give them energy and pleasure (e.g. playing football, going out with friends, reading a book), and how they might incorporate some of these activities in their new daily lives [14]. Next participants are encouraged to reflect upon how they normally handle worries, and to discuss this topic with their partner. Finally common emotional reactions and postnatal depressive symptomatology is covered. The importance of being open about these emotions and supportive of one another is stressed, as is the importance of seeking help when deemed necessary.

Session 4 (approximately 5 weeks post-partum):

- Birth experiences.
- Mood swings and postnatal depressive symptomatology.
- The first time at home with a newborn.
- Couplehood.

This session is carried out by a midwife as well as a healthcare visitor. The aim is for the newborn parents to share birth experiences, and their experiences in their new roles as parents so far. The topic of common emotions and postnatal depressive symptomatology is revisited. Next groups of four are asked to discuss how being a parent is different to what they expected, which challenges they consider to be the greatest, how they cope with/handle these challenges, and what have been the greatest joys. The parents are able to ask the midwife and the healthcare visitor practical questions during the break. After the break, using the communication framework, couples are asked to discuss what the best change has been in their partner after becoming a parent, what has worked really well in the relationship, and in sharing household tasks, and what could make it even better. Finally the healthcare visitor talks about sex (including contraception) and intimacy after becoming parents.

Pilot study

The feasibility and face validity of the programme has been pilot- tested among 35 couples by qualitative interviews, and observation of participants and facilitators (unpublished data).

Ethics–risk/benefits

The trial is approved by and registered with the regional ethics committee, and will be carried out in accordance with the Declaration of Helsinki in its latest form as well as national laws and regulations.

There are no known risks of participating in the trial. We assume that participants in the experimental group will benefit from more in depth antenatal classes in small groups, however, we cannot rule out the possibility that the experimental group may experience an initial increase in worries about issues related to birth and parenting. Participants randomised to the control group may experience some disappointment. To date there is no conclusive evidence as to which form and format an antenatal programme should have. We therefore consider it ethically justifiable that the control group will receive standard care.

Participants are free to attend concomitant antenatal and postnatal services and parent groups. Participants will be able to withdraw from the trial at any time. Women who have a miscarriage or a stillborn child will not be continued in the trial.

Data collection

All Danes have a unique personal identification number (CPR-number) which identifies sex, date and year of birth and allows for register linkage with all population-based registers in Denmark. Data will be collected by the hospital obstetric database, the national registers, and web-based questionnaires from both parents at: baseline, i.e. time point 0 (tp 0) (at approximately 18 weeks of gestation); at 37 weeks of gestation (tp 1); at 9 weeks after expected due date (tp 2); at 6 months after expected due date (tp 3); and 1 year after expected due date (tp 4). Participants will be contacted via e-mail, and a reminder will be sent by e-mail after a week. After 2 weeks phone numbers will be sought on participants who have still not responded, and where possible they will be contacted by phone.

Blinding

It is not possible to blind the participants and the personnel in the trial. However, blinding in all other aspects of the trial will be maintained: blinded data collection on outcomes from national registers; the statistical analyses will be conducted with the two intervention groups coded as, e.g. A and B; and two conclusions will be drawn by the Steering Committee, one assuming A is the experimental group and B is the control group, and one conclusion assuming the opposite. After this the blinding will be broken.

Outcome measures

As blinding of participants and midwives and health visitors is not feasible in this trial it is desirable to specify at least one objectively assessed outcome to reduce the risk of bias, even if the outcome of most interest is subjective [17].

The primary outcome is use of epidural analgesia during labour, using data from the hospital obstetric database (as proxy variable for coping and fear of childbirth). Findings suggest that women who receive epidural analgesia experience more fear but not more pain, before the administration of epidural analgesia [18]. Structured antenatal education may improve women's ability to cope during labour resulting in lower epidural rates [8].

Secondary outcomes are: stress measured by The Swedish Parenthood Stress Questionnaire (SPSQ) [19] – questionnaire data (tp 2,3,4), and The Perceived Stress Scale (PSS) [20] – questionnaire data (tp 0,1,2,3,4). Parenting alliance – The Parenting Alliance Measure [21] – questionnaire data (tp 2,3,4)

Explorative outcomes: antenatal and postnatal depressive symptomatology and anxiety – Edinburgh Postnatal Depression Scale (tp 0,1,2), The Major Depression Inventory (MDI) (tp 3), The Hopkins Symptom Check List (SCL-25) first 10 items (anxiety score,

SCL-anxiety)(12)(tp 1,2) – questionnaire data. Breastfeeding – questionnaire data (tp 0,1,2,3). Use of healthcare services, i.e.: for the parents obstetric intervention, i.e. augmentation of labour, vacuum extraction, caesarean section – data from the hospital obstetric database (tp 2), and contact to healthcare professionals for depressive symptomatology and unscheduled postnatal visits–questionnaire data (tp 2,3). For the child, i.e. neonatal readmissions to hospital, contacts to accident and emergency departments (A and E), General Practitioner (GP) and doctor on call during the child's first year of life (composite measure). Use of the regional emergency phone line – data from the national registers (tp 4). Family medicine use and smoking – questionnaire data (tp 2,3) and register data (tp 4). Satisfaction with relationship and family break-ups – questionnaire data (tp 0,1,2,3), and data from the national registers on divorce and break-ups (tp 4). Mental well-being The Warwich-Edinburgh Mental Well-being scale (tp 1,2,3) [13].

Intermediate outcomes: parenting resources: Self-efficacy in relation to: (1) birth (tp 1), (2) discharge (tp 1), (3) parenting (tp 1,2), (4) breastfeeding (tp 0,1); couple communication (tp 0,1,2,3); social support/network (tp 0,1,2,3).

Demographic variables and individual characteristics: education, occupational social class, marital status, cohabiting status and number of children living in the household, sense of coherence, self-rated health, subjective health complaints, and long term illness.

The questionnaires include between 70 and 190 items, and take between 10 and 25 min to complete.

Process evaluation will be conducted with a mixed methods approach using quantitative questionnaire data and qualitative interviews with participants and service providers. We will examine programme fidelity, e.g. whether the protocol is followed in programme delivery, and how much of the intended programme the participants receive (dose), as well as programme reach, e.g. what proportions of the intended groups are participating in the programme, as these factors have an impact on the effect of the intervention [22]. Participants will be asked to fill in a web-based questionnaire on-site at the end of each session. The questionnaire will highlight whether the intended educational subjects of the session have been covered as well as the extent to which the participants found the information given useful. Group facilitators will be asked to fill in a similar questionnaire with the opportunity to explain why certain topics may have been omitted.

Furthermore, participant observation will be carried out during random sessions. Using in-depth interviews qualitative data will be collected from a purposive sample of participants to gain understanding of their perceptions and experiences of the NEWBORN course using interview schedules with topic guides.

Use of additional antenatal and postnatal services will be investigated by questions specifically developed for this purpose, and analysis adjusted for concomitant service use will be performed.

Cost-effectiveness analysis: the incremental societal cost of the intervention will be computed and compared to the measured outcomes. Direct health care costs and productivity costs in terms of labour market participation and short term absence will be calculated.

Statistical plan and data analysis

Sample size

We are planning a trial of experimental and control participants with one control participant per experimental participant. 2011 data from the HH Obstetric Database [23] indicate that use of epidural analgesia among pregnant women is 31%. If the true use of epidural analgesia for experimental participants is 25% (risk reduction of 19%), we will need to include 1175 participants in the experimental group and 1175 control participants to be able to reject the null hypothesis that the epidural use for experimental and control participants is equal with a probability (power) of 90%. The type I error probability associated with this test of this null hypothesis is 5%.

For the three secondary outcomes, we have estimated the power of 98% or more (Table 1).

Statistical methods

Reporting will follow the guidelines of the CONSORT-statement. Statistical analyses will be intention to treat and per protocol. The level of significance is set to 5% and power to 90%.

The analysis of the primary binary outcome will be done using the generalised linear mixed model with distribution = binomial, link = logit and 'experimental antenatal group' as a random factor. The 'antenatal subgroup' comprise the groups of 4–6 couples for the experimental participants and the collective group of control participants. The analysis will be adjusted by the protocol specified stratification variables.

If the percent missing cases >5%, the results of this analysis will be subjected to a 'worst case' and a 'best case' scenario analysis of the potential impact of missing values. Assume a beneficial effect (less use of epidural analgesia) is noted in one group (group A) as compared to the other group (group B). A worst case scenario will then be constructed where missing values in group A are imputed by a "yes" to use of epidural analgesia and missing values in group B are imputed by a "no" to use of epidural analgesia. A corresponding best case scenario will also be constructed and the result under both scenarios will be computed.

Analyses (adjusted by baseline value and protocol specified stratification variables) of perceived stress at 37 week gestation and for each of the other three secondary outcomes of the area under the curve (AUC) from 9 weeks to 1 year after due date will be done. The linear mixed model with the intervention indicator as a fixed effect and group as a random effect will be used in the analyses.

If the percent missing cases of an outcome is >5% and p of Little's test (1) <5%, a number of datasets with observed values and predicted unobserved values necessary to produce an efficiency >99% will be produced using multiple imputations (SPSS version 17 or later) (2). The primary analysis will then be that based on these data sets.

Multiplicity will be dealt with as follows: the primary outcome will be tested at the 5% level. If $p > 5\%$, the remaining null hypotheses will be accepted without test. If not, the p values of the

Table 1
Power estimations for the secondary outcomes in a trial with 2350 participants.

	Number of participants	Minimal relevant difference	Standard deviation	Type 1 error risk (%)	Power (%)*
Perceived stress scale	2350	1 Point [15]	6 Points [15]	5	98.1
Swedish Parenthood Stress Questionnaire	2350	0.1 Point [19]	0.5 Points [19]	5	99.8
Parenting Alliance Measure	2350	4 Points [21]	20 Points [21]	5	99.8

* Power estimations conducted with the programme: PS Power and Sample Size Calculations version 3.0.14 [26].

remaining four tests will be adjusted using Hommel's procedure [24]. In all events all observed p values will be reported.

Discussion

Antenatal education classes are offered to prospective parents in most countries in the Western part of the world. However, there is very limited knowledge on the effect of, as well as the content and form of antenatal education.

To our knowledge, the NEWBORN trial is the largest randomised trial to date. We will minimise the risk of bias in all important domains [25]. Although it is impossible to blind participants and investigators, we will be able to blind all other aspects of the trial. Due to the comprehensiveness of Danish registers, we will obtain blinded and objective assessment of the primary outcome.

The trial recruits participants from a single hospital in Denmark, which may reduce the external validity of findings. However, the experimental intervention is delivered by 20 different midwifes and 8 different health-visitors in 3 different local sites, which in turn will increase the generalisability. Further, the trial has very wide eligibility criteria, leaving potential findings applicable to the entire Danish population.

Previous trials and studies have mainly focused on the mother's transition into motherhood. In the NEWBORN trial we will have a strong focus on the father and the couple as a whole. This will bring valuable new knowledge to an area with limited knowledge.

It may be seen as a limitation that the experimental and the control group differ in more than one respect. The size of the groups differ and the type of teaching. They also differ in terms of the actual material presented. The study provides a comparison between the two approaches. But safe inferences pertaining to the causes of a difference between the two approaches regarding type of teaching, content of teaching and duration of teaching cannot be made.

To date, we have only planned follow-up till 1 year after due date. This leaves several limitations regarding the assessment of participant-relevant outcomes, such as the child's thriving as it grows up, the number of families that experiences divorces and break-ups, and child's use of the health-care system in both the short and the long run. We assess these outcomes in the NEWBORN trial, but we range them in the outcome hierarchy as 'exploratory'. This is done, as (1) we have very limited knowledge of the potential effect of antenatal education on these outcomes, and we have therefore not been able to perform power estimations as we have for the secondary outcomes. (2) Due to logistical and financial constraints. If additional funding can be obtained, data on all individuals can be sought in the national registers and long-term follow-up is possible.

Results from the NEWBORN trial will form a much-needed base for decision-makers regarding the form and content of antenatal education.

Trial status

Recruitment of participants started November 2012. No interim analyses have been conducted. Data collection on the primary outcome is expected to be complete medio 2014. Full data collection is expected to be complete medio 2015.

Conflict of interest

The authors declare that they have no conflict of interests.

Author's contributions

Appendix A shows how authors have contributed to the trial. All authors have read and approved the final manuscript.

Finance and insurance

The Danish Cancer Society has funded the project with 5.2 MDKK (approximately 900.000 USD) but have not been involved in any aspects related to the study of the decision to publish.

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