Group antenatal care (Pregnancy Circles) for diverse and disadvantaged women: study protocol for a randomised controlled trial with integral process and economic evaluations – an update to the published protocol

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UPDATE

Introduction

This document reports on updates to the protocol of the REACH Pregnancy Circles trial published in BMC Health Services Research [1]. The trial is a pragmatic, two-arm, individually randomised, parallel group randomised controlled trial which aims to assess the effectiveness and cost-effectiveness of a model of group antenatal care (pregnancy circles) in ethnically, culturally and linguistically diverse and disadvantaged areas of the UK. The trial is registered with the ISRCTN registry: ISRCTN91977441.

Following the publication of the protocol, amendments have been made to reflect the changes to sample size, recruitment processes, sponsor, the definition of the primary outcome variable and the classification of secondary and other outcome variables. All amendments to the protocol have been approved by the London-Surrey Borders Research Ethics Committee (ref. 17/LO/1596). The current protocol is Version 9 (03/02/2023).

Sample size and recruitment processes

The original target sample size was 1732 (866 recruits per trial arm). However, this has been increased due to the impact on intervention delivery of the Covid-19 pandemic.

In line with government and NIHR guidance, all recruitment to the pregnancy circles trial was paused in March 2020. All NHS Trusts suspended in-person group-based activities and women in the pregnancy circles were offered one-to-one care. For women in the trial randomised to the intervention arm and still receiving antenatal care, we encouraged sites to consider virtual options to continue the Circles and presented a number of other options to continue care that would be underpinned by the values of the Pregnancy Circles model, including encouraging women to continue peer support through a WhatsApp group and to self-test at home. Intervention dose offered was then calculated based on a scoring system which we applied to each Pregnancy Circle based on: number of circle sessions that had taken place before lockdown; continued continuity of carer; WhatsApp group for circle; self-testing; pregnancy circle interactive sessions implemented; non pregnancy circles interactive sessions implemented (see Table 1).

Table 1: Scoring for intervention components during Covid-19 pandemic lockdown

Scores for intervention activity (antenatal only)	
Sessions before lockdown	

7-8	6
5- 6	5
3-4	4
1-2	3
No sessions	0
Continuity of carer (antenatal)	(only counts extra if all women didn't receive this ,i.e. controls too)
Y	1
N (or everyone got)	0
WhatsApp group for circle	
Y	1
N	0
Self testing	
Any Y	1
N	0
Pregnany Circle virtual interactive antenatal sessions	
3+	3
1-2	2
N	0
Other non-Pregnancy Circle virtual antenatal sessions	(only counts extra if this wasn't offered to all women, i.e. controls too)
Y	1
N	0

Those in a pregnancy circle allocated a total of 0 points were categorised as having had 'no intervention' offered, those allocated 1-3 points were offered a 'low or very low dose of the intervention' , and those allocated 4-5 points were offered a 'moderate dose of the intervention' .

With approval from the Trial Steering Committee, the decision was made to a) exclude no or low dose intervention participants and control group participants randomised during the same period from the primary outcome analysis and b) to recruit additional women to replace them. The sample size has been further increased to maintain 90% power based on the assumption that the treatment effect in those participants who could have received a moderate dose of the intervention is halved. Thus to recruit to target as planned and make up for lost power, the target sample size has been increased to 2192 (1096 recruits per trial arm). Assumptions for the sample size calculation remain unchanged.

Since unpausing recruitment, trial sites have been given the option of recruiting participants over the phone, in addition to doing so face-to-face at antenatal booking or scan appointments.

Sponsor

The sponsor of the study changed in February 2022 from the University of East London to City, University of London.

Definition of primary outcome variable

The primary outcome is a 'healthy baby' composite measured at 1 month postnatal using routine maternity data. The composite is comprised of the following four components with the amendments/clarifications highlighted in italics:

1. Live baby (i.e. *no pregnancy loss before 24 completed weeks,* no stillbirth after 24 completed weeks of pregnancy and no neonatal death within 28 days of the birth)
2. Born at term (37 weeks and above)
3. Appropriate weight for gestational age (GROW centile > 9.99 & <90.01)
4. Not admitted for neonatal intensive care *by which we mean:*
   Intensive Care Unit (NICU), Special Care Baby Unit (SCBU) and High Dependency Unit, but not transitional care

In the original protocol, the intention had been to treat pregnancy losses before 24 completed weeks as missing for the primary outcome. However, as the study involves an intention-to-treat (ITT) comparison of the Pregnancy Circles group antenatal care intervention with standard antenatal care, it was agreed by the trial team and the Trial and Programme Steering Committees that all pregnancy losses occurring after recruitment and randomisation should be included in the primary outcome analysis. In addition to this, the definition of admission to neonatal intensive care has been clarified.

Secondary outcome variables

Some of the secondary outcomes presented in the published protocol have been re-classified as 'Additional health economic and other outcomes' due to their lower importance for assessing the effect of the intervention relative to control.

The secondary outcomes, which include the four individual components of the primary outcome are:

- Women's empowerment (includes involvement in decisions about care)
- Spontaneous vaginal delivery (SVD) defined as a woman who delivers vaginally without forceps or ventouse
- Women's satisfaction with maternity care

- Attendance at antenatal care
- Social support
- Self-efficacy
- Prenatal stress
- Breast feeding initiation
- Breast feeding continuation and exclusivity
- Health Literacy
- Mental wellbeing
- Live baby (i.e. no pregnancy loss before 24 completed weeks, no stillbirth after 24 completed weeks of pregnancy and no neonatal death within 28 days of the birth)
- Born at term (37 weeks and above)
- Appropriate weight for gestational age (GROW centile >9.99 & < 90.01)
- Not admitted to a neonatal unit, including: neonatal intensive care unit (NICU), special care baby unit (SCBU) or high dependency unit (HDU).

Additional health economic and other outcomes to be assessed are:

- Continuity of antenatal care
- Health service usage
- Caesarean delivery (planned, emergency, none)
- Infant birth weight, defined as low if less than 2500g
- Place of birth
- Postnatal depression
- Postnatal symptoms

References

1. Wiggins, M., Sawtell, M., Wiseman, O., McCourt, C., Eldridge, S., Hunter, R. Bordea, E., Mustard, C., Hanafiah, A., Hatherall, B., Holmes, V., Mehay, A., Robinson, H., Salisbury, C., Sweeney, L., Mondeh, K., Harden, A. (2020). Group antenatal care (Pregnancy Circles) for diverse and disadvantaged women: study protocol for a randomised controlled trial with integral process and economic evaluations. BMC Health Services Research, 20(1). doi:10.1186/s12913-020-05751-z.