

# **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**

Date: 07/06/2024

## **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 classification of secondary and other outcome variables. These changes were made based on recommendations by the Trial Steering Committee and made prior to the final analysis and anybody involved in the final analysis having access to unblinded data. 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 10 (06/06/2024).

### **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 and/or their role being more accurately described as mediators of the effects of the intervention rather than outcomes in their own right.

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
- Breast feeding initiation
- 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:

- Attendance at antenatal care
- Social support
- Self-efficacy
- Prenatal stress
- Breast feeding continuation and exclusivity
- Health Literacy
- 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.