

SWAT 251: Increasing participation of South Asian women/birthing people in gestational diabetes trials

Objective of this SWAT

To evaluate methods intended to increase trial participation amongst South Asian women/birthing people, who are more likely to develop gestational diabetes (GDM) and have previously been underserved by research.

Additional SWAT Details

Primary Study Area: Recruitment

Secondary Study Area: Barriers and facilitators; Document design and delivery; EDI; Participant identification and consent; Sites and staff

Who does the SWAT intervention target: Healthcare Professionals; Patients

Estimated resources needed to conduct the SWAT: High

Estimated cost of the SWAT (£): 29,450

Findings from Implementation of this SWAT

Reference(s) to publications of these findings:

Primary Outcome Findings:

Cost:

Background

Gestational diabetes (GDM) affects 8% (~50,000) of UK pregnant women/birthing people. South Asian women/birthing people are twice as likely to develop GDM compared to White European women/birthing people, making it particularly important that they are included in research but, in the past, they may have been under-served by research.

We wish to understand the barriers and enablers to participation of South Asian women/birthing people in GDM trials to inform the design of an 'inclusivity package' to specifically target recruitment of South Asian women/birthing people into the GILD trial of blood sugar monitoring strategies during pregnancy (ISRCTN13019598). To facilitate recruitment of South Asian women, we will work with South Asian Health Action (a charity based in Leicester to support the physical and mental health needs of the local South Asian community) and the HaPPIE research group (a group dedicated to patient and public involvement to amplify the voices of Black and Brown skin people)

Host Trial Population: Adults

Host Trial Condition Area: Sexual and Reproductive Health

Interventions and Comparators

Intervention 1: Standard recruitment materials plus an inclusivity package:

- A package of study-specific recruitment materials with inclusive messaging has been developed following focus groups conducted with South Asian woman/birthing people and their families to explore barriers to the research.
- Bespoke cultural-awareness training on how to approach, seek consent, recruit and retain South Asian women/birthing people in the trial.
- A small number of 'Community Connectors' (women/birthing people with lived experience of GDM) will be appointed to provide ad-hoc informal peer support and ad

Intervention 2: Comparator – standard recruitment materials

Method for Allocating to Intervention or Comparator: Randomisation

Outcome Measures

Primary Outcomes: Key outcomes for this SWAT are the number of South Asian women/birthing people who:

1. are approached for participation in the trial
2. give consent to participate
3. are randomised.

All outcomes are proportionate to the number of South Asian women/birthing people at each site (ONS/site level data).

Secondary Outcomes: Number of randomised South Asian women/birthing people who complete the 6-week follow-up questionnaire.

Analysis Plans

The analysis of the SWAT will be specified in the GILD SWAT statistical analysis plan. Analyses will include appropriate descriptive statistics and between-group comparisons will use appropriate regression models with analysis at the site level.

Possible Problems in Implementing This SWAT

Cultural awareness training is an additional burden on healthcare professionals' time.

References Cited in This Outline

References to This SWAT

Source of This SWAT

People to show as the source of this idea: Professor Kate Walker and Professor Eleanor Mitchell

Contact email address: Kate.Walker@Nottingham.ac.uk and Eleanor.Mitchell@nottingham.ac.uk

Date of idea: 01/10/2024

Revisions made by:

Date of revisions: