# SWAT 128: Timing of recruitment of pregnant women to participate in a trial

**Objective of this SWAT**
To evaluate the effects on recruitment and retention of the timing of invitations to pregnant women to participate in a randomised trial.

Study area: Recruitment, Retention, Pilot Trial
Sample type: Participants
Estimated funding level needed: Low

**Background**
Adequate recruitment of trial participants is essential to the success of all trials. Yet, two-thirds of trials will not complete recruitment within their stated timeframe [1]. Pregnant women, in particular, remain under-represented in clinical research and the recruitment of pregnant women to trials has proved challenging [2]. A 2018 Cochrane Review examining methods to improve recruitment to randomised trials found a distinct knowledge gap in evidence-based recruitment strategies [3]. This SWAT will help fill this gap by assessing if the timepoint at which pregnant women are invited to take part in a trial affects the number of women recruited to and retained in the trial. It seeks to determine: when should pregnant women be asked to join a trial?

**Interventions and comparators**
Intervention 1: Participant recruitment at 35 weeks to 36 weeks + 6 days gestation
Intervention 2: Participant recruitment at 37 weeks to 38 weeks + 6 days gestation

Index Type: Method of Recruitment

**Method for allocating to intervention or comparator**
Randomisation

**Outcome measures**
Primary: • evaluation of randomisation, allocation and concealment processes (through focus group interviews and data extracted from routinely collected data);
• estimate variable parameters to inform sample size for a definitive trial, including the standard deviation of the outcome measure.
Secondary: • proportion of eligible women recruited (extracted from routinely collected data);
• proportion of recruited women that complete trial (extracted from routinely collected data).

**Analysis plans**
The primary analysis is the comparison between groups of the proportion of eligible women who are recruited, randomised into and retained in the study. This will be assessed by study-specific checklists.

**Possible problems in implementing this SWAT**
A potential disadvantage of all cluster randomised trials is the potential of clustering between individual units. This might introduce bias to the estimate of the comparative effects of different timing of participant recruitment.

**References**
1. Tooher R, Middleton PF, Crowther CA. A thematic analysis of factors influencing recruitment to maternal and perinatal trials. BMC Pregnancy Childbirth 2008; 8: 36.
2. Frew PM, Saint-Victor DS, Isaacs MB, et al. Recruitment and retention of pregnant women into clinical research trials: an overview of challenges, facilitators, and best practices. Clinical Infectious Diseases 2014; 59 (Suppl 7): S400–7.
3. Treweek S, Pitkethly M, Cook J, et al. Strategies to improve recruitment to randomised trials. Cochrane Database of Systematic Reviews 2018; (2): MR000013.

**Publications or presentations of this SWAT design**

**Examples of the implementation of this SWAT**

People to show as the source of this idea: Elaine M Finucane, Linda Biesty, Deirdre Murphy, Amanda Cotter, Eleanor Molloy, Martin O'Donnell, Shaun Treweek, Paddy Gillespie, Marian Campbell, John J. Morrison, Alberto Alvarez-Iglesias, Gill Gyte, Declan Devane
Contact email address: elainemay.finucane@nuigalway.ie
Date of idea: 1/JUN/2018
Revisions made by:
Date of revisions: