How can we improve recruitment to clinical trials during pregnancy? A mixed methods investigation

Dr Wendy Lawrence
Associate Professor of Health Psychology

Sofia Strömmer, Taylor Rose, Christina Vogel, Daniella Watson, Jo Botell, Nick Harvey, Cyrus Cooper, Hazel Inskip, Janis Baird, Mary Barker

MRC Lifecourse Epidemiology Unit, University of Southampton
NIHR Southampton Biomedical Research Centre, University of Southampton and University Hospital Southampton NHS Foundation Trust
Rationale

Why are trials in pregnancy important?

- A mother’s quality of diet influences the health & development of the fetus/baby & has implications for the child’s risk of chronic disease later in life.
- A “teachable moment” when women go through emotional & physical changes, & could be more open to making lifestyle changes (eg nutritional) that may improve their health & the health of their baby.
- A “window of opportunity” to conduct clinical trials, but one that comes with some obstacles.

Bruce & Hanson, 2010; Phelan, 2010
Pregnancy trials

- Recruiting to trials in pregnancy is difficult but important.
- Pregnancy trials often require large sample sizes to detect typically small differences in clinical outcomes for the mother or baby.
- Much of what we know comes from women who have agreed to take part in trials.

Kinnunen et al, 2008; Poston et al, 2015
Aims

• Understand why some pregnant women choose NOT to take part in clinical trials.
• Explore their reasons alongside those of women who DO take part.
• Identify barriers to participation.
• Propose strategies to increase recruitment.
Mixed Methods

Participants: women taking part in MAVIDOS\textsuperscript{1} or SPRING\textsuperscript{2}

• RCTs of Vitamin D\textsuperscript{1,2} & lifestyle support (HCS)\textsuperscript{2}.
• Sent invitations to take part in an interview after completing the trial – approx 3-4mths post-birth.
• Interviewed face-to-face at home.

Decliners: women invited to take part in SPRING

• At their routine NHS 12 week ultrasound appointment, invited to complete a short questionnaire about their reasons for declining.
• Telephone interview for the convenience of the women.
Decliners’ Reasons for Not Participating [from Questionnaire]

Participants could select multiple reasons

- I'm too busy: 97
- Don't want to/can't take pills: 95
- Don't like blood tests: 70
- Don't want a DXA scan: 68
- Don't want to take part in a study: 54
- Feel too unwell: 23
- Sounds complicated/don't understand it: 12
- No point if I'm in the control group: 12
- I'm already taking/ could easily get vitamin D: 11
- Risk to pregnancy or baby: 11
- Live too far away: 4
- Personal health: 3
- Too many personal questions: 3
- Difficulties organising child care: 3
- Still deciding: 1
Results: Characteristics of those taking part in interviews

- **Participants** (N=44)
  - Mean age: 34 years
  - 41% Had no other children in household
  - 54% Educated to degree level

- **Decliners** (N=30)
  - Mean age: 33 years
  - 47% Had no other children in household
  - 53% Educated to degree level
Thematic analysis

F2F interviews with trial participants & telephone interviews with decliners

What I think about the study

- "Anything to help protect them, or teach people to protect their babies in the future. I think it’s great."
- "I’m a bit of a control freak. You haven’t got 100% control."
- "I was quite impressed actually. They ran through the whole thing... exactly what was going to happen throughout the process."
- "It’s giving something extra to the fetus, you’re not quite sure how it’s going to affect them."
- "Difficult getting time off for additional appointments and arranging child care."
- "They always tell you that they book in advance... it was always easy if I could let work know... and then I just worked around them."
- "I was worried about the risks of asthma and eczema."
- "I knew it wasn’t going to... there was no way it could bring any harm to the baby... so it was fine."

What might get in the way of taking part

Deciding to take part

- Self-efficacy
- Trust in medical research

What concerns me
Interpretation of Findings

Differences in levels of **trust in medical research** & **self-efficacy** (confidence in their ability to overcome any barriers in order to meet trial requirements) between women who participated & those who declined:

- **Participants** believed that the research would cause no harm, while **decliners** felt they would be taking a risk.

- When faced with potential obstacles, **participants** found ways around them while **decliners** felt they were insurmountable.
We hypothesise that there is no point addressing self-efficacy UNTIL a critical level of trust has been established.
Implications:
How to Improve Recruitment 1

Good practice in clinical trials demands genuine patient & participant involvement. So we MUST acknowledge the perspective of the target population by:

- adopting a person-centred approach to recruitment;
- seeking patient/participant involvement (PPI) in designing trials;
- continuing to conduct PPI activities throughout the study to ensure all stages are aligned with the target population’s needs and beliefs;
- respecting potential participants’ views and addressing any concerns (not minimising these, as can be seen as understandable.)
Implications: How to Improve Recruitment 2

- **Build trust** in medical research and researchers.

Meet the Study Team

- Recommendations for building trust include:
  - improving visibility of the research team pre-recruitment;
  - providing testimonials from previous participants (requested by our participants);
  - advertising trial safety & ethical conduct.
Enhance self-efficacy so women feel able to overcome barriers to undertaking the trial requirements, such as hospital appointments or blood tests.

- Train trial staff in an empowering style of communication (such as “Healthy Conversation Skills”) so that recruiting feel:
  - their concerns are being respected and acknowledged;
  - supported to identify strategies to overcome any practical problems associated with participation.

Implications:
How to Improve Recruitment 3

Barker et al, JHP 2011; Black et al, PHN 2014; Lawrence et al, JHP 2016; Barker et al, Healthcare 2017
• MAVIDOS & SPRING study teams
• The women who spoke to us & shared their thoughts & experiences with us
• Our funders
• To you for listening!
• Any questions?