# What we learnt - recruiting prenatal mothers to an RCT addressing the prevention of overweight in early childhood?


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## KEY WORDS

Recruitment, health promotion, survey, overweight, prenatal, randomised control trial



## ABSTRACT

**Objective**
To identify and explore the experiences of recruiting prenatal women into a randomised control trial which involves a family-focused early intervention program addressing the prevention of overweight and obesity over the first two years of life.

**Design**
A number of open-ended brainstorming sessions allowed the research nurses to self reflect on their recruitment experiences. These sessions were used to explore factors that impacted on recruitment.

**Setting**
Recruitment for the trial took place in the antenatal clinics of two hospitals in south west Sydney (NSW Australia) from March 2007 - March 2008 one of the most socially and economically disadvantaged areas of Sydney.

**Main Outcome measures**
To gain insight into the issues surrounding recruitment of prenatal women and to identify the main themes that facilitated or impeded recruitment.

**Results**
Findings suggested that recruitment to a randomised control trial in the prenatal period resulted in particular barriers. Three theme clusters were identified; engaging participants, content of informational material and organisational issues.

**Conclusion**
Fostering stronger communication between research staff and clinical staff would have enabled easier identification of the target group and having access to the target population at earlier stages of pregnancy would have been beneficial.

**Recommendation**
Having a rigorous recruitment plan, and evaluating recruitment strategies in future studies of this nature, would be central to understanding why prenatal women involve themselves in research trials. Obtaining the assistance of clinical and administration staff with recruitment strategies would also be strongly recommended.

## BACKGROUND

It is well documented that in nursing research it is difficult to recruit participants for randomised controlled trials. Many fail to achieve adequate sample sizes within the specified time frame and have to extend recruitment periods. (Newal et al 2009; Tooher et al 2008; Wilson and Rose 1998). This scheduling problem leads to budget problems, the possibility of inadequate sample sizes leading to low statistical power and extensions to the intervention phase of the program. (Toerien et al 2009; Tooher et al 2008; McDonald et al 2006; Watson and Torgerson 2006) Healthy Beginnings, (Wen et al 2007) a randomised control trial (RCT) conducted in south west Sydney was no exception. The time required for recruitment was estimated as six months based on a pilot study, which had to be extended a further six months.

The Healthy Beginnings Trial (HBT), funded by the National Health and Medical Research Council (NHMRC #393112) involves a family-focused early intervention program addressing the prevention of overweight and obesity in early childhood. The study aims to explore the effectiveness of trained nurses delivering an intensive, home-based program for first-time mothers of newborn babies, focusing on child and family eating patterns, television viewing, opportunities for physical activity and anthropometric measures. The HBT has been carried out in the most socially and economically disadvantaged areas of Sydney.

This paper explores what was learnt from the recruitment phase of the HBT.

### The HBT recruitment

Recruitment for the trial took place in the antenatal clinics of two hospitals in south west Sydney (NSW Australia) from March 2007 - March 2008. Ethics approval was obtained from the Ethics Committee of Sydney South West Area Health Service. Prior to recruitment, Principal Investigators held meetings with Directors and Nurse Unit Managers where study aims and the recruitment process were discussed. Research nurses employed to undertake the intervention phase of the program commenced recruitment of participants for the first two months and were then joined by research assistants.

Face to face recruiting was selected for this RCT as it was considered the most effective way of explaining the program, building rapport with the potential participants and getting informed consent. Informed consent must be voluntary, and participants must have adequate information to make a decision on whether to take part or not, and be aware of the implications of participating. (NHMRC 2007) The aim of the informed consent procedure was to ensure a mutual understanding of what was involved, the benefits and mutual expectations.

First-time mothers were approached in antenatal clinics, informed of the project, and asked if they would like to participate. All aspects of the program were explained and women received an information sheet outlining the study and ethical components. There was an opportunity to ask questions, participants were made aware the program was voluntary, they could drop out at anytime and all information was treated confidentially. If they agreed to take part, a consent form was signed for participation in the study for a two year period, home visits, randomisation, data collection and intervention. Posters and flyers were also used to promote the project and assist in recruitment.

Following the first six months of recruitment the number of participants was half the target number, and the project directors decided to extend the recruitment phase for a further six months. Following the first two months of recruitment additional strategies were introduced including recruitment from smaller outreach clinics, posters in waiting rooms of pathology and ultrasound departments and discussions with the Division of General Practice to assist with recruitment through doctor's surgeries.

### Method of this study

As the HBT did not intend to directly evaluate recruitment methods or reasons participants declined to be involved, a descriptive approach was used to explore what was learnt from the recruitment

phase of the HBT. Open-ended reflection sessions led by Principal Investigators were held with the research nurses. Open-ended brainstorming sessions, where the research nurses self reflected on their recruitment experiences, were used to explore factors that facilitated or impeded recruitment. Once a long list of factors, issues, and specific cases was developed, recurrent themes were generated. There were three recurrent themes that emerged including engaging participants, content of informational material and organisational issues.

**Engaging Participants**

Recruiters found face to face recruiting challenging for two key reasons. Firstly the RCT needed first-time mothers and it was difficult to identify this population as the waiting area catered for a number of different clinics. All women in the clinic waiting area were approached, which as well as being a slow process, led to some people being asked if they were pregnant with their first child when they were there for another reason. It was also difficult to remember who had been previously approached, which meant that some mothers who had already declined to be involved were asked to participate again.

Secondly the diverse, cultural, educational and socio-economic backgrounds of potential participants at the clinic proved time consuming as each part of the program was explained in different ways to different people to ensure understanding. Potential participants were also wary of the length of the study, being involved with research and anticipated future constraints with their employment.

**Material/Content**

Although the information sheet was written as simply as possible, a number of mothers found it confusing and difficult to understand. A flyer giving basic information and showing pictures of the gifts was put up around the clinics. This was used in conjunction with the information sheet and assisted with understanding the study.

**Organisational Issues**

Initial recruitment took place in busy outpatient clinics of two hospitals in Sydney south west. The number of waiting rooms varied and often multiple clinics were running consecutively. This became difficult in approaching potential participants as recruiting staff could not always assume all women were expecting a baby, particularly as there was no access to medical files.

The environment of the clinics varied in comfort, layout and atmosphere. Maintaining privacy was an issue as the project was discussed with the potential client in the waiting area within close proximity to other people.

Although staff were aware of the HBT RCT and permission had been given to recruit from the antenatal clinics, the demanding nature of the clinics in hospital settings and the lack of time for clinic staff to assist with something outside of their primary role had a negative impact on recruitment.

## DISCUSSION

**Engaging Participants**

Once a potential participant was identified as being part of the target group for the RCT a number of factors impacted on successful recruitment. Special considerations involving pregnant women in studies were taken into account. They may feel a protective duty to their baby and decline to participate, while others consider the baby's father in all decisions involving the pregnancy (Mohanna and Tunna 1999). Cultural practices can also influence participation (Gul and Ali 2010). A number of women from culturally and linguistically diverse backgrounds that were approached by the research nurses were told by their partners they could not participate. If the partner was not in attendance they often asked if they could return the consent by mail after discussing the program at home, and discussion with the partner or the change in context when back at home tended to reduce participation from this subgroup.

Potential participants came from diverse backgrounds so face to face recruiting enabled the approach to be adapted to individual respondents. This was important when explaining a Randomised Control Trial. Although potential participants may understand research they do not always understand the need for randomisation, (Tooher et al 2008) therefore it

was important for recruiting staff to mention that both groups would assist the mother in raising their first child.

Client attitudes were also a challenge to recruitment. A sceptical belief in research (Tooher et al 2008; Gates et al 2004) along with the negative representation by the media plays a role and will often increase the difficulty of recruitment to a research project. Recruiters felt a number of women with a negative attitude towards participation displayed distrust in research and the workings of the health service in general.

The lack of interest in the dynamics of the study and time management issues can also contribute to potential study participants disinterest (Gul and Ali 2010). This was no different for Healthy Beginnings where potential participants were asked to be part of the study for two to two and a half years. The recruiters stated refusals included issues with busy lives, people couldn't be bothered with research, or they were going back to work soon after baby's birth.

The Sydney south west area includes a number of suburbs with socioeconomic disadvantage and although recruiters were unaware of each potential participant's demographic, a number of refusals could have been related to factors impacting on this as evidence suggests age, income and education and higher rates of refusal are found in participants with low income, low education and health awareness (Gul and Ali 2010).

**Material/Content**

An information sheet for participants outlining the study and ethical requirements is a necessary component for recruiting to Randomised Control Trials. It is given to the mothers so they are aware of the ethical requirements of the project. Readability of the information, educational levels of the participants and previous experiences with the health service can all play a role in signing a consent (Steinke 2004). As the geographical area and socio economic backgrounds of the participants was so diverse the research nurses found the terminology difficult for some potential participants to understand and therefore not very useful. The use of colourful flyers, samples of the gifts and resources may have been more beneficial at the recruitment stage.

**Organisational Issues**

Diverse outpatient clinics made identification of antenatal clients difficult; this alongside identifying the target population of first time antenatal mothers was a major difficulty for recruitment staff. Access to clinical records would have been beneficial for a number of reasons including identification of the target population and placement of an information flyer for the potential participant. Knowing the number of clients for each clinic may also have enabled the recruiter to better manage their time.

For some potential clients discussing the RCT in a crowded waiting area was an issue as it was difficult to maintain privacy. In a number of cases the response of the participant appeared to have an effect on those around them. If they responded favourably the recruiter found others would respond this way. It also had the same effect if there was a negative response. One recruiter felt the best way around this was to speak to all the people in the waiting room about the program and then approach people individually. While other recruiters felt a small room or private space may have assisted with recruitment.

Although staff were aware of the RCT and permission had been given to recruit from the antenatal clinics the demanding nature of the clinics in hospital settings and the lack of time for clinical staff to assist with something outside of their primary role had no impact on recruitment. Support for recruitment in smaller outlying clinics was more encouraging. These clinics were less busy and staff would identify first time mothers. Recruiting staff were able to approach the correct target group, use their name and this often led to a successful outcome.

## CONCLUSION

Clearly clinician's perception of the study, busy work schedules and understaffing (Gates et al 2004) impacted on assistance with recruiting. Although Principal Investigators engaged Directors and Nurse

Unit managers prior to the commencement of the study ongoing updates and discussions regarding recruitment would have been beneficial with staff working in the recruitment areas. As well as providing an insight into the challenges faced by staff it would have provided an opportunity to foster stronger communication between research staff and clinical staff.

Accessing the target population when they book into the hospital would have enabled all first time prenatal clients to be identified. Gaining the support of administration staff at the hospital of delivery to give all first time mothers an information package about the study would have assisted the recruiters in the antenatal clinics. This strategy may also have worked with the Division of General Practice. Although the Division of General Practice for one area was approached with assistance to recruit from GP surgeries this was done later in the recruitment phase and had very little impact on recruitment numbers.

## RECOMMENDATION

It is hard to say that changes to recruitment would have influenced the time frame to recruit adequate numbers into this trial. Future studies of this nature should evaluate recruitment strategies as this is an important aspect of any trial. A more rigorous recruitment plan may have identified issues prior to the commencement of the study.

A key recommendation for further studies in this area would be to obtain the assistance of clinical and administration staff with recruitment strategies. It may take a shift in the thinking of clinicians and administration to incorporate assistance with research into their schedules and this change may need to be made at a higher organisational level.

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