Original Article

Recruiting and retaining postpartum women from areas of social disadvantage in a weight-loss trial – an assessment of strategies employed in the WeighWell feasibility study

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Abstract

Little is known about the response of post-partum women from deprived backgrounds to weight management interventions, however behavioural intervention trials in disadvantaged communities are often characterised by recruitment difficulties. Recruitment and retention is key to the robust conduct of an effective trial, and exploratory work is essential prior to a definitive randomised controlled trial. This paper describes strategies used to recruit to the WeighWell feasibility study, which aimed to recruit 60 overweight or obese post-partum women living in areas of deprivation to a trial of a weight-loss intervention. Recruitment strategies included the following: (1) distribution of posters and 'business cards'; (2) newspaper advertisements; (3) visits to community groups; and (4) personalised letters of invitation sent via the National Health Service (NHS). Potential participants were screened for eligibility following response to a Freephone number. Body mass index was calculated using self-reported body weight and height. Over 6 months, 142 women responded of whom 65 (46%) met the eligibility criteria. The most effective methods for recruiting eligible women and those who went on to complete the study ($n = 36$) were visits to community groups (37% and 42%, respectively), personalised letters (26% and 17%, respectively) and posters and 'business cards' (22% and 31%, respectively). These results emphasise the need to utilise a range of strategies beyond traditional NHS settings. Current approaches might be enhanced by sending personal contact letters via their General Practitioner to women identified as eligible at post-natal discharge. Under-reporting of body weight by self-report suggests that a threshold lower than 25 kg/m² should be utilised for screening purposes.

Keywords: post-partum, weight loss, recruitment, strategies, obesity.

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Introduction

The obesity epidemic poses a growing medical threat to the well-being of communities worldwide. Future projections for England suggest that if nothing is done

to address this issue, 36% of women could be obese by 2025 (Brown *et al.* 2010). It is recognised that women from disadvantaged backgrounds are especially vulnerable to weight gain and associated co-morbidities (Rennie & Jebb 2005). In addition, pregnancy is a life

stage where excess weight gain may occur and the post-partum period is often characterised by weight retention and/or further weight gain (Gore *et al.* 2003).

Recent evidence suggests that obesity at the outset of pregnancy has doubled in the last 20 years from 7.6% to 15.6% and this varies by social disadvantage with 9.9% of women from the least deprived areas categorised as obese compared with 16.4% of women from the most deprived (Heslehurst *et al.* 2010). Studies suggest that obese women regard pregnancy as an ideal time to make changes to improve their lifestyle choices and the post-partum period is a time when many obese women want to lose weight (Smith & Lavender 2011).

Robust trials of post-partum weight-loss programmes are needed to inform cost-effective evidence-based practice in this key public health area and this high-priority population subgroup (NICE 2010). Adequate recruitment and retention in intervention trials is essential to the robust and ethical conduct of such trials if cost-effective and valid results are to be obtained. Kuhlmann *et al.* (2008) in a review of post-partum weight-loss trials noted that refusal and attrition rates (31% at 6 months and 43% by 12 months) were high, decreasing confidence in the generalisability of the findings.

It has been estimated that less than 50% of trials meet their recruitment and retention targets or meet them without extending the trial period (McDonald *et al.* 2006). Such recruitment challenges were highlighted in a recent Cochrane Review (Treweek *et al.* 2010), which emphasised the significant implications both financially, for trials requiring extensions, and ethically, for participants recruited into underpowered trials. There is also the potential for further

investigations to cease or be delayed following the reporting of clinically significant findings as statistically non-significant due to a lack of power. The importance of recruitment and referral is one recognised in the Standard Evaluation Framework for weight management evaluations by the National Obesity Observatory (2009). The authors suggest that evaluation of recruitment methods should therefore be built into trial design.

Empirical evidence to support particular strategies to increase recruitment to trials is limited, especially those involving low-income populations (El-Khorazaty *et al.* 2007), although it is known that undertaking behavioural intervention trials in disadvantaged communities is often characterised by recruitment and retention difficulties (Craig *et al.* 2008). Little is known about the response of post-partum women from deprived backgrounds to weight management interventions. However, it is likely that adherence to weight-loss programmes in the post-partum period may be more challenging for low-income mothers. Exploratory work is therefore essential prior to the conduct of a definitive randomised control trial (RCT) in order to test strategies devised to optimise recruitment in this hard to reach group and retain women to study completion.

This paper aims to assess the strategies used to optimise recruitment to and retention within the WeighWell feasibility study, results of which will inform the design of a definitive RCT.

Materials and methods

The WeighWell feasibility study (Craigie *et al.* 2011) aimed to develop and implement a weight-loss intervention for post-partum women living in areas of

Key messages

- Only a small proportion of overweight post-partum women living in disadvantaged areas expressed interest in a weight-loss programme.
- There is significant under-reporting of body weight among post-partum women.
- Recruitment methods that use community-based approaches involving personal contacts with groups and posters and 'business cards' placed in community settings offer greatest scope.
- Identifying eligible women at post-natal discharge and sending personal contact letters to women living in target areas via their General Practitioner, and increased efforts through existing community groups merit testing.

WeighWell:
A weight management study for mothers of young children

• Had a baby within the last 18 months? ✓
• Need a bit of help with weight management? ✓
....This could be the study for you!
The WeighWell study aims to help women in the Tayside area who have recently had a baby to improve their lifestyle and manage their weight.

For further information and to get involved:
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Freephone 0800 917 9055 or Tel 01382 496788
email: a.craigie@dundee.ac.uk

Recruiting up to: 31st October 2009

Logos: University of Dundee, University of Aberdeen, MRC Medical Research Council, NHS Tayside

Fig. 1. WeighWell 'business card'.

social deprivation to inform a future RCT design. The feasibility study aimed to recruit 60 women between August 2009 and January 2010. The study was undertaken in Tayside, Scotland. Women were eligible for participation if they were 6–18 months post-partum (selected as a result of formative work), with a body mass index (BMI) ≥ 25 kg/m², living in areas of deprivation [Scottish Index of Multiple Deprivation (SIMD) deciles 1–5, Scottish Government 2009] and with no contraindication to weight loss (pregnancy or medical). Following baseline assessment, women were randomly allocated (1:1) to either receive a weight-loss programme over a 3-month period (intervention group) or to a comparison group that received delayed weight-loss advice after 3 months.

The intervention comprised a personalised dietary prescription of estimated energy requirements minus 500 kJ, with oral and written information given on food groups, frequency of consumption and portion size. Personalised physical activity goals were also set towards achieving the current recommendations of 150 min of moderate to vigorous activity per week. Participants were provided with 4-week walking plans, a pedometer and a logbook for self-monitoring weight throughout. The personalised intervention was delivered via 3 monthly 'face-to-face' counselling sessions (and three telephone follow-ups) by a dedicated, trained counsellor using motivational interviewing techniques, goal setting and feedback strategies to guide change in energy intake and increase physical

activity with an emphasis on low-cost, home-based lifestyle changes. The comparison group received no further contact beyond the weight-loss booklet until follow-up assessment at 12 weeks. After follow-up assessment, the comparison group received a one-off consultation with a lifestyle counsellor.

Strategies and elements of the study design adopted to optimise recruitment were informed by evidence from the literature, interviews with midwives, health visitors and community support staff, and focus group discussions with the target group (Craigie *et al.* 2010). Four main recruitment strategies were utilised:

Posters and 'business cards' (Fig. 1) were distributed to a variety of locations within low-income areas that mothers of young children were likely to visit (Table 1). General Practitioner (GP) surgeries where >30% of the patient list lived in the 15% most deprived postcode data zones of the population were sent letters with study information sheets and asked to display posters and pass on the recruitment business cards provided to potentially eligible women. All GPs were also encouraged to contact the study team for more information. Posters were designed to be simple, easily read and had multiple tear off slips attached with contact details of the study team to aid participant response.

Newspaper advertisements were placed in the local press (both daily and evening papers) and a community newspaper. The content reflected the information

Table 1. Recruitment strategies employed (*n* = number of loci)

Strategy	Location	<i>n</i>
Poster/'business cards'	Local pharmacies	32
	Supermarkets	16
	Shops	12
	Medical centres	7
	Libraries	11
	Local halls	25
	Sports centres	4
	Post offices	4
	Nurseries/play centres/crèches	5
	Community notice boards	3
	Workplaces	1
	Child and family centres	5
	Community newsletter	1
Newspaper advertising	Local press	2
Visits to community groups		39*
Letters sent to	Post-partum women (via breastfeeding coordinator, NHS Tayside)	472
	Focus group participants (earlier study)	18
	GP surgeries (Health Visitor/GP/Practice Nurse)	15

*Some groups were visited more than once.

GP, General Practitioner; NHS, National Health Service.

given in the recruitment poster and provided contact details of the study team.

Visits were made to community groups held in low-income areas across Dundee, Angus and Perthshire by an experienced, highly motivated health professional. Community groups included mother and toddler groups, groups held in local libraries, pram pushing groups, leisure centres, family centres and social work projects aimed at the target population. Oral and written information about the study was given to potential participants. A response sheet was completed by potential participants and returned to the study team who contacted them by telephone to screen for eligibility.

Personalised letters of invitation were sent to post-partum women living in areas of social deprivation within Dundee who had delivered between September 2008 and February 2009 and therefore met the WeighWell 'months post-partum' criteria. Women who had participated in focus group discussions during the formative work, which informed the design of the feasibility study, were also contacted. Women interested in taking part were invited to call the study centre or email for more information.

Response was facilitated by the provision of a Free-phone telephone number. Women who responded but were less than the minimum months post-partum were re-contacted when eligible. Women were asked to self-report body weight and height. BMI was calculated by screening staff and eligibility established.

Elements of the study design were adopted to encourage recruitment by reducing participant burden. These included reimbursement of childcare and travel costs, and the provision of the Freephone telephone number. Flexibility was offered in time and place of appointments with 'out of hours' and home visits as an option. Telephone contact was maintained with participants to remind them of intervention sessions and assessment visits and to reschedule missed appointments. Study questionnaires were administered by the study coordinator to mitigate for potential low-literacy levels. Counsellors used were highly motivated health professionals who have experienced in working with mothers from low-income areas and received training on motivational interviewing and delivery of the intervention.

Ethical approval was provided by the Fife and Forth Valley NHS Research Ethics Committee 09/S0501/44.

Results

One hundred forty-two women responded to publicity materials and were screened for eligibility. Of those, 65 (46%) were eligible, 13 (9%) met the inclusion criteria but declined to participate and 52 (37%) proceeded to randomisation (Fig. 2). The possible pool of women meeting the eligibility criteria during the 6-month recruitment period was estimated to be

1216 (based on data on BMI, SIMD and date of delivery extracted from the local maternity database).

Recruitment methods

Visiting community groups was the most successful strategy to generate interest and identify eligible participants (Table 2). Over one-third (37%) of eligible women became aware of the study in this way,

Fig. 2. Recruitment and retention to the WeighWell study. BMI, body mass index; SIMD, Scottish Index of Multiple Deprivation.

Table 2. A comparison of recruitment strategies by eligibility, recruitment and retention rates

Strategy	Location	Responded <i>n</i> = 142	Ineligible <i>n</i> = 77	Eligible <i>n</i> = 65	Recruited <i>n</i> = 52	Retained <i>n</i> = 36
Poster/'business cards' (%)		36 (25)	22 (29)	14 (22)	13 (25)	11 (31)
	Local pharmacies	6	3	3		
	Supermarkets and shops	14	7	7		
	Medical centres	9	5	4		
	Libraries/halls/sports centres	4	4	0	0	0
	Post office	1	1	0	0	0
	Don't know	2	2	0	0	0
Newspaper advertising (%)	Local press	15 (11)	9 (12)	6 (9)	4 (8)	2 (6)
	Community newsletter	2 (1)	1 (1)	1 (2)	1 (2)	0 (0)
Visits to community groups (%)		53 (37)	29 (38)	24 (37)	19 (37)	15 (42)
Letters sent to (%)	Post-partum women (via breastfeeding coordinator, NHS Tayside)	29 (20)	12 (16)	17 (26)	12 (23)	6 (17)
	Focus group participants	1 (1)	0 (0)	1 (2)	1 (2)	1 (3)
	Health Visitor referral	3 (2)	1 (1)	2 (3)	2 (4)	1 (3)
Word of mouth (%)		3 (2)	3 (4)	0 (0)	0 (0)	0 (0)

NHS, National Health Service.

followed by personalised letters (26%) and the use of posters and 'business cards' circulated in a range of community locations (21%). Given the potential reach of newspaper and community newsletter communications, it is surprising that only 11% were identified through this route. Referrals from Health Visitors were low (3%).

Visiting community groups was also the most effective strategy for identifying participants who proceeded to randomisation and those who completed the study (37% and 42%, respectively). However, while personalised letters had been effective at attracting eligible women, posters and 'business cards' were found to be more effective at attracting those who went on to be randomised and particularly for those who completed the study (23% and 17% for personalised letters, respectively, vs. 25% and 31% for the posters and 'business cards').

When analysed according to eligibility, strategies that were more successful at attracting eligible than ineligible women were personalised letters (16% ineligible vs. 26% eligible) and health visitor referral (1% ineligible vs. 3% eligible). Invitation by posters and 'business cards', visits to community groups, newspaper advertising and word of mouth were as, if not more, likely to generate response from ineligible women (Table 2).

Reasons for ineligibility

Seventy-seven women who responded to the publicity materials were ineligible on the grounds of living in an area with an SIMD decile >5 (*n* = 51, 65%), BMI <25 kg/m² (*n* = 14, 18%), months post-partum (*n* = 6, 8%) or being either pregnant or having medical contraindications (*n* = 6, 8%) (Table 3). It is notable that a comparison of self-reported and measured BMIs among our eligible study population showed 68% of participants underestimated their BMI at screening.

Reasons for dropout

Retention rates were 76% in the intervention arm and 61% in the comparison arm. Of women who did not complete in the intervention arm, dropout was after the first or second consultation. Of the seven women who dropped out, two had become pregnant; one had a close family bereavement (grandmother and main carer) and one had a partner with serious illness (cancer). Nine women dropped out of the comparison arm before the 3-month follow-up assessment was completed. One woman in the comparison arm had become pregnant and one was unhappy with her randomisation allocation, but the remaining seven withdrew due to unknown but possibly modifiable reasons.

Table 3. Response to recruitment strategies by reasons for ineligibility

Strategy	Location	Ineligible <i>n</i> = 77	SIMD >5 <i>n</i> = 51	BMI <25 kg/m ² <i>n</i> = 14	Months post-partum <i>n</i> = 6	Pregnant/medical contraindications <i>n</i> = 6
Poster/business cards' (%)	Local pharmacies	22 (29)	18 (35)	1 (7)	2 (33)	1 (17)
	Supermarkets and shops	3	3			
	Medical centres	7	5	1	2	1
	Libraries/halls/ sports centres	5	5			
	Post office	4	3			
Newspaper advertising (%)	Don't know	1	1			
	Local press	2	1			
	Community newsletter	9 (12)	5 (9)	1 (7)	2 (33)	1 (17)
	Visits to community groups (%)	1 (1)	0 (0)		1 (17)	
Letters sent to (%)	Post-partum women (via breastfeeding coordinator, NHS Tayside)	29 (38)	18 (35)	8 (57)	1 (17)	2 (33)
	Focus group participants	12 (16)	7 (14)	3 (21)	0 (0)	2 (33)
	Health Visitor referral	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		1 (1)	1 (2)	0 (0)	0 (0)	0 (0)
Word of mouth (%)		3 (4)	2 (4)	1 (7)	0 (0)	0 (0)

BMI, body mass index; NHS, National Health Service; SIMD, Scottish Index of Multiple Deprivation.

Discussion

The current findings illustrate some of the problems in undertaking behavioural-based interventions in women living in socially disadvantaged areas (Michie *et al.* 2008). The findings may not be generalisable to all population groups but serve to highlight some key challenges for health professionals working in maternal health. It is estimated that the number of eligible women who made contact with the study team was 5% of the possible population and this highlights the difficulties in recruiting this target group.

In terms of engaging and retaining participants, recruitment methods that use community-based approaches involving personal contacts with groups and/or posters and 'business cards' placed in community settings offer greatest scope. Visiting community groups is however time-consuming, costly and runs the risk of contamination between intervention and comparison groups. Posters and 'business cards' while cheap and easy to implement are non-specific and are as likely to attract response from ineligible as eligible women even when attempting to target areas of social deprivation. It is notable that a large proportion of women (54%) were excluded at screening suggesting that the targeting of our recruitment strategies was only partially effective in reaching the intended population. The majority of ineligible women were excluded on the basis of SIMD. Although distribution was targeted at areas of social deprivation, no mention was made on publicity materials of this eligibility criterion as it was thought to be too sensitive.

Almost one-fifth of ineligible women (18%) were excluded on self-reported BMI at telephone screening. A comparison of self-reported and measured BMIs among our eligible study population showed considerable underestimation of body weight at screening, which is consistent with findings reported by Dauphinaud *et al.* (2009). This finding suggests a lower threshold for overweight than the 25 kg/m² could be utilised for screening purposes so that more women are invited for baseline measurements before exclusion.

Current evaluation of weight-loss programmes is to use a 12-month follow-up assessment (Scottish Intercollegiate Guidelines Network 2010) in order to

evaluate short-term weight loss *and* maintenance of this loss, which will have the greatest effect on obesity-related co-morbidities. Short-term weight loss may also be important for women in the inter-partum period (which may only be a few months) where weight retention between pregnancies has been demonstrated to be associated with maternal and perinatal complications (Villamor & Cnattingius 2006). The current study examines early retention because it was considered inappropriate to undertake a full trial of 12-month follow-up without recruitment and early retention data. Loss to follow-up of 31% was similar to that reported by Leermakers *et al.* (1998) of 27% and less than the 40% reported by O'Toole *et al.* (2003), although neither of these studies targeted low-income women. The findings highlight the challenge between the medical case for weight loss and the reality of identifying ways to engage women in increasing physical activity and restricting intakes of food and drink (when home based) while coping with the demands of child rearing. Multiple physical and psychological morbidities, limited financial resources and social isolation may exacerbate these challenges (Chang *et al.* 2009). It may be challenging to implement measures to mitigate for these factors, however some psychological support, e.g. information on stress management techniques, may be possible. Loss to follow-up was more of a problem with the comparison group and additional measures, e.g. maintaining closer contact via phone, email or text or the provision of non-lifestyle incentives to 'buy' loyalty to the study, might improve retention.

The results of the WeighWell study emphasise the need to utilise a wide range of recruitment strategies beyond traditional NHS settings. Two approaches to enhance recruitment offer promising opportunities and merit testing:

Firstly, identifying eligible women at postnatal discharge and sending them a personal contact letter via their GP (rather than by the study team). Studies suggest that endorsement by the GP and clinical staff improves recruitment to trials in low-income populations (Cole *et al.* 2002). It has also been shown that a personalised letter of invitation with GP endorsement achieves better participation rates than the same letter without mention of the GP (Nicholson *et al.*

2011). This would be achievable without the GP's actual involvement to minimise research burden to GPs. Although NICE (2010) suggests health professionals such as Health Visitors should support postpartum weight loss and formative work (Craigie *et al.* 2010) identified face-to-face recruitment using community groups, midwives and health visitors as of most potential in recruitment terms, the low-referral rates from Health Visitors suggest that this may not be an optimal recruitment strategy. In addition, following implementation of Hall 4 guidelines, the focus of Health Visitor work has shifted to families with complex social needs and so exposure to large numbers of overweight or obese post-partum women may be limited. We have also identified a hesitance from health professionals to broach this emotive subject and detrimentally affect the client/carer relationship that might impact on other areas of care (unpublished data).

Secondly, enhanced efforts through existing community groups where mothers can meet research staff face to face in a supportive environment are supported by our findings. We found this to be the most successful recruitment strategy and efforts should be made to maximise its potential.

Further research is required to test enhanced recruitment and retention strategies with an additional qualitative component to explore the factors that attract women to and detract from enrolment and participation in a weight-loss intervention trial.

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Conflicts of interest

The authors declare that they have no conflicts of interests.

Contributions

MM was involved in the delivery of the study and has contributed to the analysis, interpretation and preparation and drafting of the manuscript. AMC was involved in the coordination and delivery of the study and has contributed to the analysis, interpretation and drafting of the manuscript. KLB was involved in the delivery of the study and has contributed to the analysis, interpretation and drafting of the manuscript. ST was involved in the conception and design of the study and has contributed to the drafting of the manuscript. ASA conceived the study, participated in its design and coordination and helped in the drafting of the manuscript. All authors read and approved the final manuscript. The Weigh-Well team oversaw the conduct of study and commented on this manuscript.

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