

## Original Article

# Effectiveness of strategies for recruiting overweight and obese Generation Y women to a clinical weight management trial

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**Aim:** Limited research in young overweight and obese women indicates that they are difficult to recruit to weight management trials, with attrition higher and weight loss success lower than middle to older age participants. This study aimed to evaluate the effectiveness of different recruitment strategies for a clinical weight loss trial in overweight and obese Generation Y women. **Methods:** Overweight and obese (BMI  $\geq 27.5$  kg/m<sup>2</sup>) women aged 18-25 years (n=70) were required for a 12 month clinical weight management trial including diet, exercise and behaviour modification. Contact with researchers and eventual recruitment are reported for the various strategies employed to engage participants. Data reported as % or mean $\pm$ SE. **Results:** Recruitment was challenging with only 50 of the total 70 participants recruited within the scheduled time frame (24 months). Just over one quarter (27%) of volunteers assessed were recruited. Flyers posted around local tertiary education campuses were the most successful method, yielding 36% of included participants. This was followed by advertisements on the local area health service intranet (26%) and in local and metropolitan newspapers (16%). **Conclusions:** Recruitment of overweight and obese Generation Y women for a clinical weight loss trial was difficult. Multiple strategies targeted at this age and gender group were required. Less rigorous selection criteria and reduced face-to-face intervention time may improve recruitment and retention rates into clinical trials for this age group.

**Key Words:** weight, Generation Y, women, recruitment, intervention

## INTRODUCTION

Studies specifically investigating obesity treatment in young women are under-represented in the obesity literature.<sup>1</sup> Adult weight loss trials generally recruit mixed age volunteers and are skewed towards middle to older age samples. In the Australian National Health and Medical Research Council Clinical Practice Guidelines for the management of overweight and obesity in adults, the mean age of study participants in interventions is generally more than 40 years.<sup>2</sup> Recent weight loss trials from the USA National Institutes of Health included less than 1% of participants aged 25 years or less.<sup>3</sup>

Weight management trials are generally designed for middle-aged to older adults with worsening comorbidities and may have less relevance to young participants. Lower rates of obesity-related comorbidities are evident at this life stage, and motivation for weight loss may be predominantly driven by self-esteem and body image concerns.<sup>2,4</sup> Nevertheless, young women who are obese are already more likely to have hypertension, asthma, headaches, back pain, difficulty sleeping and irregular menstruation than healthy weight women.<sup>5</sup> They also have a greater risk of the polycystic ovarian syndrome (PCOS) and gestational diabetes,<sup>6</sup> with higher birth weight babies, who in turn have an increased risk of future obesity.<sup>7</sup>

Lifestyle factors which may not be addressed in adult weight loss trials but which are positively associated with weight gain in young women include moving away from the family home and entering a marriage or de facto relationship.<sup>8,9</sup> Young women may have limited experience preparing and cooking food and tend to actively participate in social activities which increase exposure to energy-dense take-away foods and alcohol.<sup>9-11</sup> In addition, physical activity levels decline rapidly in women between the ages of 18-29 years,<sup>12</sup> and increased sedentary behaviour promotes weight gain.<sup>9,11</sup>

Recruitment challenges in this age group may also be a barrier for participation in clinical weight loss trials.<sup>1</sup> Difficulties associated with recruitment and retention may lead to trials in young adults having smaller sample sizes and being shorter in duration.<sup>1,13</sup> Effective methods to recruit and retain young adults in weight management

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trials are largely unexplored, especially for adults from 'Generation Y', the demographic cohort born in the late 20<sup>th</sup> and early 21<sup>st</sup> centuries that are highly familiar with communications, media, and digital technologies.<sup>14</sup> The aim of this study was to describe the process and issues associated with the recruitment of overweight and obese young women to a weight management trial. The purpose was to achieve a better understanding of how best to engage young adult females from Generation Y in weight management trials.

## MATERIALS AND METHODS

### *Participants*

Overweight or obese (BMI  $\geq 27.5$  kg/m<sup>2</sup>) young women (18-25 y) were recruited to a 12 month randomised controlled trial comparing iso-energetic higher-protein and higher-carbohydrate weight loss diets.<sup>15</sup> Random allocation (random block design per every four participants) was prepared by a researcher not involved in participant enrolment or assignment. Participants were required to attend regular face-to-face visits (weekly for 3 months, fortnightly from 3-6 months then monthly from 6-12 months) for dietetic counselling and behaviour modification therapy and follow a standardised exercise program (30 min of brisk walking daily).<sup>16</sup> Ethics committees in Australia do not support payment of participants for research studies but reimbursement of participant expenses and/or small incentives are permitted. Participants in this study received shopping vouchers to the total value of AUD \$100 to support food purchases, encourage compliance and discourage attrition. The study was conducted at a tertiary hospital based obesity clinic (Metabolism and Obesity Services, Royal Prince Alfred Hospital, Sydney, Australia).

The recruitment phase to enrol 70 women was planned to be a maximum of 24 months. A wide range of recruitment strategies using a variety of media were used to directly target young women and their friends or family members and health care professionals with young adult patients. These included print (local and metropolitan newspapers, magazines and general practitioner newsletters), radio (metropolitan stations), online (local area health service intranet, youth services and health websites), flyers (local tertiary education campuses, hospitals and resident letterboxes), written correspondence (local health professionals, newly registered obesity clinic patients) and hospital patient databases.

Potential volunteers registered their interest via phone or email. A face-to-face screening visit prior to randomisation was used to assess participant suitability, collect medical history, socio-demographic information (including reason for enrolment), dieting behaviour and organise screening blood tests. Successful methods for recruitment to participation were documented at this face-to-face visit and subsequently utilised repeatedly to enhance the recruitment rate. Specifically, participants were verbally asked "How did you hear about the study?"

### *Eligibility criteria*

Young women aged 18 to 25 years, fluent in English, able to attend scheduled visits, complete the prescribed exercise program, maintain adequate contraception and not

vegetarian were included. Exclusion criteria included pregnancy or lactation, secondary causes of obesity, previous bariatric surgery, formally diagnosed psychiatric illness and untreated obstructive sleep apnoea. Participants were also excluded if they were smokers or used medication known to affect appetite, metabolic rate or body weight. All subjects were required to be iron replete and off supplements at trial entry.

### *Ethics and statistics*

All procedures followed were in accordance with the Declaration of Helsinki and were carried out with adequate understanding and written consent of the participants. The authors also certify that the study obtained approval from the Ethics Review Committee (Royal Prince Alfred Hospital Zone) of the Sydney South West Area Health Service (Protocol Number X05-0085) and Human Research Ethics Committee of The University of Sydney (Protocol Number 8286). The trial was registered with the Australian New Zealand Clinical Trials Registry (ACTRN12609000307202).

Statistical analysis was performed using SPSS for Windows Version 17 (SPSS Inc, Chicago, USA) and Microsoft Excel 2007 (Microsoft Corporation, Redmond, USA). All results are displayed as a percentage or mean  $\pm$  SE.

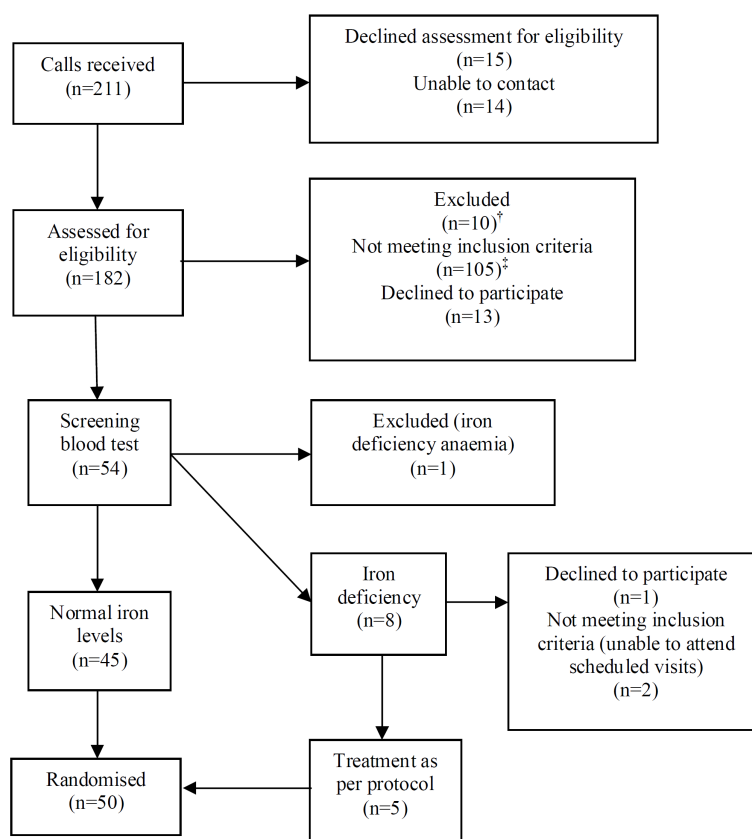
## RESULTS

### *Recruitment*

The recruitment phase of 24 months resulted in 50 of the targeted 70 women enrolled into the trial. Most of the 211 callers registering interest in the trial were young women; however 9% ( $n=19$ ) were family members and one was a general practitioner. A total of 182 volunteers consented to assessment for eligibility (Figure 1). Of these, 63% ( $n=115$ ) did not meet the eligibility criteria and 7% ( $n=13$ ) declined to proceed. Seventeen percent ( $n=9$ ) of eligible volunteers who underwent an initial screening blood test had iron deficiency or iron deficiency anaemia. Five were ultimately recruited after undergoing iron replacement therapy.

The majority of included participants were recruited using flyers posted around nearby tertiary education campuses (36%) (Table 1). Anecdotally, flyers were more effective when placed in private (behind toilet doors) compared to public (noticeboard) locations. Advertisements on the local area health service intranet were the second most effective method (26%). Advertisements in local and metropolitan newspapers were the third most effective means of recruitment (16%). Website and radio, written correspondence and hospital patient databases were less successful, each yielding less than 5% of participants. Trial staff noted that volunteers responded more promptly and positively when contacted by mobile phone text messaging rather than voice calls.

The approximate cost to recruit the 50 participants was \$15,400 AUD (~\$308 AUD per participant). The only paid advertising methods used were those distributed by local newspapers (totalling ~\$800 AUD), health websites (totalling ~\$300 AUD) and local resident letterbox drops (totalling ~\$1000 AUD). As these advertising methods were both expensive and not found to be most effective,



**Figure 1.** Recruitment flow-chart. <sup>†</sup> Psychiatric illness, n=1; smoking, n=5; medication that affected appetite, metabolic rate, weight or immune function, n=2; unable to stop taking iron supplements, n=1; not blinded to the intervention, n=1. <sup>‡</sup> BMI <27.5 kg/m<sup>2</sup>, n=23; male, n=2; age≠18-25, n=32; unable to attend scheduled visits, n=35; unwilling to follow exercise program, n=3; pregnant or breastfeeding, n=3; unwilling to eat meat, n=5; unwilling to stop following another diet program, n=2.

**Table 1.** Relative effectiveness of recruitment methods for randomised participants

Media	Recruitment method	Number of advertisements or correspondence	n (%)
Print	Local newspapers <sup>†</sup>	2	3 (6)
	Metropolitan newspapers	3	5 (10)
	Health & lifestyle magazines	4	2 (4)
	General practitioner newsletters	2	0 (0)
Radio	Metropolitan stations	1	1 (2)
Online	Local area health service intranet	Continuous	13 (26)
	Youth services websites	2	2 (4)
	Health websites <sup>†</sup>	2	0 (0)
Flyers	Local tertiary education campuses	Continuous	18 (36)
	Local hospitals	Continuous	2 (4)
	Local resident letterboxes <sup>†</sup>	5 (each delivery 3000 flyers)	2 (4)
Written correspondence	Local health professionals		
	Tertiary hospital based obesity clinic referring doctors <sup>‡</sup>	1	1 (2)
	University health service doctors	1	0 (0)
	Metropolitan hospital nutrition departments	1	0 (0)
Hospital patient databases	Newly registered obesity clinic patients <sup>‡</sup>	Continuous	0 (0)
	Tertiary hospital based obesity clinic <sup>‡</sup>	1	0 (0)
	Tertiary hospital based obesity research group <sup>‡</sup>	1	0 (0)
Other	Word of mouth	Continuous	1 (2)

<sup>†</sup> Included paid advertising

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their use was limited in this trial (Table 1). Flyers and letters to local health professionals were printed and posted internally or in person by the researcher. The esti-

mated printing/postage cost was approximately \$1,000 AUD and researcher time approximately three hours per week (two hours for posting flyers and organising adver-

tising and one hour for screening) over 100 weeks of recruitment (~\$12,600 AUD for a casual research assistant).

### Participant characteristics

Mean age of participants at enrolment was 22.7±0.3 years. Most were from European (76%) backgrounds. Reasons reported as being the motivation for study participation included: professional support (28%), long-term follow-up (24%), accountability and motivation associated with enrolment in a clinical trial (24%), contributing to medical research (22%) and dietary advice from a reputable source (18%). Common factors motivating weight loss were improvement in personal health (64%), feeling better and improved self-esteem (34%), fitting into clothes (18%), improved appearance (12%) and fitness (12%). Two participants (4%) wanted to improve fertility. Most participants reported living with parents (46%) or a partner (30%), having a family history of overweight (96%) and studying (52%) or working full-time (40%). Socio-demographic data are shown in Table 2.

No participants had previously been in a weight loss trial before. However most were not weight loss naïve (96%), with mean number of methods used previously to lose weight 4.7 ± 0.5. Just over a quarter (26%) of participants had tried at least seven methods to lose weight. Health professionals such as general practitioners (30%) or dietitians (28%) were consulted for weight management support by less than one third of participants.

Out of the 50 participants randomised to the trial, a total of 31 (62%) completed six months (20 sessions) and 26 (52%) completed 12 months (27 sessions) of the study.

**Table 2.** Socio-demographic characteristics

Variable	Category	n (%)
Ethnicity	European	38 (76)
	Asian	3 (6)
	South American	3 (6)
	Middle Eastern	3 (6)
	African	1 (2)
	Mixed heritage	2 (4)
First or second degree relatives overweight or obese	0	2 (4)
	1	15 (30)
	2	13 (26)
	3+	20 (40)
Relationship status	Partner	24 (48)
	Single	26 (52)
Parental status	Children	2 (4)
	No children	48 (96)
Work status	Full-time/Part-time	20 (40)/4 (8)
	Student <sup>†</sup>	26 (52)
Living arrangement	Self	3 (6)
	Parent or family member	23 (46)
	Partner	15 (30)
	Share house	9 (18)
Person who shops	Self ± other	39 (78)
	Parent or family member	11 (22)
	Partner	0 (0)
Person who cooks	Self ± other	39 (78)
	Parent or family member	8 (16)
	Partner	3 (6)

<sup>†</sup>Majority also worked part-time

Reasons for attrition (by 12 months) included discontinuation of intervention (n=12), loss to contact (n=11) and exclusion due to significant psychiatric illness (n=1). Reasons for discontinuation of the intervention included illness (n=5); too difficult (n=2); unable to attend scheduled visits due to change in work or living situation (n=3); limited time (n=1); not losing weight (n=1).

### DISCUSSION

This study describes the process and issues associated with the recruitment of overweight and obese young women to a weight management trial. The recruitment was slow, with approximately two recruitments per month. This finding was in line with other studies that report the recruitment of younger participants to research studies to be more difficult than for middle-age to older cohorts.<sup>13</sup> This study shows that multiple strategies directed to the age and gender group are required. The most successful methods targeted local tertiary education institutions (where there were large numbers of young women) and nearby work environments that presumably minimised travel. Flyers posted around local tertiary education campuses were time consuming but most successful. Advertisements via the local area health service intranet and local and metropolitan newspapers were also effective, as demonstrated in a previous weight loss trial in younger adolescents.<sup>1</sup> Despite these methods proving the most successful, it is important to emphasise that they still failed to support successful recruitment of the target number of participants within the planned time frame. Although generally lower cost approaches were used, the expenditure per participant which was approximately \$308 AUD (\$15,400 AUD) was still a substantial part of the study budget. These findings may reflect the specific demographic of the population who were in the surrounds of the clinical trial site, which included a teaching hospital and a number of universities and tertiary training institutions.

Advertisements in magazines, general practitioner newsletters, websites and radio as well as local resident letterbox drops, letters to affiliated health professionals and searches of hospital patient databases were generally ineffective. Possible reasons for this finding include approaches which required an intermediary recruiter and the trial site location in a large acute care facility. Social networking sites for recruitment were not used in this study and this should be explored further.

The ratio of screened volunteers to enrolled participants was approximately 4:1, and probably exceeds the ratio for older adult recruitment to weight loss interventions.<sup>17</sup> The restricted gender and age range, rigorous selection criteria and lack of physical co-morbidity which presumably drives older adult enrolment in trials may have all influenced recruitment rates. The ability to attend regular face-to-face scheduled visits was also an issue for this group. Previous research shows that young women prefer face-to-face weight loss management,<sup>10</sup> but in a protocolised trial this may be too restrictive. Recent literature suggests that high-frequency telephone contact can be just as effective for weight loss.<sup>18</sup> While this option may be difficult in a clinical trial setting where physical measurements are required, a distance compo-

ment (internet or mobile phone text message) to a clinical trial which indicates flexibility and utilises popular communication methods of this population may improve both recruitment and retention rates.<sup>19</sup> Anecdotally participants in this study responded well to communication via text messages which has also been noted in other trials.<sup>20</sup>

Recruitment subtexts and individual tailoring (as is often used in commercial weight loss programs) may be factors in the recruitment of young adults. Interestingly, despite the reported importance of self-esteem and body image drivers for weight reduction in young women,<sup>4,11,21</sup> the majority of our participants stated their motivating factor for weight loss was improvement in personal health and wellbeing. Perhaps self-esteem and physical appearance were strong motivating factors for many women in this cohort, but they might have considered health as an additional or more socially desirable reason. Thus, targeting self-esteem and visual appearance in recruitment might have been valuable, provided these were incorporated into the trial protocol.

This study demonstrates some of the challenges in the recruitment of young women into clinical weight management trials. Future weight loss trials should be able to incorporate some of these findings into protocol planning. Different recruitment challenges may exist for young women with a different socio-demographic profile and these data could not be extrapolated to young adult males, for whom data are virtually non-existent. In retrospect, it would have been useful to have collected information about which recruitment strategies were most successful in engaging interest about the trial but this detail was only collected for participants who were randomised. Less rigorous selection criteria and reduced face-to-face intervention time may improve recruitment and retention rates into clinical trials. This is a potential area for future research as the relationship between recruitment and retention rates is not well described.

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#### AUTHOR DISCLOSURES

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### 招募 Y 世代過重及肥胖女性參與臨床體重管理試驗策略之成效

目的：有關過重及肥胖年輕女性之研究很有限，且指出招募她們參與體重管理試驗有困難；相較於中老年參與者，年輕女性之個案流失率較高且減重成功機會較低。本篇研究目的是，針對 Y 世代過重及肥胖女性參與臨床減重試驗，評估不同招募策略之成效。方法：預定招募 70 位 18-25 歲之過重及肥胖 ( $BMI \geq 27.5 \text{ kg/m}^2$ ) 女性，做滿 12 個月的臨床體重管理，包括飲食、運動和行為矯正。與研究者保持聯繫，最後招募情形以不同招募策略方式呈現，資料以百分比或平均值 $\pm$ 標準誤表示。結果：在預定招募期間內(24 個月)，只招募到 50 位，未達 70 位。接受評估的自願者中約只有 1/4 (27%) 納入試驗中。而以張貼在地方高等教育校園中的傳單最為成功，約佔 36% 參與者。其次為藉由地方健康服務網站廣告而招募的，佔 26%；透過地區及都會區報紙，則佔 16%。結論：招募 Y 世代過重及肥胖女性參與臨床體重管理試驗很不容易；針對該年齡、性別之族群，需要多方向的策略。減少嚴格的篩選條件和面對面介入時間，或可改善招募成效及避免試驗中此年齡層之個案流失。

**關鍵字：**體重、Y 世代、女性、招募、介入