

# Testing the effectiveness of a novel, evidence-based weight management and lifestyle modification programme in primary care: the Healthy Weight Initiative

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## ABSTRACT

**Introduction.** Primary care prevention strategies that support and provide tools for general practice have the potential to slow and reverse rates of overweight and obesity. **Aim.** To test the effectiveness of a novel 12-week, online, structured, evidence-based weight management and lifestyle modification programme in general practices. **Methods.** Between August 2018 and March 2020, participants with a body mass index (BMI)  $\geq 25$  were recruited from general practices in the Hunter New England and Central Coast Primary Health Network region of Australia. Practices were randomly assigned to deliver a 'low-intensity' (LI) or 'high-intensity' (HI) variant of the programme. Practitioners were trained in programme delivery. The intervention involved weekly progress and accountability checks and scripted education sessions on evidenced-based nutrition, physical activity and lifestyle modification. The trial included follow-up evaluations at 6 and 12 months. **Results.** In total, 695 participants were recruited from 26 practices. At the end of the 12-week programme, participants in the HI treatment arm lost an average of 3.2 kg (s.d. 3.8) and 29% (50/172) achieved clinically significant weight loss ( $>5\%$  of initial body weight). Positive results were maintained at evaluations by participants in the HI treatment arm who attended, but only 31% of participants at 6 months and 21% at 12 months were followed up. **Discussion.** Participant engagement and retention and practitioner workload burden are key factors in the design of weight management programmes in primary care. Many lessons can be obtained as a result of this trial, and programme adjustments have been identified to improve its delivery model.

**Keywords:** chronic disease prevention, evidence-based weight management, general practice, GP-led weight management, nutrition, obesity, physical activity, primary care.

## Introduction

Overweight and obesity rates are high in the Hunter New England and Central Coast Primary Health Network region.<sup>1</sup> In 2018, high body mass-attributable hospitalisations in this region were the second highest among Primary Health Networks across New South Wales, with males recording 1035/100 000 hospitalisations due to obesity and females 734/100 000.<sup>1</sup> Additionally, 2017–18 age-standardised obesity rates are higher in the Hunter New England and Central Coast Primary Health Network than both state and national rates. Obesity affects not only a person's health, but it also has substantial health care and economic costs for Australian communities.<sup>2</sup>

Weight management interventions in Australian primary care have had limited uptake and weight loss success.<sup>3</sup> Mostly, this is also the case internationally. A meta-analysis of results from 15 international randomised controlled trials (RCTs) found a mean weight loss of 1.36 kg at 12 months and concluded that behavioural weight loss interventions in primary care yield very small reductions in body weight, which are unlikely to be clinically significant.<sup>4</sup> This absence of success, along with other general practitioner (GP)

## WHAT GAP THIS FILLS

**What is already known:** Currently, general practices in Australia do not have sufficient access to preventive evidenced-based models of care for the management of overweight and obesity. Several barriers exist regarding general practitioners (GPs) delivering preventive care and management of overweight and obesity.

**What this study adds:** This research provides evidence that GP-led evidenced-based weight management programmes in general practice have the potential to impact increasing overweight and obesity rates. All primary care settings should be strengthened by having access to evidenced-based models of care as part of an overall prevention strategy to address Australia's overweight and obesity rates.

barriers such as perceived insufficient time and self-efficacy, difficulty initiating weight conversations,<sup>3</sup> lack of evidenced-based tools and effective and individualised treatment and referral options, affect GP-led weight management interventions in primary care.<sup>5</sup> Taken together, these reasons may explain why weight management or weight gain prevention programmes in primary care have so far been limited.

Previous research suggests that type and level of care provided by clinicians in general practice varies and particularly, there are differences in care for overweight and obese patients provided by GPs, practice nurses and specialised allied health practitioners (eg dietitians, exercise physiologists).<sup>6</sup> One reason for this may be that training varies in the specific areas of nutrition, physical activity and behavioural interventions required for successful obesity management.<sup>7</sup> For GPs and practice nurses, there is only modest training in these areas compared to training given to specialised allied health practitioners.<sup>8</sup> Even so, Australian research has shown that patients prefer their GP to play a role in their weight management, rather than taking medications or being referred to dietitians.<sup>9,10</sup>

According to the current National Health and Medical Research Council guidelines for the management of overweight and obesity in primary care, general practice is ideally suited to initiate and coordinate multidisciplinary weight management programmes.<sup>6</sup> The guidelines also state that patients' usual healthcare provider (GPs or practice nurses) should play a prominent role in initiating discussions, providing assistance in developing weight management programmes, referring when required, and monitoring and reviewing progress.<sup>6</sup> Acknowledging this, along with the barriers highlighted above, strategies and tools that empower GPs by providing obesity-focused practice resources and education to practice staff, could help mitigate perceived barriers and are seen as critical to implementing effective weight gain and chronic disease prevention programmes in general practice.<sup>11</sup>

This paper describes the effectiveness of the Healthy Weight Initiative in general practices in the Hunter New England and Central Coast Primary Health Network region. Primary care in the study region currently lacks 'prevention-focussed' evidenced-based models of care for the management of overweight and obesity. Our goal was to address this gap. Our primary aim was to test the effectiveness of a novel model of care; an online, structured and scripted evidence-based weight management and lifestyle modification programme running over 12 weeks. Our prevention-focussed hypothesis was that intervening before overweight or obese persons develop a related chronic disease will reduce health and economic burdens to the healthcare system and improve long-term health outcomes for individuals.

## Methods

### Study design

A clustered RCT was conducted at selected general practices across the Hunter New England and Central Coast Primary Health Network region between August 2018 and March 2020. We use the template for intervention description and replication (TIDieR) checklist for replicability to present information about the intervention.<sup>12</sup>

The Healthy Weight Initiative was designed as a 'scripted' practitioner question and patient answer model that could be delivered by GPs, practice nurses, and allied health staff of study practices, mitigating variation in practitioner knowledge, skills and confidence in delivery of healthy eating, physical activity and lifestyle modification advice. 'Scripting' the programme also meant that many general practices with limited capacity and staff (eg small rural practices) could deliver the programme.

### General practice and patient recruitment

General practices were recruited through an expression of interest (EOI) process. Practices responding to the EOI were screened for their capacity and ability to deliver the programme. The practices were stratified by Remoteness Areas<sup>13</sup> and then randomly allocated to one of two study arms by Hunter Medical Research Institute's statisticians. Practices were financially compensated for their time delivering the programme to the equivalent of a standard GP consultation or practice nurse general visit.

Patients were recruited through self-enquiry, identification and invitation by their GP or via programme promotional material placed in waiting rooms. Inclusion criteria reflected the study's prevention-focussed hypothesis and were: understanding conversational English; aged 18–65 years; body mass index (BMI)  $\geq 25$ , without a diagnosed pre-existing chronic disease (heart disease, diabetes, cancer and stroke); no history of eating disorders; not currently pregnant or breast feeding. Australia's overall poor dietary food intake<sup>10</sup> and physical

activity behaviours,<sup>11</sup> regardless of weight and BMI, along with the limitations of the BMI measure,<sup>12,13</sup> were other reasons for a BMI  $\geq 25$  being chosen over a  $>27$  or  $>30$  BMI inclusion criterion.

## Programme delivery

After the study processes were explained and patients consented to participate, reception staff booked participants' first session and emailed (via an online 'email automation' service) an introductory welcome letter that contained further information and an evidenced-based study resources toolkit. The information pack included three hard copy resources: a 24-h food diary; the Depression, Anxiety and Stress Scale – 21 Items (DASS-21) questionnaire,<sup>14</sup> a validated screening scale; and the Three Factor Eating questionnaire-R18<sup>15</sup> to screen for disordered eating behaviour. Participants were not paid for their involvement in the trial, but they were supplied with a wearable activity tracker (Garmin) wrist band or a pedometer (if Garmin was unsuitable) for tracking physical activity.

The two study arms were 'low-intensity' (LI; control) and 'high-intensity' (HI; intervention). Both arms received the same week 1 (baseline), week 12 and evaluation assessments and programme resources. The HI arm had 10 additional weekly measurements, evidenced-based education and support sessions on healthy eating, physical activity and lifestyle modification. Programme delivery and topics are shown in Table 1. The Healthy Weight Initiative programme baseline, final and evaluation health assessments included nutritional and physical activity level assessments, mental health screening using the DASS-21, eating behaviour assessment using the Three Factor Eating questionnaire-R18 and patient goal setting (healthy eating, physical activity and lifestyle choices) focussing on improvement rather than meeting the Australian Guideline for healthy eating and physical activity goals.<sup>16,17</sup>

The Healthy Weight Initiative programme was delivered by GPs, practice nurses and allied health staff in each practice through face-to-face visits in the practice. Trial data were captured and participant progress was tracked through a modified version of the Visual Fitness Planner, which was uploaded to the computers in participating clinicians' rooms before practitioner training. The original Visual Fitness Planner is a commercial gym software 'sales generational tool' (<https://vfp.us/>). Intended to inspire positive behaviour change, the software produces a three-dimensional image of individuals from anthropometric measurements to provide an objective view of each individual's body.<sup>18</sup> The programme's contents were drawn from Australian physical activity and healthy eating guidelines<sup>16,17</sup> and other evidenced-based federal and state government web pages, guidelines and health promotion materials. The software was modelled and constructed by Visual Fitness Planner developers in the United States.

**Table 1.** Programme delivery items for high- and low-intensity trial arms.

| Schedule  | High-intensity programme                  | Low-intensity programme                   |
|-----------|---|---|
| Week-1    | Initial assessment                        | Initial assessment                        |
| Week-2    | Lifestyle and motivation                  | No scheduled session                      |
| Week-3    | Nutrition – Where Are You Now?            | No scheduled session                      |
| Week-4    | Physical Activity and Lifestyle           | No scheduled session                      |
| Week-5    | Nutrition – Making the Right Choices      | No scheduled session                      |
| Week-6    | Progress Review 1                         | No scheduled session                      |
| Week-7    | Move More, Sit Less                       | No scheduled session                      |
| Week-8    | Nutrition – Portion Control               | No scheduled session                      |
| Week-9    | Progress – Your Physical Activity         | No scheduled session                      |
| Week-10   | Progress Review 2                         | No scheduled session                      |
| Week-11   | Managing Setbacks                         | No scheduled session                      |
| Week-12   | Final assessment – Celebrate Your Success | Final assessment – Celebrate Your Success |
| 6-months  | Evaluation 1                              | Evaluation 1                              |
| 12-months | Evaluation 2                              | Evaluation 2                              |

## Clinician training

Practice staff of both study groups received 1-h training in facilitating the programme. Training involved a Primary Health Network Healthy Weight Initiative project officer taking the practice-nominated clinicians through the programme scripting and entering fictitious patient responses. During the training, the project officer answered practitioner questions and provided tips for delivery, with instructions to refer the participants to the resources toolkit if practitioners were unable to answer participants' questions using their existing professional expertise. Healthy Weight Initiative resources are an online amalgamation of potential patient questions, answered by weblinks that direct participants to publicly available government guidelines and resources for healthy eating, physical activity and making better lifestyle choices. This approach encouraged patient ownership and placed the onus and accountability on participants, an essential component of any weight management programme.<sup>6</sup> Monthly support from the project officers (via phone and email) was also available to all practitioners throughout the trial.

## Primary and secondary outcome measures

The study's primary outcome was weight loss over 12 weeks, measured in kilograms to 1 decimal point using the practices' own digital scale. Height was measured using the practices' own stadiometer and BMI was calculated (weight in kilograms divided by height in metres squared). Clinicians were asked

to take all measurements using the same equipment throughout the programme.

The secondary outcome was waist circumference in centimetres (cm) measured using a non-extensible steel tape, at the narrowest point between the lowest rib and the top of the iliac crest or hipbone. Patient and practitioner experience was measured through a survey developed by the Primary Health Network.

### Statistical analysis

The sample size was powered for the primary outcome of weight loss and each practice recruited a nominal maximum of 48 patients directly from their usual general practice consultations at random. The study was powered to detect a change in weight of 0.25 s.d. (Cohen's  $d = 0.25$ ), with 80% power at a  $P$ -value of 0.05. We estimated this would require 250 patients in both treatment arms: 50 participants from five practices. To account for the clustering effect, a design effect of 2 was calculated (intra-cluster correlation = 0.02), which increased the sample to 500 in both treatment arms: 50 participants from 10 practices. To account for some loss to follow up, the number of practices recruited was increased to 13 per treatment arm.

The intention-to-treat (ITT) analysis included all participants who completed baseline demographic data collection (age, gender, and Aboriginal and Torres Strait Islander status) and who were eligible based on their baseline weight measurement ( $BMI \geq 25$ ). For missing data, multiple imputation under the missing-at-random assumption fulfilled the ITT requirement. Fixed effects were included for potentially confounding demographic variables and for the stratification variable geographical remoteness (ARIA+). The analysis reports data in mean  $\pm$  standard deviation (s.d.) format.

Change in weight from baseline to 12 weeks was assessed using analysis of covariance (ANCOVA) linear mixed effects regression, both as absolute weight loss and percentage weight loss. Absolute weight loss was adjusted for baseline weight. Change in waist circumference was assessed using the same methodology, with adjustments for their baseline values. Survey responses were assessed using ordinal logistic regression between the two treatment arms.

### Ethics approval

The Healthy Weight Initiative trial was approved by the Hunter New England Human Research Ethics Committee (2019/ETH01191). This clustered randomised control trial was undertaken with appropriate informed consent of participants or guardians through each practice at sign up.

### Results

There were 29 general practices that responded to the initial EOI process. Subsequently, three withdrew their interest,

**Table 2.** Baseline practice characteristics.

|                            | Low-intensity<br>(Control) ( $n = 13$ ) | High-intensity<br>(Intervention) ( $n = 13$ ) |
|----------------------------|---|---|
| Remoteness classification  |   |   |
| RA1                        | 4                                       | 4   |
| RA2                        | 5                                       | 5   |
| RA3                        | 4                                       | 4   |
| Number of GPs per practice |   |   |
| 1–3                        | 5                                       | 4   |
| 4–7                        | 3                                       | 4   |
| 7–10                       | 3                                       | 2   |
| >10                        | 1                                       | 2   |

deciding that they would be unable to deliver the programme as required. In total, 26 practices were recruited into the trial. Baseline practice characteristics are shown in [Table 2](#). The programme was delivered by 22 practice nurses, two GPs, one practice nurse and GP combination, and one dietitian.

From the 26 practices, 695 participants (ITT population) were recruited to participate: 547 female (79%) and 148 males (21%). We do not know how many potential participants declined involvement. Of the total ITT population, 390 participated in the HI study arm and 305 participated in the LI arm. Patient mean age (s.d.) was 45.6 (12.6) years. The ITT population included 71 (10%) participants who indicated they were of Aboriginal and or Torres Strait Islander descent. The demographics by Remoteness Classification (RA coding) for the ITT population showed that the number of participants who resided in the RA1 (major cities of Australia), RA2 (inner regional Australia) and RA3 (outer regional Australia) areas was 240, 344 and 111 respectively. At baseline, 557 (80%) participants recorded a BMI indicating obesity (HI:  $n = 310$ , LI:  $n = 247$ ). Baseline characteristics, practice and participant retention are displayed in [Table 3](#), [Figs 1, 2](#).

### Primary and secondary outcomes

Participants in the HI arm lost more weight than participants in the LI arm. The amount of weight lost depended on the participant's baseline weight, with heavier participants losing more weight than lighter participants. Over the 12 intervention weeks, average weight loss was 3.2 kg (s.d. 3.9) for the HI arm and 1.7 kg (s.d. 4.1) for the LI group. After accounting for other effects (gender, age, Indigenous Australian status), participants in the HI arm lost 1.4 kg (95% CI =  $-2.312$ ,  $-0.505$ ;  $P = 0.003$ ) more weight and an estimated 1.46% (95% CI =  $-2.420$ ,  $-0.500$ ;  $P = 0.004$ ) more than participants in the LI arm. Almost one-third (29%) of the HI group lost a clinically significant ( $>5\%$  of initial body weight) amount of weight ( $n = 50/172$ ), compared to 17% of the participants ( $n = 22/133$ ) in the LI group.

**Table 3.** Baseline patient characteristics.

|   | Low-intensity<br>(Control)<br>(n = 305) | High-intensity<br>(Intervention)<br>(n = 390) | Total<br>(n = 695) |
|---|---|---|--------------------|
| Age, mean (s.d.)                                    | 45.8 (12.1)                             | 45.5 (13.1)                                   | 45.6 (12.6)        |
| Female  | 244 (80%)                               | 303 (78%)                                     | 547 (79%)          |
| Male  | 61 (20%)                                | 87 (22%)                                      | 148 (21%)          |
| Remoteness classification, n (%)                    |   |   |                    |
| RA1   | 105 (34)                                | 135 (35)                                      | 240 (35)           |
| RA2   | 150 (49)                                | 194 (50)                                      | 344 (49)           |
| RA3   | 50 (16)                                 | 61 (16)                                       | 111 (16)           |
| Aboriginal and Torres Strait Islander Status, n (%) |   |   |                    |
| Yes   | 26 (9)                                  | 45 (12)                                       | 71 (10)            |
| Retained at 12 weeks, n (%)                         |   |   |                    |
| Dropped   | 172 (56)                                | 218 (56)                                      | 390 (56)           |
| Retained  | 133 (44)                                | 172 (44)                                      | 305 (44)           |
| Steps (daily),<br>mean (s.d.)                       | 6733 (3828)                             | 6342 (5364)                                   |                    |
| Depression<br>mean (s.d.)                           | 3.9 (4.2)                               | 4.9 (5.9)                                     |                    |
| Above normal (%)                                    | 11                                      | 18  |                    |
| Anxiety, mean (s.d.)                                | 3.1 (3.8)                               | 3.7 (5.0)                                     |                    |
| Above normal (%)                                    | 12                                      | 15  |                    |
| Stress, mean (s.d.)                                 | 5.5 (4.8)                               | 6.6 (6.3)                                     |                    |
| Above normal (%)                                    | 4                                       | 11  |                    |

Waist circumference decreased in both arms, but with greater effect in the HI group, who lost an average of  $-3.9$  cm from their waist circumference compared to an average of  $-2.2$  cm for the LI group. After adjusting, HI participants' waist circumference reduced by an estimated  $1.33$  cm (95% CI =  $-2.562$ ,  $-0.088$ ;  $P = 0.036$ ) more than participants in the LI arm. The primary and secondary outcome results are shown in Table 4.

Most responded positively to the participant experience survey in both treatment arms of the study, but participants in the HI arm responded more positively. More than 90% of participants in the HI group provided the maximum positive response to most questions (11/16), especially questions in relation to the clinician's delivery of the programme. The scores are shown in Table 5.

Only 15 clinicians at seven practice locations completed the survey, so there was insufficient data to analyse these responses comparatively and meaningfully. The scores are shown in Table 6.

### Follow-up assessments at 6 and 12 months

Outcome data collected at the 6- and 12-months evaluations were not modelled due to the high dropout rate making

assumptions of representativeness impossible. At 6 and 12 months, in the HI arm, 63.6 and 73.3% respectively dropped out and in the LI arm, 77 and 85.2% respectively dropped out. For data collected at 12-weeks' post intervention, it was feasible to assume that the data were missing at random and could be accounted for by patient characteristics measured at baseline. However, at 6 and 12 months, it would be much more likely that the data were not missing at random.

Average weight and waist circumference losses achieved at 12 weeks were recorded at both evaluations. Of participants who returned in the HI group, the average weight and waist circumference loss of 3.8 kg and 4 cm at 6 months were greater than the recorded results at 12 weeks. Results on primary and secondary outcomes at the 6- and 12-month evaluations are shown in Table 7.

## Discussion

This study's aim was to test the effectiveness of a novel model of care developed to support general practice in managing the care of people in the Hunter New England and Central Coast Primary Health Network region who were overweight and obese. Results at the end of the 12-week programme were promising and clinically significant for 29% of the participants in the intervention (HI) group ( $n = 50/172$ ). Positive results were also demonstrated in participant average weight and waist circumference levels, with the HI group averages showing  $-3.2$  kg weight,  $-3.9$  cm waist circumference losses at 12 weeks. These group averages were maintained at 6- and 12-month evaluations by participants in the HI group who attended the follow-up sessions, but participant losses to follow-up were a major issue across both arms.

The results show that the Primary Health Network's Healthy Weight Initiative demonstrated similar results to other general practice weight management interventions internationally. For example, results from a counterweight study in the United Kingdom showed an average 3.0 kg weight loss, and 26.1% of participants who attended an evaluation achieved a clinically significant weight reduction at 12 weeks.<sup>19</sup> Similarly, the US National Institutes of Health review study of 29 RCTs<sup>20</sup> and the Think Health! Study<sup>21</sup> both found a net (mean) weight loss at 12 months of  $-3.3$  kg for participants who returned for their evaluations. Results of the Healthy Weight Initiative were also similar to an Australian GP-led weight management programme, 'the Change Program', which demonstrated that one-third of the participants lost  $>5\%$  of their initial body weight.<sup>9,22</sup> We also acknowledge that commercial 12-week weight loss interventions often achieve better results than primary care weight management interventions;<sup>23</sup> however, there are often considerable differences between the two with regards to time (length) of sessions,<sup>24</sup> type of support provided, patients' ability to pay, and evidence-base, potentially limiting comparability in most circumstances.

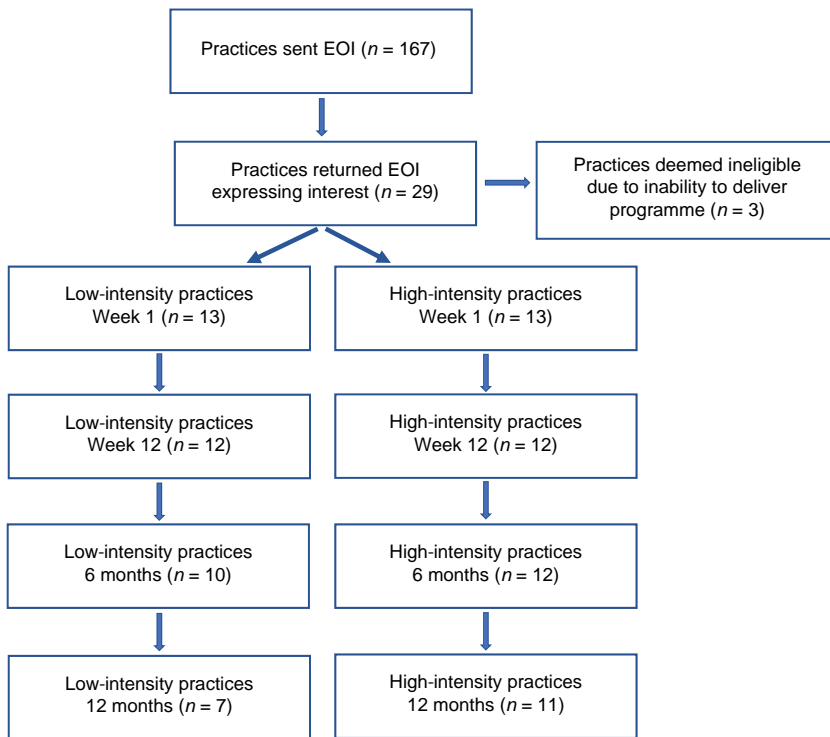


Fig. 1. Practice participation flow diagram.

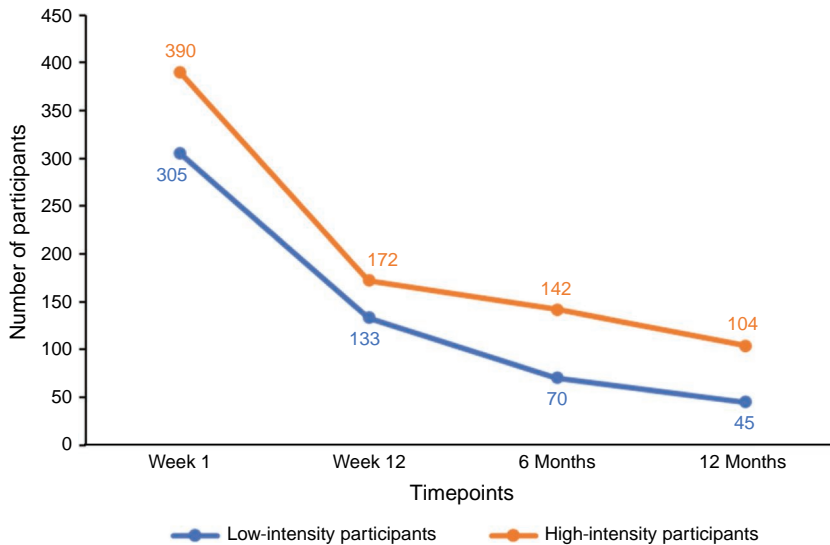


Fig. 2. Participant flow.

Although there were some positive aspects and results in this trial, there were also important challenges and concerns related to loss to follow up and poor survey response rates from practitioners. A similar 12-week obesity intervention in primary care in the UK (the PWeR study) found that scheduled ‘basic nurse support’ at week 2, week 4 and 3 months after baseline (three support sessions in total) proved to be the optimum number of patient–practitioner support sessions over the 12 weeks.<sup>25</sup> Our results, which show that 17% of the LI group also achieved clinically significant weight loss with two sessions (across 12 weeks),

indicates that a smaller number of face-to-face sessions can also achieve positive results. Finding the middle ground with scheduled face-to-face sessions is likely to be important in mitigating patient and practice drop out in primary care weight management programmes.

Despite the regular (usually monthly) check-ins between the Primary Health Network staff and practitioners, which occurred in person where possible and phone or email otherwise, participant loss to follow up was considerable. This leads to two key questions: why did the loss to follow up occur?; and what other factors need considering when

**Table 4.** Low-intensity (LI) and high-intensity (HI) primary and secondary outcomes.

|  | Week 1 LI (n = 305) | Week 12 LI (n = 133)       | Week 1 HI (n = 390) | Week 12 HI (n = 172) |
|--|---------------------|----------------------------|---------------------|----------------------|
| Weight (kg), mean (s.d.)               | 98.7 (19.3)         | 95.1 (19.0)                | 98.7 (19.7)         | 95.0 (19.3)          |
| Median (Q1, Q3)                        | 97.0 (84.6, 109.6)  | 92.5 (81.0, 106.0)         | 96.0 (84.0, 109.8)  | 94.0 (80.6, 105.0)   |
| Range                                  | 59.0–179.9          | 57.1–150.0                 | 58.9–166.0          | 59.0–170.3           |
| Weight difference (kg), mean (s.d.)    |                     | -1.7 (4.1)                 |                     | -3.2 (3.9)           |
| HI vs LI adjusted ITT (95% CI) P-value |                     | -1.41 (-2.31, -0.50) 0.003 |                     |                      |
| Weight difference (%), mean (s.d.)     |                     | -1.8 (4.4)                 |                     | -3.2 (3.8)           |
| HI vs LI adjusted ITT (95% CI) P-value |                     | -1.46 (-2.42, -0.50) 0.004 |                     |                      |
| BMI (kg/m <sup>2</sup> ), mean (s.d.)  | 35.5 (5.9)          | 34.9 (6.1)                 | 35.4 (6.4)          | 34.3 (6.3)           |
| Median (Q1, Q3)                        | 34.5 (31.1, 39.2)   | 34.3 (30.6, 37.8)          | 34.3 (30.5, 39.2)   | 33.5 (29.9, 37.8)    |
| Range                                  | 25.0–55.3           | 23.5–53.8                  | 25.1–63.4           | 23.7–57.9            |
| WC (cm), mean (s.d.)                   | 108.1 (14.9)        | 105.9 (14.3)               | 107.7 (14.1)        | 103.8 (13.8)         |
| Median (Q1, Q3)                        | 107.0 (97.0, 118.0) | 105.0 (96.5, 116.5)        | 106.2 (98.0, 116.2) | 103.2 (94.0, 112.0)  |
| Range                                  | 66.0–160.0          | 72.5–149.0                 | 74.0–154.0          | 73.0–148.0           |
| WC difference (cm), mean               |                     | -2.2                       |                     | -3.9                 |
| HI vs LI adjusted ITT (95% CI) P-value |                     | -1.32 (-2.56, -0.09) 0.036 |                     |                      |

BMI, body mass index; HI, 'high-intensity – intervention'; ITT, intention to treat; ITT Imputed Model (n = 695); LI, 'low-intensity – control'; s.d., standard deviation; WC, waist circumference.

introducing and implementing a weight management programme into a general practice? Research suggests that similar weight management trials (in terms of numbers enrolled, length of study, facilitation methods) in primary care often have large losses to follow up and issues with patient retention.<sup>19</sup> In contrast, studies with much smaller participant numbers often maintain higher retention rates,<sup>9,26</sup> suggesting that future research or iterations of the programme would benefit from better screening of practices, potentially including a 'readiness for change' assessment for participants before enrolment, and greater attention to mitigating participant drop out and practice disengagement.

With respect to future opportunities to improve implementation, Primary Health Network staff have identified potential adjustments to improve programme facilitation in the practices and mitigate the high dropout rates seen in this study. These adjustments are based on clinician feedback and findings from other similar studies. They include: extending the initial training session to include health coaching skills, motivational interviewing and readiness for change; changing face-to-face sessions for online modules and having a maximum of four to five face-to-face sessions over the 12 months; better identification and screening of practices and practitioners on their ability to deliver the programme; including more relevant evidenced-based chronic disease prevention information in the resources provided; and altering the programme to target participants with a BMI > 30 and accommodate patients with co-morbidities.

There are two benefits of altering the number of sessions. First, it would reduce patient and practitioner workload,

which may have contributed to the high dropout rates. Second, it would also allow exploring the feasibility and acceptability (possibly through further research) of a more sustainable financial model whereby practices could leverage GP management plan (GPMP) item numbers and the MBS billing system. This financial factor would encourage practice owners to implement this type of model in their general practice, and also would support GPs in addressing some of the barriers associated with weight management in primary care while adhering to the current guidelines for the management of overweight and obesity.<sup>6</sup>

Such adjustments would provide general practice (if the trial's many lessons are built into a new modified version) an evidenced-based new model of care that addresses barriers to change in practice<sup>27,28</sup> and provide the opportunities in primary care for weight management raised by the Department of Health's National Obesity Summit.<sup>29</sup> These opportunities include providing GPs a scripted tool to support them in talking to patients about their weight, to weigh their patients, use GP management plans for treating obesity, and improve training and support, which will also contribute to improving GPs' engagement with the complexities of obesity and its comorbidities.<sup>29</sup> This trial provides valuable lessons on what works for the programme (and also what needs improving) in developing a tool to support general practice and GPs in managing overweight and obesity. The Healthy Weight Initiative was a pilot programme and this trial suggests that major modifications and further research into refining the programme would be beneficial.

**Table 5.** Participant survey results: raw scores and percentages.

|   | <b>Very good</b>         | <b>Good</b>                | <b>Fair</b>                 | <b>Poor</b>               | <b>Very poor</b>                         |
|---|--------------------------|----------------------------|-----------------------------|---------------------------|--|
| How would you evaluate the way the facilitator listened to you during the visit?  | 103 (79)/157 (94)        | 25 (19)/9 (5)              | 3 (2)/1 (1)                 | 0 (0)/0 (0)               | 0 (0)/0 (0)                              |
| How would you evaluate the way the facilitator involved you in decisions about the management of your weight?                           | 95 (73)/147 (89)         | 29 (22)/18 (11)            | 6 (5)/1 (1)                 | 1 (1)/0 (0)               | 0 (0)/0 (0)                              |
| How would you evaluate this facilitator's explanation of educational content?   | 87 (67)/149 (90)         | 30 (23)/14 (8)             | 7 (5)/3 (2)                 | 3 (2)/0 (0)               | 2 (2)/0 (0)                              |
| How would you evaluate the amount of time the facilitator gave you?   | 107 (82)/158 (95)        | 19 (15)/7 (4)              | 2 (2)/2 (1)                 | 2 (2)/0 (0)               | 0 (0)/0 (0)                              |
|   | <b>Yes, completely</b>   | <b>Yes, mostly</b>         | <b>Yes, a little</b>        | <b>No, not really</b>     | <b>No not at all</b>                     |
| Did he or she really find out what your concerns were?  | 96 (73)/143 (86)         | 32 (24)/22 (13)            | 3 (2)/1 (1)                 | 0 (0)/0 (0)               | 0 (0)/0 (0)                              |
| Did he or she let you say what you thought was important?   | 113 (86)/151 (92)        | 14 (11)/14 (8)             | 4 (3)/0 (0)                 | 0 (0)/0 (0)               | 0 (0)/0 (0)                              |
| Did he or she discuss with you your main goals or priorities?   | 96 (74)/155 (94)         | 30 (23)/8 (5)              | 3 (2)/2 (1)                 | 1 (1)/0 (0)               | 0 (0)/0 (0)                              |
|   | <b>Yes, definitely</b>   | <b>Yes, to some extent</b> | <b>No, not really</b>       | <b>No, not at all</b>     | <b>No, I haven't needed such support</b> |
| Has the program provided everything you need to help you manage your weight?  | 51 (39)/119 (71)         | 35 (27)/42 (25)            | 30 (23)/5 (3)               | 12 (9)/1 (1)              | 3 (2)/0 (0)                              |
| In the last 12 months, have you had enough support from local services or organisations to help you manage your weight?                 | 43 (33)/89 (54)          | 33 (25)/40 (24)            | 28 (21)/9 (5)               | 16 (12)/6 (4)             | 11 (8)/22 (13)                           |
|   | <b>Yes, definitely</b>   | <b>Yes, to some extent</b> | <b>No, not really</b>       | <b>No, not at all</b>     |  |
| Did the facilitator help you to feel that you could prevent some health problems?   | 90 (69)/150 (90)         | 35 (27)/14 (8)             |                             | 5 (4)/1 (1)               | 1 (1)/1 (1)                              |
| Did the facilitator give you a sense of control over the management of your weight?   | 93 (72)/150 (90)         | 27 (21)/15 (9)             |                             | 6 (5)/1 (1)               | 3 (2)/0 (0)                              |
| Did the facilitator help you feel that sticking with your identified goals would make a difference?                                     | 97 (75)/153 (93)         | 28 (22)/12 (7)             |                             | 3 (2)/0 (0)               | 2 (2)/0 (0)                              |
| Did the facilitator help you to feel that your everyday activities such as nutrition and lifestyle make a difference in your health?    | 103 (80)/155 (93)        | 21 (16)/11 (7)             |                             | 3 (2)/0 (0)               | 2 (2)/0 (0)                              |
|   |                          | <b>No</b>                  | <b>Yes, once</b>            | <b>Yes, several times</b> |  |
| Were there times when you had difficulty getting the advice you needed?   |                          | 116 (89)/162 (98)          | 6 (5)/2 (1)                 | 8 (6)/1 (1)               |  |
|   | <b>Yes, definitely</b>   | <b>Yes, to some extent</b> | <b>No, not at all</b>       |                           |  |
| Did you have confidence in the facilitator/s you saw or spoke to?   | 112 (86)/163 (98)        |                            | 17 (13)/3 (2)               | 1 (1)/0 (0)               |  |
|   | <b>Totally confident</b> | <b>Very confident</b>      | <b>Moderately confident</b> | <b>A little confident</b> | <b>Hardly confident at all</b>           |
| How confident are you that you can maintain changes in your health habits like diet and physical activity, even during times of stress? | 43 (33)/83 (50)          | 32 (25)/57 (34)            | 38 (29)/23 (14)             | 8 (6)/3 (2)               | 9 (7)/1 (1)                              |

Data are shown as: low-intensity (%)/high-intensity (%).

Strengths of this study include an evidenced-based programme design that supports current recommendations and guidelines, and multiple imputation for missing data in statistical analyses due to the high dropout rates. This study had several limitations. The effect of practitioner motivation could not be assessed in the primary and

secondary outcome results. We did not conduct a cluster analysis to account for within- and between-practice variation in terms of staffing and practitioner expertise. These limitations could have been managed by improvements to practice recruitment, practitioner training protocols, and the trial's design. Although positive weight loss group averages



**Table 6.** Practitioner survey results.

|   | Yes, definitely | Yes, to some extent | No, not really | No, not at all |
|---|-----------------|---------------------|----------------|----------------|
| Did you increase your knowledge of healthy lifestyle and weight management education throughout the delivery of this programme?                               | 0/4             | 1/5                 | 0/3            | 2/0            |
| Did your confidence increase in discussing healthy lifestyle and weight management with participants?   | 1/4             | 0/8                 | 0/0            | 2/0            |
| Did you find the scripting provided in the programme beneficial?  | 1/5             | 0/3                 | 0/3            | 2/1            |
| Did you find the resources provided within the programme beneficial?  | 0/6             | 1/4                 | 0/2            | 2/0            |
| Did you find the weekly reports provided within the programme beneficial?   | 0/8             | 0/3                 | 0/0            | 3/1            |
| Did you find the interactive components of the programme beneficial (eg the avatar, the health risks graph and lifestyle costs calculator)?                   | 1/7             | 0/3                 | 0/2            | 2/0            |
| Did you find the delivery of the programme to be time efficient?  | 0/7             | 1/3                 | 0/1            | 2/1            |
| Did you feel the participants enjoyed the weekly education sessions?  | 0/7             | 0/5                 | 0/0            | 2/0            |
| Do you feel the participants benefited from the programme?  | 1/7             | 0/5                 | 0/0            | 2/0            |
| Do you feel that the participants have increased their nutritional knowledge relating to weight management?   | 1/6             | 0/6                 | 0/0            | 2/0            |
| Do you feel that the participants have increased their physical activity knowledge relating to weight management?   | 1/5             | 0/5                 | 0/2            | 2/0            |
| Do you feel that the participants have increased their lifestyle factors knowledge relating to weight management?   | 1/5             | 0/7                 | 0/0            | 2/0            |
| How confident are you that participants will be able to maintain changes in their health habits like diet and physical activity, even during times of stress? | 0/2             | 1/9                 | 0/1            | 2/0            |

Data are presented as low-intensity arm (n)/high-intensity arm (n)

**Table 7.** Primary and secondary outcomes at the 6- and 12-month evaluations.

|  | 6 months LI (n = 70) | 12 months LI (n = 45) | 6 months HI (n = 142) | 12 months HI (n = 104) |
|--|----------------------|-----------------------|-----------------------|------------------------|
| Weight (kg), mean (s.d.)                         | 98.0 (21.0)          | 97.8 (22.2)           | 94.9 (20.4)           | 95.3 (19.7)            |
| Weight difference (kg), mean (Wk 1 – Evaluation) | -0.7                 | -0.9                  | -3.8                  | -3.4                   |
| BMI (kg/m <sup>2</sup> ), mean (s.d.)            | 35.7 (6.7)           | 35.4 (7.0)            | 34.4 (6.9)            | 34.3 (6.4)             |
| WC (cm), mean (s.d.)                             | 107.1 (14.4)         | 107.2 (16.9)          | 103.7 (15.2)          | 104.2 (14.2)           |
| WC difference, mean (cm)                         | -1                   | -0.9                  | -4                    | -3.5                   |

BMI, body mass index; HI, 'high-intensity – intervention'; LI, 'low-intensity – control'; s.d., standard deviation; WC, waist circumference.

were maintained at follow up by patients who attended, changes to optimise retention and attendance are needed in future programme developments.

In conclusion, the Healthy Weight Initiative programme provides general practice support organisations a baseline for developing a new model of care option for weight management in efforts to address the overweight and obesity rates in the Hunter New England and Central Coast Primary Health Network region. The HI arm demonstrated larger weight loss benefits than the LI arm, which were sustained by engaged participants. The large participant loss to follow up suggests that participant retention and practitioner workload are key factors in the design of primary care weight management programmes. All primary care settings should

be strengthened by having access to evidence-based weight management programmes as part of an overall prevention strategy to address Australia's overweight and obesity rates. Overall, the trial was a success regarding lessons learned and identifying programme adjustments needed in building a tool to support GPs and general practice in delivering an evidenced-based weight management programme.

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