Study Protocol
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## Healthy Weight for Life programme: Evaluating the practice and effectiveness of a weight loss maintenance programme in the private health insurance setting

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#### **Abstract**

**Background:** Australian private health insurers are increasingly involved in the delivery of chronic disease management programmes to their members, recognising the importance of decreasing and managing lifestyle risk factors and the impact such factors have on health service utilisation. One such secondary prevention programme is the Healthy Weight for Life programme, an intensive weight loss and lifestyle modification programme that has been designed for overweight and obese private health insurance members in Australia. Together with the insurer, the Healthy Weight for Life service provider developed and implemented a long-term maintenance programme that supports participants who complete the Healthy Weight for Life programme to maintain the weight loss they achieved during the programme. Various studies have shown that evidence-based weight management programmes can be effective; however, the results may vary in different contexts. **Objective:** This article presents the evaluation rationale and framework designed to assess the process and impact of the long-term maintenance programme on weight loss maintenance, other health-related benefits and participants' experience with the programme.

**Methods:** The evaluation will comprise a number of inter-related sub-studies balancing evaluation of programme effectiveness and implementation. The maintenance programme presented a unique opportunity for researchers to partner with private health insurance and a service provider to assess a real-world programme in the under-researched area of weight loss maintenance in this setting and emphasises the importance of evaluating such programmes given the potential the private health insurance context has in the future delivery of health care.

## **Keywords**

Weight loss maintenance, real-world evaluation, partnership, private health insurance

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## Introduction

## Background

Almost two-thirds of Australian adults are overweight or obese, and obesity-related non-communicable conditions result in 7% of the total national health burden.¹ While Australia has a universal government health scheme (Medicare), it also has government policy which encourages participation in private health insurance,² and approximately 57.1% of all Australians have some level of private health insurance.³ Private health insurance can cover medical treatment, including hospital cover, as well as 'ancillary' health care which includes chronic disease management programmes (CDMPs). Along with existing health services,

Australian private health insurances have emerged as important providers of CDMPs to help prevent and manage non-communicable disease.<sup>4</sup> Testing and implementing prevention programmes through health insurers therefore

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represent an important opportunity for chronic disease prevention and management.

Many CDMPs, which aim to address chronic disease risk factors or to reduce diagnosed chronic disease complications, are inherently focused on supporting healthy lifestyles and weight loss. CDMPs in Australia have been shown to successfully improve lifestyle risk factors<sup>5</sup> and reduce hospital utilisation and costs.<sup>6</sup> Understanding weight loss maintenance following CDMPs is under-researched, especially in the private health insurance context.

Interventions targeting lifestyle-related behaviours to maintain weight loss have been shown to be moderately effective, 7 so too have programmes that extend programme contact. 8,9 It is argued that the provision of extended contact for weight loss maintenance should be considered a necessity, alongside research to improve extended care programmes using cost effective modes (e.g. telephone or Internet). 8

## The Healthy Weight for Life programme (phases 1-3)

The Healthy Weight for Life (HWFL) programme is an 18-week intensive weight loss and lifestyle modification programme offered Australia wide by private health insurance companies to members aged 18+ years with a chronic disease (osteoarthritis (OA), type 2 diabetes or cardiovascular disease) who have a body mass index (BMI)  $\geq 28 \text{ kg/m}^2$ (https://www.healthyweightforlife.com.au). There are multiple entry points for participants into the programme including direct medical referral and invitation from the participant's health insurance fund. In the latter pathway, the health insurer identifies participants for the initial HWFL programme through relevant diagnoses information recorded on insurance claims. These participants are invited to register for the programme, which requires approval from their general practitioner or medical specialist. Programme costs are paid for by the participants' health insurance. HWFL offers three programmes: OA HWFL, Heart Health HWFL and Type 2 Diabetes HWFL.

The remotely delivered weight loss programme consists of three 6-week phases over 18 weeks (Figure 1).10 For all programme groups, each phase includes a portion-controlled eating plan (including KicStart™ meal replacements) and recommendations for daily gentle physical activity such as walking or swimming. For individuals in the OA HWFL programme, physiotherapist-developed strength, balance and mobility exercises are delivered. The centralised Care Support Team (HWFL Team) comprises health professionals with experience in supporting overweight and obese individuals in lifestyle behaviour change. They provide support, advice and personal motivation to participants as well as tracking participants' symptoms and programme progress via an online portal, phone, SMS, email, private electronic message board and mail. Specialised programme management software enables multiple communication and data collection channels for each individual patient and supports reproducible delivery of the programmes across large cohorts of participants.

Participants tend to be middle-aged and older adults, with an average age of 64 years and an average initial BMI of 34.3 kg/m<sup>2</sup>.<sup>11</sup> More than 80% of participants complete the programme and lose on average of between 7.5% and 8.3% of their initial body weight.<sup>11,12</sup>

# Development of the HWFL long-term maintenance programme (phase 4)

The HWFL programme service provider (Prima Health Solutions) in collaboration with an Australian private health insurer identified a need to provide support to HWFL graduates to maintain weight loss achieved during the programme. As part of formative research to inform the design of a weight loss maintenance programme, a university research team conducted focus groups drawn from all HWFL graduates. The results indicated that participants would like a long-term maintenance programme (LTMP) to assist with weight loss maintenance and improved health outcomes.<sup>13</sup> Particularly, participants indicated a preference for ongoing programme support including contact with the programme support team. This led to the development of the HWFL LTMP by Prima Health Solutions, combining focus group insights and consultations with the private health insurer to develop and deliver the LTMP (see Figure 1).

## Long-term weight maintenance programme

Insurance members who complete the 18-week HWFL programme are eligible to register for the LTMP for a further 24 months (Figure 1), regardless of their weight change status. They are invited, by email, to participate in the LTMP at the time of completing the HWFL programme. The LTMP is tailored to suit individual needs and includes unlimited member contact with the HWFL team, access to an online portal and active and regular case review. As with the HWFL programme, participants may contact the HWFL team more frequently if required. Participants agree to reporting requirements of the health insurer (including monthly self-reported body weight and waist circumference through the online portal). Outreach by the team is activated when participant's self-reported data (or a lack of data reporting) indicate a need for contact.

Based on individual need, a participant may additionally be offered a health insurer—funded 'pulsed' intervention including a booster pack of 50 KicStart sachets; support from the HWFL team to assess barriers to weight loss, set goals and develop a measurable action plan; and a follow-up review phone call. Individual need is identified by the HWFL team through one-on-one discussions with the participant where (a) the participant indicates that further assistance is required to maintain their weight loss or (b) the participant is

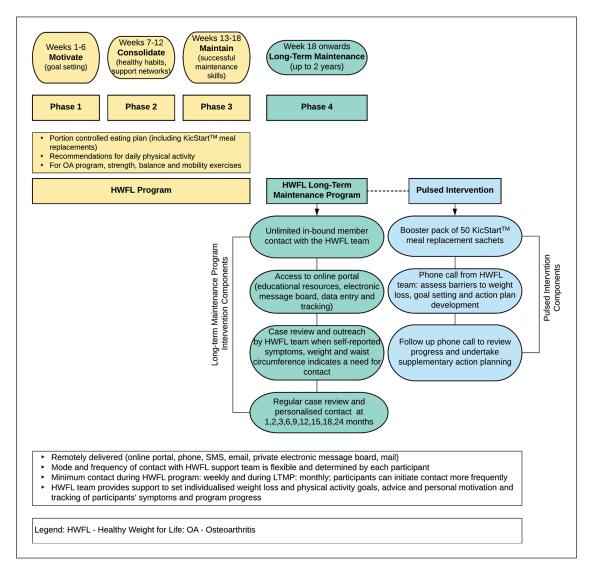


Figure 1. Phases of the HWFL and HWFL long-term maintenance programme.

struggling to maintain weight loss and would benefit from re-commencing an intensive intervention phase to balance their energy intake and physical activity. The pulsed intervention is offered once every 12 months, with the first available a minimum of 12 weeks after completing the HWFL programme. One-on-one discussions between a participant and the HWFL team ensure that the timing of the pulsed intervention is appropriate to the participant's readiness and ability to follow the agreed action plan.

## LTMP evaluation rationale and opportunity for co-production of evidence

The LTMP design was inspired by research-based evidence of the impact of the HWFL programme<sup>11,12</sup> and informed by a combination of guidelines for the management of adult overweight and obesity<sup>14,15</sup> as well as 'practice wisdom'.<sup>16</sup>

Although a specific theoretical framework was not articulated, the LTMP is underpinned by established and effective behaviour change strategies including goal setting, self-monitoring, feedback and reinforcement as illustrated in Figure 2.<sup>17</sup> The LTMP represents a unique partnership between researchers, a health insurer and a service provider and a formal research evaluation opportunity for generating practice-based evidence about weight loss maintenance in the Australian private health insurance setting in an area where the evidence base is scarce.

The evaluation of the LTMP is based on the evaluation framework of Bauman and Nutbeam, <sup>18</sup> which outlines formative, process, impact and outcome stages of evaluation in building evidence for public health programmes. The emphasis of our evaluation is on assessing whether a previously tested intervention (HWFL programme) can be extended to meet the needs of the priority population to maintain their

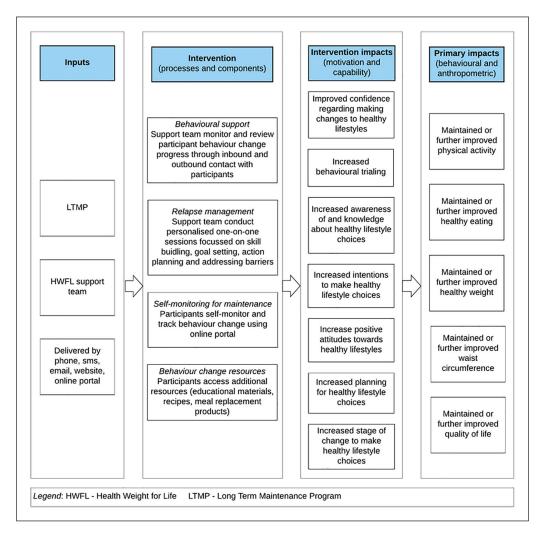


Figure 2. Conceptual framework for the potential effects of the Healthy Weight for Life long-term maintenance programme.

weight loss rather than on establishing a causal relationship between an untested intervention and an outcome. 19 The evaluation design is similar to that used in assessing other realworld lifestyle intervention programmes<sup>20,21</sup> where a tightly controlled research design was not practical due to the realworld nature and purpose of the evaluation (i.e. focus on effectiveness and practice not efficacy). While measuring effectiveness is paramount, these evaluations also document for whom and under what conditions a programme works and what factors impede or facilitate participation. As with these previous studies, the current evaluation uses a number of inter-related sub-studies and both quantitative and qualitative methods to triangulate information, thus providing a balance between evidence of programme effectiveness (i.e. impact) and evidence of programme implementation (i.e. process). 18,22 The combination of such evidence can provide comprehensive insights into programme strengths, challenges and recommendations for future refinement of the LTMP.

This article describes the evaluation framework designed to assess the process and impact of the first 12 months of this practice-based programme of unknown effectiveness on maintaining weight loss and other health benefits in a private health insurance context. We used a conceptual framework for the potential effects of the LTMP to drive the research evaluation questions (Figure 2).

To assess impact across the three programme groups (i.e. OA, type 2 diabetes or cardiovascular disease), this evaluation asks the following:

- What is the impact of the LTMP on change in anthropometric measures (i.e. weight loss maintenance, further weight loss or weight regain) 6 and 12 months after starting the LTMP?
- What is the impact of the LTMP on change in or maintenance of lifestyle risk factors (i.e. diet and physical activity) 6 and 12 months after starting the LTMP?
- 3. What is the pattern of weight change across the HWFL programme and the first 12 months of the LTMP?

- 4. What effect does LTMP have on change in psychosocial factors, general health, function and quality of life 6 and 12 months after starting the LTMP?
- 5. What factors are associated with weight loss maintenance?

To assess process from the participants' perspective, this evaluation asks the following:

- 6. What are the socio-demographic characteristics of participants who register for the LTMP?
- 7. How do participants use and interact with the programme and does this vary across the three programme groups?
- 8. How often do participants engage with the LTMP support team?
- 9. How acceptable is the programme to participants?

#### **Methods**

## Evaluation design and study samples

A pre- and post-test design was considered the most appropriate and pragmatic design for this real-world evaluation, 18,23 comprising two related studies and samples. The main cohort study comprises all LTMP participants who provide informed consent, with the purpose of evaluating the impact of the LTMP on anthropometric changes. An independent sub-study (a sub-sample of the main cohort) includes participants consenting to contact from researchers and to provide additional information to assess lifestyle risk factor and psychosocial change in LTMP participants. The HWFL team will recruit independent sub-study participants at LTMP registration. Researchers will contact those willing to be part of the independent sub-study directly and seek informed consent prior to commencing the first survey. In addition, sub-study participants will be prospectively and randomly sampled to participate in a qualitative study investigating participant experiences of using the LTMP.

Ethics approval for the evaluation of the LTMP was granted by the University of Sydney Human Ethics Committee (project no. 2017/760).

## Data collection

The methods, measures and timing of data collection are outlined in Table 1 and described in detail below. While the LTMP is offered to participants for a 24-month period, this evaluation study focuses on the first 12 months due to budget and time constraints.

Main cohort study data collected from participants by Prima Health Solutions include body weight, height and socio-demographic information on initial registration for the HWFL programme, and body weight on completion of the HWFL programme. LTMP participants provide monthly self-reported body weight and waist circumference. OA participants are actively encouraged to provide data on pain, function, symptoms and quality of life. Where possible, the HWFL team asks participants who withdraw from the programme for their reasons at the time of withdrawal. Prima Health Solutions will provide data collected during the initial HWFL programme and the LTMP for analysis.

Researchers will conduct three telephone surveys with each *sub-study* participant: at LTMP commencement and after 6 and 12 months. Each survey uses a standardised script, asking the same questions about lifestyle and psychosocial behaviours and general health and physical function (Supplemental File 1). Further telephone interviews will be conducted with a sample of sub-study participants at approximately 6 months after starting the LTMP to investigate their experiences of using the LTMP (Supplemental File 2). Interviews will be audio recorded and transcribed verbatim.

## **Evaluation** measures

#### Impact measures

Anthropometrics (main cohort study). Participants are asked to provide, via an online portal or by phone, self-reported body weight (kg) and waist circumference (cm) monthly according to standardised instructions. They are instructed to weigh themselves weekly at the same time of the day while wearing light clothing or underwear and no shoes. Waist circumference measurement instructions ('For consistent waist measurements: Measure down 35-40 cm from the "U shaped" notch at the base of your throat. Measure your waist here each time') are printed on a tape measure provided at registration for the HWFL programme. BMI (kg/m<sup>2</sup>) will be calculated and used as an overall measure of weight status according to the World Health Organization (WHO)<sup>24</sup> classifications used to determine normal weight (18.5-24.99 kg/m<sup>2</sup>), overweight (25–29.99 kg/m<sup>2</sup>) and obese ( $\geq$ 30 kg/ m<sup>2</sup>). Two analyses will be conducted including the whole programme cohort and including only participants who lost ≥2% of initial weight, the starting point for health benefits of weight loss,<sup>25</sup> to measure anthropometric change. Withinindividual change in body weight (i.e. weight regain: ≥25% of initial weight loss, maintenance of weight loss: <25% of initial weight loss<sup>26</sup> or further weight loss) will be calculated at 6 and 12 months. The pattern of initial within-individual weight and waist circumference change during the 18-week HWFL programme and the first 12 months of the LTMP will also be assessed.

Lifestyle behaviours (independent sub-study). The Active Australia Questionnaire (AAQ) will be used to assess changes in walking and moderate and vigorous physical activity behaviour from the beginning of the LTMP to 6 months and to 12 months; specifically, frequency and minutes of continuous walking and moderate and vigorous physical activity.<sup>27</sup> The AAQ has been widely used in Australian

Table 1. Evaluation measures and timing of data collection.

| Evaluation measures             | Evaluation indicators   | HWFL long-term maintenance programme (LTMP) Year I |                       |   |   |   |   |   |     |   |   |   |    |   |    |
|---------------------------------|---|--|-----------------------|---|---|---|---|---|-----|---|---|---|----|---|----|
|                                 |   | Time (m  | Time (months)         |   |   |   |   |   |     |   |   |   |    |   |    |
|                                 |   | Initial<br>contact                                 | <b>0</b> <sup>a</sup> | I | 2 | 3 | 4 | 5 | 6   | 7 | 8 | 9 | 10 | П | 12 |
| Impact measures                 |   |  |                       | - |   |   | - | - |     |   |   |   |    |   |    |
| Anthropometric measures         | Weight (kg)   | M  | Μ                     | Μ | Μ | Μ | Μ | Μ | Μ   | Μ | Μ | Μ | Μ  | Μ | Μ  |
|                                 | Height (cm)   | M  |                       |   |   |   |   |   |     |   |   |   |    |   |    |
|                                 | Waist circumference (cm)  | M  | Μ                     | Μ | Μ | Μ | Μ | Μ | Μ   | Μ | Μ | Μ | Μ  | Μ | Μ  |
| Lifestyle risk factor variables | Daily fruit and vegetable consumption   |  | S                     |   |   |   |   |   | S   |   |   |   |    |   | S  |
|                                 | Physical activity (walking, moderate and vigorous sessions, and minutes/week) |  | S                     |   |   |   |   |   | S   |   |   |   |    |   | S  |
|                                 | Sitting (minutes/day)   |  | S                     |   |   |   |   |   | S   |   |   |   |    |   | S  |
| Psychosocial variables          | Confidence  |  | S                     |   |   |   |   |   | S   |   |   |   |    |   | S  |
|                                 | Planning  |  | S                     |   |   |   |   |   | S   |   |   |   |    |   | S  |
|                                 | Social support  |  | S                     |   |   |   |   |   | S   |   |   |   |    |   | S  |
|                                 | Stage of change   |  | S                     |   |   |   |   |   | S   |   |   |   |    |   | S  |
| General health and function     | General health  |  | S                     |   |   |   |   |   | S   |   |   |   |    |   | S  |
|                                 | Physical ability and performing everyday tasks                                |  | S                     |   |   |   |   |   | S   |   |   |   |    |   | S  |
| Process measures                |   |  |                       |   |   |   |   |   |     |   |   |   |    |   |    |
| Recruitment and reach           | Socio-demographic profile of participants (gender, date of birth, postcode)   | М  |                       |   |   |   |   |   |     |   |   |   |    |   |    |
|                                 | Population representativeness   | Μ  |                       |   |   |   |   |   |     |   |   |   |    |   |    |
| Programme use                   | Type of programme (OA, T2D, CVD)  | M  |                       |   |   |   |   |   |     |   |   |   |    |   |    |
|                                 | Compliance (portal login; data provision)                                     | M  | Μ                     | Μ | Μ | Μ | Μ | Μ | Μ   | Μ | Μ | Μ | Μ  | Μ | Μ  |
|                                 | Participation in pulsed intervention  |  |                       |   |   | Μ |   |   | Μ   |   |   | Μ |    |   | Μ  |
| Dose received                   | Frequency of reporting and engagement   |  |                       |   |   |   |   |   |     |   |   |   |    |   | S  |
| Acceptability of LTMP           | Factors which facilitated engagement  |  |                       |   |   |   |   |   | S   |   |   |   |    |   |    |
|                                 | Barriers to engagement  |  |                       |   |   | Μ |   |   | M/S |   |   | Μ |    |   | Μ  |

M: main cohort study self-reported data collected by HWFL team; S: independent cohort sub-study telephone survey data collected by evaluators; OA: osteo-arthritis; T2D: type 2 diabetes; CVD: cardiovascular disease; HWFL: Healthy Weight for Life.

surveys and has been found to have acceptable convergent validity with the general older adult population in Australia. Based on their AAQ responses, participants will be classified as either sufficiently active, insufficiently active or inactive as defined by the Australian national physical activity guidelines. Sufficiently active is defined as having more than 150 min of moderate physical activity or more than 75 min of vigorous physical activity, or an equivalent combination of both, including walking for adults aged 18–64 years and at least 30 min of physical activity on five or more days in the last week for those older than 64 years. Time spent sitting per day will be measured using a single question previously used with an Australian population of a similar age.

Participants will be asked to report their daily fruit and vegetable consumption using two short dietary questions.<sup>33</sup> We will use the Australian national guidelines to determine whether participants meet (i.e. consume two or more serves of fruit per day and consume five or more serves of vegetables per day) the recommended daily consumption of fruit and vegetables or not.<sup>34</sup>

Psychosocial indictors (independent sub-study). Participants' confidence<sup>35</sup> to do regular physical activity, to eat healthier and to achieve their weight-related goals will be assessed using a sliding scale of 1–10. Planning<sup>36</sup> for physical activity and healthy eating will be assessed using a 4-point Likert-type scale measure. Social support<sup>37</sup> for physical activity and healthy eating will be assessed using a 4-point Likert-type scale measure. Current habits and intentions for behaviour change for physical activity and having a healthy diet will be assessed using questions guided by the Trans-theoretical Model of Stages of Change.<sup>38</sup>

General health indicators (independent sub-study). General health will be assessed using a single-item question with established reliability, <sup>39</sup> as well as whether their health limits their daily physical functioning, using a set of 10 questions. <sup>40</sup>

Functional and quality of life indicators (main cohort OA participants). The Knee injury and Osteoarthritis Outcome Score (KOOS) or Hip disability and Osteoarthritis Score

alf participant completed HWFL programme within 4 weeks of registering for LTMP, data collected at completion of HWFL programme will be used as baseline data.

(HOOS) will be used to measure perceived general health and function in OA participants. These validated question-naires cover pain, disease-specific symptoms, activity of daily living function, sport and recreation function and knee-or hip-related quality of life and are appropriate for use with older individuals. 41,42

#### Process measures

Recruitment and reach. Participants' socio-demographic information (gender, date of birth and residential postcode) will be collected by the HWFL team at initial contact to profile users of LTMP. Participants' age will be calculated from date of birth. Postcodes will be used to define Socio-Economic Indexes for Areas<sup>43</sup> and Accessibility/Remoteness Index of Australia Plus as measures of social advantage and disadvantage and accessibility to services.<sup>44</sup>

Programme use. We will assess the way participants use the LTMP from enrolment data for each of the specific programmes (OA, type 2 diabetes or cardiovascular disease), as well as for the pulsed intervention. Programme compliance will be measured by portal logins and whether participants provide data according to the reporting expectations of their health insurer.

Dose received. Sub-study participants will be asked about frequency and mode of communication with the HWFL team during the first 12 months of the LTMP as an indication of delivery and receipt of the intervention.

Acceptability and experience of LTMP. Main cohort participants who withdraw from the programme will be asked their reasons for withdrawal where possible. A qualitative study will investigate sub-study participants' experiences of using the LTMP by exploring factors related to their engagement with the programme, as well their understanding and use of intervention components. The qualitative study will comprise telephone interviews with a researcher experienced and trained in conducting interviews, which will be approximately 30–40 min. A semi-structured discussion guide developed by the research team and reviewed by the HWFL service provider will be used. Where possible, participants who have withdrawn from the LTMP will be included in the qualitative study.

LTMP resources. We will estimate costs associated with programme delivery to calculate overall cost per participant in Australian dollars. Where possible, standard unit costs (e.g. average Australian wage rates) will be used to determine a time value. Where this is not feasible, market rates will be used to determine the price paid for purchased commodities.

## Sample size

All participants who consent to the main cohort study will be included. As the LTMP is a new programme, the participation

rate is unknown, but is anticipated to be approximately 40% based on similar programmes. <sup>45,46</sup> To detect a weight change of 25% of initial weight loss at 6 and 12 months, 66 sub-study participants will be needed. This assumes a pre-post correlation of 0.7 between baseline measurement and two follow-up measurements and a mean initial weight loss of 7.9 kg, <sup>11</sup> allowing for a 10% attrition rate, with approximately 99% power and 5% significance (two-tailed). The participant experience qualitative study aims to interview 15–30 participants; however, the final number will be determined when data saturation has been reached. <sup>47</sup>

## Statistical analysis

Socio-demographic characteristics of participants will be analysed descriptively and presented as counts and proportions. We will test the socio-demographic representativeness of the main cohort sample compared to the general population and to the health-insured population<sup>3</sup> using chi-square analysis. Furthermore, Cronbach's alpha will be calculated to evaluate the internal consistency of reduced item psychosocial scales.

We will test the effect of time on primary and secondary outcomes using mixed models to account for repeated observations within individuals and compare the 6- and 12-month follow-up to baseline using post-estimation contrasts. Linear models will be used for continuous outcomes and generalised linear models for categorical outcomes. All models will be adjusted for demographic factors (age, gender, level of social disadvantage and residential location). Analyses will be conducted using SPSS Statistics 25 and SAS software version 9.4 using a threshold of p < 0.05 for statistical significance.

The transcribed interviews from the qualitative study will be imported into NVivo 11, coded and analysed to generate themes describing participants' experiences and perceptions of using the LTMP using an inductive approach.<sup>48</sup>

## **Discussion**

This article describes the design rationale and methodology for the evaluation framework used to assess the impact of a LTMP for weight loss and health benefits following an intensive lifestyle modification programme. Systematic evaluation of such an intervention can produce implementation evidence with strong practice and sustainability relevance (i.e. external validity) as well as evidence of effectiveness. If effective, the evaluation results will build evidence for embedding a weight loss maintenance phase into Australian private health insurance CDMPs, thus filling a gap in existing evaluation literature.

The LTMP is an intervention subject to commercial, time and budget constraints evident in the complex real-world context, and this pragmatic evaluation framework aims to assess the process of implementing the LTMP and its effectiveness. A review of effective weight loss maintenance

interventions identified a paucity of studies that assessed programme implementation and reported external validity factors, as well as highlighting the uncertainty of effectiveness of these interventions in the real world. 49 We have included outcomes beyond weight loss, as well as a process evaluation of the LTMP to ensure the consideration of contextual factors. Integrated into the evaluation framework, this will provide information that will add to the limited evidence base and can be used for programme improvement and enhancing participant engagement.

The LTMP conceptual framework (Figure 2) was useful in presenting the complexity of programme components, which needed to be flexible enough to allow the HWFL team to tailor the programme to suit each individual participant. A pre–post evaluation design was deemed the most practical and appropriate to measure the implementation and impact of the LTMP. Although randomised controlled trials (RCTs) are considered the 'gold standard' of evaluation design, their use in real-world programme evaluation is not always practical or possible. A less rigid, yet still rigorous, research design such as that described here is better able to yield information that can be used to provide practice-based evidence of real-world programme effectiveness and implementation.<sup>23</sup>

Researchers, private health insurance and the service provider co-produced the evaluation framework for the LTMP. Such partnerships are important to evidence-based public health and can facilitate the evaluation of real-world interventions.<sup>50</sup> These collaborations which combine scientific rigour with a practice-based setting are often complex, with conflicting views between stakeholders and are therefore rare. 51,52 In the current case, although the LTMP service provider recognised the value of evaluation research, the constraints of everyday programme delivery and their reporting requirements posed some challenges to the evaluation development and measurement. The challenges related to blending evaluation needs into existing programme procedures to minimise the effect of the evaluation on programme delivery for both staff and participants. As such, the evaluation required flexibility on the part of the researchers and a design sensitive to the operational systems of the programme.<sup>53</sup> The sometimes-discordant views of those in partnership required negotiating what data were realistic to collect from participants in the practice context. For example, we had hoped that information that was additional to the usual LTMP selfreported data could be collected as part of data routinely collected during the LTMP. This was not feasible due to the time impost on service provider staff and data-system constraints. We therefore developed the independent sub-study to collect this data.

#### Strengths and limitations

Effective prevention of weight regain is important, with weight regain after weight loss a common trend.<sup>7</sup> It is worth noting that community-wide change in weight loss is unlikely

given that overweight and obesity rates have continued to increase over the last 15–20 years and as such, normative comparison will provide a useful reference for the interpretation of the results of this evaluation in the absence of a control group. Although the study design chosen is appropriate to the real-world setting, alternative evaluation designs include time series designs and the use of waiting list controls.

Evaluating the service delivery of the LTMP (e.g. whether the service provider adhered to an intervention plan or assessment of whether all intervention components were delivered or not) is not included in our evaluation questions, which is a limitation. As only those who consent to sub-study participation are included, self-selection bias is possible. We will however compare the sub-study participant characteristics with the main cohort study. While self-reported body weight and height could be considered a limitation of this study, a validation study among mid-older Australians found that these measures were valid when calculating BMI used to classify weight according to low, healthy, overweight and obese weight individuals.54 Although underestimation of body weight is common, this bias has reduced in recent times possibly due to increased social acceptance of overweight and obesity.55

## **Conclusion**

This study provides a valuable opportunity to evaluate the effectiveness and implementation of an intervention delivered directly to the intended population. A co-production approach was necessary in creating the evaluation framework which yields real-world effectiveness application and the ability to influence ongoing implementation improvement for weight loss maintenance. Developed away from a purely research-driven context, this pragmatic evaluation framework addresses both impact and process outcomes for the LTMP, and importantly its implementation. The results will add to the evidence base of weight loss maintenance programmes delivered by private health insurers who have an increasing role in CDMP.

#### **Declaration of conflicting interests**

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: L.L. is the CEO and Scientific Director of Prima Health Solutions, which delivers the Healthy Weight for Life programme. The remaining authors have no conflicting interests to disclose.

### Ethical approval

Ethical approval for this study was obtained from the University of Sydney Human Research Ethics Committee (project no. 2017/760).

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Centre. B.M. is supported by a University Postgraduate Award at The University of Sydney.

#### Informed consent

Informed consent (as approved by the University of Sydney Human Research Ethics Committee) for this study is in two parts:

- Main cohort: verbal consent will be obtained from all participants by the programme service provider for the following:
  - Their de-identified data to be used for evaluation purposes.
  - To be contacted by researchers to provide additional information as part of the evaluation of the programme (i.e. sub-study).
- Sub-study: if verbal consent is provided to be contacted by researchers, when first contacted by researchers, written consent will be provided to take part in three telephone surveys.

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#### Supplemental material

Supplemental material for this article is available online.

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