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THE SCHOOL OF HEALTH SCIENCE, UNIVERSITY OF NEWCASTLE

PROJECT NO. 20662

# INVESTIGATING WEIGHT LOSS APPROACHES THROUGH A SYSTEMATIC LENS: ENGAGING WORKERS WITH OBESITY THROUGH A COORDINATED TREATMENT PATHWAY

## *THE COAL MINES WEIGHT LOSS TRIAL*


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## GLOSSARY

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| **BMI** | Body mass index (BMI) is the international index of weight-for-height that is commonly used to classify overweight and obesity in adults. It is defined as a person's weight in kilograms divided by height in metres squared (kg/$m^2$). A person with a BMI of 25 or greater is classified as Overweight, and 30 or greater as Obese. |
| **CON** | Control group (Standard Care) |
| **CS** | Coal Services |
| **CSH** | Coal Services Health |
| **HMRI** | Hunter Medical Research Institute |
| **HWI** | Healthy Weight Initiative Program |
| **ICC** | Intra -class correlation |
| **IQR** | Inter-quartile range (95% of all values fall within this range) |
| **MR** | Meal Replacement |
| **GP** | General Practitioner or General Practice |

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## EXECUTIVE SUMMARY

Obesity is a growing concern in the New South Wales (NSW) coal mining industry, with recent data indicating that 87% of workers are overweight or obese, a figure significantly higher than the national average (66%), and up from 83% a decade ago. This trend poses serious health and safety risks, including increased absenteeism, reduced productivity, and higher rates of injury and illness. In response, this study conducted by the University of Newcastle, aimed to evaluate the effectiveness of two structured weight loss interventions: the Healthy Weight Initiative (HWI) program and Meal Replacements, compared to Standard Care (medical referral pathway).

**Rationale for the Study**

The NSW coal mining industry traditionally focuses on obesity through the lens of safety and injury prevention, with less emphasis on chronic health conditions. Given the rising rates of obesity and its associated risks, there is a pressing need to explore effective, evidence-based interventions tailored to the unique demands of the coal mining workforce. This study was designed to assess whether the Healthy Weight Initiative program or Meal Replacements could offer better outcomes than the existing medical referral pathway for coal mine workers with obesity, and to identify factors influencing intervention success.

**Aim**

The primary aim of this study was to assess the effectiveness of two 12-week weight loss interventions— i) the Healthy Weight Initiative (HWI) program and ii) Meal Replacements—among coal mine workers with obesity (BMI ≥ 30 kg/m²). In addition, the study also compared their effectiveness to Standard Care, which typically involves referral to a general practitioner. The research also explored whether individual worker characteristics, such as age, gender, or job location (above or below ground), influenced the effectiveness of the interventions. The study focused on a range of health outcomes, including changes in weight, waist circumference, blood pressure, diet quality, and quality of life, to determine whether either intervention offered measurable advantages over the current standard care approach.

**Methods**

This was a three-arm, randomised controlled trial involving 119 participants recruited from the NSW coal mining workforce. Participants were randomly assigned to one of three groups: HWI (n=40), Meal Replacements (n=39), or Standard Care (n=40). Interventions lasted 12 weeks, with follow-up assessments at 12 weeks and 6 months.

- **HWI**: A structured 12 session lifestyle modification program delivered by trained allied health professionals employed by Coal Services Health (CS Health), focusing on nutrition, exercise, and behaviour change. The program was delivered either face-to-face at CS Health offices or through one-on-one online sessions, depending on participant availability and preference.
- **Meal Replacements**: Participants were asked to replace two meals and/or snacks per day using a commercially available product (The Man/Lady Shake).
- **Standard Care**: Current Cardiovascular risk management guidelines for the NSW coal industry include referral of workers with a BMI of ≥ 30kg/m$^2$ (identified at Order 43 medicals) to their GP for management. It was therefore anticipated that participants in this trial were likely to

have been referred to their GP following their most recent Order 43 medical. Participants were asked to review the weight loss resources provided (via website links and QR codes) at their Order 43 medical, and if they were seeing their GP as part of standard care, they were also encouraged to discuss weight loss options with their GP.

The primary outcome measured in the trial was body weight. Secondary outcomes included waist circumference, blood pressure, diet quality, and quality of life. Data were analysed using mixed-effects regression models.

**Key Findings**

Healthy Weight Initiative compared to Meal Replacements and Standard Care.

- **Weight Loss**: Both HWI and Meal Replacement participants lost more weight on average at 12 weeks compared to those in Standard Care, however the differences were not statistically significant.
- **Waist Circumference**: HWI participants had a significantly greater reduction in waist circumference at 12 weeks compared to Standard Care.
- **Blood Pressure**: HWI participants showed a significant reduction in systolic blood pressure at 12 weeks compared to both Meal Replacements and Standard Care.
- **Diet quality**: HWI participants had significantly improved diet quality scores at 12 weeks compared to both Meal Replacements and Standard Care.
- **Quality of life**: The HWI group reported significantly higher psychological well-being scores at both 12 weeks and 6 months compared to both Meal Replacements and Standard Care.

At 6 months there were no statistically significant differences between any of the groups for any other outcomes measures.

**Compliance**: HWI participants attended an average of 8 out of 12 sessions in the 12 week intervention period. Meal Replacements participants consumed just over half the number of shakes prescribed, indicating low adherence to the intervention.

**Worker Characteristics**: Preliminary analysis suggests that weight loss outcomes were consistent across gender, age groups, and job locations (surface or underground), indicating minimal variation in effectiveness based on these worker characteristics.

**Support**: Support was a key factor in successful weight loss, with Meal Replacement and Standard Care participants expressing a need for more structured guidance. While HWI participants valued the support received during the intervention period they noted that continued follow-up was important to sustain progress.

**Participant Feedback**: HWI participants reported higher satisfaction, better support, and greater confidence in maintaining weight loss than Meal Replacements and Standard Care. The Meal Replacement intervention was the preferred option for potential participants at pre-intervention screening, but many cited intolerance, boredom and lack of support in post intervention survey or interview. Standard care participants expressed dissatisfaction with the lack of structured guidance and GP referral mechanisms.

**Conclusion**

The Healthy Weight Initiative: This trial provides evidence that the HWI is an effective program for improving health outcomes among coal mine workers in NSW and should be considered for wider implementation. Overall, participants in the HWI program experienced superior health outcomes compared to those in other intervention arms and reported higher levels of satisfaction. However, sustaining these benefits beyond the 12-week program remains a challenge, highlighting the need for extended support.

The Meal Replacement strategy showed potential for short-term weight loss (self report) but lacked the behavioural support necessary for long-term success. Participants found the regimen difficult to maintain and reported limited improvements in diet quality and quality of life and was not better than Standard Care or the HWI.

Standard Care as currently implemented, demonstrated few effective outcomes. Many participants did not recall being referred to a GP following their most recent Order 43 medical, or did not follow through with appointments. The passive nature of this approach, relying on self-motivation and online resources, was insufficient for meaningful change.

**Future Recommendations**

Building on the insights gained from this trial, several key recommendations are proposed to enhance the effectiveness and sustainability of weight management strategies within the NSW coal mining industry:

1. **Expand the Healthy Weight Initiative (HWI) program**: Given the positive outcomes and high participant satisfaction, there is strong justification for encouraging increased uptake of the HWI program across industry. Extending support beyond the initial 12-week period could help participants maintain momentum and achieve longer-term health improvements. Ongoing engagement potentially up to 12 months may be beneficial.

2. **Develop integrated hybrid models**: Combining the initial appeal and simplicity of meal replacements with the structured guidance and behavioural support of programs like HWI could offer a more balanced and sustainable approach. This hybrid model could serve as a motivational “kick-start” followed by a transition into lifestyle-based strategies that promote lasting change, however further research is required.
3. **Strengthen GP referral pathways**: While GP referrals remain a key component of standard care, the study highlighted gaps in follow-through and weight loss support. Enhancing these pathways ensuring clear communication between Order 43 medical practitioners, workers and GPs could improve engagement and outcomes.
4. **Invest in tailored, evidence-based interventions**: The coal mining workforce has unique characteristics and challenges, including shift work, remote locations, and both sedentary and physically demanding roles. Any future interventions should be designed with these factors in mind, ensuring they are accessible, flexible, and culturally appropriate.
5. **Co-designing weight loss programs** with stakeholders would advantage the industry and increase the likelihood of success while providing appropriate support for the workforce. Continued investment in research and innovation will be essential to refine these approaches and ensure they meet the evolving needs of the workforce.

This trial provides a foundation for future research and policy development aimed at improving the health, safety and well-being of coal mine workers through structured, supportive, and sustainable weight management strategies.

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# 1. INTRODUCTION

This report presents the results of the project titled *Investigating weight loss approaches through a systematic lens: Engaging workers with obesity through a coordinated treatment pathway* (Health and Safety Grant Number 20662). The report describes the effectiveness of two weight loss interventions for individuals identified with Obesity Grade I, II or III during standard Coal Services Health screening. It examines relationships between intervention effectiveness and worker characteristics and compares outcomes with the current practice of GP referral for those identified with obesity.

## 1.1 CONTEXT

### 1.1.1 THE COAL MINING INDUSTRY

***Health and Safety Standards for Coal Mines in Australia***

The mining sector in Australia has always maintained a strong emphasis on safety and injury management and legislation exists to ensure the safety and health of coal mine workers. Within the occupational health and safety domain, there has been less consistency in approach to maintaining health of workers than for other areas.[1] In NSW, coal mine workers are governed by the Coal Industry Act 2001,[2] the Work Health and Safety Act 2011[3] and the Work Health and Safety Regulation 2017,[4] and under the Order 43 (Industry Health Scheme) are required to undergo a pre-placement medical assessment and periodic medical assessments every three years.[5] Order 43 health assessments screen for potential occupational health risks such as dust related respiratory diseases and also help to detect health issues that may impact a workers' ability to safely perform their role in the coal mine. This includes general health, cardiovascular health, and lifestyle factors such as weight and body mass index (BMI).[5, 6]

***Importance of Health and Wellbeing***

The World Health Organization defines health as a "state of complete physical, mental and social well-being and not merely the absence of disease or infirmity".[7] Ensuring the health of workers in the coal mining industry contributes significantly to the long-term sustainability of mining operations.[8] Prioritisation of the health of workers has been shown to result in the cultivation of safer, more productive and sustainable working environments.[8] Research has shown that when workers are healthy, they are at a reduced risk for illness and injury, are more productive and efficient, and have higher morale and job satisfaction than workers who are not healthy.[8]

***Importance of Weight Management***

Obesity, high blood pressure and increased waist circumference are associated with increased cardiovascular risk. In the NSW coal mining industry, measurements of cardiovascular risk factors including body weight are required at recruitment and periodically throughout employment.[9] Under the current CS Health CVD Risk Guidelines,[10] NSW coal mine workers identified as having a body mass index (BMI) between 30 kg/m$^2$ and 49kg/m$^2$, or weight >120kg, may be referred to their GP for medical management, including dietary and exercise advice, where appropriate. Workers with BMI greater than 50kg/m$^2$, in safety critical roles, are additionally deemed temporarily unfit for their current role until further medical investigations and management has occurred.[10]

## 1.2 RATIONALE

### 1.2.1 THE PROBLEM

***Increasing Overweight and Obesity in the NSW Coal Mining Industry***

Obesity remains a significant health concern in the NSW coal industry. Rates of overweight and obesity among NSW coal mine workers are notably higher than national averages, with 87% of the workforce being overweight (39.6%) or obese (47.4%)[11] compared with 34% (overweight) and 32% (obese) nationally.[12] These values have increased substantially since 2012-2014, when workforce data showed an overall rate for overweight and obesity of 83.4%.[1] Factors thought to be contributing to these high rates of overweight and obesity include shift work,[13] lower consumption of fruit and vegetables, compared to the general population, the sedentary nature of some mining roles and a culture of episodic hazardous drinking.[8] Workers classified as obese have higher rates of absenteeism and presenteeism, reduced productivity, increased risk of fatigue, and increased risk of injury and illness (with a slower recovery rate).[1] This results in increased workers' compensation costs, and increased risk of disability and death.[1]

***Effectiveness of Health Promotion Initiatives within the NSW Coal Mining Industry***

The aim of health promotion activities in the mining industry is to create a workplace that prioritises worker longevity, physical and mental health, and a place where coal mine workers can thrive.[14] There have been limited workplace health promotion initiatives previously trialled in the NSW coal mining industry targeting overweight and obesity.[1, 15, 16] Further research to determine the effectiveness of workplace health promotion initiatives, particularly those relating to weight management, given increasing overweight and obesity rates, may be beneficial.

### 1.2.2 THE SOLUTION

***Determining the Effectiveness of Weight Management Initiatives in NSW Coal Mine Workers***

Obesity is one of the main priority health areas for investment for the NSW coal mining industry, alongside respiratory health and mental health.[17, 18] Effective weight management has potential for significant benefit.[1] Exploring approaches to manage excessive weight at the time of identification could help improve individual outcomes for coal mine workers who are overweight or obese. However, it is crucial to evaluate weight loss services in the coal mining context to match at-risk individuals with appropriate services and programs that meet their specific health needs.[1] This research trial investigated two different weight management approaches for workers in the NSW coal mining industry, and compared them with current practice (Standard Care). The Healthy Weight Initiative program (HWI) described below, has been consistently offered to workers by CS Health since 2021. Meal replacements have become popular in recent years and are potentially a suitable weight loss option for coal mine workers, and therefore worth investigating for their feasibility and effectiveness.

### *i) Healthy Weight Initiative (HWI)*

The HWI is a commercial 12-session supported weight management and lifestyle modification program that was designed by the Hunter New England and Central Coast Primary Health Network.[19] The program focusses on personalised goal setting, and provides participants with nutrition, exercise and lifestyle advice and resources to help people to achieve their health goals and maintain positive lifestyle changes.[19] The focus on nutrition highlights the importance of diet quality in relation to the impact of weight loss interventions.[20]

The program was initially piloted in GP practices, with outcome data showing that it was successful in supporting participants to lose weight.[19] Following this, CS Health started delivering the HWI program to NSW coal mine workers, however there has been variability in uptake and level of engagement. While reported CS Health outcome data (including weight and waist circumference) has been positive, its effectiveness in this population has not been extensively evaluated.

### *ii) Meal Replacements*

Meal replacements in the form of shakes have been shown to be successful in the promotion of weight loss in overweight and obese adults.[21-23] In particular, meal replacements have been noted for their role in 'kick starting' weight loss, providing motivation for further weight management.[24] It has been suggested that meal replacements could potentially be a mechanism to assist in weight loss among coal mine workers, however no evidence of their utility in the mining industry has been established.[25]

### *iii) Standard Care*

Currently, NSW coal mine workers identified as having a BMI between 30 and 49 kg/$m^2$ or a weight greater than 120 kg at a medical assessment are: (i) referred to their GP for medical management, including dietary and exercise advice where appropriate, and (ii) provided with a written resource containing website links and QR codes directing them to a range of services and information to assist in improving their health. The worker is responsible for making an appointment with the GP to discuss the ongoing management of any identified health issues. While it is expected that GPs establish medical management plans with the worker to assist them in losing weight, no specific advice is given to GPs about how best to support workers, and there is no requirement for GPs to report progress with weight management back to CS Health. Research indicates that comprehensive weight management plans with regular follow-ups and personalised advice led by GPs can be effective in achieving significant weight loss and improving health outcomes.[19, 26]

## 1.3 PROJECT AIMS

I. Assess the effectiveness of weight loss interventions for workers identified with Obesity Grade I, II or III (BMI ≥ 30kg/$m^2$) during periodic (Order 43) medicals.

II. Compare current practice of referring workers with a BMI ≥ 30kg/$m^2$ to their GP for management with alternative treatment strategies.

III. Identify relationships between treatment effectiveness and worker characteristics.

## 1.4 RESEARCH QUESTIONS

For coal mine workers identified with obesity (BMI ≥30 kg/$m^2$) in the NSW Coal Mining industry:

1. Are 12-weeks of either i) a meal replacement program or ii) a commercial weight management and lifestyle modification program (The Healthy Weight Initiative) effective weight loss interventions?
2. Is either i) a meal replacement program or ii) the Healthy Weight Initiative program more effective than the current medical referral practice in lowering weight, waist circumference, and blood pressure and in improving diet quality, or quality of life?
3. Are there any relationships between treatment effectiveness and worker characteristics?

# 2. METHODS AND MATERIALS

## 2.1 STUDY DESIGN

This study was a 3-arm assessor-blinded randomised controlled trial (RCT), designed to assess the effectiveness of two weight loss interventions for coal mine workers with obesity (BMI ≥ 30 kg/m$^2$) and to compare these with Standard Care. Participants were randomly assigned to one of three groups: two treatment arms (Meal Replacement or Healthy Weight Initiative) and a control arm (Standard Care). Each intervention was delivered over a 12-week period, with follow-up assessments at 12 weeks and 6 months.

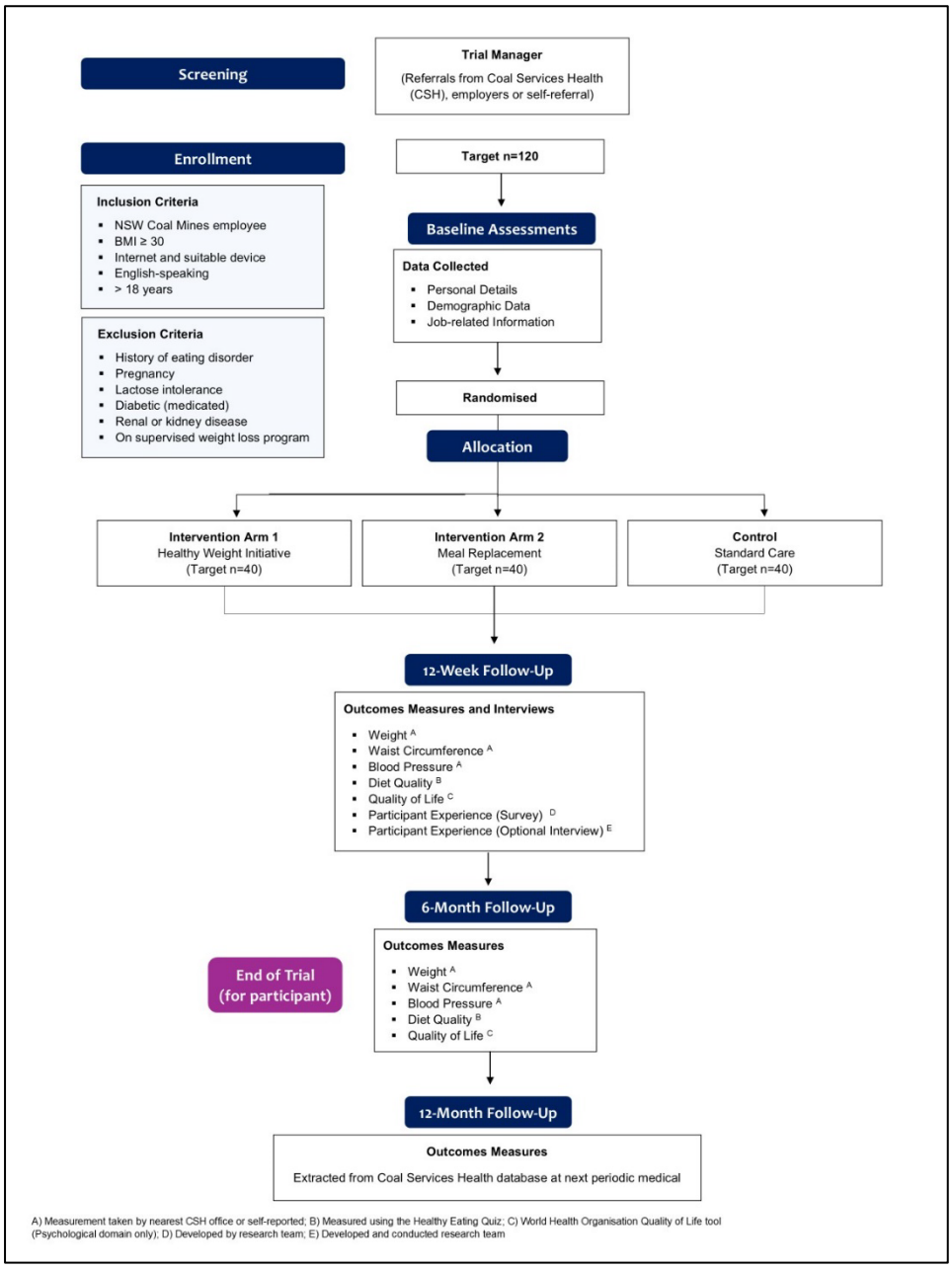


**Figure 1.** Study outline.

## 2.2 ETHICS

This study was approved by the University of Newcastle Ethics Committee Reference No: H-2023-0289 (06/09/2023). All participants were provided with written information about the study aims and gave informed consent.

## 2.3 PARTICIPANTS AND RECRUITMENT

Study participants were current coal mine workers in the NSW coal mining industry recruited between October 2023 and July 2024. Workers were informed of the study by either i) flyers distributed by CS Health nursing staff to workers during Order 43 periodic medicals, ii) flyers distributed by CS Health via the Coal Services website and social media, industry forums and email communication to employers and other industry stakeholders, or iii) word of mouth. Interested workers could self-refer to the trial manager.

CS Health nursing staff identified eligible workers (BMI ≥ 30 kg/$m^2$) during periodic medicals, discussed the trial with those interested, and provided written study information (Participant information sheet (PIS) and Consent Form). Contact details of consenting workers were then forwarded to the trial manager. Workers were given 24-48 hours to consider participation, with the option to contact the trial manager for additional information. Self-referred workers who responded to flyers, were emailed the PIS and Consent Form, and after 48 hours, were asked to confirm their decision to proceed via verbal or email confirmation, or by providing online consent. All potential participants, including those who self-referred, were screened for eligibility by the trial manager.

Eligibility criteria for inclusion: BMI ≥30 kg/$m^2$; access to the internet and a suitable device for video conferencing; a valid email address; the ability to speak conversational English; age >18 years. Exclusion criteria included a self-reported history of eating disorders; pregnancy or plans for pregnancy during the trial; lactose intolerance; use of prescription diabetes medication; kidney disease; participation in another weight loss program during the study period, or regular use of meal replacement products.

Following baseline assessment via an online survey, participants were randomly assigned to one of three groups, with 40 participants enrolled in the Healthy Weight Initiative and Standard Care groups, and 39 in the Meal Replacement group.

## 2.4 INTERVENTIONS

Each intervention was delivered over a 12-week period, with follow-up assessments at 12 weeks and 6 months.

### 2.4.1 HEALTHY WEIGHT INITIATIVE (HWI)

Participants received a commercially available program delivered by Coal Services Allied Health staff. Staff were accredited allied health professionals, such as physiotherapists, exercise physiologists, or occupational therapists who had been trained by experienced CS Health staff to deliver the program. The Healthy Weight Initiative (HWI) is a weight management and lifestyle modification program developed by the NSW Hunter New England and Central Coast Primary Health Network. It provides

guidance on nutrition, exercise, and behaviour change strategies. Initially piloted in GP practices, it has demonstrated effectiveness in helping participants achieve weight loss[19]. The program emphasises personalised goal setting and provides participants with resources and guidance on nutrition, exercise, and lifestyle changes to support long-term health improvements. The program consists of 12 sessions, typically held weekly, however the frequency could be adjusted based on participant availability or health status. The first and last sessions take approximately 60 minutes to complete, while the remaining sessions are shorter in duration taking approximately 30 minutes. Participants could attend sessions in person at a Coal Services (CS) office (either Lithgow, Mudgee, Speers Point (Newcastle), Singleton, Woonona or Gunnedah), or could choose a combination of face-to-face and online sessions. Weight, waist circumference and blood pressure measurements were taken during the first and any subsequent face-to-face sessions where possible. The number of sessions attended during the 12-week intervention period was tracked, and compliance based on attendance. Participants also attended a 6-month follow up appointment.

### 2.4.2 MEAL REPLACEMENTS

Anecdotally, some coal mine workers have reported using commercially available meal replacement shakes for weight loss, specifically mentioning The Man Shake and The Lady Shake by Cranky Health Pty Ltd. These products are extensively advertised throughout NSW, with marketing that emphasises their convenience, simplicity, and effectiveness, appealing to those who may not be interested in traditional weight loss products. [22] Due to the high brand recognition, popularity with men, competitive pricing, availability and access, and comparative nutritional content with other health category meal replacements, The Man and Lady Shakes were selected as the Meal Replacements for the trial. The Man and Lady Shake are available in a variety of flavours, and according to the manufacturer contain high-quality whey protein, low GI carbohydrates, fibre, [25] vitamins and minerals, and contain 871 kJ per serving.[23]

Participants were asked to select their preferred flavours and their preference for Man or Lady Shakes, and efforts were made to provide the requested options. A 12-week supply of shakes powder were home-delivered by Australia Post. Participants were instructed to consume two shakes per day for 12 weeks, with each shake replacing either a meal or a snack. Participants were instructed to mix one 56 gram scoop of Man or Lady Shake with water or milk to make each shake. Links to sample meal plans from the Man Shakes website www.themanshake.com.au and a copy of The Man Shake Guide the-man-shake-guide.pdf were also provided via email.

Participants were also emailed a tracking form to record the number of shakes consumed and were asked at the 12-week assessment how many shakes they had consumed during the 12-week intervention period and/or how much product remained. Compliance with the intervention was assessed by the number of shakes consumed.

### 2.4.3 STANDARD CARE

The control group received standard care for a 12 week period. While standard care relates to a range of health assessments in the NSW coal mining industry, for obesity, standard care is determined by BMI assessed during Order 43 medicals. For workers with BMI ≥ 30 kg/m$^2$ this typically includes referral to a GP for medical management. Additionally, participants receive a

summary of their health assessment results from CS Health, which includes links and QR codes to various resources aimed at improving their health. These resources include the "Get Healthy Coaching Service," https://www.gethealthynsw.com.au/, the Eat for Health/Australian Guide to Healthy Eating website https://www.eatforhealth.gov.au/, and the Nutrition Australia website https://nutritionaustralia.org . These educational resources were also emailed to participants randomised to this group.

After six months, participants in the control group were offered the option to receive one of the interventions: either 12 weeks of Meal Replacement shakes or enrolment in the Healthy Weight Initiative program delivered by Coal Services Allied Health staff however participant progress was not evaluated as part of this trial.

## 2.5 DEMOGRAPHIC DATA

Baseline demographic data were collected from consenting participants either from the CS Health medical records database or via an online questionnaire. Study data were collected and managed using REDCap[27, 28] electronic data capture tools hosted at Huter Medical Research Institute (HMRI). This included personal details such as name, date of birth, phone number, and email. Demographic data also included gender at birth, ethnicity, education level, cardiovascular risk score[29, 30] smoking status and alcohol risk score.[31] Additionally, job-related information was gathered, including the participant's role, job classification (including similar exposure group (SEG), work location, shift details, and travel distance to work.

## 2.6 OUTCOME MEASURES

Outcome measures were assessed at 12 weeks and at 6 months. The primary outcome for the study was weight (kg) at the 12-week follow-up. Secondary outcomes included waist circumference (cm) and systolic and diastolic blood pressure (mmHg), diet quality and quality of life.

Baseline measurements for weight, waist circumference, and blood pressure were collected from participants who consented, either during their initial HWI program appointment (for those randomised to the HWI trial arm) or from the CS Health database (HA2) if their most recent periodic medical was less than three months prior to screening. Remaining participants self-reported this data; the trial manager provided instructions on how to self-measure these variables, and participants were emailed guidelines for measuring weight, waist circumference, and blood pressure (see Appendix 1 for more detail).

Follow-up measures for HWI participants were those obtained closest to the 12-week and 6-month marks. Participants in the Meal Replacement and Standard Care groups whose baseline measures were obtained from the CS Health medical database were asked to attend follow-up appointments at 12 weeks and at 6 months. If attending appointments was not possible, participants were asked to self-report their measurements (see details above). Participants who self-reported at baseline were encouraged to self-report throughout the study using the same equipment each time. Only measurements within 6 weeks of the expected follow-up time were included in the analysis.

Diet quality (Healthy Eating Quiz[32]) and Quality of life (QoL) (WHOQOL- BREF Australian Version[33]) (May 2000) were assessed via online surveys at each assessment.

An online feedback survey was also conducted at 12 weeks, and semi-structured interviews were conducted after the 6-month follow up assessment with a selection of participants to gather in-depth feedback on their experiences during the intervention arms. At the time of this report appropriate qualitative analysis was not undertaken (so methodology not reported).

## 2.7 RANDOMISATION

After completing the baseline assessment, participants were randomly assigned to one of three intervention groups using permuted block randomisation and stratified by age and primary job location (surface or underground).

## 2.8 SAMPLE SIZE

Sample size estimation indicated that 120 participants would provide 80% power to detect a difference between at least two of the arms of the trial with a significance level of 5% (Type 1 error rate). This calculation assumed a medium effect size (Cohen's F = 0.3) and accounted for a 20% follow-up attrition rate.

## 2.9 STATISTICAL ANALYSIS

Descriptive statistics are presented as means and standard deviations or medians and interquartile ranges (IQR) for continuous variables and number and percentages for categorical variables. Time from baseline is presented as a mean and range.

To check if weight, waist, and blood pressure measurements from different sources showed good agreement, the average differences between paired measurements were compared and the Pearson correlation coefficient was calculated. The intraclass correlation coefficient (ICC) was used to assess agreement between all three sources, using a two-way random effects model. All measurements were included in the analysis, regardless of when they were collected.

All outcomes were modelled using mixed effects regression models, which included fixed effects for treatment arm (Standard Care, Meal Replacements or Healthy Weight Initiative), time (categorical; baseline, 12 weeks and 6 months), the interaction between treatment and time, strata (above or below ground), and participants age at baseline, and a random intercept for participant to account for repeated measures over time. Weight, waist circumference and the psychological domain of the WHOQOL-BREF were modelled using linear mixed effects regression models with the 'lmer' function from the 'lme4' package.[34] Due to heteroskedasticity in linear models, systolic and diastolic blood pressure and the Healthy Eating Quiz total scores were modelled using ordinal mixed effects regression models with the 'clmm' function from the 'ordinal' package.[34, 35] These models were fitted with adaptive Gauss-Hermite quadrature with 3 quadrature points. Type III p-values for the interaction terms are presented in addition to pairwise differences between the estimated marginal means of each treatment group at each follow-up point, and the difference in change from baseline, calculated using the 'emmeans' package.[36]

Mixed models are consistent with the intention-to-treat principle, assuming data are missing at random, and all randomized participants have a least one measurement at any time. All participants had completed the baseline survey and had scores for Quality of life and the Healthy Eating Quiz. One participant (0.8%) had no measurements for weight and waist circumference and nine participants (7.6%) had no blood pressure measurements at any time. Due to the low amount of missingness, baseline measurements were imputed for these participants using mean imputation.

P-values less than 0.05 were considered statistically significant. The type III p-value for the interaction term from the weight model was considered the primary outcome. All further analyses were considered secondary, and no adjustments were made to p-values. All analyses were performed in R version 4.4.25.

# 3. RESULTS

## 3.1 FLOW OF PARTICIPANTS THROUGH THE TRIAL

Three hundred and fifty-two workers expressed interest in the trial and 119 were subsequently enrolled. Of the 119 participants, 26 (22%) were referred by CHS nursing staff, while the remaining 93 (78%) were self-referred. Figure 2 illustrates the flow of participants through the trial. Six participants withdrew prior to week 12. Eighty-three (60%) completed all or some follow-up assessments at 12 weeks, and 63 (49%) at 6 months. All data available by 30/01/25 was in this analysis.

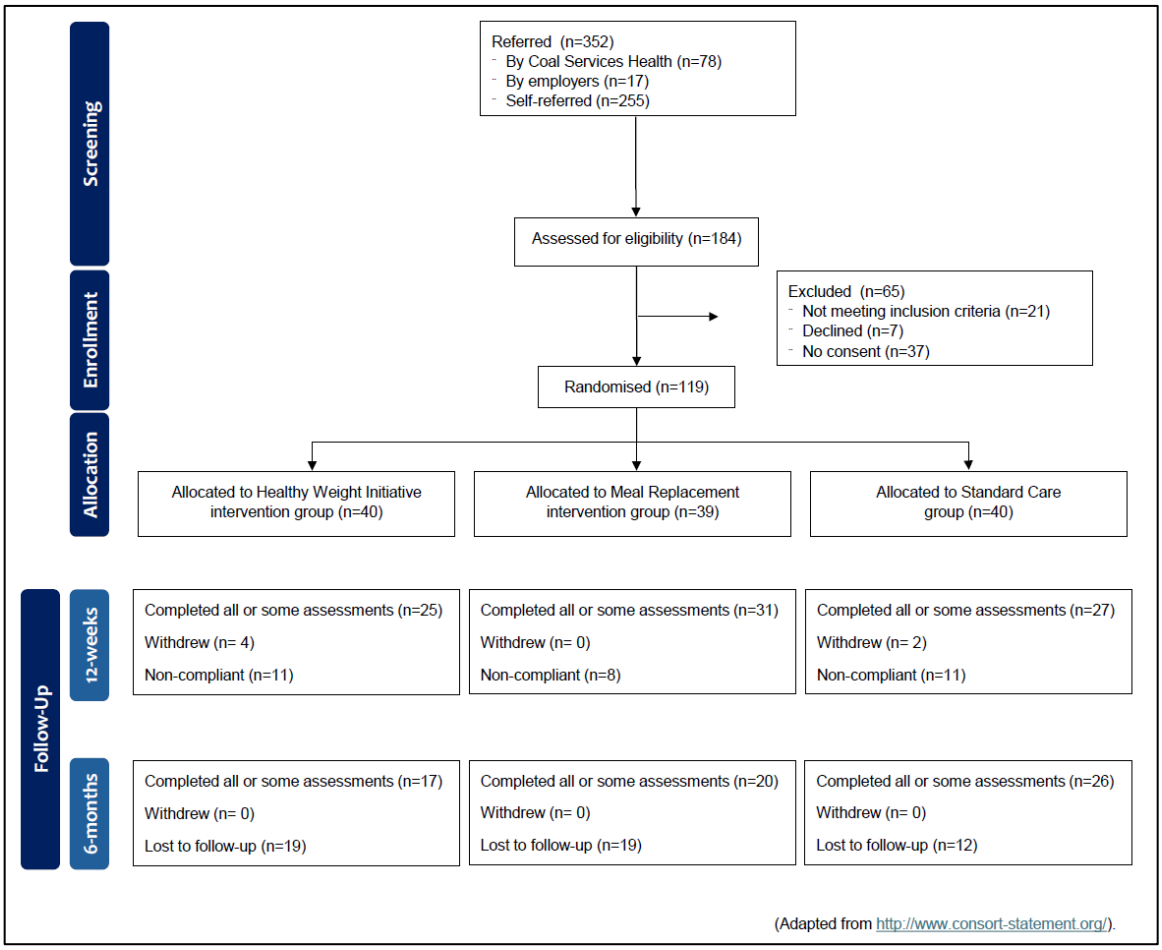


**Figure 2.** Flow of participants through the trial.

## 3.2 PARTICIPANT CHARACTERISTICS

Participant characteristics at baseline are summarized in Table 1. Job classifications are summarised in Appendix 2. The median BMI was 35.6 (IQR 33.4 – 39.7) kg/m$^2$ classified as Grade II Obesity. Most (94%) were low risk for cardiovascular disease (<5% in the CVD risk score) at their most recent periodic medical.

The study population was a reasonable representation of the current coal mining workforce in NSW,[11] however there was a higher percentage of females (18% vs. 9%) and a lower median age (42 years, IQR 36-50). The study sample also had a higher representation of people identifying as Caucasian (86% vs. 80%) and Aboriginal and/or Torres Strait Islander (6% vs. 0.7%) compared with the current coal mining workforce. Seventy-eight percent of participants reported that they worked predominantly above ground compared with 69% of the current workforce. Sixteen percent of the study population reported living away from home for work and 67% reported that they were shift workers. Participants reported a median commute of 50 km or 70 minutes.

**Table 1**. Participant Characteristics at baseline.

| **Characteristic** | **Overall** (n = 119) | **Standard Care** (n = 40) | **Meal Replacements** (n = 39) | **Healthy Weight Initiative** (n = 40) |
|---|---|---|---|---|
| **Age at Screening**, Median (IQR) | 42 (36 - 50) | 39 (35 - 47) | 44 (37 - 51) | 43 (36 - 51) |
| **Gender,** n (%) | | | | |
| Female | 21 (18) | 7 (18) | 6 (15) | 8 (20) |
| Male | 98 (82) | 33 (83) | 33 (85) | 32 (80) |
| **Ethnicity** | | | | |
| Aboriginal and/or Torres Strait Islander, n (%) | 6 (5.0) | 2 (5.0) | 3 (7.7) | 1 (2.5) |
| Caucasian, n (%) | 95 (80) | 30 (75) | 33 (85) | 32 (80) |
| Other ethnicity, n (%) | 4 (3.4) | 3 (7.5) | 1 (2.6) | 0 (0) |
| **Highest level of education completed,** n (%) | | | | |
| No formal qualifications | 2 (1.7) | 0 (0) | 1 (2.6) | 1 (2.5) |
| School or Intermediate Certificate (or equivalent) | 6 (5.0) | 3 (7.5) | 0 (0) | 3 (7.5) |
| High School or Leaving Certificate (or equivalent) | 25 (21) | 6 (15) | 10 (26) | 9 (23) |
| Trade/apprenticeship | 36 (30) | 11 (28) | 13 (33) | 12 (30) |
| Certificate/diploma | 36 (30) | 13 (33) | 11 (28) | 12 (30) |
| University Degree (Bachelor) | 9 (7.6) | 5 (13) | 1 (2.6) | 3 (7.5) |
| Higher University degree (e.g. Grad Dip, Masters, PhD) | 5 (4.2) | 2 (5.0) | 3 (7.7) | 0 (0) |
| **Current smoker,** n (%) | | | | |

| Characteristic | Overall (n = 119) | Standard Care (n = 40) | Meal Replacements (n = 39) | Healthy Weight Initiative (n = 40) |
|---|---|---|---|---|
| No | 111 (93) | 36 (90) | 38 (97) | 37 (93) |
| Yes | 7 (5.9) | 3 (7.5) | 1 (2.6) | 3 (7.5) |
| Not recorded | 1 (0.8) | 1 (2.5) | 0 (0) | 0 (0) |
| **Alcohol Use Disorders Test (AUDIT) score,** Median (IQR) | 3.0 (1.0 – 5.0) | 4.0 (2.0 – 6.0) | 3.0 (1.0 – 5.0) | 2.0 (0.0 – 4.0) |
| Unknown (n) | 10 | 2 | 4 | 4 |
| **CVD Risk Score**, n (%) | | | | |
| <5% - Low Risk | 90 (94) | 33 (100) | 29 (88) | 28 (93) |
| 5-<10% - Intermediate risk | 5 (5.2) | 0 (0) | 4 (12) | 1 (3.3) |
| ≥10%- High Risk | 1 (1.0) | 0 (0) | 0 (0) | 1 (3.3) |
| Unknown | 23 | 7 | 6 | 10 |
| **BMI (kg/m²),** Median (IQR) | 35.6 (33.4 – 39.7) | 34.6 (32.2 – 36.8) | 35.4 (33.7 – 38.1) | 36.9 (33.6 – 40.2) |
| Unknown, (n) | 6 | 4 | 2 | 0 |
| **Shift worker**, n (%) | 67 (56) | 22 (55) | 23 (59) | 22 (55) |
| **Lives away from home to work**, n (%) | 16 (13) | 5 (13) | 5 (13) | 6 (15) |
| **Commute length** (km), Median (IQR) | 50 (25 – 77) | 50 (35 – 100) | 35 (20 – 55) | 50 (18 – 77) |
| Unknown, (n) | 3 | 3 | 0 | 0 |
| **Commute time** (minutes), Median (IQR) | 70 (40 – 80) | 73 (65 – 80) | 70 (30 – 90) | 72 (53 – 85) |
| Unknown. (n) | 78 | 28 | 22 | 28 |
| **Job location**, n (%) | | | | |
| Underground | 26 (22) | 9 (23) | 8 (21) | 9 (23) |
| Surface | 93 (78) | 31 (78) | 31 (79) | 31 (78) |

## 3.3 MEASUREMENT SOURCES

The original intent in this trial was to obtain all measurements of weight, waist circumference and blood pressure from CS Health, either from the CS Health database, or from HWI data for participants randomised to this group. Due to the unanticipated large number of workers who self-

referred, and/or had not had a recent medical, measurements for some participants were allowed to be self-reported. While HWI and CS Health measures were prioritised for inclusion in this report, as some participants with CS Health data available also self-reported, we were able compare the accuracy of the self-reported data.

The agreement between measurements and the correlation between sources is included in Appendix 3 (Table 1). Self-reported weight was on average 2kg higher than that from CS Health medicals and 0.7kg lower than HWI. CS Health measured weight was on average 2.5kg lower than HWI. Despite the difference in these averages, the intraclass correlation between all three sources was excellent (r=0.95) suggesting excellent agreement between sources and we are therefore confident that for self-report participants who used the same method each time (e.g. same scales) any changes seen in these results are valid.

Waist measurements had high correlation and good agreement across all sources. Systolic blood pressure had high correlation and good agreement, whereas the agreement between diastolic blood pressure from different sources was poor, suggesting the measurements were highly dependent on the source.

The source of measurements by treatment group is summarised in Appendix 3 (Tables 2-3). HWI measurements were prioritised, and CS Health baseline measurements taken more than 3 months prior to screening were excluded from the analysis for this report.

## 3.4 FOLLOW-UP TIMES FOR PRIMARY OUTCOME

The mean follow-up time for weight measurements at the 12-week time point was 12.3 weeks and ranged from 6 to 17.9 weeks from the start of the intervention. The mean 6-month follow-up time was 26.9 weeks and ranged from 21.3 to 31.7 weeks.

## 3.5 COMPLIANCE WITH INTERVENTIONS

### 3.5.1 HEALTHY WEIGHT INITIATIVE (HWI)

Data from this group included measurements taken at the initial HWI session (baseline) and at the session attended closest in time to 12 weeks after baseline, provided it occurred a minimum of 6 weeks after baseline. Participants attended a mean (SD) of 8.1 (3.1) (range 2 to 12) sessions. Only 2 participants attended all 12 sessions in the allotted 12 weeks. Participants were encouraged to continue to attend all remaining sessions, however any further progress or measurements are not reported here.

### 3.5.2 MEAL REPLACEMENTS

During the 12-week online assessment, compliance with the meal replacement intervention was self-reported. Full compliance required consumption of 14 shakes per week, or 168 shakes throughout the entire period. Out of 39 participants, 28 provided information on their meal replacement intake. On average, they consumed 8.2 (SD 3.2) shakes per week (or 1.2 shakes/day) and 90.2 (SD 47.7) shakes over the 12 weeks of the intervention.

### 3.5.3 STANDARD CARE

The standard care group was not asked specifically whether they attended a GP appointment or accessed any of the resources provided to them during the 12-week intervention period, therefore level of compliance in this group was not assessed.

## 3.6 ADVERSE EVENTS

Three adverse events were reported to the trial manager by participants in the meal replacement group. All events were classified as non-serious and mild. Although these events were related to the intervention, they were not unexpected effects of the treatment. Two participants reported gastrointestinal upsets. One participant chose to reduce their intake to one shake per day after discussing symptoms with the chief investigator and the second stopped taking Man Shakes because they caused stomach upset and hunger throughout the day. The third participant reported being sick throughout the trial due to an unrelated illness and was unable to tolerate the meal replacement shakes. No adverse events were reported by participants in the HWI or Standard Care groups.

## 3.7 RESEARCH FINDINGS

### 3.7.1 EFFECTIVENESS OF INTERVENTIONS

*"Are 12-weeks of either i) a meal replacement program or ii) a commercial weight management and lifestyle modification program (The Healthy Weight Initiative) effective weight loss interventions?"*

Effectiveness is determined by examining the average amount of weight lost for each intervention. The means and standard deviations (SD) for each outcome in each group at 12 weeks and 6 months are shown in Table 2. The table summarises data from participants for whom data was available at the time this report was written. Approximately 70% of participants at 12 weeks, and 50% at 6 months had data available for most outcome variables. As the data is incomplete, no inferences can be made about the effectiveness of the interventions. The sample size study was insufficient to test whether differences from baseline to 12 weeks or from baseline to 6 months were statistically significant.

**Table 2.** Means and standard deviations for each outcome are reported by group and time point. The number of participants with weight measurements by group is also included.

| | | Baseline | | 12 weeks | | 6 months | |
|---|---|---|---|---|---|---|---|
| **Outcome** | **Group** | **N** | **Mean (SD)** | **N** | **Mean (SD)** | **N** | **Mean (SD)** |
| **Weight** (kg) | Standard care | 36 | 110.1 (15.8) | 25 | 111.4 (19.2) | 23 | 105.3 (17.3) |
| | Meal replacements | 37 | 114.3 (17.4) | 31 | 112.0 (17.6) | 14 | 108.2 (15.2) |
| | Healthy Weight Initiative | 40 | 119.0 (19.7) | 33 | 115.6 (21.6) | 17 | 104.2 (13.5) |
| **Waist** (cm) | Standard care | 35 | 114.5 (11.4) | 24 | 115.4 (15.2) | 24 | 110.8 (12.3) |
| | Meal replacements | 37 | 116.6 (11.4) | 31 | 114.4 (13.9) | 14 | 110.6 (11.6) |
| | Healthy Weight Initiative | 40 | 120.4 (11.6) | 33 | 115.3 (13.5) | 17 | 107.9 (10.5) |
| **Systolic blood pressure** (mmHg) | Standard care | 32 | 131.3 (10.8) | 18 | 128.9 (11.0) | 19 | 125.2 (15.2) |
| | Meal replacements | 36 | 128.6 (10.9) | 28 | 127.8 (10.0) | 14 | 125.1 (8.9) |
| | Healthy Weight Initiative | 37 | 135.2 (13.8) | 21 | 124.3 (9.3) | 6 | 130.0 (10.8) |
| **Diastolic blood pressure** (mmHg) | Standard care | 32 | 84.1 (7.7) | 18 | 85.4 (9.8) | 19 | 84.0 (8.8) |
| | Meal replacements | 36 | 81.4 (8.1) | 28 | 81.1 (7.4) | 14 | 84.1 (10.0) |
| | Healthy Weight Initiative | 37 | 87.8 (9.7) | 21 | 84.0 (5.4) | 6 | 87.0 (13.4) |
| **WHOQOL-BREF Domains** | | | | | | | |
| Physical | Standard care | 40 | 71.5 (13.3) | 24 | 70.5 (14.4) | 25 | 73.0 (12.3) |
| | Meal replacements | 39 | 65.0 (12.7) | 27 | 68.4 (16.0) | 18 | 72.2 (10.5) |
| | Healthy Weight Initiative | 39 | 70.2 (13.2) | 23 | 80.8 (11.8) | 13 | 85.7 (10.7) |
| Psychological | Standard care | 40 | 56.9 (14.3) | 24 | 62.3 (16.7) | 25 | 60.8 (15.1) |
| | Meal replacements | 39 | 58.3 (17.7) | 27 | 59.9 (17.8) | 18 | 65.7 (11.7) |
| | Healthy Weight Initiative | 39 | 60.1 (13.5) | 23 | 74.6 (10.5) | 13 | 79.2 (12.4) |

| | | Baseline | | 12 weeks | | 6 months | |
|---|---|---|---|---|---|---|---|
| **Outcome** | **Group** | **N** | **Mean (SD)** | **N** | **Mean (SD)** | **N** | **Mean (SD)** |
| Social support | Standard care | 40 | 63.8 (20.3) | 24 | 65.3 (15.3) | 25 | 65.7 (16.2) |
| | Meal replacements | 39 | 58.3 (25.7) | 27 | 54.3 (28.2) | 18 | 59.7 (25.1) |
| | Healthy Weight Initiative | 39 | 67.9 (15.6) | 23 | 79.7 (15.7) | 13 | 83.7 (11.3) |
| Environment | Standard care | 40 | 69.6 (12.9) | 24 | 68.5 (12.1) | 25 | 69.9 (13.4) |
| | Meal replacements | 39 | 66.1 (14.1) | 27 | 64.5 (17.0) | 18 | 72.4 (13.1) |
| | Healthy Weight Initiative | 39 | 68.8 (11.1) | 23 | 75.8 (14.0) | 13 | 79.8 (12.5) |
| **Healthy Eating Quiz** Total | | | | | | | |
| | Standard care | 40 | 28.2 (7.5) | 24 | 28.7 (7.7) | 25 | 28.6 (8.1) |
| | Meal replacements | 39 | 30.4 (9.1) | 27 | 30.3 (9.6) | 18 | 33.3 (7.2) |
| | Healthy Weight Initiative | 40 | 27.2 (8.7) | 21 | 33.7 (10.1) | 13 | 31.8 (8.9) |

Diet quality score range (0-73). Higher scores reflect better diet quality. Quality of life score range 0-100. *See Appendix 4 for Diet quality scores by food categories

### 3.7.2 COMPARISON OF INTERVENTIONS

*"Is either i) a meal replacement program or ii) the Healthy Weight Initiative program more effective than the current medical referral practice in lowering weight, waist circumference, and blood pressure and in improving diet quality, or quality of life?"*

**Difference between treatment groups over time, and at 12 weeks and 6 months**
Mixed effects regression analysis allowed comparisons between the groups to be made to determine if any of the interventions are 'better' than the others using data from participants who completed all assessments and accounting for any missing data by using the "intention-to-treat principle."

Changes from baseline at two time points (12 weeks and at 6 months) were calculated and any significant differences between treatment groups determined in two ways:

i. **Differences over time** were assessed in the regression modelling by looking at any patterns of change over the 6 months of the trial. These were compared between the three interventions- Healthy Weight Initiative, Meal Replacements and Standard Care.
ii. **Differences in any changes from baseline between groups** at the 12 weeks and at the 6 month follow ups for all outcomes were compared. Three comparisons were assessed for each outcome at each time point- a) Meal replacements v. Standard Care: b) HWI v. Standard Care, and c) HWI v. Meal Replacements.

The results of the statistical analysis are presented in Appendix 5 and are summarised below by outcome measures.

**Weight**

i. There was no statistically significant difference in the change in weight over time between the treatment groups.
ii. There were no statistically significant differences in the change in weight from baseline at 12 weeks or 6 months between any of the treatment groups. Participants in the Meal Replacement group did have greater change in weight from baseline at 12 weeks than those in the Standard Care group. The difference was 3.01 kg which almost reached significance (p=0.053).

**Waist**

i. There was no statistically significant difference in change in waist measurements over time between the treatment groups.
ii. At 12 weeks one comparison was significant. Participants in the HWI group had a statistically significant greater change in waist measurements from baseline compared to Standard Care. Participants in the HWI group had an average decrease in waist circumference from baseline 4.36cm greater than those in the Standard Care group. There were no other statistically significant differences between the treatment groups at 12 weeks or 6 months.

**Systolic blood pressure**

i. There was no statistically significant difference in change in systolic blood pressure over time between the treatment groups.

ii. At 12 weeks, the change in systolic blood pressure from baseline to 12 weeks for the HWI group demonstrated greater changes (decreases) than either the Standard Care or the Meal Replacement groups. These differences were statistically significant. The odds of lower systolic blood pressure at 12 weeks compared to baseline was 16% higher for the HWI group compared with the Standard Care group.

Similarly, the odds of lower systolic blood pressure at 12 weeks for the HWI group compared with the Meal Replacement group was again 16% higher.

There was no significant difference in change in systolic blood pressure from baseline between any of the treatment groups at 6 months.

**Diastolic blood pressure**

i. There was no statistically significant difference in change in diastolic blood pressure over time between the treatment groups.

ii. There were no statistically significant differences in the change in diastolic blood pressure from baseline at either 12 weeks or at 6 months between groups for any of the interventions.

**Quality of life (Psychological domain of WHOQOL-BREF)**

i. There was a statistically significant difference in change in quality of life score from baseline over time between the groups.

ii. There was a statistically significant difference in the change in quality of life score from baseline at both 12 weeks and at 6 months. Participants in the HWI group scored 10.34 point higher compared to baseline than those in Standard Care, and 10.48 points higher compared to baseline than those in the Meal Replacements group at 12 weeks, and 10.4 points and 9.4 points higher than Standard Care and Meal replacement groups respectively at 6 months.

In addition, at both follow-up times, participants in the HWI group had statistically significant greater scores compared with both Standard Care and Meal Replacements group. At 12 weeks, participants in the HWI group scored on average 13.08 points higher than those in the Standard Care group, while the difference between HWI and Meal Replacement group at 12 weeks was 12.41 points.

These differences remained significant at 6 months, where the difference between HWI and Standard Care was 13.13 points, and the difference between HWI and Meal Replacement groups was 11.34 points.

There were no significant differences between Standard Care and Meal Replacements at either follow-up time.

**Diet quality (Healthy Eating Quiz Score)**

i. There was a statistically significant difference between treatment groups over time for Total Healthy Eating Quiz (HEQ) scores (overall diet quality).

ii. There were two statistically significant differences found between groups in the change in

HEQ scores from baseline at 12 weeks. The HWI group performed better in change from baseline at 12 weeks than both Standard Care and Meal Replacement groups, indicating an improvement in overall diet quality for the HWI group. The odds of a greater total HEQ score at 12 weeks compared to baseline was 5.7 times higher in the HWI group compared to Standard Care. While the odds of a higher total HEQ score at 12 weeks compared to baseline was 11.53 times higher in the HWI group compared to the Meal Replacement group.
There were no significant differences in the odds of a higher total HEQ score between any of the treatment groups at 6 months.

### 3.7.3 EFFECT OF WORKER CHARACTERISTICS ON WEIGHT LOSS

*"Are there any relationships between treatment effectiveness and worker characteristics?"*

A preliminary analysis was undertaken to determine whether there were any relationships between treatment effectiveness and selected worker characteristics. Weight loss at 12 weeks by gender, age, and job location are presented in Table 3. The sample study size was insufficient to test for any statistically significant differences, however the differences in weight loss between genders, age categories, or job locations appear minimal.

**Table 3.** Mean (SD) weight loss (kg) by gender, age category and job location at 12 weeks by treatment group.

| | Healthy Weight Initiative | | | Meal Replacements | | | Standard Care | | |
|---|---|---|---|---|---|---|---|---|---|
| | n | Mean Weight Loss (kg) | SD | n | Mean Weight Loss (kg) | SD | n | Mean weight loss (kg) | SD |
| **Gender** | | | | | | | | | |
| Female | 8 | -1.3 | 3.1 | 6 | -2.0 | 4.1 | 7 | -5.0 | 3.7 |
| Male | 32 | -2.9 | 3.7 | 33 | -3.3 | 4.7 | 33 | -2.7 | 4.1 |
| **Age (years)** | | | | | | | | | |
| <30 | 4 | -1.1 | 2.0 | 1 | | | 4 | -5.3 | 5.2 |
| 31-50 | 25 | -2.6 | 4.0 | 28 | -3.1 | 4.7 | 32 | -2.7 | 4.2 |
| >50 | 11 | -2.8 | 3.3 | 10 | -3.2 | 4.5 | 4 | -4.2 | 1.9 |
| **Job Location** | | | | | | | | | |
| Surface | 31 | -2.1 | 3.3 | 31 | -3.0 | 4.1 | 31 | -3.3 | 4.2 |
| Underground | 9 | -3.9 | 4.4 | 8 | -3.7 | 7.4 | 9 | -2.0 | 3.8 |

## 3.8 POST-INTERVENTION FEEDBACK SURVEY AND INTERVIEWS

Of the 119 participants enrolled in the study n=71 (59.6%) completed the post-intervention survey at 12 weeks. A summary of individual items and responses is included in Appendix 6. A selection of participants (n=19) was also interviewed after completing the trial to gain further insight. The findings from the survey and interviews are summarized below.

### 3.8.1 OUTCOMES

**(achieving desired weight-loss goals, confidence in maintaining weight loss)**

In the HWI group, 30% of participants achieved all or most of their goals and 70% felt confident or extremely confident in maintaining their weight loss, while in the Meal Replacement group, 21% achieved all or most goals with 21% feeling confident, and in the Standard Care group, only 13% achieved all or most goals with 30% feeling confident.

Comments from interviews reflected the survey responses, one participant (female, ID 14) from the standard care said "*I was hoping for 5-6 kilos… I didn't go well at all*" and from the meal replacement group (Male, ID 10) "*I did lose 12, but after I finished the shakes, I put it all back on too ... it probably took about 6 months to put the weight back on"*. From the HWI group "*Ali was really good and you know, I was exercising, I was eating right, and I was doing all those things*" – (Female, ID 8).

### 3.8.2 PROGRAM DELIVERY

**(addressing individual needs, strategies and techniques, clarity of instructions, usefulness of resources)**

The HWI group generally reported higher satisfaction with the program's adequacy, effectiveness, clarity of instructions, and usefulness of resources compared to the Meal Replacement and Standard Care groups. The HWI group also had a high percentage of participants who found the frequency and duration of sessions appropriate.

One participant (Male, ID1) summarized the general feeling as

> "*I was given meal plans. I was shown how much you know current meal plans had in them like calorie-wise and all that, and what could have been substituted to make it a healthy meal plan and everything. The only thing you could improve on is a personal waiter or something like that [laughs]*"

### 3.8.3 SUPPORT

The HWI group reported the highest levels of satisfaction across most support categories, particularly with trial admin staff and allied health staff who delivered the HWI program. The Meal Replacement group also showed high satisfaction, especially with friends and trial admin staff. The Standard Care group had mixed satisfaction levels, with the highest satisfaction reported for friends and family support. Overall, most participants across all groups reported satisfaction with the support they received. The Meal Replacement group had a small percentage of participants who were not satisfied at all or only slightly satisfied with family and food support, while the Standard Care group had one participant who was not satisfied at all with support from their doctor or GP.

From the interviews, a participant (Male, ID10) in the meal replacement group outlined the thoughts about support of many:

*“Having someone to help you, like talking to a dietitian ... I'm an expert at driving a truck, but I’m not an expert in diets … there's too much information that contradicts itself and you think, well, it used to be easy when I was a kid, there was 3 meals a day you were supposed to have with veggies, but now, everything's bad and everything's good the next week and you just, I don't know.”*

Or from the Healthy Weight Initiative (Female, ID7)

*"Just having someone there to keep you accountable."*

And from the standard care arm, a participant (female ID 15) indicated:

*"I was hoping for … not the shakes ones, but the monitored one where you'd actually check in with the coal services and stuff like that, actually be a bit more accountable, that’s what I was hoping for.”*

### 3.8.4 SATISFACTION

Overall, satisfaction with weight loss, the weight-loss program, and current diet varied across the groups. The HWI group showed high satisfaction, particularly with their diet (70% satisfied) and the weight-loss program (75% satisfied or very satisfied). The Meal Replacement group had mixed results, with moderate satisfaction levels across all areas, including 36% satisfied with their diet. The Standard Care group had the lowest satisfaction, with only 13% satisfied with their diet and 22% satisfied or very satisfied with the weight-loss program, indicating a need for improvement in this approach.

A participant in the HWI, (female, ID7) *"I was very satisfied. It was consistently … able to get him with … people … when I needed to pretty much and they were available for me around my roster."*

### 3.8.5 RECOMMENDATION

In summary, the HWI group had the highest percentage of participants likely or very likely to recommend the program to colleagues (80%), followed by the Meal Replacement group (54%). The Standard Care group had the lowest recommendation levels with only 35% likely or very likely to recommend the program.

### 3.8.6 GP REFERRALS

Current CS Health guidelines advise that workers identified as obese at their Order 43 medicals should be referred to their GP for weight management, including dietary and exercise advice, where appropriate. Only 31% of respondents recall being referred to their GP following their most recent Order 43 medical, with 86% of those attending their appointments. Among those who attended, 79% recall weight loss, diet, and exercise were discussed with their GP.

# 4. DISCUSSION

The primary aim of this study was to evaluate the effectiveness of two weight loss interventions (the Healthy Weight Initiative (HWI) program and a meal replacement intervention for coal mine workers who were identified as obese (BMI $\geq$ 30kg/m$^2$). The interventions ran for 3 months, and weight (and other health outcomes) were measured at the completion of the intervention (at 12 weeks) and at a 6 month follow up. It was not possible to determine whether the average change in weight for either the HWI or the Meal Replacements groups was statistically significant due to the number of participants in each group who completed the intervention and both follow up assessments and the large heterogeneity (variability) in initial weight and amount of weight loss during the trial (e.g. some participants lost no weight and others increased weight). Worker characteristics, including gender, age and job location did not appear to be related to weight loss outcomes for either intervention.

A secondary aim of the trial was to compare current standard care of referring workers with a BMI greater than 30kg/m$^2$ to their GP with the above two interventions. At 12 weeks, there was no significant difference in weight loss between either the HWI and Standard Care, or between Meal Replacement and Standard care, however waist circumference, systolic blood pressure, quality of life measures (psychological domain) and diet quality showed significantly greater changes in the HWI group compared with Standard Care and Meal Replacements at 12 weeks. At 6 months neither intervention was better than Standard Care for any outcomes other than quality of life.

## 4.1 INTERVENTION OUTCOMES

### 4.1.1 HEALTHY WEIGHT INITIATIVE (HWI)

Participants randomised to this intervention arm were highly satisfied with the program. While not all participants were able to complete all 12 sessions within the 12 weeks intervention period, they reported many positive outcomes in follow up surveys and interviews, indicating that this is a robust program with sustained outcomes for participants. Participants indicated it was the support provided from staff in this program that assisted in their success.

Participants in the HWI program intervention arm experienced superior health outcomes compared to those in other intervention arms. The reduction in waist circumference and systolic blood pressure in the HWI group at 12 weeks suggest that participation in the program can effectively reduce central obesity (a risk factor for metabolic disease) and provide immediate cardiovascular benefits. However, as these outcomes were not significantly different to standard care at 6 months, it may be that further support beyond the 12 weeks could be necessary to lower cardiovascular risk in the long term. In a recent systematic review of behavioural weight loss programs, participants who had more than 12 contacts during interventions lost significantly more weight than those with fewer contacts. [37] It is possible that the HWI group may have achieved even greater weight loss if assessed at the end of 12 sessions rather than at 12 weeks, given the average number of sessions attended by 12 weeks was 8.

The HWI program also resulted in an improvement in diet quality for the participants. This is an important outcome for this program independent of weight loss or reductions in waist circumference and blood pressure. Diet quality is an independent indicator of health and well-being, and studies show there is a critical link between diet quality and long-term health outcomes.[38] In addition, the consistently higher quality of life scores across all domains for the HWI group at both 12 weeks and 6

months, emphasise the holistic benefits of this comprehensive weight management and lifestyle modification program.

While the HWI program showed significant short-term improvements immediately post-program, the findings at 6 months highlight the challenge of sustaining health benefits over time. The positive effects of the program on weight, waist circumference and blood pressure were not significantly different to standard care at 6 months, suggesting that ongoing support is necessary for the workforce to maintain positive health effects beyond participation in the program. This indicates that future participants would benefit from ongoing support and follow up beyond the scheduled 12 weeks of the intervention to ensure sustained health benefits. The HWI program currently delivered by CS Health includes 12 sessions and 6- and 12-month follow-up sessions to all participants.

Data from the surveys and post-trial interviews indicated that overall, participants were highly supportive of the HWI program and would recommend it to their colleagues.

### 4.1.2 MEAL REPLACEMENT

The meal replacement products chosen for this trial were The Man (or Lady) Shakes (Cranky Health Pty Ltd), which are advertised extensively in NSW, and were selected due to their appeal, particularly with men, who are traditionally less likely to volunteer for weight loss trials.[39, 40] There were twelve flavour varieties for this product, however, even with this variety participants indicated that two shakes a day for 12 weeks was difficult to maintain, this is supported by the reported reduced compliance to intervention. Participants also indicated they became hungry or were 'sick' of liquid food substitutes by the end of the trial period. There was a mixed response from participants about satisfaction with this arm of the trial, with some achieving good weight loss initially, but then rebounding with weight by the end of the trial period. Most participants felt there was not enough support in this arm of the trial to sustain the weight loss over time.

The Meal Replacement intervention arm (i.e. Man or Lady Shakes) was the most sought-after option mentioned by workers during screening for inclusion in this trial, with many mistakenly believing they could choose this option as part of the trial. There was some concern expressed by participants that if they were not randomly allocated to this arm of the trial then they would cease to participate. However, there was no evidence that drop out occurred as a direct result of randomisation to another intervention arm.

Minimal support was provided to this group over the 12 weeks to mimic real-life conditions, allowing participants to determine how best to incorporate meal replacements into their routines. Despite being provided with copies of and web-links to product publications (guides and sample meal plans), many participants felt unsupported over the 12-week intervention and consumed significantly fewer shakes than instructed.

At 12 weeks, weight loss in the Meal Replacement group was greater than in the Standard Care group (with the difference almost reaching statistical significance), but was not different from the HWI group. This could indicate the potential for short-term weight loss success. However, weight loss at 6 months was not significantly different to Standard Care. No other health outcomes including quality of life or diet quality were better than Standard Care or the HWI groups in the short or long term. Previous studies have suggested that if changes in diet and other lifestyle factors are not addressed in

conjunction with a meal replacement programs, then initial weight loss is less likely to be maintained.[41]

While specific studies on the use of meal replacements in the mining industry are limited, there is evidence supporting the effectiveness of meal replacements in similar high-demand work environments and in shift workers[22, 42] and there may be a role for these in the coal mining industry. However, several study participants reported they were adversely affected during the trial, and although symptoms were non-serious, the possibility of gastrointestinal upsets needs to be considered when recommending meal replacement programs.

### 4.1.3 STANDARD CARE

Cardiovascular risk management guidelines for the NSW Coal Industry[10] provide guidance to doctors on how obesity should be managed. Workers with BMI ≥ 30 kg/m$^2$ or weight >120kg may be referred to a GP for medical management including dietary and exercise advice, where appropriate. However, this study highlights that this referral process may not be optimal, and not all workers who recall being referred to their GP attend their appointments. The latest CS Health periodic health data (2022-2025)[11] shows that obesity rates have increased significantly within the NSW coal mining workforce, with 87% of the workforce now overweight or obese (BMI ≥ 25 kg/m$^2$), compared to 83.4% previously reported.[1] Forty seven percent of NSW coal mine workers are currently obese (BMI ≥30 kg/m$^2$) compared to 36% from CS Health Periodic medical data collected from all of industry in 2012-2014 .[43] This suggests that the current medical referral pathway has not been effective in supporting workers to reduce BMI. This is reflected in the results of this study, especially in the survey and interviews, where participants reported that they did not feel they had adequate support from online information and GP visits alone.

The Standard Care group had poorer outcomes at 12 weeks than both the Meal Replacement group and the HWI group for all outcome measures. Data collected from participants via the post-trial survey and the post-trial interviews indicate that workers were not satisfied with the Standard Care approach. Many reported not remembering being referred to their GP or if they did remember, they reported not attending. Of those that did attend, most reported discussing diet, exercise and lifestyle changes necessary to lead to weight loss with the GP, but then did not receive support to implement these changes.

It was interesting to note that most participants from this group who were still engaged with the study at 6 months and were given the option of Meal Replacements or joining the HWI program after study completion, opted to try Meal Replacements, signifying a strong preference for this type of intervention.

## 4.2 SUPPORT

In both the survey and interview data, participants reiterated the importance of sufficient support, both during the trial (the first 3 months) and into the follow up period (at six months). Evidence indicates that weight loss is sustained over time when participants are provided long term support.[44, 45] It appears that in the survey and interview data participants felt more support was

needed during the trial in the meal replacement and standard care groups, and for all groups into the follow up period (6 months).

## 4.3 RECRUITMENT AND RETENTION

It was anticipated that there would be challenges in recruiting sufficient workers to this trial in the required timeframe, however, recruitment was completed in approximately nine months, exceeding expectations. Contrary to our assumption that referrals would primarily come from nursing staff at Coal Services Health during periodic medicals, we found significant interest from the workforce itself, with most referrals coming directly from workers. This indicated a strong concern among workers about their overall health and their weight. Support and encouragement from management in mine sites was high with workers reporting hearing about the study from a variety of communications, including emails, social media, pre-start meetings, "toolbox talks", Occ. Health and Safety officers and from flyers placed with high visibility in workplaces.

Retention of workers in the study was also higher than expected, with 60% of participants completing at least 12 weeks in the trial. This dropped to 49% by 6 months, which was not unexpected given participants were left to continue in the trial unsupported during this phase. The retention rate compares favourably with other weight loss trials, where rates often range from 50% to 70% over similar intervention periods.[46]

Engagement at 6 months was higher in the Standard Care group compared to other intervention arms. This is likely due to the incentive allowing participants in this group to choose either intervention program following completion of the 6-month assessments. Most participants from the Standard Care group (80%) opted for the Meal Replacement program over the HWI.

## 4.4 STRENGTHS AND LIMITATIONS

This was an ambitious randomised controlled trial aimed at comparing the effectiveness of two real-world weight loss strategies in the coal mining industry against the current standard. Interest from workers was exceptionally high, making recruitment relatively easy.

Participants were cooperative, with all expressing personal goals and motivation to lose weight and achieve better health outcomes. Many also expressed altruistic reasons for volunteering, hoping to contribute to better outcomes for the industry. However, there were some limitations that may have affected the trial and should be considered when interpreting the results or planning further studies.

**Sample Size:** In weight loss trials, high variability in outcome measures requires large sample sizes to test the effectiveness of interventions. Due to budget and time frame constraints for this trial, the number of workers we could feasibly recruit was insufficient to definitively answer all the research questions originally proposed.

**Measurements:** Measurements were obtained from multiple sources, and possible bias was introduced by including self-reported measurement and non-blinded assessors. Sub-group analysis though suggested that self-report was not significantly problematic for the outcomes of interest.

**Compliance to Intervention:** The HWI program consists of 12 sessions, however most participants had not completed all sessions within 12 weeks. We assessed all groups at 12 weeks to ensure valid comparisons, and results may have differed if participants were assessed after the entire program was completed.

The number of shakes consumed by the Meal Replacement group was less than prescribed, therefore results reflect the experience of being in a meal replacement program rather than the effectiveness of the prescribed intervention

**Missing Data**: Despite using valid statistical methodology (Intent-to-treat (ITT)) to account for participants who dropped out of the trial (30% by 12 weeks and 47% by 6 months), it is possible that bias may have been introduced. For example, if participants who did not lose weight were more likely to drop out, the ITT analysis may overestimate the true effect of an intervention.

**Qualitative analysis:** A complete qualitative analysis of interviews was not undertaken.

## 4.5 CONCLUSION

This trial provides evidence that the HWI is an effective program promoting weight loss and improving health outcomes among coal mine workers in NSW and should be considered for wider implementation. The HWI program showed statistically significant short-term improvements in waist circumference, systolic blood pressure, diet quality and quality of life compared to meal replacement and standard care groups, although sustaining these benefits over the long term remains a challenge.

Meal Replacements were popular among participants and showed potential for short-term weight loss, but compliance to two shakes per day and lack of behaviour change support appear to limit their effectiveness.

The study also highlighted the need for better adherence to cardiovascular risk management guidelines and more effective referral pathways to GPs. Overall, the findings underscore the importance of continuous support, follow-up, and tailored interventions to achieve and maintain long-term health benefits in this population.

## 5. POTENTIAL ROAD MAP FOR INDUSTRY CONSIDERATION

The following section is provided as a point for further discussion for the NSW Coal industry and coal mine workers. These are the thoughts and ideas of the research team and have not been tested for effectiveness. It is anticipated that further research will be required before the making decisions around implementing any of the following points.

1. **Expand the Healthy Weight Initiative (HWI) program**:

Given the positive outcomes and high participant satisfaction, there is strong justification for encouraging increased uptake of the HWI program across industry. Extending support beyond the initial 12-week period could help participants maintain momentum and achieve longer-term health improvements. Ongoing engagement potentially up to 12 months may be beneficial.

6. **Develop integrated hybrid models**:

Combining the initial appeal and simplicity of meal replacements with the structured guidance and behavioural support of programs like HWI could offer a more balanced and sustainable approach. This hybrid model could serve as a motivational "kick-start" followed by a transition into lifestyle-based strategies that promote lasting change, however further research is required.

7. **Strengthen GP referral pathways**:

While GP referrals remain a key component of standard care, the study highlighted gaps in follow-through and weight loss support. Enhancing these pathways ensuring clear communication between Order 43 medical practitioners, workers and GPs could improve engagement and outcomes.

8. **Invest in tailored, evidence-based interventions**:

The coal mining workforce has unique characteristics and challenges, including shift work, remote locations, and both sedentary and physically demanding roles. Any future interventions should be designed with these factors in mind, ensuring they are accessible, flexible, and culturally appropriate.

9. **Co-designing weight loss programs**

Codesigning intervention programs with stakeholders would advantage the industry and increase the likelihood of success while providing appropriate support for the workforce. Continued investment in research and innovation will be essential to refine these approaches and ensure they meet the evolving needs of the workforce.

**Summary of future directions**

This trial provides evidence that the Healthy Weight Initiative is an effective program promoting weight loss and improving health outcomes among coal mine workers in NSW coal mining workforce and should be considered for wider implementation.

This trial also supports further investigation into the use of meal replacement as a kick start to weight loss that might lead to more sustained weight loss if done in conjunction with a program like the HWI.

Regardless of the approach, additional support to that currently offered is required, especially beyond 3 months and potentially up to 12 months to ensure sustained weight loss through lifestyle change.

Further research is warranted into what additional support options would be beneficial and feasible to ensure sustainability of weight loss and behaviour change. Codesign with key stakeholders including workers is suggested to improve success.

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# 7. APPENDICES

## APPENDIX 1. SELF-REPORT MEASUREMENT INSTRUCTIONS

Please weigh yourself on the same set of scales throughout the trial (e.g. at your GP, local chemist, gym or home). Instructions for taking your weight and waist circumference are below.

**How to weigh yourself**

Weigh yourself without shoes, and remove any outer layers of clothing.

Please do this on the same set of scales throughout the trial.

**How to measure your waist**

- Find the top of your hip bone and the bottom of your ribs.
- Breathe out normally.
- Place the tape measure midway between these points and wrap it around your waist.
- Check your measurement.

## APPENDIX 2. JOB CLASSIFICATIONS OF PARTICIPANTS

**Table 4.** Job classifications of participants.

| Characteristic | Overall (n = 119) | Standard Care (n = 40) | Meal Replacements (n = 39) | Healthy Weight Initiative (n = 40) |
|---|---|---|---|---|
| **SEG, n (%)** | | | | |
| CSHP001 - CHPP - CHPP | 6 (5.0) | 3 (7.5) | 1 (2.6) | 2 (5.0) |
| CSHP002 - CHPP - CHPP Maintenance | 2 (1.7) | 1 (2.5) | 1 (2.6) | 0 (0) |
| CSHS001 - Open cut - Surface Mobile Equipment | 18 (15) | 6 (15) | 7 (18) | 5 (13) |
| CSHS002 - Open cut - Surface Mobile Equipment | 4 (3.4) | 1 (2.5) | 1 (2.6) | 2 (5.0) |
| CSHS003 - Open cut - Surface Technical / Management | 3 (2.5) | 1 (2.5) | 1 (2.6) | 1 (2.5) |
| CSHS004 - Open cut - Surface Mobile Equipment | 1 (0.8) | 1 (2.5) | 0 (0) | 0 (0) |
| CSHS006 - Open cut - Surface Maintenance | 6 (5.0) | 0 (0) | 2 (5.1) | 4 (10) |
| CSHS007 - Open cut - Blast Crew | 5 (4.2) | 2 (5.0) | 1 (2.6) | 2 (5.0) |
| CSHS008 - Open cut - Surface Technical / Management | 2 (1.7) | 0 (0) | 0 (0) | 2 (5.0) |
| CSHS009 - Open cut - Surface Drilling | 1 (0.8) | 1 (2.5) | 0 (0) | 0 (0) |
| CSHS013 - Open cut - Administration | 8 (6.7) | 2 (5.0) | 3 (7.7) | 3 (7.5) |
| CSHS014 - Open cut - Surface Maintenance | 5 (4.2) | 0 (0) | 2 (5.1) | 3 (7.5) |
| CSHS020 - Open cut - Surface Other | 11 (9.2) | 4 (10) | 5 (13) | 2 (5.0) |
| CSHU001 - Underground - Longwall | 1 (0.8) | 0 (0) | 1 (2.6) | 0 (0) |
| CSHU002 - Underground - Development / Continuous Miner | 6 (5.0) | 2 (5.0) | 1 (2.6) | 3 (7.5) |
| CSHU003 - Underground - Underground Maintenance | 7 (5.9) | 2 (5.0) | 2 (5.1) | 3 (7.5) |
| CSHU006 - Underground - Outbye / Production / Support | 2 (1.7) | 0 (0) | 1 (2.6) | 1 (2.5) |

| Characteristic | Overall (n = 119) | Standard Care (n = 40) | Meal Replacements (n = 39) | Healthy Weight Initiative (n = 40) |
|---|---|---|---|---|
| CSHU008 - Underground - Deputy | 1 (0.8) | 1 (2.5) | 0 (0) | 0 (0) |
| CSHU009 - Underground (surface) - Surface Maintenance | 1 (0.8) | 1 (2.5) | 0 (0) | 0 (0) |
| CSHU013 - Underground - Administration | 2 (1.7) | 1 (2.5) | 1 (2.6) | 0 (0) |
| CSHU014 - Underground - Resin Worker | 1 (0.8) | 0 (0) | 1 (2.6) | 0 (0) |
| CSHU017 - Underground - Underground Gas drainage | 1 (0.8) | 1 (2.5) | 0 (0) | 0 (0) |
| CSHU018 - Underground - Underground Technical / Management | 4 (3.4) | 1 (2.5) | 1 (2.6) | 2 (5.0) |
| CSHU020 - Underground - Outbye / Production / Support | 1 (0.8) | 0 (0) | 1 (2.6) | 0 (0) |
| CSHU021 - Underground (surface) - Surface Other | 3 (2.5) | 1 (2.5) | 2 (5.1) | 0 (0) |
| CSHU022 - Underground - Underground other | 6 (5.0) | 3 (7.5) | 2 (5.1) | 1 (2.5) |
| Not Recorded | 11 (9.2) | 5 (13) | 2 (5.1) | 4 (10) |

SEG = standard exposure groups

## APPENDIX 3. SOURCE OF WEIGHT MEASUREMENTS BY TREATMENT GROUP

**Table 5.** Source of weight measurements by treatment group*

| | Baseline Source | | | 12-Week Source | | | 6-Month Source | | |
|---|---|---|---|---|---|---|---|---|---|
| | **CSH** n = 29[1] | **HWI** n = 40[1] | **Self-Reported** n = 44[1] | **CSH** n = 16[1] | **HWI** n = 32[1] | **Self-Reported** n = 41[1] | **CSH** n = 7[1] | **HWI** n = 13[1] | **Self-Reported** n = 34[1] |
| **Group, n (%)** | | | | | | | | | |
| Standard Care | 12 (33) | 0 (0) | 24 (67) | 4 (16) | 0 (0) | 21 (84) | 2 (8.7) | 0 (0) | 21 (91) |
| Meal Replacements | 17 (46) | 0 (0) | 20 (54) | 12 (39) | 0 (0) | 19 (61) | 5 (36) | 0 (0) | 9 (64) |
| Healthy Weight Initiative | 0 (0) | 40 (100) | 0 (0) | 0 (0) | 32 (97) | 1 (3.0) | 0 (0) | 13 (76) | 4 (24) |

[1]n (%). *multiple sources possible

**Agreement between measurements from different sources**

All measurements provided were used to calculate agreement. Excluding CSH data from appointments greater than 3 months prior to screening resulted in too few paired measurements to assess agreement.

The self-reported weight was on average 2.0kg higher than that from CSH and 0.7kg lower than HWI. CSH was on average 2.5kg lower than HWI. The correlation between these measurements was excellent, with a Pearson correlation coefficient of 0.95 between self-reported and CSH, 1.00 (rounded to 2 decimal places) between self-reported and HWI and 0.94 between CSH and HWI. The intraclass correlation coefficient (ICC) between all three sources expresses the degree to which the observed measurements are dependent on the source. An ICC of 0.95 is excellent, suggesting excellent agreement between the data sources.

The agreement between diastolic blood pressure measurements from different sources was poor. All correlations were low, at 0.08 between self-reported and CSH, 0.09 between self-reported and HWI, and 0.25 between CSH and HWI. An ICC of 0.06 indicates poor agreement, suggesting that the observed measurements were highly dependent on the source.

Waist measurements had high correlation and good agreement, while the correlation between systolic blood pressure measurements varied from moderate to high, and the ICC suggested moderate agreement.

**Table 6.** Source of waist measurements by treatment group.

| | Baseline Source | | | 12-Week Source | | | 6-Month Source | | |
|---|---|---|---|---|---|---|---|---|---|
| | **CSH** n = 28[1] | **HWI** n = 40[1] | **Self-Reported** n = 44[1] | **CSH** n = 16[1] | **HWI** n = 32[1] | **Self-Reported** n = 40[1] | **CSH** n = 7[1] | **HWI** n = 13[1] | **Self-Reported** n = 35[1] |
| **Treatment Group, n (%)** | | | | | | | | | |
| Standard Care | 11 (31) | 0 (0) | 24 (69) | 4 (17) | 0 (0) | 20 (83) | 2 (8.3) | 0 (0) | 22 (92) |
| Meal Replacements | 17 (46) | 0 (0) | 20 (54) | 12 (39) | 0 (0) | 19 (61) | 5 (36) | 0 (0) | 9 (64) |
| Healthy Weight Initiative | 0 (0) | 40 (100) | 0 (0) | 0 (0) | 32 (97) | 1 (3.0) | 0 (0) | 13 (76) | 4 (24) |

[1]n (%).*multiple sources possible

**Table 7.** Source of blood pressure measurements by treatment group*

| | Baseline source | | | 12-week source | | | 6-month source | | |
|---|---|---|---|---|---|---|---|---|---|
| | **CSH** n = 29[1] | **HWI** n = 35[1] | **Self-reported** n = 41[1] | **CSH** n = 16[1] | **HWI** n = 20[1] | **Self-reported** n = 31[1] | **CSH** n = 7[1] | **HWI** n = 4[1] | **Self-reported** n = 28[1] |
| **Treatment group, n (%)** | | | | | | | | | |
| Standard care | 12 (38) | 0 (0) | 20 (63) | 4 (22) | 0 (0) | 14 (78) | 2 (11) | 0 (0) | 17 (89) |
| Meal replacements | 17 (47) | 0 (0) | 19 (53) | 12 (43) | 0 (0) | 16 (57) | 5 (36) | 0 (0) | 9 (64) |
| Healthy Weight Initiative | 0 (0) | 35 (95) | 2 (5.4) | 0 (0) | 20 (95) | 1 (4.8) | 0 (0) | 4 (67) | 2 (33) |

[1]n (%). *multiple sources possible

## APPENDIX 4. DIET QUALITY

**Table 8.** Diet quality of Participants.

| Group | Characteristic | Baseline | 12 weeks | 6 months |
|---|---|---|---|---|
| **Diet quality** (Healthy Eating Quiz)[32] | | | | |
| Total Score | Standard care | 28.2 (7.5) | 28.7 (7.7) | 28.6 (8.1) |
| | Meal replacements | 30.4 (9.1) | 30.3 (9.6) | 33.3 (7.2) |
| | Healthy Weight Initiative | 27.2 (8.7) | 33.7 (10.1) | 31.8 (8.9) |
| Vegetables | Standard care | 9.9 (4.0) | 10.5 (3.9) | 10.6 (4.2) |
| | Meal replacements | 11.8 (5.0) | 12.0 (4.7) | 14.2 (3.4) |
| | Healthy Weight Initiative | 9.6 (5.1) | 12.8 (4.6) | 12.2 (4.6) |
| Fruit | Standard care | 3.8 (2.7) | 4.2 (2.4) | 3.7 (2.7) |
| | Meal replacements | 4.0 (2.4) | 4.4 (2.8) | 4.0 (2.4) |
| | Healthy Weight Initiative | 3.9 (2.6) | 5.5 (2.5) | 5.1 (2.1) |
| Meat | Standard care | 2.6 (1.2) | 2.7 (1.3) | 2.5 (1.3) |
| | Meal replacements | 3.0 (1.1) | 2.8 (0.8) | 3.2 (1.1) |
| | Healthy Weight Initiative | 2.4 (1.1) | 2.6 (1.4) | 2.5 (1.1) |
| Meat alternatives | Standard care | 1.7 (1.0) | 1.9 (1.1) | 2.1 (1.3) |
| | Meal replacements | 1.7 (1.3) | 1.9 (1.5) | 2.1 (1.3) |
| | Healthy Weight Initiative | 1.6 (1.1) | 2.2 (0.9) | 2.3 (1.1) |
| Grains | Standard care | 4.7 (1.7) | 4.2 (1.8) | 4.6 (1.9) |
| | Meal replacements | 4.5 (2.0) | 4.6 (2.2) | 5.4 (2.1) |
| | Healthy Weight Initiative | 4.6 (1.8) | 5.1 (2.1) | 4.9 (2.4) |
| Dairy | Standard care | 3.5 (2.0) | 3.5 (1.9) | 3.3 (1.6) |
| | Meal replacements | 3.5 (1.4) | 2.9 (1.1) | 2.7 (1.1) |
| | Healthy Weight Initiative | 3.5 (1.7) | 3.5 (1.8) | 3.2 (1.8) |
| Water | Standard care | 0.7 (0.5) | 0.7 (0.5) | 0.8 (0.4) |
| | Meal replacements | 0.7 (0.5) | 0.8 (0.4) | 0.9 (0.3) |
| | Healthy Weight Initiative | 0.7 (0.5) | 0.9 (0.4) | 0.6 (0.5) |
| Extras | Standard care | 1.4 (0.7) | 1.2 (0.6) | 1.0 (0.7) |
| | Meal replacements | 1.2 (0.7) | 1.0 (0.6) | 0.9 (0.6) |
| | Healthy Weight Initiative | 1.0 (0.7) | 1.1 (0.7) | 1.1 (0.9) |

## APPENDIX 5. AGE AND STRATA ADJUSTED DIFFERENCES

**Table 9.** Age and strata adjusted difference at follow-up and difference in change from baseline from regression modelling of each outcome.

| Outcome | Interaction p-value | Follow-Up Time | Comparison | Difference at Follow-Up (95% CI)[1] | p-value | Difference in Change from Baseline (95% CI)[2] | p-value |
|---|---|---|---|---|---|---|---|
| **Weight** | 0.373 | 12 weeks | Meal replacements - Standard care | 1.16 (-7.2, 9.5) | 0.784 | -3.01 (-6, 0) | 0.053 |
| | | | Healthy Weight Initiative - Standard care | 6.39 (-1.8, 14.6) | 0.126 | -2.37 (-5.4, 0.6) | 0.120 |
| | | | Healthy Weight Initiative - Meal replacements | 5.23 (-2.9, 13.4) | 0.207 | 0.63 (-2.2, 3.5) | 0.662 |
| | | 6 months | Meal replacements - Standard care | 2.16 (-6.4, 10.7) | 0.619 | -2 (-5.7, 1.7) | 0.282 |
| | | | Healthy Weight Initiative - Standard care | 7.61 (-0.8, 16) | 0.075 | -1.15 (-4.6, 2.3) | 0.516 |
| | | | Healthy Weight Initiative - Meal replacements | 5.45 (-3.1, 14) | 0.209 | 0.85 (-3, 4.7) | 0.660 |
| **Waist** | 0.296 | 12 weeks | Meal replacements - Standard care | -1.22 (-7.2, 4.7) | 0.687 | -2.63 (-6.5, 1.2) | 0.181 |
| | | | Healthy Weight Initiative - Standard care | 1.07 (-4.8, 6.9) | 0.720 | -4.23 (-8.1, -0.4) | **0.030** |
| | | | Healthy Weight Initiative - Meal replacements | 2.29 (-3.4, 8) | 0.432 | -1.6 (-5.2, 2) | 0.383 |
| | | 6 months | Meal replacements - Standard care | 0.35 (-6.1, 6.8) | 0.916 | -1.07 (-5.7, 3.5) | 0.647 |

| Outcome | Interaction p-value | Follow-Up Time | Comparison | Difference at Follow-Up (95% CI)[1] | p-value | Difference in Change from Baseline (95% CI)[2] | p-value |
|---|---|---|---|---|---|---|---|
| | | | Healthy Weight Initiative - Standard care | 2.69 (-3.5, 8.9) | 0.395 | -2.61 (-7, 1.8) | 0.239 |
| | | | Healthy Weight Initiative - Meal replacements | 2.35 (-4.2, 8.9) | 0.482 | -1.54 (-6.4, 3.3) | 0.531 |
| **Systolic Blood Pressure** | 0.057 | 12 weeks | Meal replacements - Standard care | 0.57 (0.2, 2) | 0.368 | 1 (0.3, 3.8) | 0.996 |
| | | | Healthy Weight Initiative - Standard care | 0.3 (0.1, 1.1) | 0.070 | 0.16 (0, 0.7) | **0.012** |
| | | | Healthy Weight Initiative - Meal replacements | 0.52 (0.2, 1.7) | 0.278 | 0.16 (0, 0.6) | **0.006** |
| | | 6 months | Meal replacements - Standard care | 0.52 (0.1, 2.2) | 0.382 | 0.92 (0.2, 4.3) | 0.918 |
| | | | Healthy Weight Initiative - Standard care | 1.05 (0.2, 6.8) | 0.963 | 0.56 (0.1, 4) | 0.557 |
| | | | Healthy Weight Initiative - Meal replacements | 2 (0.3, 12.9) | 0.465 | 0.6 (0.1, 4.3) | 0.613 |
| **Diastolic Blood Pressure** | 0.227 | 12 weeks | Meal replacements - Standard care | 0.29 (0.1, 1) | 0.059 | 0.63 (0.2, 2.5) | 0.502 |
| | | | Healthy Weight Initiative - Standard care | 0.58 (0.2, 2.2) | 0.433 | 0.26 (0.1, 1.1) | 0.069 |
| | | | Healthy Weight Initiative - Meal replacements | 2.04 (0.6, 6.7) | 0.244 | 0.41 (0.1, 1.5) | 0.184 |
| | | 6 months | Meal replacements - Standard care | 1.21 (0.3, 5.5) | 0.802 | 2.64 (0.5, 13) | 0.231 |

| Outcome | Interaction p-value | Follow-Up Time | Comparison | Difference at Follow-Up (95% CI)[1] | p-value | Difference in Change from Baseline (95% CI)[2] | p-value |
|---|---|---|---|---|---|---|---|
| | | | Healthy Weight Initiative - Standard care | 1.54 (0.2, 12.6) | 0.688 | 0.68 (0.1, 6) | 0.728 |
| | | | Healthy Weight Initiative - Meal replacements | 1.27 (0.1, 11.1) | 0.830 | 0.26 (0, 2.5) | 0.238 |
| **Psychological domain of WHOQOL-BREF** | **0.002** | 12 weeks | Meal replacements - Standard care | 0.66 (-6.6, 8) | 0.858 | -0.14 (-6.1, 5.8) | 0.964 |
| | | | Healthy Weight Initiative - Standard care | 13.08 (5.6, 20.5) | **<0.001** | 10.34 (4.1, 16.5) | **0.001** |
| | | | Healthy Weight Initiative - Meal replacements | 12.41 (5.1, 19.7) | **<0.001** | 10.48 (4.4, 16.5) | **<0.001** |
| | | 6 months | Meal replacements - Standard care | 1.79 (-5.9, 9.5) | 0.646 | 0.99 (-5.4, 7.4) | 0.759 |
| | | | Healthy Weight Initiative - Standard care | 13.13 (5, 21.2) | **0.002** | 10.4 (3.4, 17.4) | **0.004** |
| | | | Healthy Weight Initiative - Meal replacements | 11.34 (2.9, 19.8) | **0.009** | 9.4 (2, 16.8) | **0.013** |
| **Healthy Eating Quiz Total** | **0.017** | 12 weeks | Meal replacements - Standard care | 0.97 (0.2, 4.9) | 0.969 | 0.49 (0.1, 1.9) | 0.302 |
| | | | Healthy Weight Initiative - Standard care | 3.87 (0.7, 21) | 0.117 | 5.7 (1.4, 23.7) | **0.017** |
| | | | Healthy Weight Initiative - Meal replacements | 3.99 (0.7, 21.8) | 0.109 | 11.53 (2.7, 49.7) | **0.001** |
| | | 6 months | Meal replacements - Standard care | 2.55 (0.5, 14) | 0.283 | 1.3 (0.3, 5.4) | 0.721 |

| Outcome | Interaction p-value | Follow-Up Time | Comparison | Difference at Follow-Up (95% CI)[1] | p-value | Difference in Change from Baseline (95% CI)[2] | p-value |
|---|---|---|---|---|---|---|---|
| | | | Healthy Weight Initiative - Standard care | 2.44 (0.4, 14.9) | 0.333 | 3.6 (0.8, 17.2) | 0.109 |
| | | | Healthy Weight Initiative - Meal replacements | 0.96 (0.1, 6.3) | 0.966 | 2.77 (0.5, 14.5) | 0.228 |

[1]Mean difference for weight, waist, and psychological domain; Odds ratios for systolic and diastolic blood pressure; CI = Confidence Interval

[2]Mean difference for weight, waist, and psychological domain; Ratio of odds ratios for systolic and diastolic blood pressure; CI = Confidence Interval

The interaction p-value indicates whether there is a difference between any of the three trial arms in change over time. It is shown along with the pairwise differences between the marginal means of the interventions at the follow-up times and the pairwise differences in change from baseline. No adjustments were made for multiple testing therefore any statistically significant findings may still be due to chance.

## APPENDIX 6. POST-INTERVENTION FEEDBACK SURVEY RESULTS

### Outcomes

**1. To what extent have you achieved your desired weight-loss goals as a result of participating in this trial?**

| | Did Not Achieve Any Goals | Partially Achieved Some Goals | Neutral | Achieved Most Goals | Achieved All Goals | TOTAL |
|---|---|---|---|---|---|---|
| **Group** | | | | | | |
| **HWI** | | 6 | 4 | 8 | 2 | **20** |
| **Meal Replacements** | 6 | 13 | 3 | 6 | | **28** |
| **Standard Care** | 6 | 10 | 4 | 2 | 1 | **23** |
| **TOTAL** | **12** | **29** | **11** | **16** | **3** | **71** |

**2. How confident are you in maintaining the weight loss you achieved during the trial?**

| | Not Confident at All | Slightly Confident | Neutral | Confident | Extremely Confident | TOTAL |
|---|---|---|---|---|---|---|
| **Group** | | | | | | |
| **HWI** | 2 | 2 | 2 | 13 | 1 | **20** |
| **Meal Replacements** | 4 | 8 | 10 | 6 | | **28** |
| **Standard Care** | 5 | 4 | 7 | 6 | 1 | **23** |
| **TOTAL** | **11** | **14** | **19** | **25** | **2** | **71** |

### Program Delivery

**3. To what extent do you agree that the weight-loss program adequately addressed your individual needs and circumstances?**

| | Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree | No Response | TOTAL |
|---|---|---|---|---|---|---|---|
| **Group** | | | | | | | |
| **HWI** | 6 | 9 | 3 | 1 | | 1 | **20** |
| **Meal Replacements** | | 6 | 17 | 3 | 2 | | **28** |
| **Standard Care** | | 2 | 10 | 7 | 4 | | **23** |
| **TOTAL** | **6** | **17** | **30** | **11** | **6** | **1** | **71** |

**4. To what extent do you agree that the strategies and techniques taught during the intervention program were effective for weight loss?**

| | Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree | TOTAL |
|---|---|---|---|---|---|---|
| **Group** | | | | | | |
| **HWI** | 4 | 11 | 3 | 2 | | **20** |
| **Meal Replacements** | | 5 | 19 | 2 | 2 | **28** |
| **Standard Care** | | 2 | 10 | 6 | 5 | **23** |
| **TOTAL** | **4** | **18** | **32** | **10** | **3** | **71** |

**5. How clear and understandable were the instructions provided during the program?**

| | Instructions Were Very Clear | Instructions Were Clear | Neutral | Instructions Were Somewhat Unclear | Instructions Were Not Clear at All | TOTAL |
|---|---|---|---|---|---|---|
| **Group** | | | | | | |
| **HWI** | 17 | 3 | | | | **20** |
| **Meal Replacements** | 6 | 19 | 3 | | | **28** |
| **Standard Care** | 1 | 11 | 7 | 2 | 2 | **23** |
| **TOTAL** | **24** | **33** | **10** | **2** | **2** | **71** |

**6. How useful were the resources provided for you (eg printed information, links to websites)?**

| | The Resources Were Very Useful | The Resources Were Somewhat Useful | Neutral | The Resources Were Slightly Useful | The Resources Were Not at All Useful | TOTAL |
|---|---|---|---|---|---|---|
| **Group** | | | | | | |
| **HWI** | 7 | 10 | 2 | | 1 | **20** |
| **Meal Replacements** | 5 | 8 | 10 | 5 | | **28** |
| **Standard Care** | | 5 | 13 | 3 | 2 | **23** |
| **TOTAL** | **12** | **23** | **25** | **8** | **3** | **71** |

**7. How do you rate the frequency of the sessions? (HWI group only)**

| | Too Infrequent | Somewhat Infrequent | Neutral | Somewhat Frequent | Very Frequent | Not Answered | TOTAL |
|---|---|---|---|---|---|---|---|
| **Group** | | | | | | | |
| **HWI** | | | 6 | 4 | 9 | 1 | **20** |

**8. How do you rate the duration of the sessions? (HWI group only)**

| | Too Short | Somewhat Short | Neutral | Somewhat Appropriate Length | Very Appropriate Length | TOTAL |
|---|---|---|---|---|---|---|
| **Group** | | | | | | |
| **HWI** | | | 3 | 5 | 12 | **20** |

## Satisfaction

**9. How satisfied are you with your weight loss?**

| | Very Satisfied | Satisfied | Neutral | Slightly Satisfied | Not Satisfied at All | TOTAL |
|---|---|---|---|---|---|---|
| **Group** | | | | | | |
| **HWI** | 1 | 13 | 2 | 2 | 2 | **20** |
| **Meal Replacements** | | 8 | 5 | 6 | 9 | **28** |
| **Standard Care** | 1 | 3 | 8 | 6 | 5 | **23** |
| **TOTAL** | **2** | **24** | **15** | **14** | **16** | **71** |

**10. How satisfied overall were you with the weight-loss program you took part in?**

| | Very Satisfied | Satisfied | Neutral | Slightly Satisfied | Not Satisfied at All | TOTAL |
|---|---|---|---|---|---|---|
| **Group** | | | | | | |
| **HWI** | 6 | 9 | 2 | 3 | | **20** |
| **Meal Replacements** | 2 | 15 | 5 | 4 | 2 | **28** |
| **Standard Care** | 1 | 4 | 8 | 5 | 5 | **23** |
| **TOTAL** | **9** | **28** | **15** | **12** | **7** | **71** |

**11. How satisfied are you with your diet now?**

| | Very Satisfied | Satisfied | Neutral | Slightly Satisfied | Not Satisfied at All | TOTAL |
|---|---|---|---|---|---|---|
| **Group** | | | | | | |
| **HWI** | 4 | 14 | 2 | | | **20** |
| **Meal Replacements** | | 10 | 9 | 5 | 4 | **28** |
| **Standard Care** | 1 | 2 | 9 | 5 | 6 | **23** |
| **TOTAL** | **5** | **26** | **20** | **10** | **10** | **71** |

## Support

**12. What support did you receive during the program, and how satisfied were you?**

**a. HWI Group - Support and Satisfaction**

| | Very Satisfied | Satisfied | Neutral | Slightly Satisfied | Not Satisfied at All | TOTAL |
|---|---|---|---|---|---|---|
| **HWI Group** | | | | | | |
| **Friends** | 2 | 6 | 1 | | | **9** |
| **Family** | 5 | 6 | 2 | | | **13** |
| **Colleagues** | 2 | 4 | 1 | | | **7** |
| **Trial Admin Staff** | 7 | 4 | | | | **11** |
| **Therapist*** | 5 | | | | | **5** |
| **Doctor or GP** | | | | | | **0** |
| **Online Resources or Links to Websites** | 3 | 3 | 1 | | | **7** |
| **Printed Material** | 2 | 2 | | | | **4** |
| **Food (Including Shakes)** | 1 | 1 | | | | **2** |

*Dietitian, Exercise Physiologist, Physio.

### b. Meal Replacement Group - Support and Satisfaction

| | Very Satisfied | Satisfied | Neutral | Slightly Satisfied | Not Satisfied at All | TOTAL |
|---|---|---|---|---|---|---|
| **Meal Replacement Group** | | | | | | |
| **Friends** | 4 | 3 | | | | **7** |
| **Family** | 5 | 7 | 2 | 2 | 1 | **15** |
| **Colleagues** | 4 | 2 | 1 | | | **7** |
| **Trial Admin Staff** | 4 | 2 | | | | **6** |
| **Therapist*** | | | | | | **0** |
| **Doctor or GP** | 2 | 3 | | | | **5** |
| **Online Resources or Links to Websites** | 1 | 2 | | | | **3** |
| **Printed Material** | 1 | | | | | **1** |
| **Food (Including Shakes)** | 2 | 12 | 1 | 2 | 1 | **18** |

*Dietitian, Exercise Physiologist, Physio.

### c. Standard Care Group - Support and Satisfaction

| | Very Satisfied | Satisfied | Neutral | Slightly Satisfied | Not Satisfied at All | TOTAL |
|---|---|---|---|---|---|---|
| **Standard Care Group** | | | | | | |
| **Friends** | | 7 | | | | **7** |
| **Family** | 1 | 4 | 10 | | | **15** |
| **Colleagues** | 1 | 4 | 1 | | | **6** |
| **Trial Admin Staff** | 1 | 2 | 1 | | | **4** |
| **Therapist*** | | | 1 | | | **1** |
| **Doctor or GP** | 1 | 2 | | | 1 | **4** |
| **Online Resources or Links to Websites** | | 2 | 3 | | | **5** |
| **Printed Material** | | | | | | **0** |
| **Food (Including Shakes)** | | | 2 | | | **2** |

*Dietitian, Exercise Physiologist, Physio.

## Recommendation

**13. How likely would you be to recommend this weight-loss program to colleagues?**

| | Very Likely | Likely | Neutral | Unlikely | Very Unlikely | TOTAL |
|---|---|---|---|---|---|---|
| **Group** | | | | | | |
| **HWI** | 8 | 8 | 4 | | | **20** |
| **Meal Replacements** | 5 | 10 | 10 | 3 | | **28** |
| **Standard Care** | 2 | 6 | 8 | 2 | 5 | **23** |
| **TOTAL** | **15** | **24** | **22** | **5** | **5** | **71** |

## GP Experience

**14. Were you referred to your GP following your last Order 43 periodic medical?**

| | Yes | No | Unsure | TOTAL |
|---|---|---|---|---|
| **Group** | | | | |
| **HWI** | 3 | 15 | 2 | **20** |
| **Meal Replacements** | 13 | 13 | 2 | **28** |
| **Standard Care** | 6 | 17 | | **23** |
| **TOTAL** | **22** | **45** | **4** | **71** |

**15. Did you attend an appointment?**

| | Yes | No | TOTAL |
|---|---|---|---|
| **Group** | | | |
| **HWI** | 3 | | **3** |
| **Meal Replacements** | 11 | 2 | **13** |
| **Standard Care** | 5 | 1 | **6** |
| **TOTAL** | **19** | **3** | **22** |

**16. Did your GP discuss any of the following with you?**

**a. Weight Loss**

| | Yes | No | TOTAL |
|---|---|---|---|
| **Group** | | | |
| **HWI** | 2 | 1 | **3** |
| **Meal Replacements** | 9 | 2 | **11** |
| **Standard Care** | 4 | 1 | **5** |
| **TOTAL** | **15** | **4** | **19** |

**b. Diet**

| | Yes | No | TOTAL |
|---|---|---|---|
| **Group** | | | |
| **HWI** | 2 | 1 | **3** |
| **Meal Replacements** | 9 | 2 | **11** |
| **Standard Care** | 4 | 1 | **5** |
| **TOTAL** | **15** | **4** | **19** |

**c. Exercise**

| | Yes | No | TOTAL |
|---|---|---|---|
| **Group** | | | |
| **HWI** | 2 | 1 | **3** |
| **Meal Replacements** | 9 | 2 | **11** |
| **Standard Care** | 4 | 1 | **5** |
| **TOTAL** | **15** | **4** | **19** |