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# The effect of cognitive behavioral stress management on perceived stress, biological stress markers and weight loss/regain, from a diet-induced weight loss program: A randomized controlled trial

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ABSTRACT

Obesity and psychosocial stress are inter-related chronic conditions which lead to increased cardiovascular morbidity and mortality. The aim of this parallel randomized controlled trial was to determine whether the addition of a structured cognitive behavioral stress management (CBSM) on to a commercial online weight loss program, resulted in greater weight loss than the standard weight loss program in isolation. Eligible participants were adults between the ages 18–65, BMI 30–45 kg/m$^2$, with no major systemic or psychiatric conditions. Seventy-four participants were assigned according to simple randomization using computer generated random numbers to either a 3-month online Weight Watchers® program (n = 36), or Weight Watchers® plus 10 weekly sessions of CBSM (n = 38). The primary outcome was weight at 3 months compared to baseline. Secondary outcomes were weight at 12 months and subjective/objective stress system measures and metabolic markers at 3 and 12 months. The study was powered at 90% to detect a 5 kg difference in weight between the two groups at 3 months. Independent sample t-tests were used to analyze the difference in weight (in kg) between the groups and paired sample t-tests were used to analyze the difference within group at different time intervals. At follow-up, there was no significant difference in weight loss between the groups (1.8 kg, 2.1 kg). However, CBSM was effective in reducing psychological measures of stress ($p < 0.05$) and salivary cortisol (waking, 20-min post-waking) at 3-months; with the effect on stress persisting at 12-months within the CBSM group. The reduction in PSS at 3 months was significantly greater in the CBSM group (3.84, $p = 0.028$) compared to WW only group at 3 months. Addition of CBSM to a standard weight loss intervention did not improve the weight loss over the standard approach on its own, but the CBSM intervention improved psychological stress parameters and cortisol secretion in participants living with obesity.

## 1. Introduction

Obesity and modern life psychosocial stress have evolved in a similar time frame and individually contribute to cardiovascular disease, a leading cause of mortality and morbidity [1–5]. Obesity is a social stressor and vast resources are employed by individuals and health services to reduce its extent and complications. Stress, particularly in socially isolated or underprivileged groups, contributes to unhealthy eating behavior and consequent obesity [6]. Dietary restriction of 30% from baseline is generally successful in reducing weight by 5–10% over a 3-month period and commercial programs such as Weight Watchers® have been shown to be efficacious [7,8]. However, weight regain over a subsequent 6-12-month period is frequent, affecting 70–80% of dieters [9]. Psychosocial factors, including stress have been linked with weight

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regain as they can lead to high caloric intake, consumption of high energy food and low physical activity [10].

Few studies have examined the utility of a psychological strategy to enhance weight loss with concomitant measures of subjective and biological stress measures. Most of these studies did not measure weight regain after the active weight loss period. Cognitive behavioral stress management (CBSM) had been shown to reduce perceived stress and several biological stress system markers in a variety of clinical settings, including HIV infection and malignancy [11–14]. CBSM is an adaptation of cognitive behavior therapy (CBT); a treatment originally developed for depression [15] with extra components of relaxation training. CBT has been shown to improve short-term weight loss [16]. Several studies have shown that CBT improves psychological outcomes as well as weight loss [17,18]. A Cochrane review involving 36 studies with 3495 participants concluded that obese/overweight people benefit from psychological interventions: CBT (4 studies) and behavioral therapy (30 studies) were the most effective in terms of weight reduction and both were most useful when used in conjunction with diet and exercise [19].

Our aim was to conduct a randomized controlled trial to determine whether a structured stress management program, conducted in association with an established weight loss intervention, was more effective than the established intervention alone in achieving weight loss in individuals with obesity. We hypothesized that CBSM, targeted to reduce stress and negative affect and increase positive affect, delivered in a customized protocol suitable for people with obesity but without major comorbidities, would 1) augment weight loss from a standard 3-month weight loss program, 2) reduce biological markers of stress such as salivary cortisol and metabolic measures, and 3) reduce perceived stress (PSS).

## 2. Materials and methods

### 2.1. Participants

74 volunteers were recruited over a 6-month period from March to September 2017 in Adelaide, Australia. The volunteers responded to advertisements on public radio and Facebook. Inclusion criteria were: Adults 18–65 years of age, obesity- BMI 30–45; Exclusion criteria were: diagnosis of diabetes mellitus; eating disorder; symptoms consistent with, or untreated, sleep apnea; any major systemic illness, such as malignancy, connective tissue disease; glucocorticoid therapy; chronic opiate use (>10 mg morphine equivalent/day); disorders of pituitary/adrenal axis or sympathetic nervous system, severe hypertension (>160/90 mmHg); untreated hypothyroidism; psychosis (past or active); antipsychotic drug treatment; major depression (DSM–IV criteria), other active psychiatric illness; pregnancy; or unwillingness or inability to complete study protocol. Presence of other psychiatric illness was excluded by history.

Screening was performed by telephone and subsequent face to face interview (with MS) after written, informed consent was provided. Physical assessment included measuring weight, height, waist and hip circumference, blood pressure by MS. BMI (weight/height$^2$) and waist hip ratio (WHR – waist circumference/hip circumference) were calculated. Depression, a potential confounder of the CBSM intervention, was excluded using clinical interview and M.I.N.I 5.0.0/DSM-IV (August 1998) version. Participants with depression will warrant specific treatment for depression rather than stress and weight management alone, and depression and anti-depressants can influence weight gain/loss and stress levels. Other psychiatric disease was not assessed specifically, but the current or history of any psychiatric disease was an exclusion criterion. Participants were advised on how to complete the psychometric questionnaires.

### 2.2. Interventions

#### 2.2.1. Dietary intervention

A proven effective online Weight Watchers® program [7,8] was used and, as part of the program, participants had access to online/telephone customer assistance/coaching 24/7 with access to the online resources, including meal plans for three months. There was no formal assessment of adherence to the Weight Watchers® program. https://www.weightwatchers.com/au/wellbeing/how-to-lose-weight-online. Weight Watchers® is a diet plan developed first in the 1960s that encourage weight loss by making healthy food and lifestyle choices. It does not forbid any specific types of food or have any pre-prepared meals to purchase. The program allocates a certain number of points to each food item, depending on the calories, fat and fibre content and the participants have a number of points allowed per day, depending on their weight and goals.

#### 2.2.2. Cognitive behavioral stress management (CBSM) program

We developed a standardized protocol for stress management designed to assist individuals with obesity who wish to pursue weight loss. This group program based on cognitive behavioral therapy principles and modelled on the University of Miami's Stress Management and Relaxation Training [12] was developed by a team of psychologists (AP, KC, AB, JB).

The Cognitive Behavioral Stress Management (CBSM) program consisted of 90-min sessions delivered weekly for 10 weeks in a group setting. The group was led by a senior clinical and health psychologist with support from a health psychology student at the master's degree level under clinical supervision. Each session used the following broad structure: discussion of 'out of session' work, relaxation exercise, didactic presentation, as well as demonstration and practice of new skills and material. Short psychoeducational videos were also shown to further illustrate key points. The CBSM intervention did not directly target weight loss but rather aimed to teach skills to assist in the management of general stress as well as weight-related stress.

The core techniques included cognitive restructuring, behavioral activation, psychoeducation and relaxation strategies (e.g., breathing retraining, progressive muscle relaxation, guided-imagery and mindfulness). Skills were taught to develop skills in assertiveness, management of anger, as well as the development and maintenance of social support. At the end of each group session, homework that followed on from content addressed in the session was assigned. Homework assignments were then reviewed at the commencement of the next session. Participants were provided with audio recordings of relaxation practices undertaken in session to use between sessions. Participants were also given monitoring forms to record their use of the relaxation exercises. An outline of the CBSM program is available in e-resources.

#### 2.2.3. Control group

The control group was enrolled in the online Weight Watchers® program for 3 months. They had the assessments at the same intervals but did not receive the CBSM intervention.

#### 2.2.4. Study Plan

An overview of the sequence of study procedures is depicted in Fig. 1. Once the volunteers were successfully screened for eligibility, they were randomly allocated to one of two groups through simple randomization. A random number from 1 to 100 was generated for each volunteer; volunteers who drew odd numbers were allocated to control group and those with even numbers were allocated to intervention group. Participant body weights were recorded at baseline, 3-months, and 12-months. The anthropometric measurements were done by MS at the

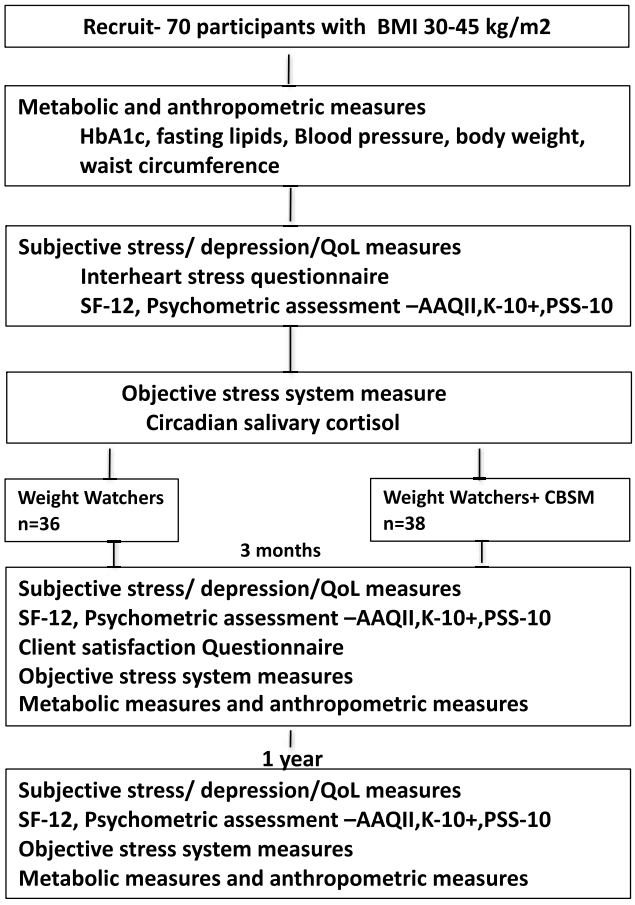


**Fig. 1. Study Plan.** PSS- Perceived Stress Score, K10+ – Kessler Psychological Distress Scale, AAQ–II– Acceptance and Actions Questionnaire, SF-12- Health status Questionnaire, QoL-Quality of Life.

initial visit and the two follow up visits. The same electronic scale was used for measuring weight for the duration of the study. Blood pressure (mean of two measures after 5 min in a resting in a seated position), waist and hip circumference were measured.

CBSM was concealed from the group randomized to Weight Watchers® only arm. If CBSM was shown to augment weight loss, it was to be offered to the non-CBSM group at the conclusion of the study.

The direct weight management intervention had two phases, Phase 1: *Weight loss phase*: Weight Watchers® on-line was followed for 3 months. Phase 2*: Weight maintenance phase*. This phase lasted 9 months. Volunteers were advised to continue with the dietary modifications from the phase 1 and continue to practice the stress reduction strategies learned during the CBSM sessions (for those who completed CBSM). There was no formal follow up during this period. They were re-assessed at 12-months with the same protocol as at the beginning and at 3-months.

#### 2.2.5. Psychometric questionnaires

Baseline psychological assessments of stress and depression were conducted using a battery of questionnaires. Psychological status and stress levels were assessed using the INTERHEART "psychosocial" questionnaire [20], Locus of Control 6 item questionnaire (LOC) [21], Kessler Psychological Distress Scale (K10) [22], Perceived Stress Scale (PSS) [23], Acceptance and Action Questionnaire- II 7 Item test (AAQ-II) [24], and a test of wellbeing- 12 -Item Short Form Survey (SF-12) [25].

Pre-recruitment, volunteers underwent a MINI (Mini International Neuropsychiatric Interview questionnaire) [26] to exclude depression, but they were not matched according to psychological parameters at baseline.

K10+ is a simple measure of psychological distress and designed to be used in a non-clinical population. A score of 10–15 indicates low levels of distress, 16–21 moderate, 22–29 high and 30–50 indicates a very high level of psychological distress [22]. The Acceptance and Action Questionnaire (AAQ-II) [23] measures psychological flexibility and experiential avoidance. PSS-10 is a measure of psychological stress. SF-12 is a short form of the SF-36, a measure of physical and mental health status [25,27]. Psychometric analysis comprised of comparing the test scores for these questionnaires at baseline, 3 months and 12 months, between and within the two groups.

### 2.3. Measures of stress system and metabolic markers

Objective measures of stress system activity included circadian salivary cortisol (waking, 20 min after waking, 1200 h, bedtime) to assess the hypothalamic-pituitary-adrenal (HPA) axis. Free cortisol has been validated in stress experiments and is unaffected by corticosteroid binding globulin which may be suppressed by weight loss if severe [28, 29]. Circadian cortisol rhythms, especially the cortisol awakening response, appear to relate to psychosocial factors, particularly social stress [30]. Metabolic measures at baseline and 3-months included HbA1c, fasting lipids and liver function tests.

#### 2.3.1. Statistical analyses

The primary outcome was weight at 3 months compared to baseline in the intervention and control groups. There were several secondary outcomes. These were weight at 12 months and subjective/objective stress system measures and metabolic markers at 3 and 12 months.

Power calculations used data from two similar studies [31,32]. Calculated sample size was 19 subjects per group (38 in total) to detect a difference in weight loss of 5 kg between the groups at 90% power.

Independent sample t-tests were used to analyze the difference in weight (in kg) between the groups and paired sample t-tests were used to analyze the difference within group at different time intervals. Results were generally expressed as mean ± standard deviation and a p value of $<0.05$ was considered significant. Response to CBSM was calculated by the change in PSS at 3 months. This was assessed by the reliable change method used in 2 publications [23,33]. From this we calculated a reliable change of PSS to be 6. Participants who had a reduction of 6 or more were considered as responders. A difference of PSS of less than +6 to −6 was considered as stable PSS and a difference of less than −6 was considered as deterioration of PSS.

We included all the participants who completed the 3 months of active intervention for our 3-month analysis and all of those who were available for follow up in our 12-month analysis, irrespective of the number of CBSM sessions attended (documented), and adherence to the online Weight Watchers® program (undocumented). We used complete-case analysis (SPSS) to address issues with missing data.

Salivary cortisol levels at each time point were compared within and between the two groups. Area under the curve and awakening response were calculated (Salivary cortisol post 20 min waking up – salivary cortisol on waking up). We did not control for baseline weight in our model. IBM SPSS statistics 27 was used for data analysis.

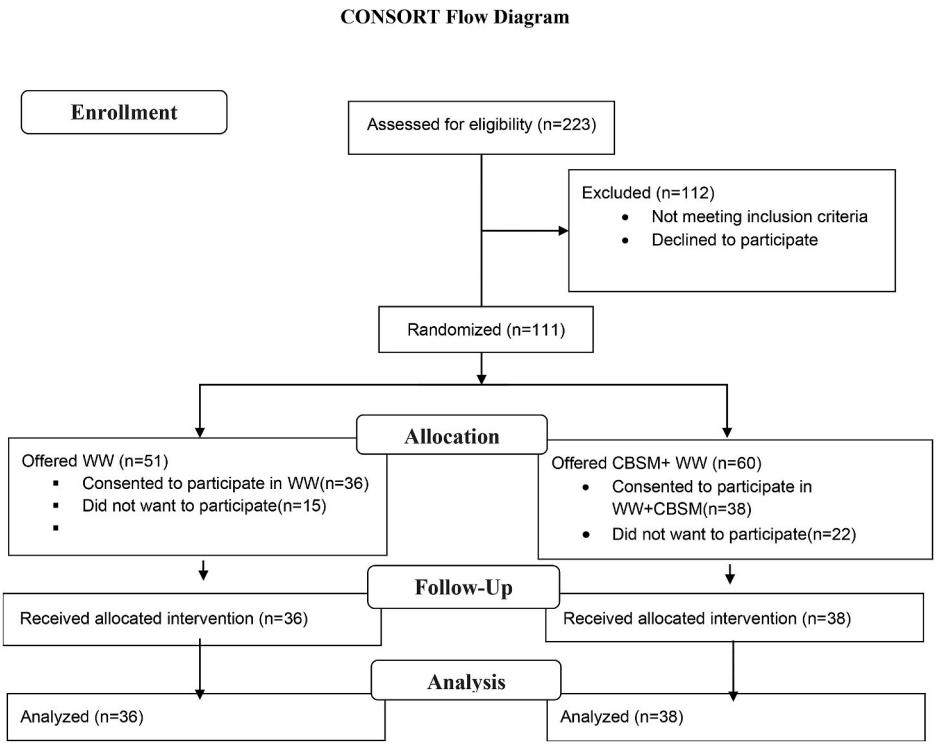


**Table 1**
Baseline characteristics (mean, SD or number and percentage) of the study population.

| | WW (n = 36) | WW + CBSM (n = 38) |
|---|---|---|
| Age (years) | 48.7 (8.2) | 46.8 (10.9) |
| Weight (kg) | 97.6 (15.1) | 101.9 (18.3) |
| Gender Female/Male | 36/0 | 33/5 |
| BMI (kg/m$^2$) | 36.5 (5.0) | 36.6 (5.5) |
| WHR | 0.84 (0.05) | 0.87 (0.07) |
| Blood pressure (mmHg) | 128/90 (16/10) | 124/88 (12/10 |
| Smoking | 2 (5%) | 1 (3%) |
| Alcohol intake standard drinks | | |
| 0-<1/week | 19 (52%) | 16 (42%) |
| 1–10/week | 17 (47%) | 20 (53%) |
| >10 | 0 | 2 (5%) |
| Exercise | 22 (61%) | 28 (74%) |
| Hours of exercise per week | 3.1 | 3.00 |
| HbA1c % | 5.4 (0.39) | 5.4 (0.38) |
| Triglycerides mmol/L | 1.6 (0.59) | 1.2 (0.42) |
| Total cholesterol (mmol/L) | 5.5 (1.05) | 5.1 (0.75) |
| LDL-Cholesterol (mmol/L) | 3.4 (0.8) | 3.14 (0.6) |
| HDL-Cholesterol (mmol/L) | 1.4 (0.38) | 1.4 (0.40) |
| AST U/L | 22 (5.) | 24 (11) |
| ALT U/L | 26 (9) | 31 (21) |
| ALP U/L | 74 (19) | 68 (18) |
| GGT U/L | 30 (18) | 28 (19) |

BMI – body mass index, WHR-waist/hip ratio, AST – Aspartate Aminotransferase, ALT – Alanine Aminotransferase, ALP, Alkaline phosphatase, GGT-Gamma glutamyl transferase.

## 3. Results

### 3.1. Baseline characteristics

There were 36 participants in the WW Only and 38 in the WW + CBSM group at baseline and at 3 months. The baseline characteristics of the two groups are shown in Table 1. The study population was predominantly female (93%, 69/74); Five males were randomized to WW + CBSM group. The most frequent comorbidities were hypertension, gastroesophageal reflux disease, hypothyroidism, hypercholesterolemia, and bronchial asthma. A considerable proportion of participants did not have co-morbidities (WW: n = 16, 44%; WW + CBSM: n = 11, 29%). Antihypertensives were being used by 15%, hormonal contraception or hormone replacement therapy were used by 18% and 38% of participants were not taking any medications. Twenty-two of the WW only group (61%) and 28 (74%) of the WW + CBSM group exercised regularly.

At baseline, both groups had a comparable but moderate degree of psychological distress in most parameters; the exception being higher K10+ scores in the WW + CBSM group (Table 2). The groups also reported moderate and comparable levels of stress on the PSS, and INTERHEART stress questionnaire. Overall, the two groups were well matched for relevant parameters at randomization.

Fig. 2 illustrates the anthropometric measurements in the two groups at different time points.

#### 3.1.1. Weight difference between the two groups

There was no significant difference in weight at three-month time period, {95.8 kg (15.3), 99.8 kg (19.6)} between the groups (p = 0.34) or weight loss at three-month time period, 1.8 kg (2.7) vs 2.1 kg (4.0) between the groups (p = 0.7).

There were no significant differences in the other anthropometric measurements between the groups at 3 months (Table 2).

#### 3.1.2. Weight difference within groups

At the end of 3 months the WW Only group had lost 1.81 kg (baseline 97.6 kg, 3 months 95.8 kg SD 2.7). WW + CBSM group had lost 2.1 kg (baseline 101.9 kg, 3 months 99.8 kg) (P < 001 for both groups).

#### 3.1.3. Subjective stress and psychological measurements between the groups

There was no significant difference between the group means for PSS, AAQ-II, SF12 or any other psychometric score at 3 months (Table 3). However, the reduction in PSS from baseline to 3 months was significantly greater the in the WW + CBSM group at 3.84 (SD 5.62) compared to WW only group which was 0.0 (SD 8.6) p = 0.037 (Fig. 3).

**Table 2**
Anthropometric and metabolic measurements at baseline, 3 and 12 months between groups. (Mean, SD and 95% confidence intervals).

| | baseline | | 3 months | | 12 months | |
|---|---|---|---|---|---|---|
| | WW (n = 36) | WW + CBSM (n = 38) | WW (n = 36) | WW + CBSM (n = 38) | WW (n = 28 | WW + CBSM (n = 31) |
| Weight (kg) | 97.6 (15.1) | 101.9 (18.3) | 95.8 (15.3) | 99.8 (19.6) | 97.1 (15.5) | 100.5 (20.2) |
| | 92.7–102.5 | 96.1–107.7 | 90.8–100.8 | 93.5–106.1 | 91.4–102.8 | 93.4–107.6 |
| BMI (kg/m$^2$) | 36.5 (5.0) | 36.6 (5.5) | 35.7 (5.2) | 35.8 (6.0) | 36.2 (5.2) | 35.9 (6.3) |
| | 36.9–38.1 | 34.8–38.3 | 34.0–37.4 | 33.9–37.7 | 34.3–38.1 | 33.7–38.1 |
| WHR | 0.84 (0.05) | 0.87 (0.07) | 0.83 (0.06) | 0.86 (0.07) | 0.83 (0.05) | 0.87 (0.08) |
| | 0.82–0.86 | 0.85–0.89 | 0.81–0.85 | 0.84–0.88 | 0.81–0.85 | 0.84–0.9 |
| Blood pressure (mmHg) | 128/90 (16/10) | 124/88 (12/11) | 123/86 (19/10) | 120/82 (14/9) | 124/83 (14/8) | 119/79 (14/8) |
| | 123–133 | 120–128 | 117–129 | 116–124 | 119–129 | 114–124 |
| | 87–93 | 84–91 | 83–89 | 79–85 | 80–86 | 76–82 |
| HbA1c % | 5.4 (0.4) | 5.4 (0.4) | 5.4 (0.5) | 5.4 (0.4) | | |
| | 5.3–5.5 | 5.3–5.5 | 5.2–5.6 | 5.2–5.5 | | |
| Triglycerides mmol/L | 1.6 (0.6) | 1.2 (0.4) | 1.4 (0.5) | 1.2 (0.4) | | |
| | 1.4–1.8 | 1.1–1.3 | 1.2–1.6 | 1.1–1.3 | | |
| Total cholesterol mmol/L | 5.5 (1.0) | 5.1 (0.8) | 5.3 (1.2) | 5.2 (0.8) | | |
| | 5.2–5.8 | 4.8–5.4 | 4.8–5.8 | 4.9–5.5 | | |
| LDL-Cholesterol (mmol/L) | 3.4 (0.8) | 3.1 (0.6) | 3.2 (1.0) | 3.1 (0.8) | | |
| | 3.1–3.7 | 2.9–3.3 | 2.8–3.6 | 2.8–3.4 | | |
| HDL-Cholesterol (mmol/L) | 1.4 (0.4) | 1.4 (0.4) | 1.5 (0.5) | 1.5 (0.4) | | |
| | 1.3–1.5 | 1.3–1.5 | 1.3–1.7 | 1.3–1.6 | | |
| AST U/L | 22 (5) | 24 (11) | 21 (6) | 22 (8) | | |
| | 20–24 | 20–27 | 19–23 | 19–25 | | |
| ALT U/L | 26 (9) | 31 (21) | 26 (7) | 26 (13) | | |
| | 23–29 | 24–38 | 23–29 | 21–31 | | |
| ALP U/L | 74 (19) | 68 (18) | 75 (17) | 69 (21) | | |
| | 68–80 | 62–74 | 68–82 | 61–77 | | |
| GGT U/L | 30 (18) | 28 (19) | 25 (13) | 24 (14) | | |
| | 24–36 | 22–34 | 20–30 | 19–29 | | |

BMI – body mass index, WHR-waist/hip ratio, AST – Aspartate Aminotransferase, ALT – Alanine Aminotransferase, ALP, Alkaline phosphatase, GGT- Gamma glutamyl transferase.

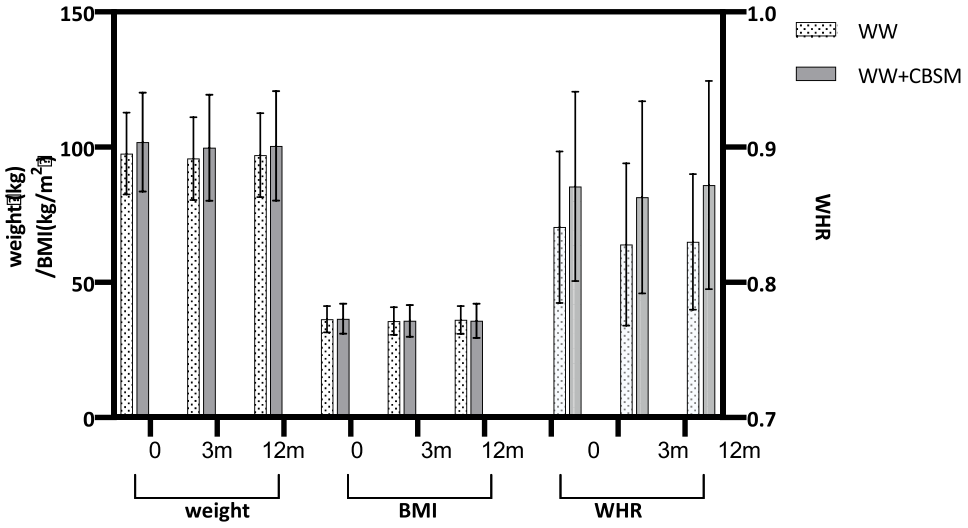


**Fig. 2. Anthropometric measurements between intervention groups over time (mean + SD).** There was a significant change in the weight from baseline to 3 months within each group, but there was no difference between the groups.

There was no significant difference in the INTERHEART stress results at 3 months in either group. Stressful major life events were comparable at 1.03 for WW + CBSM and 1.00 for the WW only group by 12 months. There were no other significant differences in the psychometric analysis between the two groups at any time point.

*3.1.4. Subjective stress and psychological measurements within the groups*

In the WW + CBSM group, PSS scores reduced by 3.84 (SD 5.6, P < 0.001), AAQ-II reduced by 3.56 (SD 8.5 p = 0.015), and Quality of life questionnaire mental health component, SF12-MCS, increased by 1.43 (SD 3.3, p = 0.014) at 3 months, in association with the CBSM program. In the WW only group the PSS score did not show any significant change (17.53,17.49, p = 0.35), AAQ-II did not change significantly (21.6,21.7) and there was no effect on the SF12-MCS (13.86,13.83).

### 3.2. Exploratory analyses

*3.2.1. Response to CBSM and weight loss*

Fig. 3 depicts the psychometric scores for the two groups. Though there was a significant reduction in the PSS scores in the WW + CBSM group compared to WW only group at 3 months (3.84 vs 0.04, p = 0.028) this was not associated with greater weight loss (weight loss 2.1 vs 1.8

**Table 3**
Psychological parameters at baseline, 3 months, and 12 months between two groups. (Mean, SD, 95% confidence intervals below the mean).

| | Baseline | | 3 months | | 12 months | |
|---|---|---|---|---|---|---|
| | WW (n = 36) | WW + CBSM (n = 38) | WW (n = 36) | WW + CBSM (n = 38) | WW (n = 28) | WW + CBSM (n = 31) |
| AAQ-II (7–49) | 21.6 (7.2) | 23.8 (7.9) | 21.7 (8.2) | 20.14 (7.3) | 20.39 (8.8) | 23.9 (9.5) |
| | 19.2–23.9 | 21.3–26.3 | 19.0–24.4 | 17.8–22.5 | 17.1–23.6 | 20.5–27.2 |
| K10+ (10–50) | 18.5 (5.6) | 21.3 (5.7) | 20.3 (7.4) | 19.8 (5.8) | 17.5 (6.2) | 20.8 (7.6) |
| | 16.7–20.3 | 19.5–23.1 | 17.9–22.8 | 17.9–21.6 | 15.2–19.8 | 18.2–23.5 |
| PSS -10 (0–40) | 17.5 (5.9) | 19.8 (5.2) | 17.5 (7.9) | 15.9 (6.2) | 15.6 (6.7) | 16.8 (7.0) |
| | 15.6–19.4 | 18.1–21.5 | 14.9–20.1 | 13.9–17.9 | 13.1–18.1 | 14.3–19.2 |
| SF-12 PCS (6–20) | 15.0 (2.34) | 14.1 (3.02) | 15.1 (3.1) | 14.8 (3.1) | 15.0 (3.2) | 15.0 (3.2) |
| | 14.3–15.8 | 13.1–15.1 | 14.1–16.1 | 13.8–15.8 | 13.8–16.2 | 13.8–16.2 |
| SF-12 MCS (5–22) | 13.9 (2.6) | 13.3 (3.1) | 13.8 (3.2) | 14.6 (2.9) | 14.7 (3.7) | 14.1 (3.7) |
| | 13.0–14.7 | 12.3–14.3 | 12.8–14.9 | 13.7–15.6 | 13.4–16.1 | 12.7–15.4 |

There was no significant difference between the two groups in any psychometric scores.
PSS- Perceived Stress Score, K10+ – Kessler Psychological Distress Scale, AAQ–II– Acceptance and Actions Questionnaire, SF-12 PCS-Health status Questionnaire – physical component summary, SF-12 MCS - Health status Questionnaire – mental component summary.

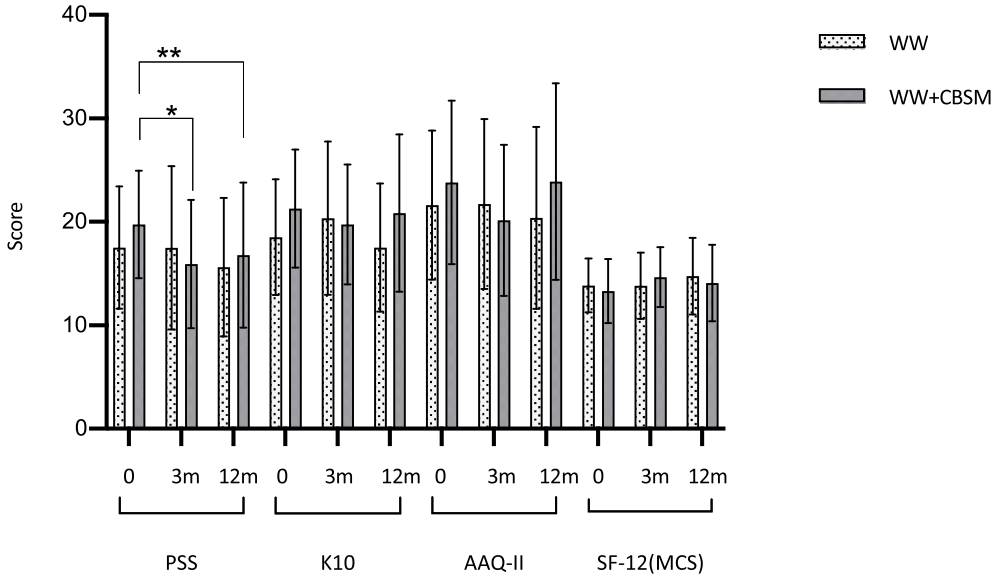


**Fig. 3. Psychometric scores for intervention groups over time.** CBSM was associated with significant reduction in PSS score at 3 and 12 months for the WW + CBSM group. No significant change in psychometric parameters was seen in the WW alone group. PSS- Perceived Stress Score -10, K10 – Kessler Psychological Distress Scale, AAQ–II– Acceptance and Actions Questionnaire, SF-12 MCS- Health status Questionnaire – mental component summary.


**Fig. 4. Salivary cortisol levels within two groups over time.** There was no significant change in salivary cortisol level at any time in the WW group. In the WW + CBSM group there was a significant reduction in the morning cortisol level at 3 months and returned to baseline at 12 months.

kg, p = 0.7). Participants responding to CBSM in the WW + CBSM group showed that the PSS responders to CBSM lost less weight at 3 months than non-responders (0.57 kg [reduced PSS] vs 2.3 kg [stable PSS] vs 7.6 kg [increased PSS]) and this difference persisted at 12 months (p = 0.04 between responders and non-responders at 3 months and p = 0.003 at 12 months).

#### 3.2.2. Weight loss and stress and psychological measurements

We selected participants from both groups who had a considerable weight loss at any time point (5% or more from baseline) and analyzed their psychometric scores. 24 out of 74 individuals had a considerable weight loss and they showed significant improvements in their psychometric scores. These included a lower PSS at 12-months (−4.95, p = 0.002), lower K10 at 12-months (−3.3, p = 0.001), increase in SF12 mental component at 12-months and increase in SF12- physical component at 12-months when compared to the no-weight loss group.

#### 3.2.3. Salivary cortisol: between the groups

At the 3 month follow up, there was no significant change in the salivary cortisol levels or awakening response between the groups.

#### 3.2.4. Salivary cortisol: within the groups

There was a significantly lower salivary cortisol level at waking (4.0 vs 3.0 nmol/L, p = 0.01) and 20 min after waking (7.7 nmol/L vs 5.7 nmoL/l, p = 0.034) in the WW + CBSM group at 3-months compared to baseline (Fig. 4). There was no significant change in the salivary cortisol levels at any time in the WW only group. Salivary cortisol levels on waking up were 3.7 vs 3.7 nmol/L, p = 0.97 and, 7.2 vs 6.5 nmol/L, p = 0.44, 20 min after waking for the WW only group.

### 3.3. Metabolic markers

There were no significant differences in the metabolic markers between the groups at 3 months (Table 2).

## 4. Discussion

WW + CBSM, delivered in a controlled study, was associated with lowering of stress scores and lower waking and 20 min post waking saliva cortisol concentrations compared to baseline in the WW + CBSM group. However, CBSM did not augment Weight Watchers® induced weight loss at 3-months (1.8–2.1 kg) or at 12-months, in fact responders to CBSM lost less weight than the non-responders in the exploratory analysis. This study was not powered for sub-group analysis, and we cannot base firm conclusions from this finding. This study explored the effect of CBSM in conjunction with a standard weight loss program, on weight loss and its effects on the biological stress system.

CBSM was associated with reduced perceived stress measured by the PSS test and salivary cortisol suggesting that the intervention was effective in stress reduction, both in terms of subjective experience and an objective stress measure. CBSM program also had an effect on the AAQ-II and SF-12 MCS component with improvement in psychological distress scores and psychological wellbeing within the group. Hence, the CBSM program not only helped reduce psychological stress but also had a positive impact on psychological distress and wellbeing. However, this reduction in stress within the WW + CBSM group did not translate to a significant reduction in weight loss compared to WW alone.

When considering the total study population, in the group with weight loss >5% from baseline (n = 24) (WW and WW + CBSM), there was a significant improvement of psychometric scores including PSS at 12-months compared to no-weight loss group. This is contrary to the findings from a recent meta-analysis including 10 randomized controlled trials with diet induced weight loss, concluding that weight loss did not increase or reduce stress [34]. The K10+ scores were lower at 12 months (3.35, p = 0.001), SF12 physical component was higher at 12 months (1.65, p = 0.003), SF12 mental component was higher at 3 (1.8, p = 0.019) and 12 months (2.2, p = 0.009).

Psychological interventions including CBT are well known to have a bi-directional effect. Increased anxiety and/stress during the treatment period have also been seen in some exposure exercises related to CBT [35]. Increased awareness of personal mental health issues and efforts to reduce their effect may distract from adherence to weight loss measures leading to a net null effect. This awareness may have led to prioritizing the need to improve psychological wellbeing above the adherence to Weight Watchers®. The accountability factor was higher with the CBSM intervention as it was a face-to-face group intervention with interactions and feedback from the therapists when compared to online Weight Watchers®.

Significantly lower morning cortisol levels were seen at 3-months within the WW + CBSM group which corresponds with the persistently lower PSS at 3- and 12-months within the group compared to baseline. Studies have shown that morning cortisol levels correlate to chronic stressful situations, such as unemployment state, better than with cortisol levels later in the day [36]. Several studies have consistently demonstrated that the cortisol awakening response is enhanced in subjects with higher stress, social stress, work overload etc. [37,38]. Metabolic markers were unchanged perhaps reflecting the modest weight loss achieved by both groups.

Obesity is relatively resistant to standard therapy with weight loss of around 5–10% achievable with 30% caloric restriction over 6 months but with a high recurrence rate – 30% weight is regained at 2 years [39]. Pharmacological treatments have had some adjunctive effects, perhaps due to the high redundancy of multitudinous weight control mechanisms [40].

Limitations: Though we did our sample size calculation using two similar studies, as we had an active control arm, the sample size may not have been adequate to detect a clinically significant weight loss. The study sample may not represent the general population with obesity, as most of our participants were female and were recruited through radio and Facebook advertisements. This mode of recruitment may have recruited a group of participants who may not represent the general population with obesity, which can add to the bias. Our study population was mostly young to middle aged Caucasian working women with young families and few males were recruited. The active control arm may have had a crossover modulatory effect through distraction, leading to effects on psychological parameters and cortisol but no net effect on weight loss. The control arm also had a positive intervention, Weight Watchers®, but it would be difficult to recruit if a no-intervention control arm was employed. The trial was associated with a relatively low weight loss overall.

## 5. Conclusions

CBSM reduced psychological stress and lowered morning cortisol concentrations after 3 months of intervention but did not augment weight loss from a standard Weight Watchers® program. CBSM may be of value in weight loss in different population groups or may assist with modest (<5 kg) weight loss or if applied differently.

## Conflict of interest

We wish to inform that we do not have any conflict of interest.

## Author statement

1. D M Manodhi K Saranapala – program implementation, data curation, methodology, analysis, writing, review
2. John Baranoff – Investigation, Program implementation, Resources, review and editing
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The authors do not have any competing interests.

## Appendix

**Table 1**
Psychological parameters at baseline (range given within parenthesis)

| | Baseline | |
|---|---|---|
| | WW | WW + CBSM |
| Locus of control (5–30) | 20.7 (±2.3) | 21.05 (±3.0) |
| AAQ II (7–49) | 21.6 (±7.2) | 23.8 (±7.9) |
| K10+ (10–50) | 18.5 (±5.6) | 21.29 (±5.7) * (p 0.039) |
| PSS-10 (0–40) | 17.53 (±5.9) | 19.76 (±5.2) |
| SF-12 PCS (6–20) | 15.03 (±2.3) | 14.11 (±3.0) |
| SF-12 MCS (5–22) | 13.86 (±2.6) | 13.32 (±3.1) |
| **INTERHEART Stress questionnaire** | | |
| **Stress at home/work mean (1–4)** | 2.97 (±0.60) | 2.87 (±0.57) |
| Experienced some periods of stress | 7 (19%) | 9 (24%) |
| Experienced several periods of stress | 23 (64%) | 25 (66%) |
| Experienced permanent stress | 6 (17%) | 4 (11%) |
| **Financial stress score means (1–3)** | 1.75 (±0.64) | 1.76 (±0.67) |
| Little or none | 13 (36%) | 14 (37%) |
| Moderate | 19 (53%) | 19 (50%) |
| High or severe | 4 (11%) | 5 (13%) |
| **Stressful life events** | 1.06 (±0.98) | 1.45 (±1.17) |
| 0 | 13 (36%) | 7 (18%) |
| 1 | 11 (30%) | 17 (45%) |
| 2 or more | 12 (33%) | 14 (37%) |

*P = 0.039.

PSS- Perceived Stress Score, K10+ – Kessler Psychological Distress Scale, AAQ–II– Acceptance and Actions Questionnaire, SF-12 PCS-Health status Questionnaire – physical component summary, SF-12 MCS - Health status Questionnaire – mental component summary.

**Table 2**
Anthropometric and metabolic measurements at baseline, 3 months and 12 months for two groups

| | WW | | | WW + CBSM | | |
|---|---|---|---|---|---|---|
| | baseline | 3 months | 12 months | baseline | 3 months | 12 months |
| Weight (kg) | 97.64 | 95.8 | 97.09 | 101.88 | 99.78 | 100.53 |
| BMI (kg/m$^2$) | 36.45 | 35.7 | 36.15 | 36.58 | 35.8 | 35.8 |
| WHR | 0.845 | 0.828 | 0.830 | 0.871 | 0.863 | 0.872 |
| Blood pressure (mmHg) | 127.7/89.5 | 122.5/85.9 | 123.5/82.6 | 123.8/87.7 | 120.0/82.0 | 119.28/79.6 |
| HbA1c | 5.38 (±0.39) | 5.38 | | 5.40 (±0.38) | 5.42 | |
| TG mmol/L | 1.6 (±0.59) | 1.4 | | 1.2 (±0.42) * | 1.1 | |
| Total cholesterol mmol/L | 5.54 (±1.05) | 5.34 | | 5.13 (±0.75) | 5.21 | |
| LDL-Cholesterol (mmol/L) | 3.37 (±0.84) | 3.17 | | 3.14 (±0.59) | 3.14 | |
| HDL-Cholesterol (mmol/L) | 1.41 (±0.38) | 1.53 | | 1.42 (±0.40) | 1.47 | |
| AST U/L | 21.5 (±5.23) | 21.4 | | 24.54 (±10.8) | 22.2 | |
| ALT U/L | 26.17 (±9.47) | 25.6 | | 30.9 (±21.28) | 26.1 | |
| ALP U/L | 73.66 (±18.62) | 74.9 | | 67.9 (±18.62) | 68.7 | |
| GGT U/L | 29.54 (±18.10) | 24.5 | | 27.53 (±18.55) | 24.11 | |

BMI – body mass index, WHR- waist/hip ratio, AST – Aspartate Aminotranferase, ALT – Alanine Aminotransferase, ALP, Alkaline phosphatase, GGT- Gamma glutamyl transferase.

**Table 3**
Psychological parameters at baseline, 3 months and 12 months for two groups.

| | WW | | | WW + CBSM | | |
|---|---|---|---|---|---|---|
| | baseline | 3 months | 12 months | baseline | 3 months | 12 months |
| AAQ (7-49) | 21.6(±7.2) | 21.7(±8.2) | 20.39(±8.8) | 23.8(±7.9) | 20.14(±7.3) | 23.87(±9.5) |
| K10+* (10-50) | 18.5(±5.6) | 20.34 (±7.4) | 17.50 (±6.2) | 21.29(±5.7) (p 0.039) | 19.76(±5.8) | 20.84(±7.6) |
| PSS * (0-40) | 17.53(±5.9) | 17.49(±7.9) | 15.61(±6.7) | 19.76(±5.2) | 15.92(±6.2) | 16.77(±7.0) |
| SF-12 PCS (6-20) | 15.03(±2.34) | 15.11(±3.1) | 15.00(±3.2) | 14.11(±3.02) | 14.76(±3.1) | 15.00(±3.2) |
| SF-12 MCS (5-22) | 13.86(±2.6) | 13.83(±3.2) | 14.75(±3.7) | 13.32(±3.1) | 14.65(±2.9) | 14.07(±3.7) |

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