BMJ Open

Investigating the effect of an online self-compassion for weight management (SC4WM) intervention on self-compassion, eating behaviour, physical activity, and body weight in adults seeking to manage weight: Protocol for a randomised controlled trial

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2021-056174
Article Type:	Protocol
Date Submitted by the Author:	05-Aug-2021
Complete List of Authors:	Brenton-Peters, Jennifer; The University of Auckland, Department of Psychological Medicine Consedine, Nathan; The University of Auckland, Department of Psychological Medicine Roy, Rajshri; The University of Auckland, Nutrition and Dietetics Serlachius, Anna; University of Auckland, Psychological Medicine
Keywords:	NUTRITION & DIETETICS, PREVENTIVE MEDICINE, PUBLIC HEALTH

Investigating the effect of an online self-compassion for weight management (SC4WM) intervention on self-compassion, eating behaviour, physical activity, and body weight in adults seeking to manage weight: Protocol for a randomised controlled trial

Jennifer Brenton-Peters[1] | Nathan Consedine[1] | Rajshri Roy[2] | Anna Serlachius[1]

Affiliations:

1. Department of Psychological Medicine, Faculty of Medical and Health Sciences, The University of Auckland, New Zealand
2. Department of Nutrition and Dietetics, Faculty of Medical and Health Sciences, The University of Auckland, New Zealand

Corresponding Author: Jennifer Brenton-Peters PDt, MA, Department of Psychological Medicine, The University of Auckland, Auckland, New Zealand. Email: jbre092@aucklanduni.ac.nz

Word count: 3,948

Abstract

Introduction: Individual weight management, defined as engaging in behaviours to maintain or lose weight, can improve health and wellbeing. However, numerous factors influence weight management outcomes, such as genetics, biology, stress, the social and physical environment. Consequently, weight management can be hard. Self-compassion, described as treating oneself kindly in times of failure or distress, has shown promise in improving weight management outcomes. The objectives of this study are two-fold: 1) to examine the efficacy of an online Self-Compassion for Weight Management (SC4WM) intervention coupled with an online commercial weight management program (WW) with increasing self-compassion and improving weight management outcomes (eating behaviour, physical activity and body weight) in comparison to the WW program only and 2) to explore whether improvements in weight management outcomes are moderated by eating restraint, weight self-stigma, perceived stress, and psychological coping.

Methods and Analysis: To achieve these objectives, 240 participants seeking to manage their weight will be randomised to either an online behavioural commercial weight management program (WW) or the online WW+SC4WM intervention. Validated measures of self-compassion, stress, weight self-stigma, eating restraint, psychological coping and weight management outcomes will be administered online at baseline, 4-weeks, and at follow-up at 12-weeks.

Ethics and Dissemination: Ethics has been granted by the University of Auckland Health Research Ethics committee. Results will be communicated in peer-review journals, conferences and a doctoral thesis. If effective in increasing self-compassion and improving weight management outcomes, the intervention could be made more widely available to supplement behavioural weight management programmes.

Clinical trial registration number: ACTRN12621000580875

Keywords: Weight management, eating behaviour, physical activity, self-compassion

Strengths & Limitations

- This is the first study to test a 100% online, Self-Compassion for Weight Management intervention (SC4WM) designed to supplement existing weight management programs.
- The study utilises a randomised controlled trial design with the online version of a commercial behavioural weight management program as an active control (WW).
- This study is limited due to the non-blinding of the first author and self-reporting of outcomes.
- This study investigates a supplemental SC4WM intervention that could increase the efficacy of online behavioural weight management program by improving self-compassion and weight management outcomes during the global pandemic and beyond.

Introduction

Successful weight management, defined as losing or maintaining body weight, can improve health outcomes.[1] However, several competing factors influence weight management behaviours (e.g., healthy eating and physical activity), including body physiology, biology, psychological wellbeing, stress management, socioeconomic status, and the physical and social environment.[2,3] Furthermore, ongoing public health restrictions to control the spread of COVID-19 and concerns about exposure mean access to in-person support may be limited and engaging in healthy behaviours can be even more challenging (e.g., accessibility to healthy food, more limited opportunity for exercise, and financial stress).[4,5] Self-compassion, the ability or tendency to respond to oneself with care and kindness in times of suffering and distress,[6] has shown promise with improving weight management outcomes (healthier eating and reduced or maintained body weight).[7] However, few studies have investigated whether the changes thought to accompany the development of self-compassion can be successfully taught and practised 100% online as a supplement to an existing weight management program.

Healthy eating and physical activity are recommended for everyone to improve health outcomes and manage weight.[8] For those living with weight-related chronic disease, such as obesity, even a small amount of weight loss (5-10% of body weight) can have positive physiological effects. For example, weight loss can lower blood lipids and improve glycemic control, resulting in reduced risk for heart disease and diabetes complications.[9] Appropriate weight management can also support psychological outcomes, including improved emotional wellbeing, self-esteem, depressive symptoms, body image, and health-related quality of life.[10] Behavioural-based weight management interventions have shown some effectiveness with weight loss and maintenance.[11,12] However, weight management history (e.g., previous

unsuccessful weight loss attempts, weight cycling) and early weight loss results (e.g., in the first 4-weeks) can influence an individual's weight management success.[13,14] Weight regain is common when individuals cannot sustain the behavioural changes needed to maintain weight loss, such as healthy eating, increased physical activity, and continued self-monitoring.[12,15-18]

Engaging in weight management can be challenging. Body weight is influenced by several factors (e.g., biology, stress, environments).[2,3] However, many people believe their behaviours *cause* their weight.[19] Therefore, the inevitable ups and downs of body weight may result in feelings of distress, shame, failure, and blame.[20-22] These feelings are exacerbated by weight stigma, which is the negative societal prejudice and stereotypes experienced by people with higher weights.[23,24] Facing weight stigma is common for adults who are engaging in weight management.[25] When internalised, weight self-stigma can create additional stress, ultimately resulting in less healthy eating and reduced physical activity.[24,26]

Furthermore, weight fluctuations are associated with stress, regardless of health behaviour.[27] The stress response activates the sympathetic nervous system, which can cause a release in hormones (e.g., cortisol), and reduce executive function (e.g., less mindful regulation of food intake).[28,29] Stress can trigger binge eating or the consumption of higher fat and higher sugar comfort foods, which may lead to weight gain over time.[30,31] Eating restraint, defined as engaging in a cognitive effort to reduce caloric intake, can support weight management outcomes.[17,32] However, those who are more restricted with their eating behaviours may paradoxically be more prone to overeating in stressful times.[33,34]

Self-compassion has shown the potential to moderate many challenges that plague weight management, including moderating the effects of stress.[35-38] Self-compassionate people treat themselves with kindness when experiencing stressful situations and appear less likely to use

avoidance as a coping mechanism.[39] Thus, self-compassion offers a way to cope with stress through the enhanced ability to regulate health-related behaviour such as healthier eating and physical activity.[38,40,41] In addition, people with greater self-compassion tend to have lower levels of internalised weight stigma[42,43] and improved emotional regulation.[40,44] Consequently, self-compassion could benefit weight management due to its ability to increase an individual's coping and self-management during stressful times.[42,45-49]

Self-compassion has many diverse definitions and intervention approaches,[50] but can be broadly defined as taking compassion inward by creating an awareness of one's suffering, combined with a subsequent desire to alleviate it.[51] Self-compassion is described as containing three components: 1) being kind towards oneself in times of failure and self-criticism, 2) considering oneself as part of a broader human experience (rather than isolated) and, 3) being mindful of negative thoughts and feelings, not overidentifying with them.[6] Both self-compassion specific and self-compassion as part of more comprehensive interventions have been shown to increase self-compassion scores (for example, measured by the self-compassion scale, SCS).[50,52,53] However, in a weight management context, most studies include self-compassion as part of broader interventions; therefore, it is hard to determine if it is self-compassion specifically contributing to the positive effects (Brenton-Peters et al., Self-compassion in weight management: A systematic review).

Nonetheless, self-compassion interventions show clear relevance and potential for improving weight management outcomes. However, the question remains on how best to deliver these interventions. In-person weight management interventions are often associated with high attrition rates.[54] Furthermore, unpredictable public health measures to control the spread of COVID-19 may lead to even higher in-person attrition and compound the challenges to engaging

in health behaviours.[4,55] Online interventions utilising cognitive behavioural therapies that are clear and simple to use have shown good effect sizes with improving health behaviours (ḡ=0.43, 95% CI 0.27-0.59).[56] Early evidence suggests that online weight management interventions show promise with supporting weight management outcomes, including online compassion-based interventions.[57-60,] However, to date, no studies have examined the effectiveness of a 100% online self-compassion intervention tailored to the full scope of weight management outcomes (e.g., eating behaviour, physical activity and body weight) as a supplement to an online version of a behavioural weight management program. Therefore, the objective of this study is to assess whether an online, mobile-friendly Self-Compassion for Weight Management (SC4WM) intervention can increase participant self-compassion and improve weight management outcomes for those engaging in an online behavioural weight management program (WW).

Methods: Participants, interventions and outcomes

Following CONSORT[61] and SPIRIT[62] guidelines, a two-armed, randomised controlled study comparing the addition of the SC4WM intervention to a widely available behavioural weight management program (WW) will be conducted. The proposed study will investigate if the online SC4WM intervention can increase self-reported self-compassion and improve weight management outcomes, defined as eating behaviour, physical activity levels, and body weight, for those in the first 4-weeks of a widely available online commercial program (WW). In addition, this study will examine potential moderating variables, including perceived stress, weight self-stigma, eating restraint, and psychological coping. This study will be delivered 100% online and undertaken over 4-weeks, with a subsequent 12-week follow-up. The RCT protocol has been prospectively registered with the Australian New Zealand Clinical Trials Registry

ACTRN12621000580875 (https://www.anzctr.org.au/ACTRN12621000580875.aspx). Protocol amendments will be communicated through the trial registry.

Participants

Participants will be New Zealand residents who are seeking to manage their weight. Inclusion criteria for participation include: 1) being an adult (≥18 years of age) and 2) seeking to manage their weight. Exclusion criteria for participation include: 1) being a current WW member, 2) pregnant or expecting to become pregnant in the next 3-months, 3) diagnosed with an active eating disorder (e.g., bulimia nervosa or anorexia nervosa), 4) being prescribed medication for weight management or newly starting a medication that may cause weight gain. All participants will be given an access code to a widely available behavioural commercial weight management program (WW). Participants will be randomised into either the WW program only (active control group) or the WW plus the supplemental SC4WM intervention. Recruitment is expected to commence in June and July 2021. Participants will be entered in a draw for an iPad as reimbursement for taking part in the randomised control trial (RCT). Participants may withdraw from the study at any time.

Participant timeline

Participants will be recruited via posters, websites (e.g., university research site) and national (New Zealand) social media posts and marketing (e.g., via community board posts on Facebook, Twitter) with a link to a secure website (REDCap).[63,64] Potential participants will click a link to the study eligibility questionnaire. If eligible to participate (e.g., not a current WW member, ≥18 years of age), they will read and download the Participant Information Sheet. After providing informed consent, participants will complete the baseline questionnaires and be randomised using a computer-generated number sequence into either the WW plus the SC4WM

intervention or WW only (active control group). Participants allocated to the SC4WM intervention will receive an access code to the SC4WM website. Please see Figure 1 for the CONSORT diagram demonstrating the flow of participants through the study.

After providing informed consent, the intervention group will fill out the baseline questionnaires and receive an access code and instructions to download the WW app and a separate link to the SC4WM website with a guest code. During the first 4-week period, participants in the intervention group will receive one automated email at the beginning of each week (via REDCap), reminding them to complete the SC4WM online modules. After consenting to participate in the study, the control group will also receive an access code and instructions to download the WW app. They will be instructed to utilise the WW program as directed and expect subsequent emails at 4-weeks and 12-weeks with follow-up questionnaires.

REDCap will send automated emails to both groups at 4-weeks from baseline (post-intervention) and 12-weeks from baseline (follow-up). After completing the final follow-up questionnaire, both groups will be provided with the opportunity to enter a draw for an iPad. See Figure 1 CONSORT diagram.

Interventions

Active Control Group

Participants randomised to the control group will partake in the current online WW *Weight Watchers reimagined* program. The WW program is a commercial behavioural weight management program that aims to support its members with healthier habits.[65] The WW program uses the Smartpoints™ food tracking system, which encourages members to make healthier food choices by assigning point values to foods requiring moderation (e.g., higher fat and higher sugar foods). In addition, the WW program promotes exercising, cultivating a

positive mindset, and tracking body weight with the objective of weight management. The most recent WW program is the myWW+ program, which includes a personalised meal plan, tracking, and peer-support online. The myWW+ program provides access to the myWW+ app that offers easy-to-use food and activity tracking, 24/7 live coaching, and a supportive network of other WW members through a WW online form.[65] The myWW+ program may contain elements of self-compassion within its content. However, the SC4WM intervention described below is designed to have a higher, more specific, and more concentrated dose of self-compassion.

Self-compassion for Weight Management (SC4WM) intervention

The SC4WM intervention was designed for the Aotearoa New Zealand population and included consultation with Māori, Indigenous peoples of Aotearoa New Zealand. The SC4WM intervention is delivered online through a mobile-friendly website separate from the WW program. Participants in the intervention group will be asked to follow the digital myWW+ program as directed by WW. Participants will need to use data or internet connectivity and an access code to log into the website content. The SC4WM intervention incorporates simple, evidence-based techniques (e.g., journaling, letter writing, reflections) to deliver a self-compassion intervention tailored to weight management outcomes (i.e., eating behaviour, physical activity, and weight monitoring). The SC4WM intervention landing page (website) provides an initial definition and background on self-compassion and quick access to each module. See Figure 2. *SC4WM Landing Page*. The SC4WM intervention is based on taking the meaning of compassion inward, being mindful of personal suffering or distress, and applying the principles of mindfulness, self-kindness, and shared humanity.[6,50,66] The SC4WM has four modules designed to specifically target participants' relationship with each weight management outcome, including self-compassion for eating behaviour, self-compassion for physical activity,

and self-compassion for body weight. Each module includes an adapted construal journal,[67] meditation, and reflection activity[68] incorporating the principles of self-compassion to eating behaviour, physical activity behaviour, and body weight. It is recommended that participants complete one module in sequence per week. It is not expected that there will be any harm associated with this intervention; however, the SC4WM website will have links for additional mental health support in participants' local areas (New Zealand). See Table 1.

Table 1. *SC4WM modules*

Module	Objective
Module 1: EAT.	Cultivate a more self-compassionate attitude towards eating behaviours. Includes journaling, meditation, and reflections designed to create mindfulness of eating behaviour, feeling of shared humanity and self-kindness to the challenges of eating well.
Module 2: MOVE.	Develop a more self-compassionate attitude towards physical activity behaviours. Includes journaling, meditation, and reflections designed to create a mindful awareness of physical activity, a feeling of connection, and self-kindness to the challenges of engaging in physical activity.
Module 3: WEIGH.	Foster a more self-compassionate attitude towards body weight. Includes journaling, meditation, and reflections designed to create a mindful reaction to body weight, an awareness that they are not alone in their struggles, and bringing kindness to the scale.
Module 4: UNIFY.	Cultivate a more self-compassionate attitude toward weight management as a whole. Includes the selection of activities/practises for the participant to continue with after the intervention.

Outcome Measures

Informed consent and outcome measures will be collected using REDCap. Potential participants will first be screened based on whether they seek to manage their weight and the study inclusion and exclusion criteria (e.g., ≥18 years of age, not a current WW member). Completing questionnaires at baseline, post-intervention (4-weeks), and follow-up (12-weeks) will take participants approximately 25 minutes. REDCap will collect demographic data via self-report (e.g., sex, age, height, ethnicity, income, pre-existing weight-related chronic diseases and

weight loss history, e.g., number of previous weight loss attempts). Validated questionnaires will be used to assess self-compassion, weight management outcomes, and potential moderators at baseline, 4-weeks and 12-weeks after baseline. Since self-compassion is most useful when faced with a struggle or failure, participants will report on the degree of their struggle with weight loss or maintenance at baseline, 4-weeks, and the 12-week follow-up. Adherence to both the WW program and the SC4WM intervention will be self-reported at 4-weeks and the 12-week follow-up. This study will utilise validated measures which are referenced and described below.

Primary outcome

To confirm that the intervention increased participant self-compassion compared to the WW program, we will use the Self-Compassion Scale (SCS[52]) at baseline, and at 4- and 12-weeks follow-up. The SCS is a well-validated scale with high internal validity, Cronbach's *a* between .76 and .94 in previous studies.[69] The SCS indexes how participants typically respond towards themselves in times of failure or distress.[6,70] Using a scale of 1= almost never to 5= almost always, participants are asked questions related to 6-subscales, self-kindness: "*I am loving towards myself when I am feeling emotional pain"*; self-judgement: "*I am disapproving of my own flaws and inadequacies*"; Common humanity: "*When things are going badly for me, I see the difficulties as part of life that everyone goes through*"; isolation: "*When I think about my inadequacies, it tends to make me feel more separate and cut off from the world"*; mindfulness: "*When something upsets me I try to keep my emotions in balance*"; and over-identification: "*When I'm down and out, I remind myself that there are lots of other people in the world feeling like I am*." The scale can be analysed both in terms of specific subscales (i.e., self-kindness, mindfulness, common humanity, isolation, overidentification and self-judgement) as well as generating a total SCS score.[52]

Secondary outcomes

The Weight Control Strategies Scale (WCSS) will be utilised to measure changes in participants' eating behaviour and physical activity behaviour.[71] The WCSS has subscales to measure weight control strategies commonly used in weight management programs, including dietary choices, physical activity and self-monitoring. The WCSS is a well-validated scale with a Cronbach's $a > .79$ and as high as .94 in a WW™ population.[17] The WCSS has also been modified to fit the WW™ program specifically (e.g., low-calorie foods has been changed to low point foods).[17] The WCSS asks participants on a scale of 0= never and 4= always to describe the strategies and behaviours they engage in when trying to lose or maintain weight loss over the last month. For example, "*I had several servings of fruits and/or vegetables each day." "I engaged in a moderate-intensity exercise like brisk walking or something similar to brisk walking for at least 30 minutes a day."* Scale items are totalled and divided by the number of items (total mean score). Separate subscale scores are achieved by summing all items in a subscale and dividing by the number of subscale items (total mean subscale score).[71]

The impact of the SC4WM intervention on body weight outcomes will be determined by self-reported body weight and height to calculate body mass index (BMI, kg/m^2). Self-reported body weight has been seen to strongly correlate with objectively measured body weight.[17,18]

The overall objective of weight management is to support both physical and psychological health.[8] Therefore, potential improvements in emotional wellbeing will be assessed using the WHO-5 Well-being Scale.[72] The WHO-5 is a brief well-validated scale with good internal reliability (a= .84). Participants will be asked how they have been feeling over the last two weeks, with a higher number indicating better emotional wellbeing. For example, "*I*

have felt cheerful and in good spirits." is rated on a scale of 0 to 5 with 0 meaning 'at no time' and 5 'all the time.' A total score is calculated by summing all items.

Potential moderators

To assess participant eating restraint, the *Revised Rigid Restraint Scale* (RRRS[73]) will be used. The RRRS is a validated 12-item scale designed to assess participants' thoughts, feelings, and behaviours related to restrictive and guilty eating behaviours. The RRRS has good internal reliability with a Cronbach's *a* of > .80 in previous studies.[73] Participants are asked to rate how often statements describe their thoughts, feelings or behaviour regarding eating using on a 5 item scale, 1 being 'never' to 5 'always.' For example, "*There are certain unhealthy foods that I try not to eat in any quantity*." All items are summed to assess dispositional eating restraint. A higher RRRS total score is indicative of higher eating restraint.[65]

The *Weight Self-Stigma Questionnaire (WSSQ[74])* is included in this study to measure the extent to which individuals have internalised weight self-stigma. The WSSQ is a 12-item scale used to measure weight self-stigma on a scale of 1 (completely disagree) to 5 (completely agree). For example, '" *I don't have enough self-control to maintain a healthy weight."* All items are summed to calculate a total score, or two subscales, self-devaluation and fear of enacted stigma. The WSSQ was designed to help evaluate if interventions reduce weight self-stigma.[74] The WSSQ is correlated with the Weight Bias Internalisation Scale and predicts quality of life and self-esteem.[75] The WSSQ has good internal reliability with a Cronbach's *a* of .81 in a similar study.[76]

The Perceived Stress Scale (PSS[77]) will be used to measure stress over the last month. The PSS is a 14-item scale that asks participants to rate feelings and thoughts over the last month related to coping with change, ability to handle personal problems, and control irritations on a

scale of 0 'never' to 4 'very often.' For example, "*In the last month, how often have you felt nervous or 'stressed*'?" The PSS total score is obtained by summing all 14-items. A higher score indicates higher perceived stress in the past month. The PSS is a well-validated scale with high internal reliability Cronbach's alpha of 0.88 in a previous study.[77]

To assess psychological coping, the 28-item *brief COPE*[78] will be used. The brief COPE is the most frequently used coping scale; thus, it is a well-validated measure with a median Cronbach's alpha of 0.68 and a range of 0.55 to 0.92.[79] The brief COPE has 14 subscales that can be used to evaluate the frequency with which coping strategies are used (e.g., self-distraction, active coping, denial, emotional support, behavioural disengagement). Participants use a scale of 1= I haven't been doing this at all to 4= I have been doing this a lot. Each subscale item is added together. In addition, the previously described WCSS consists of an assessment of psychological coping specific to weight management.[71] Based on a scale of 0= never and 4 being always, participants will be asked to describe how often they engaged in psychological coping strategies in the past month. For example, "*If I regained weight, I thought about my past successes and reminded myself that I could get back on trac*k."

Adherence

Participants in both groups will be asked how often they use the WW app or digital online program "*How many days did you use the WW program?"* at 4-weeks and 12-weeks from baseline. Participants in the intervention group will also be asked how many modules of the SC4WM intervention they completed and how many days they use the SC4WM activities post-intervention (4-weeks) and at follow-up (12-weeks from baseline).

Methods: Data collection, management, and analysis

All participant data (e.g., demographic data, weight management outcomes) will be collected using validated questionnaires through REDCap. No data are collected through or by WW. Participant names will only appear on the online Consent Form; the remaining data will be automatically coded with an alphanumeric participant identification number using REDCap. Potentially identifying information will be stored securely and separately from questionnaire data. Only the research team (JBP, NC, RR, AS and a biostatistician) will have access to participant data.

Using SPSS software, data will be assessed for violations of the parametric assumptions. If parametric assumptions are met, Pearson's correlations will explore associations between the covariates and outcome measures. Independent samples t-tests and linear mixed models will explore within and between-group differences and possible interactions. Multiple linear regression and mediation analyses using bootstrapping will be conducted to explore possible mediators and moderators. If parametric assumptions are not met, non-parametric tests will be used (Spearman's rho, Kruskal-Wallis tests and Mann Whitney U tests). The analyses will be based on both intention-to-treat and per-protocol analyses (including only those participants in the intervention group who reported completing all the SC4WM modules).

Sample size

In order to calculate the required sample size to examine group differences in self-compassion, we utilised an effect size from a compassion-based intervention study in a population struggling with weight which found a small to medium effect size for self-compassion (Cohen's d=0.38).[80] Using GPower,[81] it was calculated that to detect a small to medium change in self-compassion, using an independent samples t-test (with an alpha of .05 and power of .90), 240 participants would be required (120 per treatment arm).

Hypotheses

It is expected that the SC4WM intervention group will report greater self-compassion, improved eating behaviours (e.g., increased fruit and vegetable consumption), physical activity (e.g., increased physical activity), and body weight outcomes (e.g., weight loss or less weight regained) at the 4-week and 12-week follow-up compared to the control group. We also hypothesise that the SC4WM intervention group will demonstrate improved emotional wellbeing. Furthermore, it is expected that the improvements in weight management outcomes will be moderated by a decrease in perceived stress, eating restraint and weight self-stigma, and an increase in psychological coping in the SC4MW group at the 4-week and 12-week follow-up compared to the control group.

Discussion

This study is designed to investigate whether an SC4WM intervention can improve self-compassion and weight management outcomes for those engaging in a digital, widely available behavioural commercial weight management program and begin the process of identifying potential moderators of self-compassion efficacy. The findings will be used to refine the SC4WM website and disseminate the SC4WM intervention to a broader audience.

Limitations to this study are expected to be similar to other online weight management interventions and may include low adherence to the intervention and high attrition rates.[57,82] We have tried to minimise attrition and improve adherence by keeping the intervention brief (4-weeks), engaging, and easy to access.[56,57,82] Other possible limitations are the non-blinding of the first author and relying on self-reported outcomes. Future research avenues include incorporating more objective measures of body weight and physiological effects (e.g., cortisol, heart rate variability) obtained by physicians or health professionals.

There is an urgent need to increase the scalability of weight management interventions as well as develop flexibility in delivery during the global pandemic and beyond. Self-compassion shows promise in improving weight management outcomes, including healthier eating, physical activity, and body weight and could be a useful supplement to behavioural weight management interventions such as WW. However, more research is required to investigate if online self-compassion interventions tailored to weight management outcomes can increase self-reported self-compassion and improve outcomes, especially during the first 4-weeks of engaging in weight management. If effective, the supplemental SC4WM intervention could be made more widely available to complement commercial, community and or primary care behavioural weight management programmes to improve psychological and health outcomes for those engaging in weight management, and inform future research in the area of self-compassion and weight management.

Abbreviations

SC4WM, Self-compassion for weight management online intervention

WW, Weight Watchers reimagined, commercial behavioural weight management program

myWW+, current WW program

RCT, Randomised Controlled Trial

SPIRIT, Standard Protocol Items: Recommendations for Interventional Trials

CONSORT, Consolidated Standards of Reporting Trials

REDCap, Research Electronic Data Capture

SCS, Self-Compassion Scale

WCSS, Weight Control Strategies Scale

RRRS, Revised Rigid Restraint Scale

WSSQ, Weight Self-Stigma Questionnaire

PSS, Perceived Stress Scale

SPSS, Statistical Package for the Social Sciences

Declarations

Ethics approval and consent to participate

Ethics approval has been obtained from the University of Auckland Health Research Ethics Committee on March 12, 2021 (Ethics reference #: AH3409).

Participants provide informed consent to participate and for deidentified data to be communicated in research reports including, peer-review journals, conferences and a doctoral thesis. A summary of the study findings will be provided to participants who request it.

Patient and Public Involvement

The SC4WM intervention was designed for the Aotearoa New Zealand population and included consultation with Māori, Indigenous peoples of Aotearoa New Zealand.

Consent for publication

Not applicable.

Availability of data and materials

Data sharing is not applicable to this article as no datasets were generated or analysed.

Competing interests

This study is supported by WW International, Inc. WW International, Inc. was not involved in the intervention design and will not have access to individual participant data related to this study. Furthermore, WW International, Inc. will not play any role during the analyses, interpretation of the data, or the decision to submit results.

Funding

WW International, Inc. will provide participants 12-week free access to the WW digital program and WW app.

Author contributions

JB-P: Conception and development of the SC4WM intervention and study design, wrote the first draft of the protocol manuscript. A.S (primary supervisor) and N.S.C (co-supervisor): Supervision of the conception and development of the SC4WM intervention and study design, critical revision of the manuscript, and final approval of the version to be published. RR support with study design, critical revision of the manuscript and final approval of the version to be published. All authors read and approved the manuscript for publication.

Acknowledgments

The authors would like to acknowledge Dr Chad Rethorst, in his role as WW Director, Clinical Research, Dr Michelle Cardel WW Director, Global Research and Nutrition, and Dr Gary Foster, Chief Scientific Officer WW International, Inc for providing the WW access codes. The authors would also like to thank Kate Wallace-Boyd and David Lim for recording meditations for the SC4WM intervention and Sarah Snow for NZ Māori consultation.

References

1. Guh DP, Zhang W, Bansback N, Amarsi Z, Birmingham CL, Anis AH. The incidence of co-morbidities related to obesity and overweight: a systematic review and meta-analysis. *BMC Public Health.* 2009;9:88.
2. Frood S, Johnston LM, Matteson CL, Finegood DT. Obesity, Complexity, and the Role of the Health System. *Curr Obes Rep.* 2013;2:320-326.
3. Kirk SF, Penney TL, McHugh TL. Characterizing the obesogenic environment: the state of the evidence with directions for future research. *Obes Rev.* 2010;11(2):109-117.
4. Bhutani S, Cooper JA. COVID-19-Related Home Confinement in Adults: Weight Gain Risks and Opportunities. *Obesity (Silver Spring).* 2020;28(9):1576-1577.
5. Pellegrini CA, Webster J, Hahn KR, Leblond TL, Unick JL. Relationship Between Stress and Weight Management Behaviors during the COVID-19 Pandemic among those Enrolled in an Internet Program. *Obesity Science & Practice.* 2020.
6. Neff KD. Self-Compassion: An Alternative Conceptualization of a Healthy Attitude Toward Oneself. *Self and Identity.* 2003;2:85-101.
7. Rahimi-Ardabili H, Reynolds R, Vartanian LR, McLeod LVD, Zwar N. A Systematic Review of the Efficacy of Interventions that Aim to Increase Self-Compassion on Nutrition Habits, Eating Behaviours, Body Weight and Body Image. *Mindfulness.* 2018;9(2):388-400.
8. Wharton S, Lau DCW, Vallis M, et al. Obesity in adults: a clinical practice guideline. *CMAJ.* 2020;192(31):E875-E891.
9. Wing RR, Lang W, Wadden TA, et al. Benefits of modest weight loss in improving cardiovascular risk factors in overweight and obese individuals with type 2 diabetes. *Diabetes Care.* 2011;34(7):1481-1486.
10. Lasikiewicz N, Myrissa K, Hoyland A, Lawton CL. Psychological benefits of weight loss following behavioural and/or dietary weight loss interventions. A systematic research review. *Appetite.* 2014;72:123-137.
11. Anderson J, Konz EC, Frederich RC, Wood CL. Long-term weight-loss maintenance: a meta-analysis of US studies1–3. *American Journal of Clinical Nutrition.* 2001;74.
12. Hartmann-Boyce J, Johns DJ, Jebb SA, Aveyard P, Behavioural Weight Management Review G. Effect of behavioural techniques and delivery mode on effectiveness of weight management: systematic review, meta-analysis and meta-regression. *Obes Rev.* 2014;15(7):598-609.
13. Teixeira PJ, Going SB, Houtkooper LB, et al. Pretreatment predictors of attrition and successful weight management in women. *Int J Obes Relat Metab Disord.* 2004;28(9):1124-1133.
14. Hadziabdic MO, Mucalo I, Hrabac P, Matic T, Rahelic D, Bozikov V. Factors predictive of drop-out and weight loss success in weight management of obese patients. *J Hum Nutr Diet.* 2015;28 Suppl 2:24-32.
15. Elfhag K, Rössner S. Who succeeds in maintaining weight loss? A conceptual review of factors associated with weight loss maintenance and weight regain. *Obesity Reviews.* 2006;6:67-85.
16. Paixao C, Dias CM, Jorge R, et al. Successful weight loss maintenance: A systematic review of weight control registries. *Obes Rev.* 2020;21(5):e13003.
17. Phelan S, Halfman T, Pinto AM, Foster GD. Behavioral and Psychological Strategies of Long-Term Weight Loss Maintainers in a Widely Available Weight Management Program. *Obesity (Silver Spring).* 2020;28(2):421-428.

18. McGuire MT, Wing RR, Klem ML, Lang W, Hill JO. What Predicts Weight Regain in a Group of Successful Weight Losers? *Journal of Consulting and Clinical Psychology.* 1999;67:177-185.
19. Wang C, Coups EJ. Causal beliefs about obesity and associated health behaviors: results from a population-based survey. *International Journal of Behavioral Nutrition and Physical Activity.* 2010;7.
20. Kirk SF, Price SL, Penney TL, et al. Blame, Shame, and Lack of Support: A Multilevel Study on Obesity Management. *Qual Health Res.* 2014;24(6):790-800.
21. Rand K, Vallis M, Aston M, et al. "It is not the diet; it is the mental part we need help with." A multilevel analysis of psychological, emotional, and social well-being in obesity. *Int J Qual Stud Health Well-being.* 2017;12(1):1306421.
22. Hartmann-Boyce J, Boylan AM, Jebb SA, Aveyard P. Experiences of Self-Monitoring in Self-Directed Weight Loss and Weight Loss Maintenance: Systematic Review of Qualitative Studies. *Qualitative Health Research.* 2019;29.
23. Pearl RL, Puhl RM. Weight bias internalization and health: a systematic review. *Obesity Reviews.* 2018;19(8):1141-1163.
24. Tomiyama AJ. Weight stigma is stressful. A review of evidence for the Cyclic Obesity/Weight-Based Stigma model. *Appetite.* 2014;82:8-15.
25. Puhl RM, Lessard LM, Pearl RL, Himmelstein MS, Foster GD. International comparisons of weight stigma: addressing a void in the field. *Int J Obes (Lond).* 2021.
26. O'Brien KS, Latner JD, Puhl RM, et al. The relationship between weight stigma and eating behavior is explained by weight bias internalization and psychological distress. *Appetite.* 2016;102:70-76.
27. Serlachius A, Hamer M, Wardle J. Stress and weight change in university students in the United Kingdom. *Physiol Behav.* 2007;92(4):548-553.
28. Dallman MF. Stress-induced obesity and the emotional nervous system. *Trends Endocrinol Metab.* 2010;21(3):159-165.
29. Yau YHC, Potenza MN. Stress and Eating Behaviors. *Minerva Endocrinol.* 2013;38:255-267.
30. Born JM, Lemmens SG, Rutters F, et al. Acute stress and food-related reward activation in the brain during food choice during eating in the absence of hunger. *Int J Obes (Lond).* 2010;34(1):172-181.
31. Zellner DA, Loaiza S, Gonzalez Z, et al. Food selection changes under stress. *Physiol Behav.* 2006;87(4):789-793.
32. Johnson F, Pratt M, Wardle J. Dietary restraint and self-regulation in eating behavior. *Int J Obes (Lond).* 2012;36(5):665-674.
33. Zellner DA, Loaiza S, Gonzalez Z, et al. Food Selection Changes Under Stress. *Physiology and Behavior.* 2006;87:789-793.
34. Wallis DJ, Hetherington MM. Stress and eating: the effects of ego-threat and cognitive demand on food intake in restrained and emotional eaters. *Appetite.* 2004;43(1):39-46.
35. Kirby JN, Doty JR, Petrocchi N, Gilbert P. The current and future role of heart rate variability for assessing and training compassion. *Frontiers in Public Health.* 2017;5.
36. Rockliff H, Gilbert P, McEwan K, Lightman S, Glover D. A pilot exploration of heart rate variability and salivary cortisol responses to compassion-focused imagery. *Clinical Neuropsychiatry 5 (3) (pp 132-139), 2008 Date of Publication: June 2008.* 2008;5(3):132-139.

37. Arch JJ, Brown KW, Dean DJ, Landy LN, Brown KD, Laudenslager ML. Self-compassion training modulates alpha-amylase, heart rate variability, and subjective responses to social evaluative threat in women. *Psychoneuroendocrinology.* 2014;42:49-58.
38. Terry ML, Leary MR. Self-compassion, self-regulation, and health. *Self and Identity.* 2011;10(3):352-362.
39. Allen Batts A, Leary MR. Self-compassion, stress, and coping. *Social and Personality Psychology Compass.* 2010;4.
40. Sirois F, Kitner R, Hirsch J. Self-compassion, affect, and health-promoting behaviors. *Health Psychology 34 (6) (pp 661-669), 2015 Date of Publication: 01 Jun 2015.* 2015;34(6):661-669.
41. Ferrari M, Hunt C, Harrysunker A, Abbott MJ, Beath AP, Einstein DA. Self-Compassion Interventions and Psychosocial Outcomes: a Meta-Analysis of RCTs. *Mindfulness.* 2019.
42. Palmeira L, Cunha M, Pinto-Gouveia J. Processes of change in quality of life, weight self-stigma, body mass index and emotional eating after an acceptance-, mindfulness- and compassion-based group intervention (Kg-Free) for women with overweight and obesity. *Journal of Health Psychology.* 2017;24(8):1056-1069.
43. Fekete EM, Herndier RE, Sander AC. Self-Compassion, Internalized Weight Stigma, Psychological Well-Being, and Eating Behaviors in Women. *Mindfulness.* 2021;12(5):1262-1271.
44. Kirschner H, Kuyken W, Wright K, Roberts H, Brejcha C, Karl A. Soothing Your Heart and Feeling Connected: A New Experimental Paradigm to Study the Benefits of Self-Compassion. *Clinical Psychological Science.* 2019;7(3):545-565.
45. Forbes Y, Donovan C. The role of internalised weight stigma and self-compassion in the psychological well-being of overweight and obese women. *Australian Psychologist.* 2019:No Pagination Specified.
46. Duarte C, Ferreira C, Trindade IA, Pinto-Gouveia J. Body image and college women's quality of life: The importance of being self-compassionate. *Journal of Health Psychology.* 2015;20(6):754-764.
47. Marta-Simões J, Ferreira C. Turning self-compassionate engagement into action: Impact on body appreciation among Portuguese women. *Journal of Contextual Behavioral Science.* 2019;11:21-26.
48. Ferreira C, Pinto-Gouveia J, Duarte C. Self-compassion in the face of shame and body image dissatisfaction: Implications for eating disorders. *Eating Behaviors.* 2013;14(2):207-210.
49. Albertson ER, Neff KD, Dill-Shackleford KE. Self-Compassion and Body Dissatisfaction in Women: A Randomized Controlled Trial of a Brief Meditation Intervention. *Mindfulness.* 2014;6(3):444-454.
50. Kirby JN. Compassion interventions: The programmes, the evidence, and implications for research and practice. *Psychology and Psychotherapy: Theory, Research and Practice.* 2017;90(3):432-455.
51. Gilbert P. Introducing compassion-focused therapy. *Advances in Psychiatric Treatment.* 2018;15(3):199-208.
52. Neff K. The Development and Validation of a Scale to Measure Self-Compassion. *Self and Identity.* 2003;2:223-250.

53. Raes F, Pommier E, Neff KD, Van Gucht D. Construction and factorial validation of a short form of the Self-Compassion Scale. *Clin Psychol Psychother.* 2011;18(3):250-255.
54. Miller BM, Brennan L. Measuring and reporting attrition from obesity treatment programs: A call to action! *Obes Res Clin Pract.* 2015;9(3):187-202.
55. Yeo C, Ahmed S, Oo AM, Koura A, Sanghvi K, Yeo D. COVID-19 and Obesity-the Management of Pre- and Post-bariatric Patients Amidst the COVID-19 Pandemic. *Obes Surg.* 2020;30(9):3607-3609.
56. van Genugten L, Dusseldorp E, Webb TL, van Empelen P. Which Combinations of Techniques and Modes of Delivery in Internet-Based Interventions Effectively Change Health Behavior? A Meta-Analysis. *J Med Internet Res.* 2016;18(6):e155.
57. van Beurden SB, Simmons SI, Tang JCH, Mewse AJ, Abraham C, Greaves CJ. Informing the development of online weight management interventions: a qualitative investigation of primary care patient perceptions. *BMC Obes.* 2018;5:7.
58. Cavero-Redondo I, Martinez-Vizcaino V, Fernandez-Rodriguez R, Saz-Lara A, Pascual-Morena C, Alvarez-Bueno C. Effect of Behavioral Weight Management Interventions Using Lifestyle mHealth Self-Monitoring on Weight Loss: A Systematic Review and Meta-Analysis. *Nutrients.* 2020;12(7).
59. Duarte C, Gilbert P, Stalker C, et al. Effect of adding a compassion-focused intervention on emotion, eating and weight outcomes in a commercial weight management programme. *J Health Psychol.* 2019:1359105319890019.
60. Schnepper R, Reichenberger J, Blechert J. Being My Own Companion in Times of Social Isolation - A 14-Day Mobile Self-Compassion Intervention Improves Stress Levels and Eating Behavior. *Front Psychol.* 2020;11:595806.
61. Schulz KF, Altman DG, Moher D, Group C. CONSORT 2010 Statement: Updated Guidelines for Reporting Parallel
Group Randomized Trials. *Annals of Internal Medicine.* 2010;152:726-732.
62. Chan A-W, Tetzlaff JM, Altman DG, et al. SPIRIT 2013 Statement: Defining Standard Protocol Items for
Clinical Trials. *Annals of Internal Medicine.* 2013;158:200-207.
63. Harris PA, Taylor R, Minor BL, et al. The REDCap consortium: Building an international community of software platform partners. *J Biomed Inform.* 2019;95:103208.
64. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform.* 2009;42(2):377-381.
65. WW. Introducing myWW+. WW Weight Watchers reimagined. https://www.weightwatchers.com/nz/ourprogram. Published 2020. Accessed November 30, 2020.
66. Goetz JL, Keltner D, Simon-Thomas E. Compassion: an evolutionary analysis and empirical review. *Psychol Bull.* 2010;136(3):351-374.
67. Mantzios M, Wilson JC. Making concrete construals mindful: A novel approach for developing mindfulness and self-compassion to assist weight loss. *Psychology and Health.* 2014;29(4):422-441.
68. Neff KD, Germer CK. A Pilot Study and Randomized Controlled Trial of the Mindful Self-Compassion Program. *Journal of Clinical Psychology.* 2013;69(1):28-44.

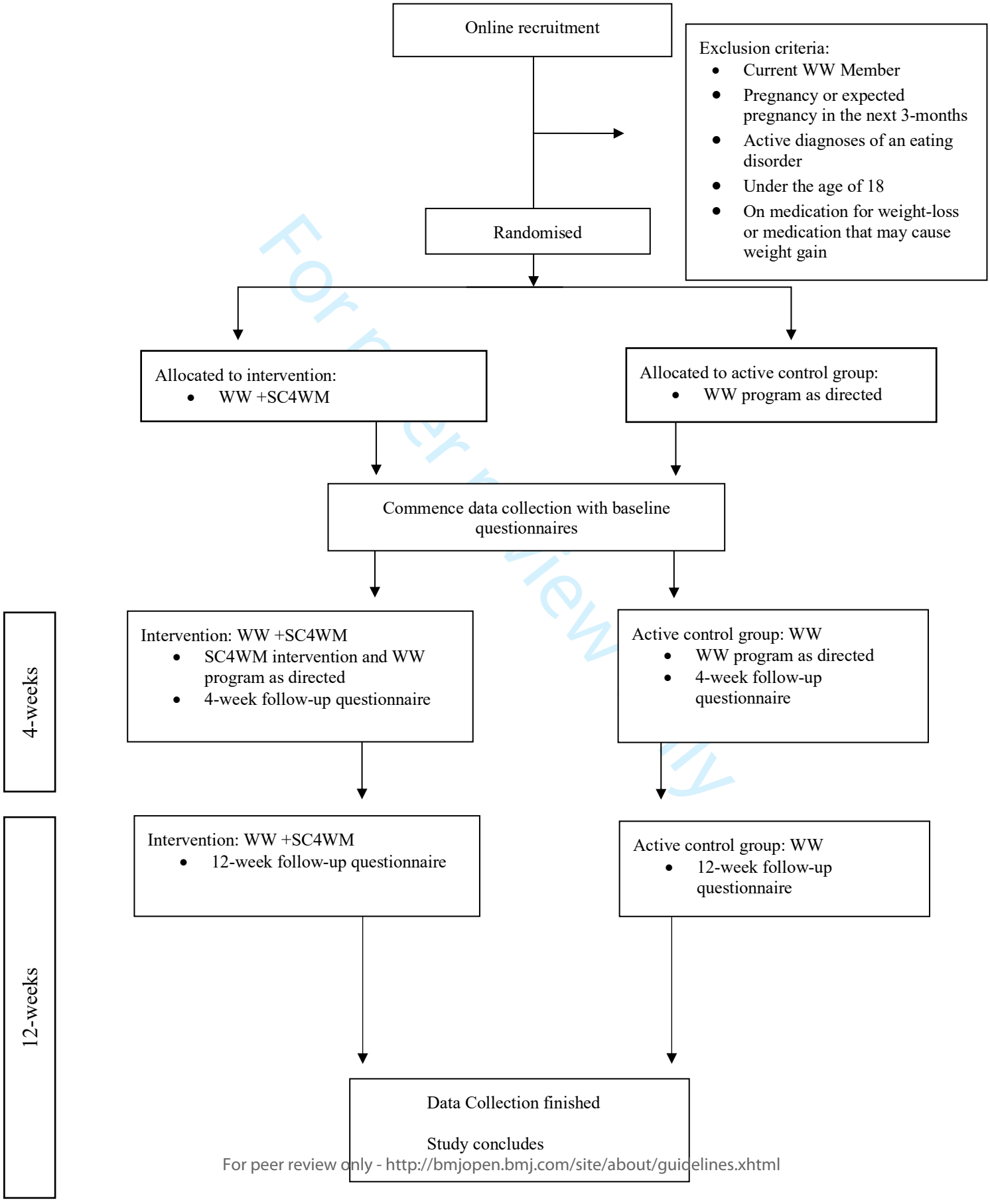
69. Sirois FM. The association between self-compassion and self-rated health in 26 samples. *BMC Public Health.* 2020;20(1):74.
70. Neff KD, Tóth-Király I, Yarnell LM, et al. Examining the factor structure of the Self-Compassion Scale in 20 diverse samples: Support for use of a total score and six subscale scores. *Psychological Assessment.* 2019;31(1):27-45.
71. Pinto AM, Fava JL, Raynor HA, LaRose JG, Wing RR. Development and validation of the weight control strategies scale. *Obesity (Silver Spring).* 2013;21(12):2429-2436.
72. Bech P, Olsen LR, Kjoller M, Rasmussen NK. Measuring well-being rather than the absence of distress symptoms: a comparison of the SF-36 Mental Health subscale and the WHO-Five well-being scale. *International journal of methods in psychiatric research.* 2003;12(2):85-91.
73. Adams CE, Leary MR. Promoting self-compassionate attitudes toward eating among restrictive and guilty eaters. *Journal of Social and Clinical Psychology.* 2007;26(10):1120-1144.
74. Lillis J, Luoma JB, Levin ME, Hayes SC. Measuring Weight Self-stigma: The Weight Self-stigma Questionnaire. *Obesity.* 2012;18(5).
75. Durso LE, Latner JD. Understanding Self-directed Stigma: Development of the Weight Bias Internalization Scale. *Obesity Journal* 2008;16.
76. Levin ME, Potts S, Haeger J, Lillis J. Delivering Acceptance and Commitment Therapy for Weight Self-Stigma Through Guided Self-Help: Results From an Open Pilot Trial. *Cognitive and Behavioral Practice.* 2018;25:87-104.
77. Cohen S, Kamarck T, Mermelstein R. A Global Measure of Perceived Stress. *Journal of Health and Social Behavior.* 1983;24(4):385-396.
78. Carver CS. You want to measure coping but your protocol's too long: consider the brief COPE. *Int J Behav Med.* 1997;4(1):92-100.
79. Kato T. Frequently Used Coping Scales: A Meta-Analysis. *Stress Health.* 2015;31(4):315-323.
80. Palmeira L, Pinto-Gouveia J, Cunha M. Exploring the efficacy of an acceptance, mindfulness & compassionate-based group intervention for women struggling with their weight (Kg-Free): A randomized controlled trial. *Appetite 112 (pp 107-116), 2017 Date of Publication: 01 May 2017.* 2017;112:107-116.
81. Faul F, Erdfelder E, Lang A, Buchner A. G*Power 3: a flexible statistical power analysis program for the social, behavioral, and biomedical sciences. *Behav Res Methods* 2007;39:175-191.
82. Ventura AD, Nefs G, Browne JL, Friis AM, Pouwer F, Speight J. Is Self-Compassion Related to Behavioural, Clinical and Emotional Outcomes in Adults with Diabetes? Results from the Second Diabetes MILES—Australia (MILES-2) Study. *Mindfulness.* 2018;10(7):1222-1231.

Figure Legend

Figure 1: CONSORT diagram. The flow of participants through the trial.

Figure 2: SC4WM landing page

Figure 1. CONSORT Diagram.



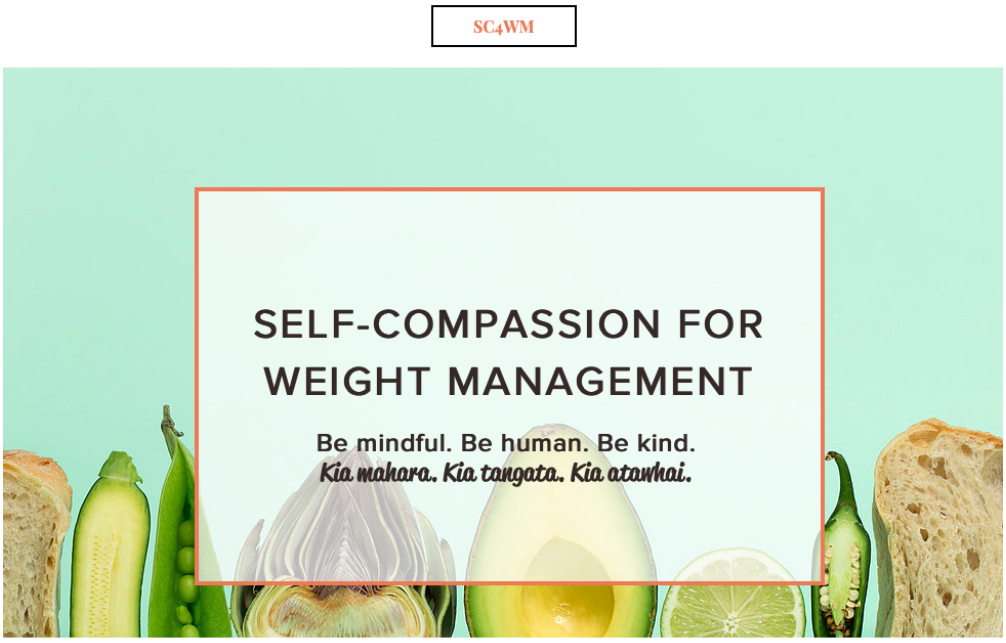


Figure 1 SC4WM Landing Page

344x226mm (72 x 72 DPI)

SPIRIT

STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Page #
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	Title page
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	Abstract Pg. 2, Methods Pg. 7, par.2
	2b	All items from the World Health Organization Trial Registration Data Set	na
Protocol version	3	Date and version identifier	na
Funding	4	Sources and types of financial, material, and other support	Declarations Pg. 21, par. 4-5
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Declarations Pgs. 21-22
	5b	Name and contact information for the trial sponsor	Title page
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	Declarations Pg. 21, par. 4
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	na
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	Background Pgs. 4-7

	6b	Explanation for choice of comparators	Background Objectives Pgs. 6-7
Objectives	7	Specific objectives or hypotheses	Background Pgs. 7 Discussion Pg.18, par 2
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	Methods Pg. 7
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	Methods Pgs. 7-8
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	Methods Pgs. 7-8
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	Methods Pgs. 11-12
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	Methods Pg. 12
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	Discussion Pg. 19 par. 2
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	na
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	Methods Pgs. 13-17
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Methods Pgs. 8-10
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	Methods Pg. 8, par. 1

Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	Methods Pg. 8, par. 2
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	Methods Pg. 8, par. 2
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	Methods Pg. 8, par. 2
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	Methods Pg. 8, par. 2
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	Discussion Pg. 19, par. 2
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	na
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	Methods Pgs. 13-17 Discussion Pg18, par 2
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	Methods Pg. 10 Discussion Pg.19, par. 2
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	Methods Pg. 8, par 1 Discussion Pg. 17, par.3

Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	Methods Pg. 17, par 3
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	Methods Pg. 17, par 3
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	Methods Pg. 17, par. 3
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	Methods Pg. 17, par. 2 Declarations Pg. 22, par 4-5
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	na
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	Methods Pg.13
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	na
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	Declarations Pg. 20, par. 2
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	Methods Pg. 7, par. 2
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	Methods Pg. 8, par 2
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	na
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	Methods Pg. 8, par 2

Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	Declarations Pg. 21, par. 4&5
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	Methods Pg. 17, par 2 Declarations Pg. 21, par 5
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	na
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	Declarations Pg. 21, par 1
	31b	Authorship eligibility guidelines and any intended use of professional writers	na
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	na
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	na
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	na

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

Investigating the effect of an online self-compassion for weight management (SC4WM) intervention on self-compassion, eating behaviour, physical activity, and body weight in adults seeking to manage weight: Protocol for a randomised controlled trial

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2021-056174.R1
Article Type:	Protocol
Date Submitted by the Author:	15-Dec-2021
Complete List of Authors:	Brenton-Peters, Jennifer; The University of Auckland, Department of Psychological Medicine Consedine, Nathan; The University of Auckland, Department of Psychological Medicine Cavadino, Alana; The University of Auckland, Roy, Rajshri; The University of Auckland, Nutrition and Dietetics Serlachius, Anna; University of Auckland, Psychological Medicine
Primary Subject Heading:	Public health
Secondary Subject Heading:	Nutrition and metabolism
Keywords:	NUTRITION & DIETETICS, PREVENTIVE MEDICINE, PUBLIC HEALTH

Investigating the effect of an online self-compassion for weight management (SC4WM) intervention on self-compassion, eating behaviour, physical activity, and body weight in adults seeking to manage weight: Protocol for a randomised controlled trial

Jennifer Brenton-Peters[1] | Nathan Consedine[1] | Alana Cavadino[3] | Rajshri Roy[2] | Anna Serlachius[1]

Affiliations:

1. Department of Psychological Medicine, Faculty of Medical and Health Sciences, The University of Auckland, New Zealand
2. Department of Nutrition and Dietetics, Faculty of Medical and Health Sciences, The University of Auckland, New Zealand
3. Section of Epidemiology and Biostatistics, Faculty of Medical and Health Sciences, The University of Auckland, New Zealand

Corresponding Author: Jennifer Brenton-Peters PDt, MA, Department of Psychological Medicine, The University of Auckland, Auckland, New Zealand. Email: jbre092@aucklanduni.ac.nz

Word count:

Abstract

Introduction: Individual weight management, defined as engaging in behaviours to maintain or lose weight, can improve health and wellbeing. However, numerous factors influence weight management outcomes, such as genetics, biology, stress, the social and physical environment. Consequently, weight management can be hard. Self-compassion, described as treating oneself kindly in times of failure or distress, has shown promise in improving weight management outcomes. The objectives of this study are two-fold: 1) to examine the efficacy of an online Self-Compassion for Weight Management (SC4WM) intervention coupled with an online commercial weight management program (WW) with increasing self-compassion and improving weight management outcomes (eating behaviour, physical activity and body weight) in comparison to the WW program only and 2) to explore whether improvements in weight management outcomes are moderated by eating restraint, weight self-stigma, perceived stress, and psychological coping.

Methods and Analysis: To achieve these objectives, 240 participants seeking to manage their weight were randomised to either an online behavioural commercial weight management program (WW) or the online WW+SC4WM intervention. Validated measures of self-compassion, stress, weight self-stigma, eating restraint, psychological coping and weight management outcomes were administered online at baseline, 4-weeks, and at follow-up at 12-weeks.

Ethics and Dissemination: Ethics has been granted by the University of Auckland Health Research Ethics committee. Results will be communicated in peer-review journals, conferences and a doctoral thesis. If effective in increasing self-compassion and improving weight management outcomes, the intervention could be made more widely available to supplement behavioural weight management programmes.

Clinical trial registration number: ACTRN12621000580875

Keywords: Weight management, eating behaviour, physical activity, self-compassion

Strengths & Limitations

- This is the first study to test a 100% online, Self-Compassion for Weight Management intervention (SC4WM) designed to supplement existing weight management programs.
- The study utilises a randomised controlled trial design with the online version of a commercial behavioural weight management program as an active control (WW).
- This study is limited due to the non-blinding of the first author and self-reporting of outcomes.
- This study investigates a supplemental SC4WM intervention that could increase the efficacy of online behavioural weight management program by improving self-compassion and weight management outcomes during the global pandemic and beyond.

Introduction

Successful weight management, defined as losing or maintaining body weight, can improve health outcomes.[1] However, several competing factors influence weight management behaviours (e.g., healthy eating and physical activity), including body physiology, biology, psychological wellbeing, stress management, socioeconomic status, and the physical and social environment.[2,3] Furthermore, ongoing public health restrictions to control the spread of COVID-19 and concerns about exposure mean access to in-person support may be limited and engaging in healthy behaviours can be even more challenging (e.g., accessibility to healthy food, more limited opportunity for exercise, and financial stress).[4,5] Self-compassion, the ability or tendency to respond to oneself with care and kindness in times of suffering and distress,[6] has shown promise with improving weight management outcomes (healthier eating and reduced or maintained body weight).[7] However, few studies have investigated whether the changes thought to accompany the development of self-compassion can be successfully taught and practised 100% online as a supplement to an existing online weight management program.

Healthy eating and physical activity are recommended for everyone to improve health outcomes and manage weight.[8] For those living with weight-related chronic disease, such as obesity, even a small amount of weight loss (5-10% of body weight) can have positive physiological effects. For example, modest weight loss can lower blood lipids and improve glycemic control, resulting in reduced risk for heart disease and diabetes complications.[9] Appropriate weight management can also support psychological outcomes, including improved emotional wellbeing, self-esteem, depressive symptoms, body image, and health-related quality of life.[10] Behavioural-based weight management interventions have shown some effectiveness with weight loss and maintenance.[11,12] However, weight management history (e.g., previous

unsuccessful weight loss attempts, weight cycling) and early weight loss results (e.g., in the first 4-weeks) can influence an individual's weight management success.[13,14] Weight regain is common due to physiological changes and when individuals cannot sustain the behavioural changes needed to maintain weight loss, such as healthy eating, increased physical activity, and continued self-monitoring.[15,16]

Engaging in weight management can be challenging. Body weight is influenced by several factors (e.g., biology, stress, environments).[2] However, many people believe their behaviours *cause* their weight.[17] Therefore, the inevitable ups and downs of body weight may result in feelings of distress, shame, failure, and blame.[18-20] These feelings are exacerbated by weight stigma, which is the negative societal prejudice and stereotypes experienced by people with higher weights.[21,22] Facing weight stigma is common for adults who are engaging in weight management.[23] When internalised, weight self-stigma can create additional stress, ultimately resulting in less healthy eating and reduced physical activity.[22,24]

Furthermore, weight fluctuations are associated with stress, regardless of health behaviour.[25] The stress response activates the sympathetic nervous system, which can cause a release in hormones (e.g., cortisol), and reduce executive function (e.g., less mindful regulation of food intake).[26,27] Stress can trigger binge eating or the consumption of higher fat and higher sugar comfort foods, which may lead to weight gain over time.[28,29] Eating restraint, defined as engaging in a cognitive effort to reduce caloric intake, can support weight management outcomes.[30,31] However, those who are more restricted with their eating behaviours may paradoxically be more prone to overeating in stressful times.[32,33]

Self-compassion has shown the potential to moderate many challenges that plague weight management, including moderating the effects of stress.[34,35] Self-compassionate people treat

themselves with kindness when experiencing stressful situations and appear less likely to use avoidance as a coping mechanism.[36] Thus, self-compassion potentially offers a way to cope with stress through the enhanced ability to regulate health-related behaviour such as healthier eating and physical activity.[37-39] In addition, people with greater self-compassion tend to have lower levels of internalised weight stigma[40,41] and improved emotional regulation.[37,42] Consequently, self-compassion could benefit weight management due to its ability to increase an individual's coping and self-management during stressful times.[40,43-45]

Both mindfulness and self-compassion have been explored in the context of weight management (see recent reviews [7,46-49]). Mindfulness is typically operationalised as self-regulation of attention, combined with curiosity, openness, and acceptance of thoughts and feelings[50] and is a part of many self-compassion interventions (e.g., Mindful Self-Compassion[6]). Relative to a "pure" mindfulness intervention, however, self-compassion may be more relevant to the challenges of weight management than mindfulness alone.[51,52] Specifically, because self-compassion reflects a way of relating to the self in times of failure and distress, it appears directly relevant to effectively managing the inevitable mistakes (e.g., diet lapses[53]), challenges (e.g., weight stigma[54]) and stress (e.g. physiological and emotional regulation[37,55,56]) inherent to weight management efforts. Self-compassion interventions encourage participants to develop a more self-compassionate way of thinking (e.g., through self-compassionate diaries[52] or self-compassion meditations[57]); both self-compassion-specific interventions and self-compassion as part of broader interventions (e.g., adding self-compassion to behavioural weight management) increase participant self-compassion in a weight management contexts.[49]

Enhancing self-compassion in the context of weight management is complex.[58] For example, it is not uncommon when first practising self-compassion to feel some discomfort (e.g.,

people may feel they do not *deserve* kindness).[59] Individuals engaging in weight management may be particularly vulnerable to feelings of discomfort due to internalised weight bias (negative attitudes and stereotypes associated with higher larger body size).[60] However, emerging research suggests that greater self-compassion can buffer the effects of weight self-stigma for individuals living with overweight or obesity.[54] Similarly, individuals may worry that *self-kindness* will undermine their motivation for losing weight.[59] Self-kindness could easily be interpreted as indulging in a favourite food after a stressful day, as opposed to taking the time to make a healthy meal.[61] Egan, Mantzios [61] qualitatively explored perceptions of self-compassion and kindness in weight management and found that people struggled to relate to the term 'self-kindness', preferring the concept of *caring for their mind.* Thus, while self-compassion does include an element of self-kindness,[6] it also involves a recognition of experiences as part of common human experiences – 'everyone struggles with weight management at times.' As well as being mindful of negative thoughts and feelings rather than overidentifying with them - 'I had a diet lapse, but that does not mean I am bad.'[6] Viewed in this way, practising self-compassion has the potential to *boost* motivation for self-improvement in face of failures[62] and promote health behaviours.[63]

Although promising, there are still notable gaps in our knowledge of self-compassion in weight management contexts. First, most studies include self-compassion as part of broader interventions (e.g., nutrition goal setting, yoga). Second, since this is an emerging area of research, most studies lack robust comparison conditions such as behavioural weight management interventions. Consequently, it is hard to determine if it is self-compassion per se that is contributing to positive outcomes rather than some non-specific element of participation.[49]

Also unclear is how to best deliver such interventions. In-person weight management interventions are often associated with high attrition rates[64] and unpredictable public health measures to control the spread of COVID-19 may increase attrition and compound the challenges to engaging in health behaviours.[4,65] Online interventions utilising cognitive behavioural therapies have shown good effect sizes with improving health behaviours ($\bar{g}$=0.43, 95% CI 0.27-0.59).[66] Early evidence suggests that online weight management interventions show promise with supporting weight management outcomes, including online compassion-based interventions.[67-70,] To this point, however, research has not contrasted the efficacy of an online self-compassion intervention tailored to weight management outcomes with a 100% online version of a behavioural weight management program, which could provide increased scalability.[49] Therefore, the objective of this study is to assess whether an online, mobile-friendly Self-Compassion for Weight Management (SC4WM) intervention can increase participant self-compassion and improve weight management outcomes for those engaging in an online behavioural weight management program (WW).

Methods: Participants, interventions and outcomes

Following CONSORT[71] and SPIRIT[72] guidelines, a two-armed, randomised controlled study comparing the addition of the SC4WM intervention to a widely available behavioural weight management program (WW) will be conducted. The proposed study will investigate if the online SC4WM intervention can increase self-reported self-compassion and improve weight management outcomes, defined as eating behaviour, physical activity levels, and body weight, for those in the first 4-weeks of a widely available online commercial program (WW). In addition, this study will examine potential moderating variables, including perceived stress, weight self-stigma, eating restraint, and psychological coping. This study will be delivered 100%

online and undertaken over 4-weeks, with a subsequent 12-week follow-up. The RCT protocol has been prospectively registered with the Australian New Zealand Clinical Trials Registry ACTRN12621000580875 (https://www.anzctr.org.au/ACTRN12621000580875.aspx). Protocol amendments will be communicated through the trial registry.

Participants

Participants were New Zealand residents who were seeking to manage their weight. Inclusion criteria for participation included: 1) being an adult (≥18 years of age), 2) New Zealand resident, and 3) seeking to manage their weight. Exclusion criteria for participation included: 1) being a current WW member, 2) pregnant or expecting to become pregnant in the next 3-months, 3) diagnosed with an active eating disorder (e.g., bulimia nervosa or anorexia nervosa), 4) being prescribed medication for weight management or newly starting a medication that may cause weight gain. All participants were given an access code to a widely available behavioural commercial weight management program (WW). Participants were randomised into either the WW program only (active control group) or the WW plus the supplemental SC4WM intervention. Recruitment commenced on June 17, 2021, and finished on October 11, 2021. Participants were able to withdraw at any time during the study. Data analysis is expected to begin in January 2022.

Participant timeline

Participants were recruited via posters, websites (e.g., university research site) and national (New Zealand) social media posts and marketing (e.g., via community board posts on Facebook, Twitter) with a link to a secure website (REDCap).[73,74] Potential participants clicked a link to the study eligibility questionnaire. If eligible to participate (e.g., not a current WW member, ≥18 years of age), participants read and downloaded the Participant Information Sheet.

After providing informed consent, participants completed the baseline questionnaires and were randomised using a computer-generated number sequence into either the online WW program plus the SC4WM intervention or the online WW program only (active control group). Participants allocated to the SC4WM intervention received an access code to the SC4WM website. Please see Figure 1 for the CONSORT diagram demonstrating the flow of participants through the study.

The intervention group filled out the baseline questionnaires and received an access code and instructions to download the WW app and a separate link to the SC4WM website with a guest code. During the first 4-week period, participants in the intervention group received one automated email at the beginning of each week (via REDCap), reminding them to complete the SC4WM online modules. The control group received an access code and instructions to download the WW app. They were instructed to utilise the WW program as directed and expect subsequent emails at 4-weeks and 12-weeks with follow-up questionnaires.

REDCap sent automated emails to both groups at 4-weeks from baseline (post-intervention) and 12-weeks from baseline (follow-up). After completing the final follow-up questionnaire, both groups were provided with the opportunity to enter a draw for an iPad. See Figure 1 CONSORT diagram.

Interventions

Active Control Group

Participants randomised to the control group partook in the online WW *Weight Watchers reimagined* program (2021). The WW program is a commercial behavioural weight management program that aims to support its members with healthier habits.[75] The WW program uses the Smartpoints™ food tracking system, which encourages members to make healthier food choices

by assigning point values to foods requiring moderation (e.g., higher fat and higher sugar foods). In addition, the WW program promotes exercising, cultivating a positive mindset, and tracking body weight with the objective of weight management. The most recent WW program is the myWW+ program, which includes a personalised meal plan, tracking, and peer-support online. The myWW+ program provides access to the myWW+ app that offers easy-to-use food and activity tracking, 24/7 live coaching, and a supportive network of other WW members through a WW online forum.[75] The myWW+ program may contain elements of self-compassion within its content. However, the SC4WM intervention described below was designed to have a higher, more specific, and more concentrated dose of self-compassion.

Self-compassion for Weight Management (SC4WM) intervention

The SC4WM intervention was designed for the Aotearoa New Zealand population and included consultation with Māori, Indigenous peoples of Aotearoa New Zealand. The SC4WM intervention was delivered online through a mobile-friendly website separate from the WW program. Participants in the intervention group were also asked to follow the digital myWW+ program as directed by WW. Participants required data or internet connectivity and an access code to log into the WW and SC4WM website content. The SC4WM intervention incorporated simple, evidence-based techniques (e.g., construal journaling,[52] letter writing, reflections[57]) to deliver a self-compassion intervention tailored to weight management outcomes (i.e., eating behaviour, physical activity, and weight monitoring). The SC4WM intervention landing page (website) provided an initial definition and background on self-compassion and quick access to each module. See Figure 2. *SC4WM Landing Page*. The SC4WM intervention was based on taking the meaning of compassion inward, being mindful of personal suffering or distress, and applying the principles of mindfulness, self-kindness, and shared humanity.[76,77] Given that

previous research has found that people may feel uneasy with the term self-compassion,[61] care was taken to frame self-compassion as a whole construct, including increasing mindfulness (as opposed to overidentification), common humanity (tempering isolation), and self-kindness as a way to care for the body and mind (attenuating self-judgement).[6,61] The SC4WM intervention has four modules designed to specifically target participants' relationship with each weight management outcome, including self-compassion for eating behaviour, self-compassion for physical activity, and self-compassion for body weight. Each module includes an adapted construal journal,[52] meditation, and reflection activity[57] incorporating the principles of self-compassion to eating behaviour, physical activity behaviour, and body weight. It is recommended that participants complete one module in sequence per week. The final module unifies all the concepts and encourages participant to make a plan to include self-compassion in the future. To reduce any discomfort, participants are urged to start slow (e.g., not to start with their biggest struggle right away). See Table 1.

Table 1. *SC4WM modules*

Module	Objective
Module 1: EAT.	Cultivate a more self-compassionate attitude towards eating behaviours. Includes journaling, meditation, and reflections designed to create mindfulness of eating behaviour, feeling of shared humanity and self-kindness to the challenges of eating well.
Module 2: MOVE.	Develop a more self-compassionate attitude towards physical activity behaviours. Includes journaling, meditation, and reflections designed to create a mindful awareness of physical activity, a feeling of connection, and self-kindness to the challenges of engaging in physical activity.
Module 3: WEIGH.	Foster a more self-compassionate attitude towards body weight. Includes journaling, meditation, and reflections designed to create a mindful reaction to body weight, an awareness that they are not alone in their struggles, and bringing kindness to the scale.
Module 4: UNIFY.	Cultivate a more self-compassionate attitude toward weight management as a whole. Includes the selection of activities/practises for the participant to continue with after the intervention.

Outcome Measures

Completion of the questionnaires at baseline, post-intervention (4-weeks), and follow-up (12-weeks) took participants approximately 25 minutes. REDCap collected demographic data via self-report (e.g., sex, age, height, ethnicity, income, pre-existing weight-related chronic diseases and weight loss history, e.g., number of previous weight loss attempts). Validated questionnaires were used to assess self-compassion, weight management outcomes, and potential moderators at baseline, 4-weeks and 12-weeks after baseline. Since self-compassion is most useful when faced with a struggle or failure, participants reported on the degree of their struggle with weight loss or maintenance at baseline, 4-weeks, and the 12-week follow-up. Adherence to both the WW program and the SC4WM intervention was self-reported at 4-weeks and the 12-week follow-up. This study utilised validated measures which are referenced and described below.

Primary outcome

To confirm that the intervention increased participant self-compassion compared to the WW program, we will use the Self-Compassion Scale (SCS[78]) at baseline, and at 4- and 12-weeks follow-up. The SCS is a well-validated scale with high internal validity, Cronbach's *a* between .76 and .94 in previous studies.[79] The SCS indexes how participants typically respond towards themselves in times of failure or distress.[6,80] Using a scale of 1= almost never to 5= almost always, participants are asked questions related to 6-subscales, self-kindness: "*I am loving towards myself when I am feeling emotional pain"*; self-judgement: "*I am disapproving of my own flaws and inadequacies*"; Common humanity: "*When things are going badly for me, I see the difficulties as part of life that everyone goes through*"; isolation: "*When I think about my inadequacies, it tends to make me feel more separate and cut off from the world"*; mindfulness: "*When something upsets me I try to keep my emotions in balance*"; and over-identification:

"*When I'm down and out, I remind myself that there are lots of other people in the world feeling like I am*." The scale can be analysed both in terms of specific subscales (i.e., self-kindness, mindfulness, common humanity, isolation, overidentification and self-judgement) as well as generating a total SCS score.[78] The SCS total score at 4-weeks (post-intervention) will be used as the primary outcome for this study. The SCS subscales will be analysed to provide a better understanding how self-compassion may support weight management outcomes (e.g., increased mindfulness, common humanity or reduced self-judgement, overidentification or isolation)[80]

Secondary outcomes

The Weight Control Strategies Scale (WCSS) will be utilised to measure changes in participants' eating behaviour and physical activity behaviour.[81] The WCSS has subscales to measure weight control strategies commonly used in weight management programs, including dietary choices, physical activity and self-monitoring. The WCSS is a well-validated scale with a Cronbach's $a > .79$ and as high as .94 in a WW™ population.[30] The WCSS has also been modified to fit the WW™ program specifically (e.g., low-calorie foods has been changed to low point foods).[30] The WCSS asks participants on a scale of 0= never and 4= always to describe the strategies and behaviours they engage in when trying to lose or maintain weight loss over the last month. For example, "*I had several servings of fruits and/or vegetables each day." "I engaged in a moderate-intensity exercise like brisk walking or something similar to brisk walking for at least 30 minutes a day."* Scale items are totalled and divided by the number of items (total mean score). Separate subscale scores are achieved by summing all items in a subscale and dividing by the number of subscale items (total mean subscale score).[81]

The impact of the SC4WM intervention on body weight outcomes will be determined by self-reported body weight and height to calculate body mass index (BMI, kg/m^2). Self-reported body weight has been seen to strongly correlate with objectively measured body weight.[30,82]

The overall objective of weight management is to support both physical and psychological health.[8] Therefore, potential improvements in emotional wellbeing will be assessed using the WHO-5 Well-being Scale.[83] The WHO-5 is a brief well-validated scale with good internal reliability (*a*= .84). Participants will be asked how they have been feeling over the last two weeks, with a higher number indicating better emotional wellbeing. For example, "*I have felt cheerful and in good spirits."* is rated on a scale of 0 to 5 with 0 meaning 'at no time' and 5 'all the time.' A total score is calculated by summing all items.

Potential moderators

To assess participant eating restraint, the *Revised Rigid Restraint Scale* (RRRS[84]) will be used. The RRRS is a validated 12-item scale designed to assess participants' thoughts, feelings, and behaviours related to restrictive and guilty eating behaviours. The RRRS has good internal reliability with a Cronbach's *a* of > .80 in previous studies.[84] Participants are asked to rate how often statements describe their thoughts, feelings or behaviour regarding eating using on a 5 item scale, 1 being 'never' to 5 'always.' For example, "*There are certain unhealthy foods that I try not to eat in any quantity*." All items are summed to assess dispositional eating restraint. A higher RRRS total score is indicative of higher eating restraint.[65]

The *Weight Self-Stigma Questionnaire (WSSQ[85])* is included in this study to measure the extent to which individuals have internalised weight self-stigma. The WSSQ is a 12-item scale used to measure weight self-stigma on a scale of 1 (completely disagree) to 5 (completely agree). For example, '" *I don't have enough self-control to maintain a healthy weight."* All items are

summed to calculate a total score, or two subscales, self-devaluation and fear of enacted stigma. The WSSQ was designed to help evaluate if interventions reduce weight self-stigma.[85] The WSSQ is correlated with the Weight Bias Internalisation Scale and predicts quality of life and self-esteem.[86] The WSSQ has good internal reliability with a Cronbach's *a* of .81 in a similar study.[87]

The Perceived Stress Scale (PSS[88]) will be used to measure stress over the last month. The PSS is a 14-item scale that asks participants to rate feelings and thoughts over the last month related to coping with change, ability to handle personal problems, and control irritations on a scale of 0 'never' to 4 'very often.' For example, "*In the last month, how often have you felt nervous or 'stressed*'?" The PSS total score is obtained by summing all 14-items. A higher score indicates higher perceived stress in the past month. The PSS is a well-validated scale with high internal reliability Cronbach's alpha of 0.88 in a previous study.[88]

To assess psychological coping, the 28-item *brief COPE*[89] will be used. The brief COPE is the most frequently used coping scale; thus, it is a well-validated measure with a median Cronbach's alpha of 0.68 and a range of 0.55 to 0.92.[90] The brief COPE has 14 subscales that can be used to evaluate the frequency with which coping strategies are used (e.g., self-distraction, active coping, denial, emotional support, behavioural disengagement). Participants use a scale of 1= I haven't been doing this at all to 4= I have been doing this a lot. Each subscale item is added together. A subscale of the WCSS will also be used to asses psychological coping. Based on a scale of 0= never and 4 being always, participants will be asked to describe how often they engaged in psychological coping strategies in the past month. For example, "*If I regained weight, I thought about my past successes and reminded myself that I could get back on trac*k."

Adherence

Participants in both groups will be asked how often they use the WW app or digital online program "*How many days did you use the WW program?"* at 4-weeks and 12-weeks from baseline. Participants in the intervention group will also be asked how many modules of the SC4WM intervention they completed and how many days they use the SC4WM activities post-intervention (4-weeks) and at follow-up (12-weeks from baseline).

Methods: Data collection, management, and analysis

All participant data (e.g., demographic data, weight management outcomes) was collected using validated questionnaires through REDCap. No data were collected through or by WW. Participant names only appeared on the online Consent Form; the remaining data was automatically coded with an alphanumeric participant identification number using REDCap. Potentially identifying information will be stored securely and separately from questionnaire data. Only the research team (JBP, NC, RR, AS and AC) will have access to participant data.

Hypotheses

It is expected that the SC4WM intervention group will report greater increases in self-compassion, improved eating behaviours (e.g., increased fruit and vegetable consumption), physical activity (e.g., increased physical activity), body weight outcomes (e.g., weight loss or less weight regained), and emotional wellbeing at the 4-week follow-up compared to the control group, and that these improvements will persist at the 12-week follow-up. It is expected greater perceived stress (PSS), eating restraint (RRRS) and weight self-stigma (WSSQ), and decreased psychological coping (WCSS subscale) at baseline will moderate the relationship between the SC4WM intervention and changes in self-compassion and weight management outcomes at 4 and 12-weeks.

Sample size

In order to calculate the required sample size to examine group differences in self-compassion, we utilised an effect size from a compassion-based intervention study in a population struggling with weight which found a small to medium effect size for self-compassion (Cohen's *d*=0.38).[91] Using GPower,[92] it was calculated that to detect a small to medium change in self-compassion, using an independent samples t-test (with an alpha of .05 and power of .90), 240 participants would be required (120 per treatment arm).

Data Analysis Plan

Using SPSS software, data will be assessed for violations of the parametric assumptions. Generalised linear mixed models will be used to explore within and between-group differences in changes in the primary (SCS total) and secondary outcomes (eating behaviour, physical activity and body weight) at the 4-week follow-up, with random intercepts for participant to account for repeated measures. Primary and secondary outcomes will also be evaluated at a 12-week follow-up. Possible moderators of the relationship between the SC4WM intervention and changes in self-compassion (e.g. greater weight self-stigma WSSQ at baseline) and weight management outcomes at 4 and 12-weeks will be explored by adding an interaction term (e.g., WSSQ*group*time) to the linear mixed models.

Baseline differences between completers and non-completers in the intervention and control groups will be evaluated using independent sample t-tests. The analyses will be based on both intention-to-treat and Complier Average Causal Effect (CACE) analytic methods.[93] CACE is preferred to per-protocol for this study as it recognises that different individuals may have different intervention needs (e.g., differing intervention doses which may be effective for each individual participant).[93] CACE modelling considers intervention outcomes (μi) and proportion of the intervention participants completed (πi) in 4 cells defined by treatment use. The mean at

each time point for the intervention and control group will be the average of $\mu 1 = \pi c \mu c 1 + \pi n \mu n 2 + \pi a \mu a 3 + \pi d \mu d 4$.[93] For example, mean self-compassion (SCS total) at each time point (e.g. 4 weeks from baseline and 12 weeks from baseline) for participants in the SC4WM intervention will be determined by grouping participants based on usage of the SC4WM intervention (e.g., 1 =completers, 2=half-completers, 3=minimal completers and 4= non-completers based on reported completion of models of the SC4WM intervention). The self-compassion means for those in the control group will be determined by grouping participants based on usage of the WW program (e.g., 1 =completers, 2=half-completers, 3=minimal completers and 4= non-completers based on reported usage of the WW program). Therefore, using CACE, the mean self-compassion score at each time point (e.g., post at 4-weeks from baseline and follow up, 12-weeks from baseline) for the intervention and control group will be the average of $\mu 1 = \pi c \mu c 1 + \pi n \mu n 2 + \pi a \mu a 3 + \pi d \mu d 4$.[93]

Participant open ended comments on their experience at 4 and 12-weeks will be analysed using directed content analysis.[94]

Discussion

This study is designed to investigate whether an SC4WM intervention can improve self-compassion and weight management outcomes for those engaging in a digital, widely available behavioural commercial weight management program and begin the process of identifying potential moderators of self-compassion efficacy. The findings will be used to refine the SC4WM website and disseminate the SC4WM intervention to a broader audience.

Limitations to this study are expected to be similar to other online weight management interventions and may include low adherence to the intervention and high attrition rates.[67,95] We have tried to minimise attrition and improve adherence by keeping the intervention brief (4-

weeks), engaging, and easy to access.[66,67,95] Maintenance of weight management outcomes (e.g., weight loss) is a well-established challenge, even with self-compassion interventions.[49,51] Integrating continued practice of self-compassion for weight management was part of the last module of the SC4WM intervention, with a follow-up at 12 -weeks to determine if between group differences in self-compassion and weight management outcomes are maintained. Future research should test the effectiveness of compassion-based interventions for relapse prevention and weight management in the longer term (6 months +). Finally, other possible limitations are the non-blinding of the first author and participants and relying on self-reported outcomes. Future research avenues include incorporating more objective measures of the intervention usage (e.g., Google Analytics), body weight and physiological effects (e.g., cortisol, heart rate variability) obtained by physicians or health professionals.

There is an urgent need to increase the scalability of weight management interventions as well as develop flexibility in delivery during the global pandemic and beyond. Self-compassion shows promise in improving weight management outcomes, including healthier eating, physical activity, and body weight and could be a useful supplement to behavioural weight management interventions such as WW. However, more research is required to investigate if online self-compassion interventions tailored to weight management outcomes can increase self-reported self-compassion and improve outcomes, especially during the first 4-weeks of engaging in weight management.

It is acknowledged that this intervention utilises a fee-based commercial weight management program which may not be accessible to all. However, testing a widely available commercial weight management program can support future public health initiatives and enhance current knowledge. For example, a RCT design utilising a robust behavioural

comparator fills a gap in the literature, specifically testing whether self-compassion can enhance weight management outcomes over and above current weight management programs. Furthermore, if found to be effective, the scalable online SC4WM program could be made more broadly available to augment weight management programmes in the community or to increase the efficacy of current public health initiatives targeting weight outcomes.

Abbreviations

SC4WM, Self-compassion for weight management online intervention

WW, Weight Watchers reimagined, commercial behavioural weight management program

myWW+, current WW program

RCT, Randomised Controlled Trial

SPIRIT, Standard Protocol Items: Recommendations for Interventional Trials

CONSORT, Consolidated Standards of Reporting Trials

REDCap, Research Electronic Data Capture

SCS, Self-Compassion Scale

WCSS, Weight Control Strategies Scale

RRRS, Revised Rigid Restraint Scale

WSSQ, Weight Self-Stigma Questionnaire

PSS, Perceived Stress Scale

SPSS, Statistical Package for the Social Sciences

Declarations

Ethics approval and consent to participate

Ethics approval has been obtained from the University of Auckland Health Research Ethics Committee on March 12, 2021 (Ethics reference #: AH3409).

Participants provide informed consent to participate and for deidentified data to be communicated in research reports including, peer-review journals, conferences and a doctoral thesis. A summary of the study findings will be provided to participants who request it.

Patient and Public Involvement

The SC4WM intervention was designed for the Aotearoa New Zealand population and included consultation with Māori, Indigenous peoples of Aotearoa New Zealand.

Consent for publication

Not applicable.

Availability of data and materials

Data sharing is not applicable to this article as no datasets were generated or analysed.

Competing interests

This study is supported by WW International, Inc. WW International, Inc. was not involved in the intervention design and will not have access to individual participant data related to this study. Furthermore, WW International, Inc. will not play any role during the analyses, interpretation of the data, or the decision to submit results.

Funding

WW International, Inc. will provide participants 12-week free access to the WW digital program and WW app.

Author contributions

JB-P: Conception and development of the SC4WM intervention and study design, wrote the first draft of the protocol manuscript. A.S (primary supervisor) and N.S.C (co-supervisor): Supervision of the conception and development of the SC4WM intervention and study design, critical revision of the manuscript, and final approval of the version to be published. A.C. development and revision of the statistical analysis plan, critical revision of the manuscript and final approval of the version to be published. RR support with study design, critical revision of the manuscript and final approval of the version to be published. All authors read and approved the manuscript for publication.

Acknowledgments

The authors would like to acknowledge Dr Chad Rethorst, in his role as WW Director, Clinical Research, Dr Michelle Cardel WW Director, Global Research and Nutrition, and Dr Gary Foster, Chief Scientific Officer WW International, Inc for providing the WW access codes. The authors would also like to thank Kate Wallace-Boyd and David Lim for recording meditations for the SC4WM intervention and Sarah Snow for NZ Māori consultation.

References

1. Guh DP, Zhang W, Bansback N, Amarsi Z, Birmingham CL, Anis AH. The incidence of co-morbidities related to obesity and overweight: a systematic review and meta-analysis. *BMC Public Health.* 2009;9:88.
2. Frood S, Johnston LM, Matteson CL, Finegood DT. Obesity, Complexity, and the Role of the Health System. *Curr Obes Rep.* 2013;2:320-326.
3. Kirk SF, Penney TL, McHugh TL. Characterizing the obesogenic environment: the state of the evidence with directions for future research. *Obes Rev.* 2010;11(2):109-117.
4. Bhutani S, Cooper JA. COVID-19-Related Home Confinement in Adults: Weight Gain Risks and Opportunities. *Obesity (Silver Spring).* 2020;28(9):1576-1577.
5. Pellegrini CA, Webster J, Hahn KR, Leblond TL, Unick JL. Relationship Between Stress and Weight Management Behaviors during the COVID-19 Pandemic among those Enrolled in an Internet Program. *Obesity Science & Practice.* 2020.

6. Neff K. Self-Compassion: An Alternative Conceptualization of a Healthy Attitude Toward Oneself. *Self and Identity.* 2003;2(2):85-101.
7. Rahimi-Ardabili H, Reynolds R, Vartanian LR, McLeod LVD, Zwar N. A systematic review of the efficacy of interventions that aim to increase self-compassion on nutrition habits, eating behaviours, body weight and body image. *Mindfulness.* 2018;9(2):388-400.
8. Wharton S, Lau DCW, Vallis M, et al. Obesity in adults: a clinical practice guideline. *CMAJ.* 2020;192(31):E875-E891.
9. Wing RR, Lang W, Wadden TA, et al. Benefits of modest weight loss in improving cardiovascular risk factors in overweight and obese individuals with type 2 diabetes. *Diabetes Care.* 2011;34(7):1481-1486.
10. Lasikiewicz N, Myrissa K, Hoyland A, Lawton CL. Psychological benefits of weight loss following behavioural and/or dietary weight loss interventions. A systematic research review. *Appetite.* 2014;72:123-137.
11. Anderson J, Konz EC, Frederich RC, Wood CL. Long-term weight-loss maintenance: a meta-analysis of US studies1–3. *American Journal of Clinical Nutrition.* 2001;74.
12. Hartmann-Boyce J, Johns DJ, Jebb SA, Aveyard P, Behavioural Weight Management Review G. Effect of behavioural techniques and delivery mode on effectiveness of weight management: systematic review, meta-analysis and meta-regression. *Obes Rev.* 2014;15(7):598-609.
13. Teixeira PJ, Going SB, Houtkooper LB, et al. Pretreatment predictors of attrition and successful weight management in women. *Int J Obes Relat Metab Disord.* 2004;28(9):1124-1133.
14. Hadziabdic MO, Mucalo I, Hrabac P, Matic T, Rahelic D, Bozikov V. Factors predictive of drop-out and weight loss success in weight management of obese patients. *J Hum Nutr Diet.* 2015;28 Suppl 2:24-32.
15. Paixao C, Dias CM, Jorge R, et al. Successful weight loss maintenance: A systematic review of weight control registries. *Obes Rev.* 2020;21(5):e13003.
16. Greenway FL. Physiological adaptations to weight loss and factors favouring weight regain. *Int J Obes (Lond).* 2015;39(8):1188-1196.
17. Wang C, Coups EJ. Causal beliefs about obesity and associated health behaviors: results from a population-based survey. *International Journal of Behavioral Nutrition and Physical Activity.* 2010;7.
18. Kirk SF, Price SL, Penney TL, et al. Blame, Shame, and Lack of Support: A Multilevel Study on Obesity Management. *Qual Health Res.* 2014;24(6):790-800.
19. Rand K, Vallis M, Aston M, et al. "It is not the diet; it is the mental part we need help with." A multilevel analysis of psychological, emotional, and social well-being in obesity. *Int J Qual Stud Health Well-being.* 2017;12(1):1306421.
20. Hartmann-Boyce J, Boylan AM, Jebb SA, Aveyard P. Experiences of Self-Monitoring in Self-Directed Weight Loss and Weight Loss Maintenance: Systematic Review of Qualitative Studies. *Qualitative Health Research.* 2019;29.
21. Pearl RL, Puhl RM. Weight bias internalization and health: a systematic review. *Obesity Reviews.* 2018;19(8):1141-1163.
22. Tomiyama AJ. Weight stigma is stressful. A review of evidence for the Cyclic Obesity/Weight-Based Stigma model. *Appetite.* 2014;82:8-15.
23. Puhl RM, Lessard LM, Pearl RL, Himmelstein MS, Foster GD. International comparisons of weight stigma: addressing a void in the field. *Int J Obes (Lond).* 2021.

24. O'Brien KS, Latner JD, Puhl RM, et al. The relationship between weight stigma and eating behavior is explained by weight bias internalization and psychological distress. *Appetite.* 2016;102:70-76.
25. Serlachius A, Hamer M, Wardle J. Stress and weight change in university students in the United Kingdom. *Physiol Behav.* 2007;92(4):548-553.
26. Dallman MF. Stress-induced obesity and the emotional nervous system. *Trends Endocrinol Metab.* 2010;21(3):159-165.
27. Yau YHC, Potenza MN. Stress and Eating Behaviors. *Minerva Endocrinol.* 2013;38:255-267.
28. Born JM, Lemmens SG, Rutters F, et al. Acute stress and food-related reward activation in the brain during food choice during eating in the absence of hunger. *Int J Obes (Lond).* 2010;34(1):172-181.
29. Zellner DA, Loaiza S, Gonzalez Z, et al. Food selection changes under stress. *Physiol Behav.* 2006;87(4):789-793.
30. Phelan S, Halfman T, Pinto AM, Foster GD. Behavioral and Psychological Strategies of Long-Term Weight Loss Maintainers in a Widely Available Weight Management Program. *Obesity (Silver Spring).* 2020;28(2):421-428.
31. Johnson F, Pratt M, Wardle J. Dietary restraint and self-regulation in eating behavior. *Int J Obes (Lond).* 2012;36(5):665-674.
32. Zellner DA, Loaiza S, Gonzalez Z, et al. Food Selection Changes Under Stress. *Physiology and Behavior.* 2006;87:789-793.
33. Wallis DJ, Hetherington MM. Stress and eating: the effects of ego-threat and cognitive demand on food intake in restrained and emotional eaters. *Appetite.* 2004;43(1):39-46.
34. Rockliff H, Gilbert P, McEwan K, Lightman S, Glover D. A pilot exploration of heart rate variability and salivary cortisol responses to compassion-focused imagery. *Clinical Neuropsychiatry 5 (3) (pp 132-139), 2008 Date of Publication: June 2008.* 2008;5(3):132-139.
35. Arch JJ, Brown KW, Dean DJ, Landy LN, Brown KD, Laudenslager ML. Self-compassion training modulates alpha-amylase, heart rate variability, and subjective responses to social evaluative threat in women. *Psychoneuroendocrinology.* 2014;42:49-58.
36. Allen Batts A, Leary MR. Self-compassion, stress, and coping. *Social and Personality Psychology Compass.* 2010;4.
37. Sirois F, Kitner R, Hirsch J. Self-compassion, affect, and health-promoting behaviors. *Health Psychology 34 (6) (pp 661-669), 2015 Date of Publication: 01 Jun 2015.* 2015;34(6):661-669.
38. Terry ML, Leary MR. Self-compassion, self-regulation, and health. *Self and Identity.* 2011;10(3):352-362.
39. Ferrari M, Hunt C, Harrysunker A, Abbott MJ, Beath AP, Einstein DA. Self-Compassion Interventions and Psychosocial Outcomes: a Meta-Analysis of RCTs. *Mindfulness.* 2019.
40. Palmeira L, Cunha M, Pinto-Gouveia J. Processes of change in quality of life, weight self-stigma, body mass index and emotional eating after an acceptance-, mindfulness- and compassion-based group intervention (Kg-Free) for women with overweight and obesity. *Journal of Health Psychology.* 2017;24(8):1056-1069.

41. Fekete EM, Herndier RE, Sander AC. Self-Compassion, Internalized Weight Stigma, Psychological Well-Being, and Eating Behaviors in Women. *Mindfulness.* 2021;12(5):1262-1271.
42. Kirschner H, Kuyken W, Wright K, Roberts H, Brejcha C, Karl A. Soothing Your Heart and Feeling Connected: A New Experimental Paradigm to Study the Benefits of Self-Compassion. *Clinical Psychological Science.* 2019;7(3):545-565.
43. Forbes Y, Donovan C. The role of internalised weight stigma and self-compassion in the psychological well-being of overweight and obese women. *Australian Psychologist.* 2019:No Pagination Specified.
44. Ferreira C, Pinto-Gouveia J, Duarte C. Self-compassion in the face of shame and body image dissatisfaction: Implications for eating disorders. *Eating Behaviors.* 2013;14(2):207-210.
45. Albertson ER, Neff KD, Dill-Shackleford KE. Self-Compassion and Body Dissatisfaction in Women: A Randomized Controlled Trial of a Brief Meditation Intervention. *Mindfulness.* 2014;6(3):444-454.
46. Carriere K, Khoury B, Gunak MM, Knauper B. Mindfulness-based interventions for weight loss: a systematic review and meta-analysis. *Obes Rev.* 2018;19(2):164-177.
47. Dunn C, Haubenreiser M, Johnson M, et al. Mindfulness Approaches and Weight Loss, Weight Maintenance, and Weight Regain. *Curr Obes Rep.* 2018;7(1):37-49.
48. Mantzios M, Wilson J. Mindfulness, Eating Behaviours, and Obesity: A Review and Reflection on Current Findings. *Current Obesity Reports 4 (1) (pp 141-146), 2015 Date of Publication: 2015.* 2015;4(1):141-146.
49. Brenton-Peters J, Consedine NS, Boggiss A, Wallace-Boyd K, Roy R, Serlachius A. Self-compassion in weight management: A systematic review. *J Psychosom Res.* 2021;150:110617.
50. Bishop SR, Lau M, Shapiro S, et al. Mindfulness: A Proposed Operational Definition. *Clinical Psychology: Science and Practice.* 2004;11:230-241.
51. Mantzios M, Wilson JC. Exploring mindfulness and mindfulness with self-compassion-centered interventions to assist weight loss: Theoretical considerations and preliminary results of a randomized pilot study. *Mindfulness.* 2015;6(4):824-835.
52. Mantzios M, Wilson JC. Making concrete construals mindful: A novel approach for developing mindfulness and self-compassion to assist weight loss. *Psychology and Health.* 2014;29(4):422-441.
53. Thogersen-Ntoumani C, Dodos LA, Stenling A, Ntoumanis N. Does self-compassion help to deal with dietary lapses among overweight and obese adults who pursue weight-loss goals? *Br J Health Psychol.* 2020.
54. Hilbert A, Braehler E, Schmidt R, Lowe B, Hauser W, Zenger M. Self-Compassion as a Resource in the Self-Stigma Process of Overweight and Obese Individuals. *Obesity Facts 8 (5) (pp 293-301), 2015 Date of Publication: 29 Oct 2015.* 2015;8(5):293-301.
55. Luo X, Qiao L, Che X. Self-compassion Modulates Heart Rate Variability and Negative Affect to Experimentally Induced Stress. *Mindfulness.* 2018;9(5):1522-1528.
56. Ferrari M, Hunt C, Harrysunker A, Abbott MJ, Beath AP, Einstein DA. Self-compassion interventions and psychosocial outcomes: A meta-analysis of rcts. *Mindfulness.* 2019:No Pagination Specified.
57. Neff KD, Germer CK. A Pilot Study and Randomized Controlled Trial of the Mindful Self-Compassion Program. *Journal of Clinical Psychology.* 2013;69(1):28-44.

58. Mantzios M, Egan HH. On the role of self-compassion and self-kindness in weight regulation and health behavior change. *Frontiers in Psychology.* 2017;8(FEB).
59. Germer CK, Neff KD. Self-compassion in clinical practice. *J Clin Psychol.* 2013;69(8):856-867.
60. Carels RA, Wott CB, Young KM, Gumble A, Koball A, Oehlhof MW. Implicit, explicit, and internalized weight bias and psychosocial maladjustment among treatment-seeking adults. *Eat Behav.* 2010;11(3):180-185.
61. Egan H, Mantzios M. A qualitative exploration of self-kindness and "treating oneself" in contexts of eating, weight regulation and other health behaviors: Implications for mindfulness-based eating programs. *Frontiers in Psychology.* 2018;9(MAY).
62. Breines JG, Chen S. Self-Compassion Increases Self-Improvement Motivation. *Personality and Social Psychology Bulletin.* 2012;38(9):1133-1143.
63. Phillips WJ, Hine DW. Self-compassion, physical health, and health behaviour: a meta-analysis. *Health Psychol Rev.* 2021;15(1):113-139.
64. Miller BM, Brennan L. Measuring and reporting attrition from obesity treatment programs: A call to action! *Obes Res Clin Pract.* 2015;9(3):187-202.
65. Yeo C, Ahmed S, Oo AM, Koura A, Sanghvi K, Yeo D. COVID-19 and Obesity-the Management of Pre- and Post-bariatric Patients Amidst the COVID-19 Pandemic. *Obes Surg.* 2020;30(9):3607-3609.
66. van Genugten L, Dusseldorp E, Webb TL, van Empelen P. Which Combinations of Techniques and Modes of Delivery in Internet-Based Interventions Effectively Change Health Behavior? A Meta-Analysis. *J Med Internet Res.* 2016;18(6):e155.
67. van Beurden SB, Simmons SI, Tang JCH, Mewse AJ, Abraham C, Greaves CJ. Informing the development of online weight management interventions: a qualitative investigation of primary care patient perceptions. *BMC Obes.* 2018;5:7.
68. Cavero-Redondo I, Martinez-Vizcaino V, Fernandez-Rodriguez R, Saz-Lara A, Pascual-Morena C, Alvarez-Bueno C. Effect of Behavioral Weight Management Interventions Using Lifestyle mHealth Self-Monitoring on Weight Loss: A Systematic Review and Meta-Analysis. *Nutrients.* 2020;12(7).
69. Duarte C, Gilbert P, Stalker C, et al. Effect of adding a compassion-focused intervention on emotion, eating and weight outcomes in a commercial weight management programme. *J Health Psychol.* 2019:1359105319890019.
70. Schnepper R, Reichenberger J, Blechert J. Being My Own Companion in Times of Social Isolation - A 14-Day Mobile Self-Compassion Intervention Improves Stress Levels and Eating Behavior. *Front Psychol.* 2020;11:595806.
71. Schulz KF, Altman DG, Moher D, Group C. CONSORT 2010 Statement: Updated Guidelines for Reporting Parallel Group Randomized Trials. *Annals of Internal Medicine.* 2010;152:726-732.
72. Chan A-W, Tetzlaff JM, Altman DG, et al. SPIRIT 2013 Statement: Defining Standard Protocol Items for Clinical Trials. *Annals of Internal Medicine.* 2013;158:200-207.
73. Harris PA, Taylor R, Minor BL, et al. The REDCap consortium: Building an international community of software platform partners. *J Biomed Inform.* 2019;95:103208.
74. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for

providing translational research informatics support. *J Biomed Inform.* 2009;42(2):377-381.
75. WW. Introducing myWW+. WW Weight Watchers reimagined. https://www.weightwatchers.com/nz/ourprogram. Published 2020. Accessed November 30, 2020.
76. Goetz JL, Keltner D, Simon-Thomas E. Compassion: an evolutionary analysis and empirical review. *Psychol Bull.* 2010;136(3):351-374.
77. Neff KD. Self-Compassion: An Alternative Conceptualization of a Healthy Attitude Toward Oneself. *Self and Identity.* 2003;2:85-101.
78. Neff K. The Development and Validation of a Scale to Measure Self-Compassion. *Self and Identity.* 2003;2:223-250.
79. Sirois FM. The association between self-compassion and self-rated health in 26 samples. *BMC Public Health.* 2020;20(1):74.
80. Neff KD, Toth-Kiraly I, Yarnell LM, et al. Examining the factor structure of the Self-Compassion Scale in 20 diverse samples: Support for use of a total score and six subscale scores. *Psychol Assess.* 2019;31(1):27-45.
81. Pinto AM, Fava JL, Raynor HA, LaRose JG, Wing RR. Development and validation of the weight control strategies scale. *Obesity (Silver Spring).* 2013;21(12):2429-2436.
82. McGuire MT, Wing RR, Klem ML, Lang W, Hill JO. What Predicts Weight Regain in a Group of Successful Weight Losers? *Journal of Consulting and Clinical Psychology.* 1999;67:177-185.
83. Bech P, Olsen LR, Kjoller M, Rasmussen NK. Measuring well-being rather than the absence of distress symptoms: a comparison of the SF-36 Mental Health subscale and the WHO-Five well-being scale. *International journal of methods in psychiatric research.* 2003;12(2):85-91.
84. Adams CE, Leary MR. Promoting self-compassionate attitudes toward eating among restrictive and guilty eaters. *Journal of Social and Clinical Psychology.* 2007;26(10):1120-1144.
85. Lillis J, Luoma JB, Levin ME, Hayes SC. Measuring Weight Self-stigma: The Weight Self-stigma Questionnaire. *Obesity.* 2012;18(5).
86. Durso LE, Latner JD. Understanding Self-directed Stigma: Development of the Weight Bias Internalization Scale. *Obesity Journal* 2008;16.
87. Levin ME, Potts S, Haeger J, Lillis J. Delivering Acceptance and Commitment Therapy for Weight Self-Stigma Through Guided Self-Help: Results From an Open Pilot Trial. *Cognitive and Behavioral Practice.* 2018;25:87-104.
88. Cohen S, Kamarck T, Mermelstein R. A Global Measure of Perceived Stress. *Journal of Health and Social Behavior.* 1983;24(4):385-396.
89. Carver CS. You want to measure coping but your protocol's too long: consider the brief COPE. *Int J Behav Med.* 1997;4(1):92-100.
90. Kato T. Frequently Used Coping Scales: A Meta-Analysis. *Stress Health.* 2015;31(4):315-323.
91. Palmeira L, Pinto-Gouveia J, Cunha M. Exploring the efficacy of an acceptance, mindfulness & compassionate-based group intervention for women struggling with their weight (Kg-Free): A randomized controlled trial. *Appetite 112 (pp 107-116), 2017 Date of Publication: 01 May 2017.* 2017;112:107-116.

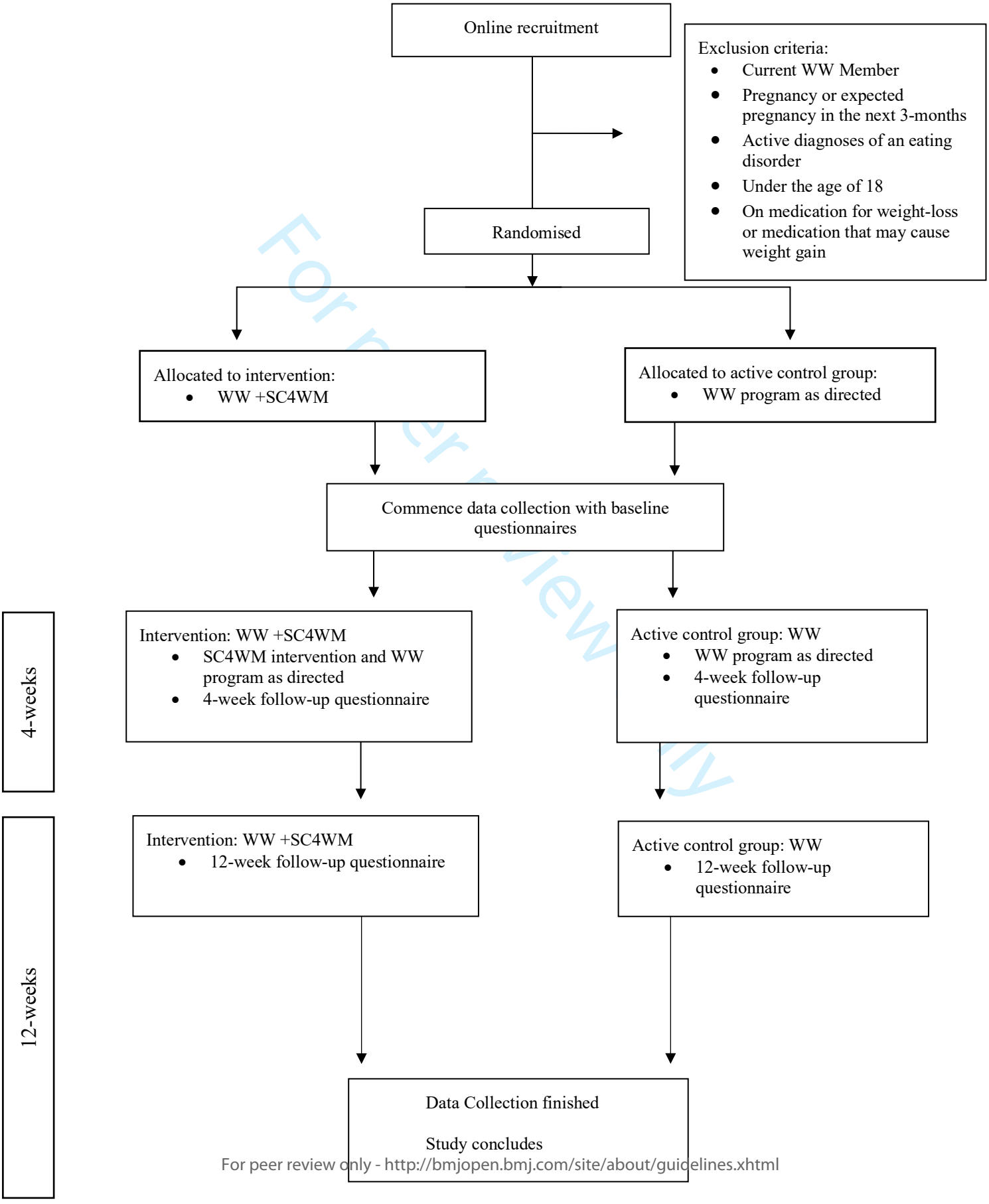
92. Faul F, Erdfelder E, Lang A, Buchner A. G*Power 3: a flexible statistical power analysis program for the social, behavioral, and biomedical sciences. *Behav Res Methods* 2007;39:175-191.
93. Connell AM. Employing complier average causal effect analytic methods to examine effects of randomized encouragement trials. *Am J Drug Alcohol Abuse.* 2009;35(4):253-259.
94. Hsieh HF, Shannon SE. Three approaches to qualitative content analysis. *Qual Health Res.* 2005;15(9):1277-1288.
95. Ventura AD, Nefs G, Browne JL, Friis AM, Pouwer F, Speight J. Is Self-Compassion Related to Behavioural, Clinical and Emotional Outcomes in Adults with Diabetes? Results from the Second Diabetes MILES—Australia (MILES-2) Study. *Mindfulness.* 2018;10(7):1222-1231.

Figure Legend

Figure 1: CONSORT diagram. The flow of participants through the trial.

Figure 2: SC4WM landing page

Figure 1. CONSORT Diagram.



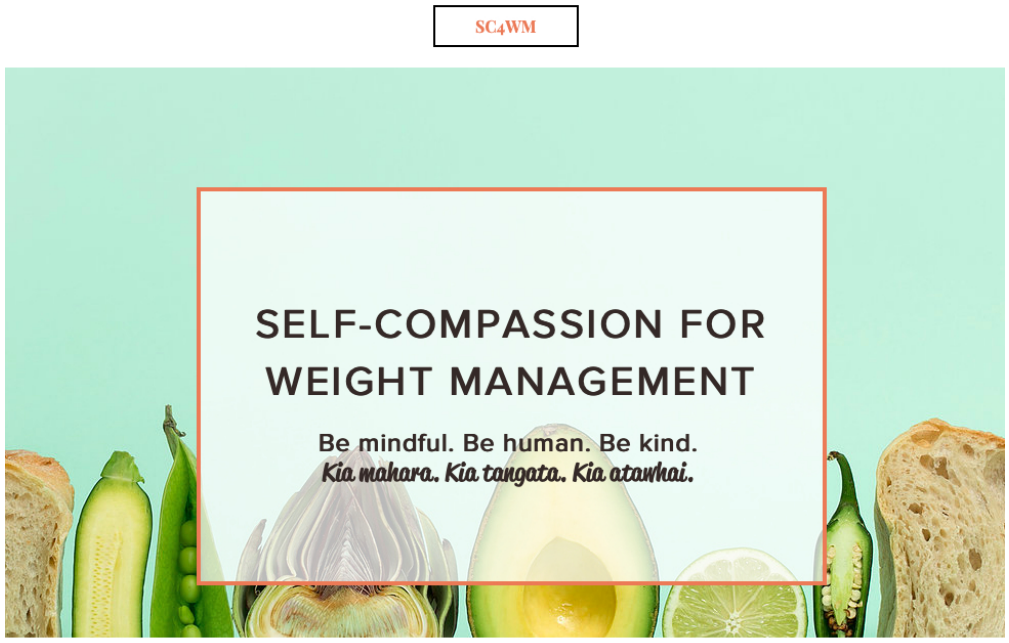


Figure 1 SC4WM Landing Page

344x226mm (72 x 72 DPI)

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Page #
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	Title page
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	Abstract Pg. 2, Methods Pg. 7, par.2
	2b	All items from the World Health Organization Trial Registration Data Set	na
Protocol version	3	Date and version identifier	na
Funding	4	Sources and types of financial, material, and other support	Declarations Pg. 21, par. 4-5
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Declarations Pgs. 21-22
	5b	Name and contact information for the trial sponsor	Title page
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	Declarations Pg. 21, par. 4
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	na
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	Background Pgs. 4-7

	6b	Explanation for choice of comparators	Background Objectives Pgs. 6-7
Objectives	7	Specific objectives or hypotheses	Background Pgs. 7 Discussion Pg.18, par 2
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	Methods Pg. 7
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	Methods Pgs. 7-8
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	Methods Pgs. 7-8
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	Methods Pgs. 11-12
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	Methods Pg. 12
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	Discussion Pg. 19 par. 2
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	na
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	Methods Pgs. 13-17
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Methods Pgs. 8-10
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	Methods Pg. 8, par. 1

Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	Methods Pg. 8, par. 2
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	Methods Pg. 8, par. 2
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	Methods Pg. 8, par. 2
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	Methods Pg. 8, par. 2
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	Discussion Pg. 19, par. 2
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	na
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	Methods Pgs. 13-17 Discussion Pg18, par 2
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	Methods Pg. 10 Discussion Pg.19, par. 2
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	Methods Pg. 8, par 1 Discussion Pg. 17, par.3

Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	Methods Pg. 17, par 3
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	Methods Pg. 17, par 3
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	Methods Pg. 17, par. 3
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	Methods Pg. 17, par. 2 Declarations Pg. 22, par 4-5
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	na
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	Methods Pg.13
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	na
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	Declarations Pg. 20, par. 2
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	Methods Pg. 7, par. 2
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	Methods Pg. 8, par 2
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	na
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	Methods Pg. 8, par 2

Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	Declarations Pg. 21, par. 4&5
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	Methods Pg. 17, par 2 Declarations Pg. 21, par 5
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	na
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	Declarations Pg. 21, par 1
	31b	Authorship eligibility guidelines and any intended use of professional writers	na
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	na
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	na
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	na

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.