Research Article

Obesity Facts

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Supporting Weight Management during COVID-19: A Randomized Controlled Trial of a Web-Based, ACT-Based, Guided Self-Help Intervention

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Keywords

 $Obesity \cdot Overweight \cdot COVID-19 \cdot Acceptance and Commitment Therapy$

Abstract

Introduction: Adults with overweight and obesity are vulnerable to weight gain and mental health deterioration during the COVID-19 pandemic. We developed a web-based, guided self-help intervention based on Acceptance and Commitment Therapy (ACT) that aims to support adults with overweight and obesity to prevent weight gain by helping them to manage their eating behaviours, be more physically active, and protect their emotional wellbeing ("SWiM-C"). SWiM-C is a guided self-help programme using non-specialist guides to enhance scalability and population reach while minimizing cost. This study evaluated the effect of SWiM-C on bodyweight, eating behaviour, physical activity, and mental wellbeing in adults with overweight and obesity over 4 months during the COVID-19 pandemic in the UK. Methods: We randomized adults (BMI \geq 25 kg/m²) to SWiM-C or to a wait-list standard advice group. Participants completed outcome assessments online at baseline and 4 months. The primary outcome was self-measured weight; secondary outcomes were eating behaviour, physical activity, experiential avoidance/ psychological flexibility, depression, anxiety, stress, and wellbeing. We estimated differences between study groups in change in outcomes from baseline to 4 months using linear regression, adjusted for outcome at baseline and the randomization stratifiers (BMI, sex). The trial was pre-registered (ISRCTN12107048). Results: 486 participants were assessed for eligibility; 388 participants were randomized (196 standard advice, 192 SWiM-C), and 324 were analysed. The adjusted difference in weight between SWiM-C and standard advice was -0.60 kg (-1.67 to 0.47, p = 0.27). SWiM-C led to improvements in uncontrolled eating (-3.61 [-5.94 to -1.28]), cognitive restraint (5.28 [2.81–7.75]), experiential avoidance (-3.39 [-5.55 to -1.23]), and wellbeing (0.13 [0.07-0.18]). Conclusions: SWiM-C improved several psychological determinants of successful weight management and had a protective effect on wellbeing during the pandemic. However, differences in weight and some other outcomes were compatible with no effect of the intervention, suggesting further refinement of the intervention is needed.

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Introduction

During the COVID-19 pandemic, social distancing and isolation measures coupled with disruption of routines, stress, and emotional turmoil are likely to lead to changes in eating and physical activity [1]. Evidence suggests that food consumption and weight increased during the pandemic while physical activity decreased, particularly among those with higher BMI [2–6]. Previous research on deviation from routines (e.g., during holidays) suggests that small weight changes can become permanent and lead to considerable weight gain over time, with those with overweight and obesity at higher risk for weight gain [7]. This is particularly concerning as individuals with overweight and obesity are at increased risk for complications related to COVID-19, such as risk of hospitalization and mortality [8].

Among people living with obesity, more than half (55%) reported that their mental health had worsened during the first COVID-19 lockdown in a recent UK-based survey [6]. Adverse mental burden may lead to emotional eating and decreased physical activity [9–14] and thus to increases in bodyweight [15].

During the pandemic, disruptions to existing health services meant that novel, remote ways of delivering weight management and mental health care were required. Evidence shows that interventions based on ACT [16] are the most effective behavioural treatment for long-term weight change among third-wave cognitive behaviour therapies and may improve mental wellbeing and psychological determinants of weight control [17]. Existing ACT-based interventions are usually face to face, psychologist-led, and expensive [17]. Remotely delivered, scalable, and cost-effective interventions are needed, but evidence is scarce. A recent systematic review identified only three studies on remote, ACTbased weight management interventions [17]. Evidence suggests self-help interventions are effective for weight loss [18] and that technology-mediated interventions can result in clinically significant weight loss [19]. Meta-analyses indicate that support from a coach can enhance weight-loss effects of digital interventions, but further evidence from randomized trials is needed [19]. We developed a web-based, ACT-based, guided selfhelp intervention (SWiM-C; Supporting Weight Management during COVID-19) that aimed to help adults with overweight and obesity to manage their weight and eating behaviour, be more physically active, and protect their emotional wellbeing during the COVID-19 pandemic.

We evaluated the effect of SWiM-C on bodyweight in adults with overweight and obesity over 4 months. The secondary aim was to evaluate effects on eating behaviour, physical activity, mental health, experiential avoidance/psychological flexibility, and wellbeing. Based on the extant literature, we predicted that participants in the intervention group would have lower weight, better eating behaviour (lower uncontrolled eating and emotional eating, higher cognitive restraint), higher physical activity, and better mental health (lower scores on depression, anxiety, and stress, higher scores for wellbeing) compared to the standard advice group.

Materials and Methods

Study Design

In a parallel group, two-arm trial, we randomized eligible participants to either the SWiM-C intervention or a standard advice wait-list control group. Participants completed quantitative outcome assessments online at baseline and after 4 months. The trial was pre-registered (ISRCTN12107048). A CONSORT checklist is provided in online supplementary Table 4 (for all online suppl. material, see www.karger.com/doi/10.1159/000524031).

Intervention

SWiM-C is a web-based, ACT-based, guided self-help intervention that aims to support adults with overweight and obesity to prevent weight gain by helping them to manage their eating behaviours, be more physically active, and protect their emotional wellbeing. It was developed in consultation with people with obesity and type 2 diabetes and was guided by the Medical Research Council framework for the development of complex interventions in health care [20], Intervention Mapping Protocol [21], and the person-based approach for enhancing the acceptability and feasibility of interventions [22]. The intervention includes access to an online web platform with 12 weekly "SWiM sessions." These include psychoeducation, reflective exercises, and behavioural experiments. Participants worked through sessions at their own pace and hence duration per session varied. Participants received automated email reminders to log in and complete sessions each week. After session 4 and 10, participants received a semi-structured scripted telephone call (~20 min) and a tailored email, respectively, from their SWiM coach. Coaches were trained non-specialists (we defined specialists as professionals with specialist qualifications or registration in weight management, e.g., dieticians). Coaches received online training and a detailed coach manual including semi-structured scripts to guide communications with participants. The online training lasted approximately 3 h and involved clarification of the principles of ACT and role-playing to help the coaches to practice using the manual. Participants were encouraged to weigh themselves weekly and to record their weight at the start of each session. Between sessions, participants were asked to complete reflective exercises and behavioural experiments ("SWiM Practice"), which were reviewed and discussed in communications with SWiM coaches. Further details on the intervention and its development are published elsewhere [23].

Control

The wait-list control group received standard advice in the form of a leaflet from the European Association for the Study of Obesity (EASO) on diet, physical activity, and mood during the COVID 19 pandemic, tailored to people living with obesity (online suppl. Fig. 1).

Recruitment

Participants were recruited online through mailing lists and social media advertisements from local weight management services as well as obesity and weight management organizations (e.g., EASO) and through a volunteer database from a previous trial [24]. Recruitment adverts were reviewed by a patient and public involvement group (N = 6).

Eligibility Criteria

Eligible participants were adults with overweight or obesity (age \geq 18 years; BMI \geq 25 kg/m²) who had a good understanding of written English, were willing to be randomized to either intervention or a standard advice group and to complete outcome assessments online, and who owned a set of bodyweight scales. Participants were excluded if they had received bariatric surgery in the 2 years prior to the study.

Randomization

Participants were allocated to study arms in a 1:1 allocation using block randomization (block size 6) stratified by BMI classification $(25-<30, 30-<40, 40+ kg/m^2)$ and sex (male, female). The randomization sequence was computer-generated by the trial statistician and incorporated into the trial database by the data manager. The sequence was unknown to all other personnel, including study coordinators, outcome assessors, and investigators. Randomized allocation was revealed to participants via an email which included details of the allocated intervention.

Procedure

Adverts and email invitations included a link to a secure webform which was used to provide participant information, confirm eligibility, and obtain informed, written consent. After consent, baseline data were collected using online questionnaires. Participants were then randomized to SWiM-C or standard advice. Participants received an email with details of their allocated intervention. Those allocated to SWiM-C received a weblink to access the website, whilst those allocated to standard advice were emailed the EASO leaflet. Participants in SWiM-C were instructed to complete one session per week (though they were able to work through the website in their own time). At 4 months, all participants were emailed a weblink to complete follow-up questionnaires online. Although the intended intervention duration was 3 months, we followed up at 4 months to allow time for participants to complete all sessions before follow-up. After completing follow-up assessments, participants in the standard advice group were provided access to SWiM-C.

Sample Size

Based on a previous weight management trial over a similar period [25], the planned sample size was 360 which, allowing for 20% loss to follow-up, enabled detection of a 1-kg between-group difference in change in weight from baseline to follow-up with 90% power and 95% confidence. We assumed a standard deviation (SD) of 6 kg for weight and a correlation between baseline and follow-up measures of 0.9.

Outcomes

The primary outcome was change in self-reported weight from baseline to 4 months (kg). Secondary outcomes included cognitive restraint, emotional eating, and uncontrolled eating (Three-Factor Eating Questionnaire [TFEQ-R21] [26], with one score of 0-100 per sub-scale), experiential avoidance/psychological flexibility (Acceptance and Action Questionnaire Weight Related-Revised [AAQW-R] [27], scores: 10-70, with lower scores indicating less experiential avoidance and more psychological flexibility), volume of total physical activity in MET-min per week (International Physical Activity Questionnaire [IPAQ] [28]), depressive symptom severity (Patient Health Questionnaire [PHQ-8] [29], scores: 0-24), anxiety symptom severity (Generalized Anxiety Disorder 7-item scale [GAD-7] [30], scores: 0-21), perceived stress (Perceived Stress Scale [PSS-4] [31, 32], scores: 0-16), and wellbeing/ capability (ICECAP-A [33], scores: 0-1). We assessed age (years), sex, ethnicity, educational qualifications, and marital status at baseline

Statistical Analyses

Analyses were pre-specified in a statistical analysis plan which was reviewed by all co-authors (available at www.isrctn.com/IS-RCTN12107048).). Data were analysed using R version 4.0.0 and R Studio version 1.0.153. Baseline characteristics of the sample were summarized descriptively (means and SDs for continuous variables, number and percentage of individuals within each category for categorical variables). Individuals were included in the analysis in the group to which they were randomized, regardless of their adherence to the intervention. Participants with missing outcome data at follow-up were excluded. Participants reporting biologically implausible weight loss from baseline to follow-up were excluded [34]. Our hypothesis was that there would be a difference between groups in weight change from baseline to 4 months and we conducted a two-sided statistical test.

The primary analysis estimated baseline-adjusted differences between the study groups in change in weight from baseline to 4 months. We used a linear regression model with change in weight as the dependent variable and included baseline weight, the randomization stratifiers (sex, BMI classification), and intervention group as covariates. Analogous models were used for secondary outcomes. Participants with missing outcome data at baseline were included in the analysis using the missing indicator method [35]. Given recent calls to improve interpretation of statistical findings by avoiding dichotomization of findings into "significant"/"nonsignificant" [36], we did not define a significance criterion and instead aimed to interpret the importance of effect sizes and their confidence intervals.

To assess whether assumptions of linear regression were met, we inspected the frequency distribution of the standardized residuals for normality. Heteroscedasticity was explored by examining the regression plot of the standardized residuals of the outcome against the standardized predicted values of the model. Where we found evidence of an intervention effect on an outcome but the residuals were not normally distributed, we assessed the robustness of the effect by redoing the analysis using a log-transformed outcome. We report *p* values only for the main effects analysis of the primary outcome; 95% confidence intervals are reported for all outcomes/comparisons. We performed a sensitivity analysis using multiple imputation by chained equations (MICE) to impute missing values for weight at 4 months. This assumes data are missing at random. The multiple imputation model included all variables included in the regression model as well as other baseline variables that had univariate associations (p < 0.2) with missingness. We also undertook a per-protocol analysis by including only those in the intervention group who completed at least 4 sessions, and those who completed at least 8 sessions, to assess whether the findings were influenced by adherence to the intervention.

Results

Between June 18, 2020, and September 7, 2020, 486 participants were screened; 388 were eligible and were randomized (Fig. 1). From the start of the study to completion of 4-month follow-up, 18 withdrew from the study (18 in the SWiM-C intervention group and 0 in the standard advice group). Study groups did not differ on baseline characteristics (Table 1). Participants' mean age was 50.7 (SD = 14.3) years with a mean BMI of 34.8 (7.7) kg/m^2 . The majority were female (303/388, 78.1%), white (364/388, 93.8%), and most had at least a university degree or equivalent (242/388, 62.4%). The intervention was started by 187 (97.4%) participants, 167 (87.0%) completed the coach call, 161 (83.9%) were sent tailored coach emails, 159 (82.8%) completed at least 4 sessions, 92 (47.9%) completed at least 8 sessions, and 62 (32.3%) completed all 12 sessions.

There were no missing data at baseline for any of the secondary outcomes except the IPAQ (SWiM-C: n = 21 [10.9%], standard advice: n = 30 [15.3%]). At follow-up, 324 (83.5%) participants completed the primary outcome. Participants with missing outcome data at 4 months did not differ substantially from participants without missing outcome data (online suppl. Table 1), although the percentage of participants with BMI >40 kg/m² was twice as high among participants with missing data (35/111, 31.8%) compared to those without missing data (42/277, 15.2%).

Primary Outcome

SWiM-C participants lost 1.91 kg (SD = 5.06) from baseline to 4 months, compared to 1.24 kg (SD = 4.79) in the standard advice group (online. suppl. Table 2). Following adjustment for baseline weight, BMI classification, and sex, the difference between SWiM-C and standard advice groups was -0.6 kg (95% CI: -1.67 to 0.47). The confidence interval included zero, so the data were compatible with there being no effect of the intervention on weight change (p = 0.27). We found similar results when missing weight data at follow-up were imputed (online suppl. Table 3). When including only those who completed at least 4 sessions, SWiM-C participants lost 0.78 kg (95% CI: -1.84 to 0.27 kg) more weight than the standard advice group (p = 0.15), and those who completed at least 8 sessions lost 0.95 kg (95% CI: -2.14 to 0.23) more than the standard advice group (p = 0.11).

Secondary Outcomes

For all outcomes except perceived stress, adjusted differences between study groups favoured the SWiM-C group, with SWiM-C participants reporting lower weight, depression, anxiety, experiential avoidance, uncontrolled eating, and emotional eating and higher cognitive restraint, physical activity, and wellbeing than participants in the standard advice group (Table 2). However, confidence intervals included zero for differences between study groups in depression, anxiety, stress, emotional eating, and physical activity. For the effect of SWiM-C on experiential avoidance, cognitive restraint, uncontrolled eating, and capability wellbeing, confidence intervals did not include zero. SWiM-C participants also reported higher wellbeing/capability scores compared to standard advice. Results were similar when missing outcome data at follow-up were imputed (online suppl. Table S3). As standardized residuals for the ICECAP score appeared to be not normally distributed, we repeated this analysis with log-transformed scores (adjusted difference 0.09 [0.02 - 4.72]).

Discussion

We evaluated the effect of a web-based, ACT-based, guided self-help intervention on preventing weight gain over 4 months for adults with overweight or obesity during the COVID-19 pandemic. The data were compatible with no effect of the intervention on bodyweight, physical activity, mental health, or emotional eating. The intervention improved psychological determinants known to lead to successful weight management in the longer term (uncontrolled eating, cognitive restraint, and experiential avoidance) [37, 38] and had a protective effect on wellbeing.

Fig. 1. Consort flowchart. Biologically implausible weight loss was determined using the formulae in Chen et al. [34].

(For figure see next page.)

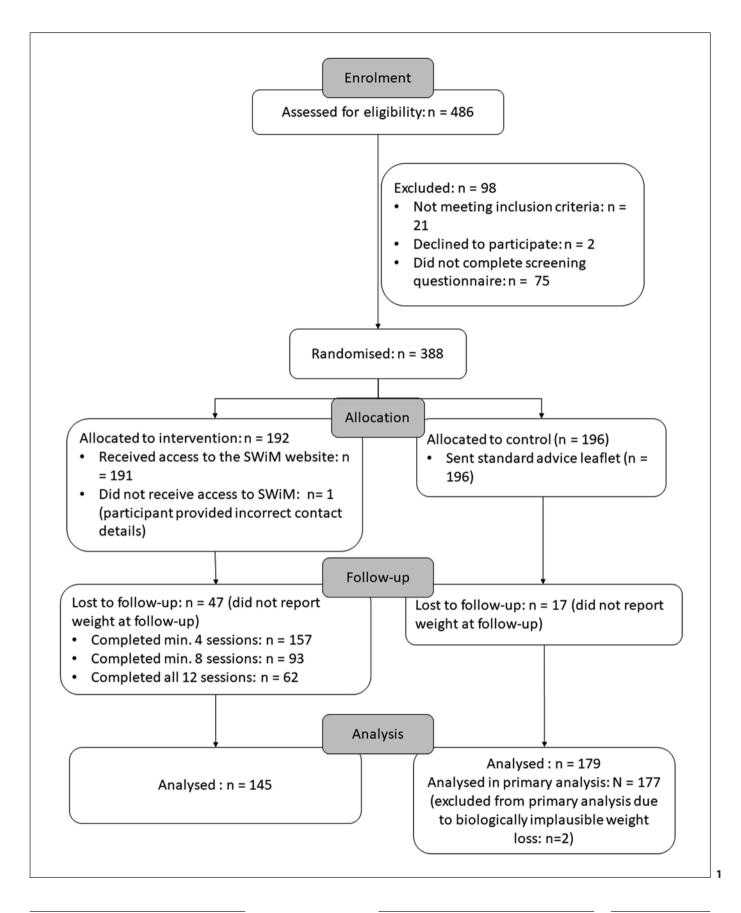


Table 1. Baseline characteristics of the sample

Variable	SWiM-C n = 192	Standard advice n = 196	Total sample N = 388	
Mean (SD) age, years	50.7 (14.3) Range: 20–86		50.3 (13.8) Range: 18–86	
Sex	hange. 20 00	Range: 18–78	nunge. to be	
Women	151 (78.6)	152 (77.6)	303 (78.1)	
Men	41 (21.4)	43 (21.9)	84 (21.6)	
Prefer not to say	0	1 (0.5)	1 (0.3)	
Ethnicity			. (,	
White	181 (94.3)	183 (93.4)	364 (93.8)	
Non-white	9 (4.7)	11 (5.6)	20 (5.2)	
None of these	1 (0.5)	0	1 (0.3)	
Prefer not to say	1 (0.5)	2 (1.0)	3 (0.8)	
Education	. (0.0)	= ()	0 (0.0)	
Below post-secondary (up to and including A-levels)	50 (26.0)	50 (25.5)	100 (25.8)	
Post-secondary	140 (72.9)	142 (72.5)	282 (72.7)	
Other	2 (1.0)	3 (1.5)	5 (1.3)	
Prefer not to say	0	1 (0.5)	1 (0.3)	
Marital status				
Single	31 (16.1)	36 (18.4)	67 (17.3)	
Married/civil partnership/cohabiting	140 (72.9)	140 (71.4)	280 (72.1)	
Widowed/separated/divorced	21 (10.9)	5 (9.2)	39 (10.1)	
Prefer not to say	0	2 (1.0)	2 (0.5)	
Mean (SD) weight, kg	98.5 (21.6)	98.1 (25.1)	98.3 (23.4)	
Mean (SD) height, cm	168.1 (7.7)	166.9 (8.4)	167.5 (8.0)	
Mean (SD) BMI, kg/m^2	34.7 (7.2)	35.0 (8.2)	34.8 (7.7)	
BMI category (kg/m ²)	\/	,	()	
25-<30	54 (28.3)	61 (31.1)	77 (19.9)	
30-<40	99 (51.8)	96 (49.0)	195 (50.4)	
40+	38 (19.9)	39 (19.9)	77 (19.9)	
Missing	1 (0.5)	0	1 (0.3)	

Table 2. Changes in outcomes between baseline and 4 months (mean, SD) by study group (SWiM-C vs. standard advice) adjusted for the randomization stratifiers (sex, BMI classification) and outcome at baseline

Outcome	Change from baseline, mean (SD)		N	,	Adjusted 95%	
	SWiM-C	standard care		differenc	difference ^a confidence interval	
Weight, kg	-1.91 ^c (5.06)	-1.24 ^c (4.79)	322	-0.60	-1.67 to 0.47	
Depression (PHQ-8)	-1.1 (5.15)	-0.62 (4.25)	325	-0.67	-1.57 to 0.22	
Anxiety (GAD-7)	-0.30 (4.18)	-0.02 (4.23)	325	-0.57	-1.39 to 0.26	
Stress (PSS-4)	-0.02 (2.99)	-0.13 (3.05)	325	0.02	–0.53 to 0.58	
Experiential avoidance/psychological flexibility (AAQW-R) ^b	-6.21 (10.68)	-3.07 (10.31)	321	-3.39	–5.55 to –1.23	
Eating behaviour (TFEQ-R21)						
Cognitive restraint	6.32 (12.86)	0.56 (11.92)	321	5.28	2.81 to 7.75	
Uncontrolled eating	-5.69 (10.46)	-2.20 (11.62)	321	-3.61	–5.94 to –1.28	
Emotional eating	-3.58 (12.35)	-2.41 (12.21)	321	-1.33	-3.74 to 1.08	
Volume of total physical activity (IPAQ) in MET-min	3.00 (29.78)	-4.09 (36.46)	279	5.72	-1.10 to 12.53	
Wellbeing/capability (ICECAP-A)	0.02 (0.15)	-0.11 (0.32)	321	0.13	0.07 to 0.18	

SD, standard deviation; ICECAP-A, ICEpop CAPability measure for Adults. ^a Adjusted for outcome at baseline and randomization stratifiers (BMI classification and sex). ^b Lower scores on AAQW-R indicate lower experiential avoidance and higher psychological flexibility. ^cThe change from baseline to 4 months only includes participants who completed outcomes at 4 months (N = 145), whereas baseline means in Table 2 include all participants (hence, mean change here differs from the difference between the means reported in Table 2).

The intervention did not lead to substantial differences in weight between groups. It should be noted that we expected an increase in weight in the standard advice group based on previous evidence of the vulnerability of people with overweight and obesity to weight gain during disruptions of routines [39] and emerging evidence indicating increases in bodyweight during COVID-19 [2, 3]. However, standard advice participants in our study lost 1.24 kg (SD = 4.79). We recruited participants mainly via social media accounts of weight management organizations; therefore, it is possible that we recruited individuals who were motivated to lose weight. This may have attenuated differences between intervention and standard advice.

According to a recent systematic review and metaanalysis, ACT-based interventions have the most consistent evidence of effectiveness for weight management among third-wave cognitive behavioural therapy interventions [17]. However, most ACT-based interventions included in the review were delivered face-to-face. Only three studies were conducted with remotely delivered ACT-based interventions; these yielded mixed findings and studies were limited by small sample sizes and/or lack of control groups [38, 40, 41]. The present study addresses this limitation by providing novel evidence from a fully powered, randomized controlled trial.

It is important to note that remotely delivered ACTbased interventions vary in the degree of guidance provided. Previous research suggests that web-based interventions are used more and have stronger effects when coupled with human contact [42]. Our intervention included one telephone and one email coach contact, but it is unclear whether this level of support is optimal. Further evidence from large, randomized controlled trials is needed to determine the optimal amount of coach contact to balance effectiveness with scalability and cost.

Our findings indicate that the SWiM-C intervention led to improvements in uncontrolled eating and cognitive restraint. Uncontrolled eating measures the extent to which individuals tend to lose control over food intake, and cognitive restraint refers to conscious restriction of food intake to control bodyweight [43]. Evidence suggests changes in eating behaviour are related to changes in weight loss in dietary weight-loss programmes [37].

Eating behaviour, according to ACT, is influenced by an individual's experiential avoidance and psychological flexibility [38]. Accordingly, our findings indicate that SWiM-C reduced experiential avoidance (i.e., attempts to control/avoid unwanted internal experiences such as negative emotions, thoughts, or cravings due to unwillingness to experience them [16, 27]) and increased psychological flexibility (i.e., the ability to act in accordance with personal values despite the presence of interfering emotions, thoughts, and physical sensations [38]). This suggests that SWiM-C helped participants to relate flexibly to their internal experiences and regulate their behaviour, which may have in turn improved uncontrolled eating and cognitive restraint. This is expected to lead to successful weight management in the longer term [37].

Participants in the standard advice group reported a decrease in wellbeing while wellbeing in SWiM-C participants remained stable. Emerging evidence indicates that the CO-VID-19 pandemic has had a negative impact on wellbeing among people with obesity [6]. Participants in our standard advice group may therefore have experienced decreases in wellbeing due to the pandemic, while SWiM-C had a protective effect. Based on data from the present study, it is unclear whether this hypothesis is accurate; we will explore this further in our process evaluation based on interviews with participants (currently underway).

It is noteworthy that observed differences between the study groups at 4 months favoured the SWiM-C group for 9 out of 10 outcomes (the exception being perceived stress), although for 6 of these the confidence intervals included zero and hence these results are also compatible with no effect of the intervention on these outcomes. Additionally, the per-protocol analysis indicated a dose-response relationship, with participants reporting more weight loss the more sessions they completed. It is unlikely that this consistency across outcomes is purely due to random chance, suggesting that intervention effects were generally favourable, though some were not strong enough to result in meaningful differences compared to standard advice over the 4-month study period. Further refinement of the intervention is needed to ensure meaningful impacts on important outcomes such as bodyweight.

For perceived stress, the difference between SWiM-C and standard advice was very small, suggesting that the intervention had no effect at 4 months. A systematic review identified only one ACT-based weight management intervention study that measured perceived stress, which found no reduction in the ACT group [17].

SWiM-C demonstrated good uptake and engagement levels for a web-based, guided self-help intervention, and our study showed excellent retention rates, with 84% completing the primary outcome postintervention. Online weight management studies often have high follow-up attrition rates [44]; however, our findings demonstrate the feasibility of conducting an online trial with only remote contact with participants. Due to its delivery format – Webbased and supported via trained non-specialists – SWiM-C is potentially scalable and less expensive than many existing behavioural weight management interventions.

Limitations

As this study was conducted in response to the rapidly emerging COVID-19 pandemic, we took a pragmatic approach to recruitment, using volunteer databases and obesity and weight management organizations. This may have resulted in a sample of individuals that may be different from the general population. For example, our sample was primarily female, White, and highly educated. Additionally, our sample included only Englishspeaking participants, and it is therefore not clear how SWiM-C would translate into other languages and cultural contexts.

Due to the restrictive measures in place to reduce transmission of COVID-19, we were unable to use trained staff to measure outcomes in person. Self-reported weight can limit accuracy and lead to under-reporting [45], although there is evidence indicating that self-reported weight and height are valid measures in men and women across different socio-demographic groups [46]. We mitigated issues related to self-reporting by providing guidance to participants on how to accurately measure and report their weight and by analysing between-group differences in changes in weight from baseline.

Another limitation is the short follow-up duration. As we responded directly to urgent needs for remote weight management interventions communicated by patient representative organizations, we chose a shorter followup timeframe to ensure we could report findings in a timely manner as the COVID-19 situation developed. Future research should explore effects of remote ACT-based weight management interventions over longer timeframes to determine if any effects on weight are sustainable. Whenever there are multiple outcomes, as here, the risk of "false-positive" findings increases; however, for outcomes for which the data were compatible with an effect of the intervention, the consistency in the direction of effect of these outcomes suggests that it is unlikely that these are false-positive results.

Conclusion

To conclude, this is the first study to evaluate remote weight management support for adults with overweight and obesity during the COVID-19 pandemic. Previous studies on remotely delivered ACT-based interventions (N = 3) are constrained by small samples and/or lack of control groups. At 4 months, SWiM-C improved several psychological determinants known to lead to successful weight management in the longer term and had a protective effect on wellbeing. It should be noted, however, that our results are inconclusive about the effect of the intervention on bodyweight, mental health, physical activity, and emotional eating. Thus, in its current form the intervention is not suitable for implementation in practice as a weight gain prevention intervention. Further refinement of the intervention is necessary to influence these outcomes as well as evaluation in larger samples.

SWiM-C is delivered digitally with guidance from a trained, non-specialist coach and is therefore easily scalable, has good population reach, and can be safely implemented in the context of the pandemic. Scalable, inexpensive, remotely delivered interventions will be needed beyond this context to meet the rise in demand for effective obesity treatments. Overall, the findings of this study add to the growing evidence on ACT-based interventions for weight management and provide novel evidence on the effectiveness of delivering such interventions remotely. Further research is needed to identify the optimal amount of guided support (e.g., amount/type of contact with a coach) and to assess effects across longer follow-up timeframes.

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Statement of Ethics

Ethical approval was obtained from the Cambridge Psychology Research Ethics Committee (Application No: PRE.2020.049) on April 24, 2020. All participants gave written, informed consent. Clinical trial registration: ISRCTN 12107048, https://www.isrctn. com/ISRCTN12107048.

Conflict of Interest Statement

F.W., J.W., M.S., S.J.S., and J.B. report no conflicts of interest. A.J.H. has consulted for Slimming World. C.A.H. reports payment or honoraria from Ethicon, Novo Nordisk, and International Medical Press for lectures, presentations, speakers' bureaus, manuscript writing, or educational events. J.M. and R.R. are Trustees for the Association of the Study of Obesity (unpaid roles). A.L.A. and S.J.G. are the chief investigators on two publicly funded (MRC, NIHR) trials where the intervention is provided by WW (formerly Weight Watchers) at no cost outside the submitted work.

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Author Contributions

A.L.A., R.R., R.A.J., F.W., J.W., M.S., S.J.S., S.J.G., J.B., C.A.H., and A.J.H. planned and designed the study. R.R. led on the development of the intervention. F.W. managed the project, and J.W. and M.S. undertook study coordination (recruitment, day-to-day management of the study). J.B. acted as patient representative. S.J.S. provided statistical input. J.M. wrote the statistical analysis plan, which all co-authors reviewed critically. J.M. carried out the analysis and wrote the first draft of the manuscript. All authors reviewed and edited the manuscript before submission.

Data Availability Statement

The dataset analysed during the current study is not publicly available. Participant consent allows for data to be shared in future analyses with appropriate ethical approval, and the host institution has an access policy (https://www.mrc-epid.cam.ac.uk/wp-content/uploads/2019/02/Data-Access-Sharing-Policy-v1-0_FINAL. pdf) so that interested parties can obtain the data for replication or other research purposes that are ethically approved. Data access is available upon reasonable request (datasharing@mrc-epid.cam. ac.uk). Study documents (study protocol, statistical analysis plan, informed consent form, participant information sheet, analytic code) are available at https://www.isrctn.com/ISRCTN12107048 or on request.

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