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An addiction-based digital weight loss intervention: A multi-centre randomized controlled trial

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Summary

Objective: This randomized clinical trial tested the effectiveness of an addiction-based digital weight-loss intervention, focusing on withdrawal/abstinence from self-identified problem foods,

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AUTHOR CONTRIBUTIONS

Alaina P. Vidmar, Sarah J. Salvy, D. Steven Fox, Jennifer K. Yee, Cambria Garell, Steven D. Mittelman conceptualized and designed the study, drafted the initial manuscript, and reviewed and revised the manuscript. Choo Phei Wee performed the statistical analysis. All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

Clinical Trial Registration: ClinicalTrials.gov identifier: NCT035008353

SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

CONFLICT OF INTEREST

Robert Pretlow is the CEO of eHealth International, Inc. and owner and developer of the app used in the study. The additional authors (Alaina P. Vidmar, Sarah J. Salvy, Choo Phei Wee, D. Steven Fox, Jennifer K. Yee, Cambria Garell, Steven D. Mittelman) have no financial relationships or conflict of interest relevant to disclose.

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snacking and excessive amounts at meals, and discomfort displacement, with and without coaching, compared to an in-person, multi-disciplinary, care model among adolescents with obesity. We hypothesized that the digital intervention with coaching would yield greater weight loss and lower delivery burden than the standard clinical arm, and greater participant engagement than the digital arm without coaching.

Methods: Adolescents were randomized to app intervention, with or without coaching, or in-person multidisciplinary obesity intervention for 6 months. The primary outcome was change in $\%BMI_{p95}$ at weeks 12 and 24. A mixed-effects linear regression model was used to assess the association between change in $\%BMI_{p95}$ and intervention arm. We were also interested in assessing delivery burden, participant engagement and evaluating the relationships between weight change and demographic characteristics, mood, executive function and eating behaviours.

Results: All adolescents ($n = 161$; BMI ≥95th%, age 16 ± 2.5 year; 47% Hispanic, 65% female, 59% publicly insured) lost weight over 24-weeks (−1.29%, [−1.82, −0.76], $p < 0.0001$), with no significant weight loss difference between groups ($p = 0.3$). Girls lost more weight than boys, whereas binge eating behaviour at baseline was associated with increase in $\%BMI_{p95}$ when controlling for other covariates. There was no association between ethnicity, mood, timing of intervention in relation to the pandemic, or executive function and change in $\%BMI_{p95}$.

Conclusions: Contrary with our hypothesis, our results showed no difference in the change in BMI status between treatment arms. Since efficacy of this digital intervention was not inferior to in-person, multi-disciplinary care, this could offer a reasonable weight management option for clinicians, based on youth and family specific characteristics, such as accessibility, resources, and communication styles.

Keywords

binge eating disorder; coaching; digital health; executive functioning; food addiction; obesity; paediatrics; weight loss

1 | INTRODUCTION

Obesity treatment for adolescents has traditionally been delivered in specialized multi-disciplinary outpatient clinics.[1–3] This delivery modality is not only labour intensive and costly, but it may also restrict the engagement and active involvement of adolescents.[2,4] Many adolescents enrolled in outpatient obesity treatment programs, drop out prematurely, which greatly limits meaningful weight loss and long-term outcomes.[2,5] In adults, digital apps for weight loss have been shown to be cost-effective while improving access to care, optimizing adherence, and decreasing labour burden on clinical staff and clinicians.[1,5–9] The efficacy of digital apps for weight management in youth is less clear.[1,9,10]

App-based intervention delivery may not only provide greater accessibility to evidence-based treatment, but it may also provide a vehicle to test novel behavioural intervention strategies. Specifically, despite debates and controversies there is a growing interest in the concept of food addiction and how this construct can be addressed in youth. Food addiction is characterized by the compulsive overeating of food types that activate the brain's reward circuitry with associated symptoms of cravings and withdrawal.[11–14] The prevalence of

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food addiction in youth with obesity is reported to be between 10 and 38%, mirroring rates reported in adults with obesity.[13,15,16] Studies in adults and children have shown that cognitive behavioural therapy that incorporate components based on addiction medicine may be beneficial among some individuals with obesity who also endorse symptoms of food addiction.[17,18] These approaches are well-suited for digital delivery as they offer real-time support of situations that arise in day-to-day life. While food addiction symptomatology may not be experienced by all youth living with obesity, addiction-based approaches may still confer benefits and, therefore, should be evaluated as potentially viable intervention strategies in this population.

To date, digital health obesity interventions for adolescents have largely been single-site, non-randomized trials. Most interventions have also included a coaching component and it is unclear whether a stand-alone digital obesity intervention, in absence of frequent and personalized coaching, yields the same results. This randomized, multi-centre trial tests the effectiveness of an addiction-based digital weight-loss intervention, with and without coaching, compared to in-person, multi-disciplinary obesity treatment on adolescents' weight loss. Specifically, participants were randomized to one of three study arms for 24-weeks: (1) interactive digital weight loss intervention alone (AppAlone), (2) interactive digital intervention with personalized phone coaching (AppCoach), or (3) a monthly, in-person, multi-disciplinary weight management program (Clinic).[19] The primary outcome was change in BMI as a percentage of the 95th percentile (%BMI_{p95}) at 12 and 24 weeks. In addition, we assessed delivery burden by capturing the staff time required for implementation of each intervention arm, as well as participant engagement defined as the number of tasks completed out of those prescribed for each intervention arm over the study period. We hypothesized that the AppCoach arm would yield greater weight loss and lower delivery burden than the Clinic arm, and greater participant engagement than the AppAlone arm.

2 | METHODS

2.1 | Study design

This three-parallel arm randomized controlled trial was initially implemented in person in January 2019. Due to the COVID-19 pandemic, all study procedures were converted to remote implementation and delivery in March 2020. Recruitment ended in July 2021. The protocol was reported by Vidmar et al., however, due to the COVID-19 pandemic, several changes were made to that protocol,[19] as outlined below.

Adolescents (ages 14–18 years) with obesity were recruited from four clinical centres in Los Angeles County, CA (Children's Hospital Los Angeles, The Lundquist Institute of Biomedical Innovation at Harbour University of California Los Angeles [UCLA], UCLA Mattel Children's Hospital, and Cedar-Sinai Medical Center), supplemented by direct mailing of flyers to families of adolescents ages 14–18 years across 40 neighbourhoods in Los Angeles County. Participants were provided with wireless body and food scales, and a smart phone (if needed) for the study period. Assessment visits were conducted either in-person or virtually via video conference at baseline, 12, and 24 weeks and lasted ~120 min (4 total visits, including initial consent visit). Participants were randomized with block

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size of three and six, balanced by sex and age. The PI was blinded as to the treatment-arm for the entire duration of the study.

Due to COVID-19 restrictions, all study procedures completed after March 2020 were conducted virtually. Study materials (body and food scales and phones) were shipped to the participant's homes, and all study interactions with participants, including the informed consent process and enrolment into the study, occurred via a secure, HIPAA-compliant videoconference platform. Study staff guided the participants to conduct anthropometric measurements throughout the study period. Participants completed validated patient reported outcomes surveys at each visit on Research Electronic Data Capture (REDCap).

All study procedures were approved by the Children's Hospital Los Angeles (CHLA) Institutional Review Board (CHLA-000186, date of approval—6/20/2018). The study was reported according to the Consolidated Standards of Reporting Trials (CONSORT) statement and is registered with ClinicalTrials.gov (NCT03500835). Written informed consent was obtained from the adolescents and one parent or guardian prior to participation. The study was conducted in accordance with the Declaration of Helsinki. Participants received a stipend for participation in the study assessments.

2.2 | Participants

Inclusion criteria were: (1) ages 14–18 years; (2) body mass index (BMI) ≥95th percentile; and (3) participant willing and able to complete the assessments and intervention protocol. Participants were ineligible for the study if they: (1) had documented diagnosis of Prader Willi syndrome, brain tumour, hypothalamic obesity, binge eating disorder, previously diagnosed eating disorder, serious developmental or intellectual disability, or current or previous pregnancy; (2) were enrolled in a weight loss intervention or previously underwent bariatric surgery; (3) were taking weight-altering medications (e.g., antipsychotics, sedatives, hypnotics, obesity medications); (4) were unable to read English, as the app was only available in English; and (5) unable to autonomously interact with the app.

2.3 | Intervention Components (Figure 1 and Table S1)

The specific details of the digital app-based intervention have been described elsewhere.[17–19] The intervention was implemented through an iPhone app called W8Loss2Go, which was securely integrated with a network-server for real-time data access and storage. The digital intervention combines evidence-based behavioural weight management techniques (e.g., self-monitoring of weight and food intake, avoidance of sugar sweetened beverages and refined grains, and portion control) and components of addiction medicine: withdrawal/abstinence from self-identified problem foods, withdrawal/abstinence from snacking and excessive amounts at meals and use of alternative activities to tolerate discomfort. The app intervention is delivered autonomously in three phases over the course of 24 weeks: (1) eliminating problem foods; (2) reducing snacking; and (3) decreasing overconsumption at mealtime. For phase 1, the app directed the participant to sequentially eliminate two self-selected problem foods at a time, with the goals of total abstinence from the food for a minimum of 10 days in a row, and craving resolution. Consumption of a

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problem food during or after this 10-day period would result in a re-start of the abstinence period. After withdrawing from two problem foods, participants started the second phase of reducing snacking by choosing time periods to avoid snacking (i.e., morning, afternoon, evening, or night-time). Once the participant had stopped snacking during their chosen time interval for 10 days, the participant then choses additional time intervals to abstain from snacking, with the overall goal of eliminating snacking between meals. After snacking was eliminated from one time, the third stage would commence and excessive food amounts at meals were targeted. In the third phase, the participants weighing all meals consumed with a digital food scale and an algorithm reduce the amounts with a goal to achieve a caloric deficit. In addition, the app home page, provided various behavioural strategies, including motivation, distraction ideas, impulse and craving control, displacement management, mindfulness activities and other tools to address stress management. Parental involvement was not required for the App arms of this intervention.[20,21]

Participants in the AppAlone arm were instructed to engage with the app independently each day for the duration of the study and attended three study visits. The study team was available to assist with any technical issues, however, no behaviour-based coaching was provided.

Participants in AppCoach arm were instructed to engage with the app each day for the duration of the study and attended three study visits. In addition, they received daily text messages and spoke to a study team member on the phone for 15-min each week. The purpose of the coach calls was to review participants experience with the App, provide support and guidance, and monitor for any adverse events or barriers to adherence. See the full study protocol for details on study team training and fidelity monitoring.

The control arm involved 18 h of in-person, multidisciplinary program delivered by a health educator, a registered dietician, psychologist and a physician.[22] The participant and one parent were required to attend each visit. The curriculum, Kids N Fitness[22] was developed at CHLA in 2000. The six-session program was delivered via monthly 90-to 120-min clinic visits focusing on goal setting, self-monitoring, healthy snacks, label reading, grocery shopping tips and mindful eating. Each session included an interactive nutrition education, physical activity, and family seminar. The participant and parent spent 3 h with a study team member, 7 h with a health educator, 3 h with a registered dietitian, 2 h with a psychologist and 3 h with a physician over the 24-week period.

2.4 | Measurements

At baseline, participants and their parent completed a demographic questionnaire (age, race/ethnicity, household composition, education, household income) and medical history. Participants were asked to complete a series of self-reported survey measures at baseline, week 12 and week 24. Measures included Yale Food Addiction Scale for Children (YFAS-c),[23] The Center for Epidemiological Studies Depression Scale for Children (CES-DC),[24] Executive Function (BRIEF-2),[25–27] Binge Eating Disorder Screener-7 (BEDS-7)[20] and Perceived Stress Scale (PSS).[28]

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2.5 | Primary outcome

2.5.1. | Anthropometrics—Prior to March of 2020, participants' height and weight were assessed by an experienced study team member at each in-person study visit. Height was measured using a Quick Medical stadiometer, accurate to 0.1 cm (Quick Medical, Issaquah, WA). Weight was measured on a self-calibrating Digital Stand Digital Scale, accurate to 0.1 kg. After March 20220, experienced staff guided the participants on a HIPAA compliant virtual platform in conducting anthropometric measurements. A parent was asked to assist with the height and weight measurements. Weight was measured on a self-calibrating Etekcity Digital Body Weight Scale, accurate to 0.2 kg (Etekcity, San Diego, CA). Height was measured using a portable wall height indicator ruler, accurate to 0.5 cm (Posh Rulers, Quick Medical, Issaquah, WA). BMI was calculated as kilograms per meter squared, BMI z-score (zBMI) and percent of the 95th percentile (%BMI_{p95}) was calculated utilizing the SAS program for the year 2000 CDC growth charts.

2.6 | Secondary outcome

2.6.1 | Implementation indicators—Reach was defined as the number of consented participants out of all patients approached. Adherence and engagement were operationalized based on the intervention delivery modalities. For both App arms, the number of minutes the participants spent engaging with the app was captured, as well as the proportion of participants who completed all three interventional components of the 24-week app intervention (i.e., self-weighing daily, checking into app daily, tracking problem foods and snacking times, weighing meals and reducing portion sizes and accessing motivation tools). In the AppCoach arm, the number of calls completed over the course of the study was recorded. To quantify adherence to each intervention arm, the required task per arm were captured. The required tasks per arm were measured as follows: AppCoach—weekly coach calls (15 min a week for 24 weeks), daily app use; AppAlone—daily app use; Clinic —in-person sessions (number of sessions out of 6 they attended). App engagement was tracked by the study team weekly, and use of the app for more than 5 min was considered engagement for that day. For the Clinic arm, adherence to the assigned intervention was operationalized as the number of in-person clinic visits completed. A one-time exit interview was completed at week 24 to evaluate participant satisfaction with the intervention arm to which they were randomized. A standardized semi-structured exit interview was completed which included questions about participants' satisfaction with the app intervention. A 5-point scale from 1 = 'strongly agree' to 5 = 'strongly disagree for the following domains: (1) satisfaction with primary app components, (2) would recommend to friends, and (3) how daily app use impacted their daily function. Participants were asked open-ended questions about their experience with the app and the likelihood of continuing to use the app once the study was over. The following data were collected throughout the study period to assess the implementation requirements (cost and labour) for each intervention arm: personnel time required for intervention implementation (including training time, visit time and preparation time), intervention specific equipment and maintenance, and cost of each activity per participant for the 6-month intervention period. A full cost-analysis evaluation of the intervention implementation is currently underway.

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2.7 | Behavioural Phenotype

Food addiction.—Addictive like eating behaviour was measured using the validated, Yale Food Addiction Scale-Children (YFAS-c).[23,29] The 25-tem scale assesses seven diagnostic criteria for substance dependence as it relates to eating. Items are answered on a 7-point Likert Scale ranging from 0 (never) to 7 (every day). Participants who report three or more symptoms and clinically significant impairment meet the criteria for food addiction (FA). The YFAS-c has shown good test–retest reliability. Reliability analyses have shown high internal consistency (Cronbach's alpha = 0.81) in the general paediatric population, and test–retest reliability between 0.79 and 0.84 in studies conducted in ethnically diverse paediatric populations. Concurrent, divergent, and convergent validity of the YFAS-c has also been reported in numerous studies.[23]

2.7.1 | Executive functioning—The Behaviour Rating Inventory of Executive Function (BRIEF-2)[25–27] was used to evaluate baseline executive function. The BRIEF-2 provides theoretically and empirically derived clinical scales that measure aspects of EF in adolescents (11–19 years old). Items are scored on a 3-point Likert scale ranging from one (never) to three (often). Theoretically and statistically derived scales measure the adolescent's ability to regulate and monitor behaviour, emotional responses, and cognitive processes. These scales can also be combined into a summary measure, the global executive functioning composite (GEC) score.[25–27] Reliability analyses have shown high internal consistency (Cronbach's alpha = 0.95) of the BRIEF-2 subscales, and for the Global Executive Composite (GEC).[27] Concurrent, divergent, and convergent validity of the BRIEF-2 has also been reported in numerous studies in children, adolescents, and adults.[27]

2.7.2 | Depression—The Center for Epidemiologic Studies Depression scale (CES-DC)[30] was utilized to measure baseline depression. The CES-DC was developed and validated in children younger than 18 years of age. The CES-DC is a 10-item self-report scale designed to measure depressive symptoms in children and adolescents. The CES-DC has been reported to as highly reliable and valid for assessing depressive symptoms across ethnic, gender and age groups. The Cronbach's Alpha coefficient for the scale was reported to be 0.75 for the general population. Concurrent, divergent, and convergent validity of the CES-DC has also been reported in numerous studies.[24,30,31]

2.7.3 | Perceived stress—The *Perceived Stress Scale (PSS)*[28] is widely used for measuring the perception of stress. The measure has demonstrated strong reliability (Cronbach's alpha = 0.74) and validity in social and health science studies.[28]

2.7.4 | Binge Eating Behaviours—The Binge Eating Disorder Screener-7 (BEDS-7)[32,33] is a 7-items brief, patient-reported screener for binge eating disorder, with an overall 100% sensitivity and 38.7% specificity for diagnosing binge eating disorder. It is validated in youth ages 12–21 years. The screener begins with a single yes/no question related to excessive overeating in the last 3 months. Participants who answer affirmatively, then answer six more psychometric questions that align with the DSM-5 criteria for diagnosing binge eating disorder.[33]

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2.8 | Statistical analysis

All statistical analyses were conducted in accordance with the planned study protocol.[19] We estimated that 180 participants (60 in each group) would provide 89% power (α= 0.05, 2 sided), to detect an effect size of 0.29 which corresponds to a difference of 4.0% $\%BMI_{p95}$ between the three groups. Analyses followed principles of intention-to-treat (ITT) and were performed in nQuery + nTerim 4.0 and Stata/SE 17 (StataCorp, College Station, TX). A two-sided significance level of 0.05 was utilized throughout the analyses. Our analysis approach is based under the assumption that data are missing at random, therefore, imputation using last observation was carried forward, and multiple imputation based on logistic regression model (for BEDS-7 scores only) were utilized to account for missing data. Results from the ITT analysis using imputation were compared as per protocol analysis with completed data. For all outcomes a per-protocol analysis was conducted for: full-program (completed full 24-week intervention period), pre-COVID (completed 24-week intervention prior to 3/15/2020), and during COVID (completed 24-week intervention after 3/16/2020). In addition, to account for impacts of the intervention dosage received on each primary outcome measure we conducted an analysis of participants who were adherent to at least 80% of the prescribed intervention modalities versus those who were non-adherence.

Participants' demographic characteristics and baseline anthropometric measurements were reported as appropriately, mean and standard deviation or median and interquartile range for continuous variables, and frequency and percentages for categorical variables. The change in $\%BMI_{95}$ between week 24 and baseline was assessed using analysis of variance (ANOVA) for all participants via ITT, per-protocol, Pre-COVID and during COVID. First, the $\%BMI_{p95}$ was analysed in log scale mixed-effects linear regression model to assess the association between change in $\%BMI_{p95}$ and demographic characteristics (sex, ethnicity, obesity related co-morbidities), CED-SC, PSS, BRIEF-2, YFAS-c, and BEDS-7 scores univariately and adjusting for recruitment site as a covariate. Then, a multivariable mixed-effects linear regression model was utilized to examine the effect of the possible factors on change in $\%BMI_{p95}$ accounting for recruitment site, demographic and other measured characteristics. The results are expressed in percent change with its associated 95th% confidence interval and p-value.

3 | RESULTS

3.1 | Participant Characteristics

Of the 236 eligible participants (clinic recruitment = 216, targeted mailing campaign = 20), 161 (68%) were consented and enrolled in the study (68% recruitment rate, See Figure 2 CONSORT Diagram). The mean age of the participants was 16 (SD: 2.5) years. The majority, 65% (105/161) of the enrolled adolescents were female, 47% were Hispanic, 57% reported annual household income <$50 000, and 59% were publicly insured. There were no significant differences in baseline characteristics between intervention arms (Table 1).

There were several notable differences between study completers and non-completers, with a higher fraction of study completers coming from households with annual income <$50 000 and/or public insurance (Table S2). In total, 79% (127/161) of participants completed

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the 3-month assessment, and 63% (102/161) completed the 6-month assessment (Figure 2). A higher fraction of completers was in the Clinic and AppCoach arms compared to the AppAlone ($p = 0.001$) and a higher percentage of completers were recruited from CHLA compared to the other recruiting sites and mail campaign ($p = 0.008$).

At baseline 35% ($n = 56$) of participants met the criteria for clinically significant food addiction on the YFAS-c with females almost three times more likely than males to meet criteria for food addiction. Twenty-five percent ($n = 41$) of participants answered yes to the following question on the BEDS-7, "During the last 3 months, did you have any episodes of excessive overeating?", consistent with binge eating behaviours. More than half ($n = 80$) of participants had some clinical impairment in executive function (GEC-T scores ≥65), onethird ($n = 61$) met criteria for depression on the CES-DC; and 75% ($n = 121$) reported high levels of perceived stress on PSS (>26) (Table 2).

3.2 | Adherence and engagement

Participants in the AppAlone and AppCoach arms were prescribed to engage with the app daily for 24 weeks (~182 days). On average, participants across both app groups, engaged with the app 37% of the prescribed time (~68/182 days, range 0–182 days). Overall, the number of days in which the participants engaged with the app was higher in the AppCoach compared to the AppAlone groups. Furthermore, in both groups' engagement was greater in the first 12 weeks than in weeks 12–24. Specifically, 51% ($n = 19/37$) of AppCoach participants engaged daily with the app in weeks 0–12, whereas 35% [$n = 13/27$] interacted with the app daily in weeks 12–24. In the AppAlone group, 22% ($n = 5/23$) of participants engaged with the app daily in the first 12 weeks, while only 9% [$n = 2/23$] used the app daily in the second half of the intervention.

Of the 60 participants in the app groups, who attended the week 24 study visit, 60% (AppAlone: n = 16/23, and AppCoach: $n = 20/37$) completed all three phases of the app program. Of the three app components, participants engaged with the problem food elimination component most frequently (~5 min per day over the 24-week intervention period). Of the 54 participants randomized to AppCoach, 50% attended at least 12 calls, with an average of 19 attended calls (range 0–24). Only 15 participants received all 24 calls (i.e., a full dose of coaching as per protocol). A majority of participants (77%; $n = 42/54$) assigned to Clinic completed all six sessions as prescribed. In total, 75% ($n = 45/60$) of completers rated the app as good to excellent, and 78% ($n = 47/60$) stated that they would recommend it to others. Three consistent themes were reported across App participants: (1) usefulness of daily reminders and assigned activities, (2) helpfulness of problem food elimination as a method to improve intake of healthier food options, and (3) positive response to having distraction ideas available to use during times of cravings. A minority of youth in both AppAlone and AppCoach reported alert fatigue from daily reminders to engage with the app and concern that the intervention required too much time each day to complete the assigned tasks. Over three-quarters of the youth in AppCoach rated their weekly phone calls with the coach as a positive experience that helped them continue to engage with the app for the study period. A majority of youth across the app groups, as their parent reported that the App allowed the youth autonomy and ownership over their

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weight management thus improved parent–child interactions regarding health during the intervention period. Among control participants and their parents, 65% rated the in-person intervention as good to excellent, and 65% stated that they would recommend it to others. A minority of parents from the control group reported challenges with getting their youth to attend the visits and discussed the burden of missing school and work to attend these extended sessions as possible barriers to sustained engagement.

3.3 | Change in $\%BMI_{p95}$ over time

There were no significant differences in $\%BMI_{p95}$ change over the course of the intervention (interaction $p = 0.9$, Figure 3, Table S3) between the three treatment arms. Based on ITT analyses, there was a modest, yet significant mean decreases in $\%BMI_{p95}$ at week 12 (% change (95thCI): −0.78 [effect size 0.01], (−1.31 to 0.24), $p = 0.004$) and at week 24 (% change (95thCI): −1.29, (−1.82 to −0.76, $p < 0.0001$, Figure 3)) compared to baseline in all three groups. There was no difference in change in $\%BMI_{p95}$ by timing of study completion as it relates to the COVID-19 pandemic (all $p > 0.05$). There was marked heterogeneity in weight loss across participants. Overall, 30% of participants lost weight during the intervention period and 35% maintained their weight. Post-intervention, 33% of AppCoach, 44% of AppAlone, and 54% of Clinic participants lost ≥3%, and 30% of AppCoach, 50% of AppAlone, and 29% of Clinic participants maintained their weight, those differences were not statistically significant (all $p > 0.05$, Figure 4).

3.4 | Univariate and multivariate linear regression analysis

In the univariate analysis there were no significant association between change in $\%BMI_{p95}$ and intervention arm, race/ethnicity, engagement, timing of intervention in relation to COVID-19, or baseline CES-DC, BRIEF-2, or YFAS-c scores (all p values >0.05). While controlling for intervention arm, recruitment site, baseline CES-DC, PSS, and YFAS-c scores, girls lost more weight than boys (adjusted (%change in $\%BMI_{p95}$ 95% CI) –13.0, (−19.1, −6.5), $p = <0.0001$, Table 2). Higher perceived stress scores (% change (95% CI): 4.1, (0.45 to 7.81), $p = 0.03$) and positive BEDS-7 (% change (95% CI): 3.3, (1.4 to 5.2), $p = 0.001$) at baseline were associated with increase in $\%BMI_{p95}$ at week 24 (Table S4). After adjusting for percent engagement, recruitment site, and baseline CES-DC, PES, BEDS-7, and YFAS-c score there was not a significant difference in $\%BMI_{p95}$ change between the three intervention arms (all adjusted $p > 0.05$). The association between YFAS-c score and $\%BMI_{p95}$ varied significantly by sex (p-value for difference in trajectory slopes $p = 0.045$). Boys had an average 1.8% decrease in $\%BMI_{p95}$ (95%CI: −3.8, 0.2), compared to an average 0.9% change in $\%BMI_{p95}$ (95%CI: −0.3,2.2) among girls. Baseline BEDS-7 score was associated with an almost 2% rate of increase in $\%BMI_{p95}$ after controlling for other covariates (adjusted %Change (95%CI): 1.9, (−0.3, 3.4), $p = 0.02$).

3.5 | Change in behavioural phenotype

At week 24, across all participants, there was a significant decrease in in YFAS-c symptom count (median change: —1 [0 to −1.5]), with no significant difference in symptom count change by intervention arm (Mean Change in YFAS-c Symptoms Count (95th%CI): Clinic: 0 (−1 to 0), AppCoach: −0.5 (−0.5 to 0), AppAlone −0.5 (−1.5 to 0), $p = 0.07$). Over half of participants showed a decrease in YFAS-c symptom count compared to baseline. There

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was no significant change in CES-DC or PSS scores at week 24 compared to baseline (all $p > 0.05$). On mixed effect linear regression model, there was no significant relationship between change in symptom count and change in $\%BMI_{p95}$ change at week 24 compared to baseline by intervention arm ($p = 0.1$).

3.6 | Cost of implementation

Consistent with our previous findings the implementation costs, including labour and other requirements, differed by intervention arm.[18] The total estimated implementation cost per participant per 6-month intervention was $1122.00 for AppAlone, $2076.00 for AppCoach and $4034 for Clinic (Table S4). These estimates do not take charges, study-specific costs, or net insurance reimbursement into account. A formal cost-effectiveness analysis is underway to estimate the impacts of both long- and short-term costs, healthcare utilization and health-related quality of life effects for the three intervention arms.

4 | DISCUSSION

The reach and success of evidenced-based, multi-disciplinary weight management programs delivered face-to-face by health professionals, are limited both by high cost and low access.[34] Scalable digital interventions are a promising alternative that are less labour intensive and costly.[1,5,9,10] Our results highlight that (1) there was no difference in the change in BMI between a digital intervention targeting withdrawal/abstinence from self-identified problem foods, withdrawal/abstinence from snacking and excessive amounts at meals, and use of alternative activities to tolerate emotional (or psychological) discomfort, with or without coaching, and an in-person, standard of care obesity treatment; (2) engagement and retention was significantly higher in the intervention arms including human interactions (coach or healthcare team); (3) girls had increased weight loss across the intervention arms compared to boys; and (4) the presence of binge eating behaviours at baseline was associated with weight gain across intervention arms.

There is limited evidence for the efficacy of digital tools as stand-alone intervention modality for paediatric weight management.[1,34,35] To date, the systematic reviews available have highlighted substantial heterogeneity in paediatric digital interventions studies, including in their design, participants and outcomes; the majority of studies also aimed only at assessing feasibility, acceptability or usability.[1,34,35] In 2022, Kouvari et al. completed a systematic review and meta-analysis and identified nine manuscripts from eight clinical trials of 582 children and adolescents with obesity who completed a digital health intervention for weight loss.[36] Pooled analysis revealed a significant decrease in weight among children assigned to the digital weight loss intervention (standardized mean difference in BMI metric [BMI or BMI z-score or BMI percentile] −0.61 SD, 95% CI −1.10 to −0.13; $p = 0.01$). The meta-analysis was limited in that many of the included studies had small sample sizes, lack of control and multi-model intervention components.[36]

Our study may be best compared to studies investigating the commercially available digital weight management program, Kurbo by WW©. Kurbo is, an evidence-based program designed for youth which includes online meetings and interaction with a personal behaviour coach. The app program incorporates traffic light food classification system, physical

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activity and behaviour change skills.[37] Consistent with our findings, Cueto et al. conducted a retrospective review of 1120 youth and reported a mean reduction in $\%BMI_{p95}$ similar to that found in the current study (−6.9% [95% CI −8.3 to −5.6] at week 24, $p < 0.001$).[37] Comparing these studies highlights that app-based weight-loss interventions tend to result in modest effect sizes with heterogeneity in outcomes across cohorts and study designs.

The app utilized in the present study has several unique features compared to other available intervention programs. Primarily, the app intervention emphasizes behavioural strategies aimed at withdrawal/abstinence from self-identified problem foods, withdrawal/abstinence from snacking and excessive amounts at meals, and alternative non-food related activities to displace discomfort.[17,18] Despite controversies over the construct of food addiction, there is growing interest in understanding how addictive-like eating behaviours in adolescents impact weight loss trajectory in response to interventions.[38–43] The components of this app intervention harness tools utilized in addiction medicine, such as cognitive behavioural therapy based skills training to assist with identifying and coping with triggers, establish behavioural coping strategies that are incompatible with over-eating, increase non-food sources of pleasure and reward, and bolstering social support for reducing addictive-like eating behaviours. As previously reported by this study group, over half of the adolescents in this cohort reported a decrease in symptom count over the study period with no difference between intervention arm or association with weight change.[44] Thus, further investigation is needed to understand which intervention components are most effective to reverse addictive-like eating symptomatology and whether these findings can be replicated and utilized to treat obesity across larger cohorts.

Given that those in the app groups achieved comparable weight loss to those in the clinic group, these findings provide initial evidence that addictive-like eating behaviours may be a modifiable target in weight-loss interventions in this age group and thus considered in the development of future weight loss interventions. Furthermore, the intervention effect sizes estimated from our current study are comparable to those from the preceding pilot study, showed a significant decrease in $\%BMI_{p95}$ in the AppCoach group over a 24-week period ($n = 18$, decrease in mean $\%BMI_{p95}$: −3%).[17,18] In contrast to the pilot study, in the current study, there were no difference in $\%BMI_{p95}$ between the app groups and the in-person clinic program. Thus, a similar degree of weight reduction is potentially achievable with significantly less burden to patients and the health-care system.

The overall study attrition was 37%, which is comparable to other paediatric weight management trials.[45,46] There were two notable differences between study completers and non-completers: (1) higher percentage of completers recruited from the primary recruitment sites compared to other recruitment sites, and (2) higher percentage of completers came from families with lower annual household income and public insurance. Consistent with previous multi-site recruitment trials, often the host site has higher retention rates attributed to greater resources, investment in time, personnel, and the intervention protocol. Similar to trend nationwide, in our region youth from lower socioeconomic background have higher rates of obesity. Specific to our region, there is limited access to free clinical weight management programs due to high volume of youth requiring this care. Thus, many youths and families are placed on wait lists and are therefore eager to participate in nocost

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programs tailored for weight management. Study retention was greater in the study arms including human interaction (AppCoach and Clinic) than in the AppAlone.[37,47–50] Higher retention, however, did not translate in significantly greater weight loss. The few randomized controlled trials of weight management programs that have directly compared different types or intensities of human support indicate that higher support is not always associated with greater engagement or weight-related outcomes.[47,49,51] Future trials leveraging innovative adaptive designs are needed to evaluate the potential benefits of supplementing digital interventions with coaching, perhaps prioritizing coaching to initial non-responders or other predictors of treatment efficacy.

Growing evidence suggests that the COVID-19 pandemic has affected the weight trajectory of many children and adolescents, most likely related to the disruption of the normal daily structure that supports healthy eating and movement.[52] Although we found no significant difference in effectiveness based on the timing of completion of the study, the magnitude of BMI change was greater among those who completed the intervention prior to March 2020. In addition, although the decrease in $\%BMI_{p95}$ was modest overall, during the pandemic, the mean population weight trajectory for many adolescents was upward during this time and thus even a stabilization or slight decrease may itself have clinical significance.[53–57]

Finally, there is increasing interest in understanding how the characteristics of youth presenting for weight management treatment may affect treatment outcomes.[39,40,57] In this sample of adolescents, we found no association between change in $\%BMI_{p95}$ and ethnicity, mood, executive function or addictive-like eating behaviours. Only sex and a positive baseline BEDS-7 score were associated with change in $\%BMI_{p95}$. One recent review discussed several developmental sex differences that could support girls responding better to a weight loss program than boys including engagement, retention and variable response to different components of an intervention, such as physical activity.[58,59] In our cohort there was no difference in engagement or adherence between girls and boys. However, this intervention did not include a physical activity component which may have influenced the efficacy in boys based on previous findings.

4.1 | Limitations

This work includes a number of limitations that should be considered when interpreting the results. First, the sample size was relatively small, and recruitment was limited to adolescents seeking weight management care in Southern California or those contacted through a targeted mailing campaign, which may limit the generalizability of our findings. Second, the study has limitations common to other studies of digital health and digital interventions including difficulty in tracking and quantifying intervention engagement in real-time and challenges in quantifying the amount of contact hours of the treatment received by each participant. The dosage was different across the three intervention arms which could have impacted the primary outcome. Third, the study is subject to some reporting bias, since all measures, including anthropometrics collected after March 2020, were self-reported by participants. Fourth, the study, as designed, was unable to fully account for other factors that may influence intervention fidelity, including coaching effects, the role of parents, or use of other resources outside the delivered intervention. Finally, the

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COVID-19 pandemic affected the study and possibly the primary outcome measures. Due to the COVID-19 pandemic, recruitment was delayed, and the withdrawal rate was higher than predicted. In addition, the confounding effect of psychosocial and economic variables that impacted participants during this crisis could not be controlled for.

5 | CONCLUSION

Taken together, our findings showed that there was no difference in the change in BMI between an app intervention, with or without coaching, and an in-person, standard of care obesity treatment. Given the epidemic of obesity in youth and the dearth of cost-effective and behaviour focused treatment options, further investigation is needed to develop and study youth-targeted digital weight management approaches, which could improve access and reduce healthcare costs. Digital interventions with similar efficacy to in person treatment should be considered by clinicians, based on youth and family specific characteristics.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Abbreviations:

%BMI$_{p95}$	percent over the 95th percentile
BEDS-7	Binge Eating Disorder Screener-7
BMI	Behaviour Rating Inventory of Executive, body mass index
CES-DC	The Center for Epidemiological Studies Depression Scale for Children
CI	confidence interval
coef	coefficient
FA	food addiction

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PSS	Perceived Stress Scale
YFAS	Yale Food Addiction Scale
zBMI	body mass index Z-score

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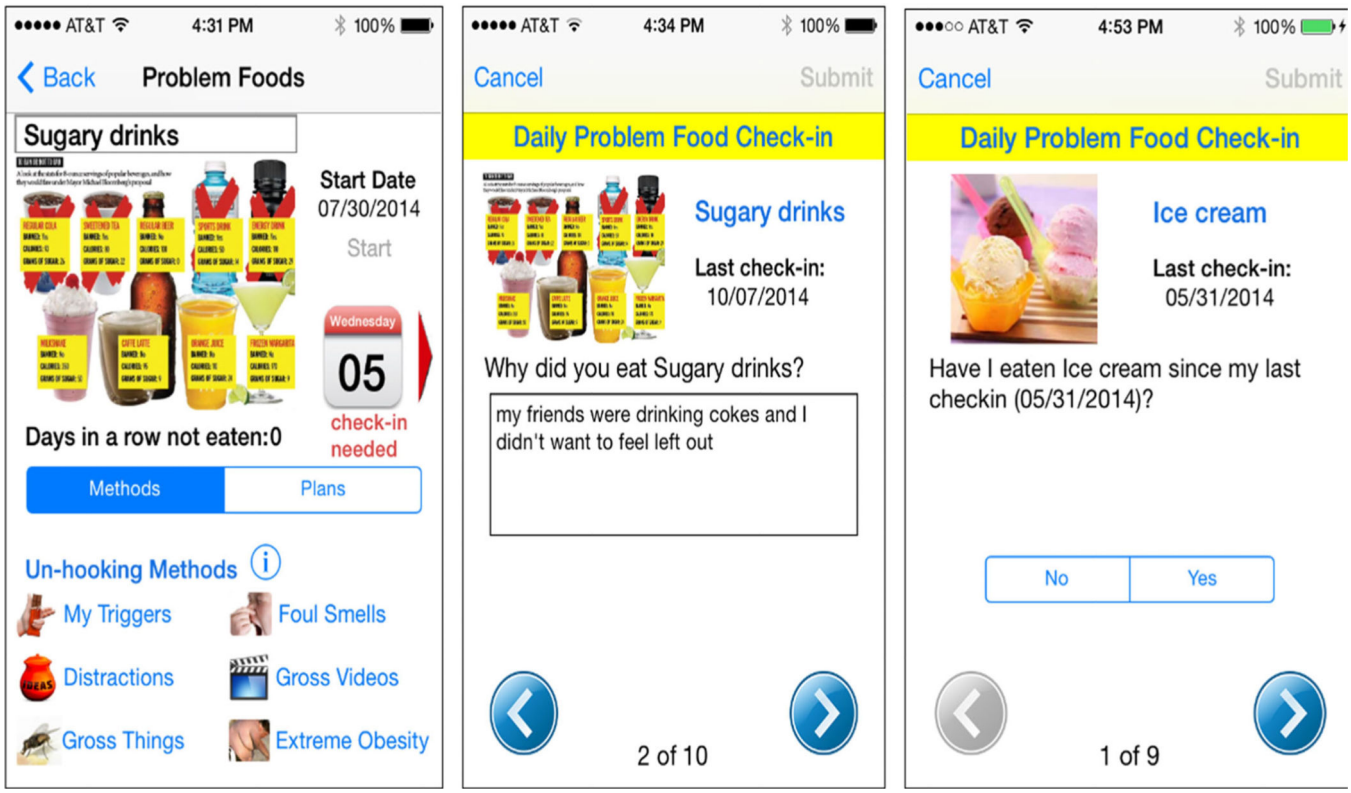

FIGURE 1.
W8Loss2Go Screen Shot

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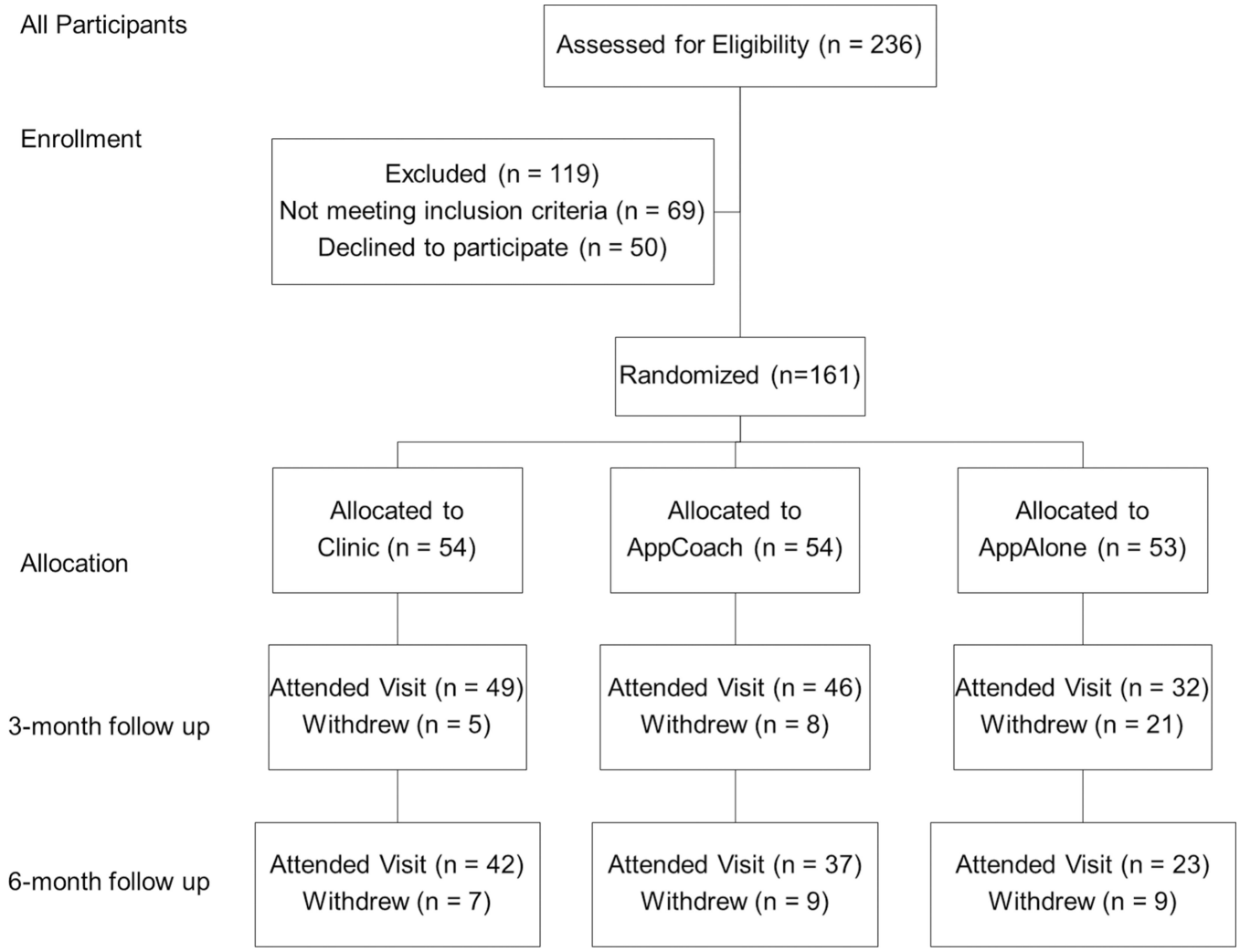

FIGURE 2.
CONSORT Diagram

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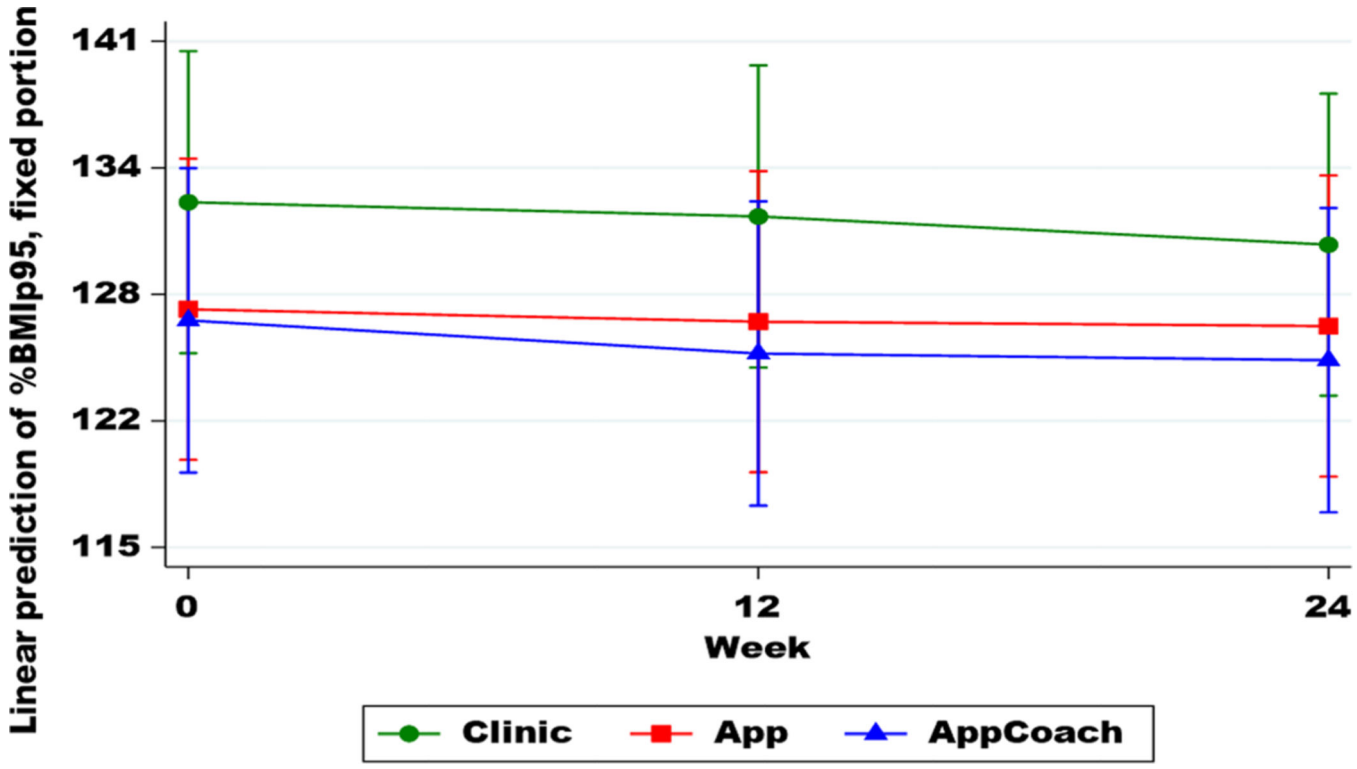

FIGURE 3.

Change in percent of the 95th percentile (%BMI_{p95}) for all participants across intervention arms over the study period

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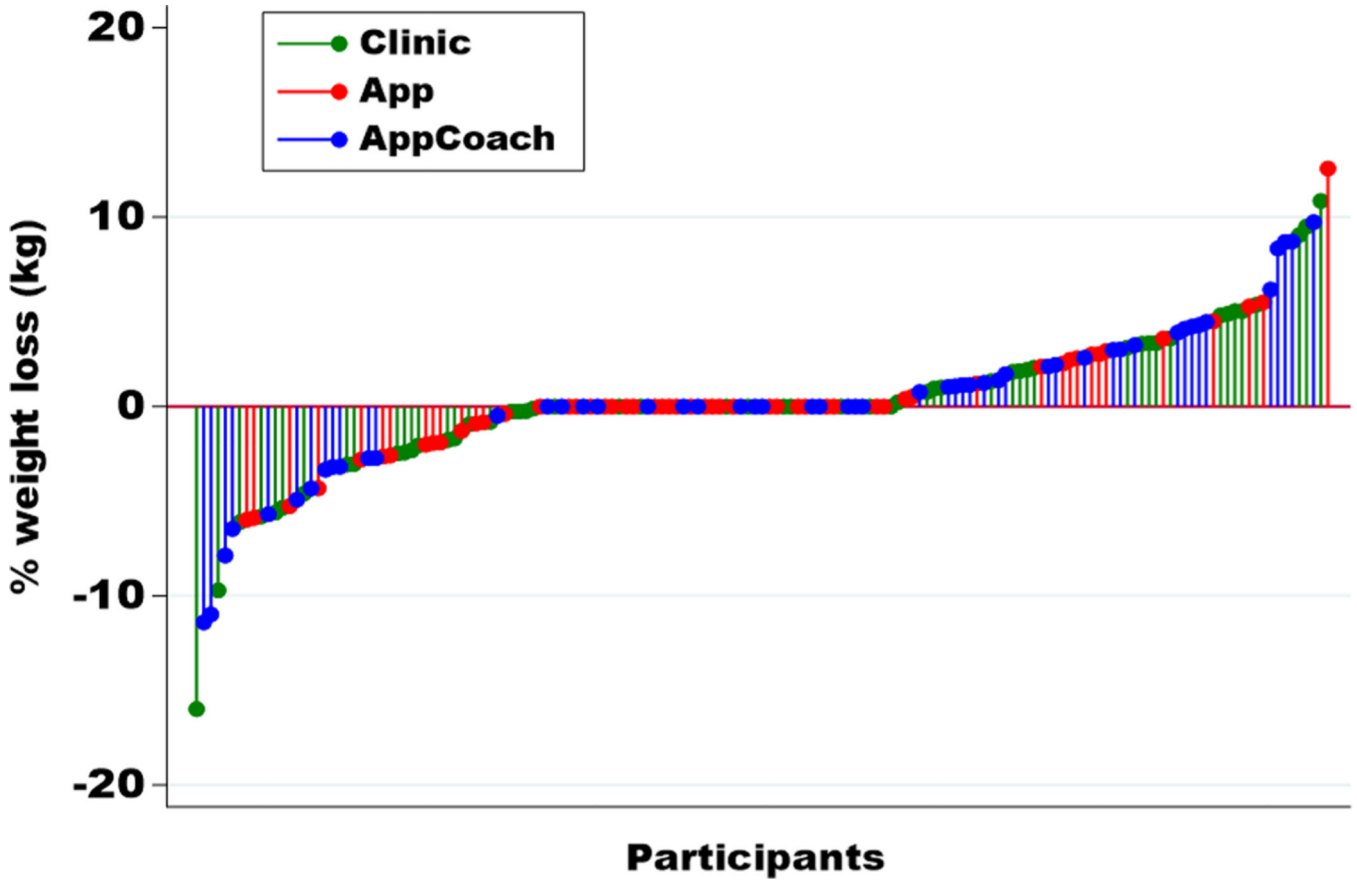

FIGURE 4.
Percent weight change for all participants across intervention arms between week 24 and baseline

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TABLE 1

Demographic, baseline anthropometric, and patient's characteristics by intervention arm based on intention to treat principle. White, Black or African American, American Indian or Alaska Native, Asian, and Native Hawaiian or Other Pacific Islander.

	Total (*N* = 161)	**Clinic (*n* = 54)**	**App (*n* = 54)**	**AppCoach (*n* = 53)**	***p***
Anthropometrics at baseline					
Weight (kg) [1]	98.5 (81.7–120.2)	104.7 (85.4–119)	93.9 (80.8–125)	97.5 (76.5–117.9)	0.7[a]
BMI z-score [2]	2.2 ± 0.5	2.3 ± 0.4	2.2 ± 0.5	2.2 ± 0.5	0.6[b]
$\%BMI_{p95}$ [1]	124.6 (109.4–147.8)	131.3 (117.4–148.8)	121.7 (109.4–145.7)	121.67 (101.66–144.98)	0.3[a]
Age [1]	16 (14–17)	16 (14–17)	16 (15–16)	15 (14–17)	0.8[a]
Sex [3]					0.4[c]
Male	56 (34.8)	15 (27.8)	22 (40.7)	19 (35.9)	
Female	105 (65.2)	39 (72.2)	32 (59.3)	34 (64.2)	
Race [3]					0.3[d]
White	64 (39.7)	20 (41)	21 (35)	23 (43)	
Black	50 (31)	16 (31)	17 (31)	16 (30)	
American Indian or Alaska Native	15 (9)	6 (11)	6 (11)	3 (7)	
Asian	12 (8)	4 (7)	4 (7)	4 (8)	
Native Hawaiian or Other Pacific Islander	5 (3)	2 (3)	1 (2)	2 (3)	
Islander					
Others	15 (9.3)	5 (9)	6 (11)	4 (8)	
Ethnicity [3]					0.1[c]
Non-Hispanic	67 (41.6)	19 (35.2)	20 (37.0)	28 (52.8)	
Hispanic	77 (47.8)	28 (51.9)	29 (53.7)	20 (37.7)	
Parent's education [3]					0.05 [d]
High school or less	78 (48.5)	27 (50)	33 (61.1)	18 (33.9)	
Trade/vocational	10 (6.2)	2 (3.7)	4 (7.4)	4 (7.6)	
College	54 (33.5)	17 (31.5)	13 (24.1)	24 (45.3)	
Graduate degree	5 (3.1)	2 (3.7)	0 (0)	3 (5.7)	

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	Total (N = 161)	Clinic (n = 54)	App (n = 54)	AppCoach (n = 53)	p
Household income [3]					0.3 [c]
<$50 000	91 (56.5)	33 (61.1)	31 (57.4)	27 (50.9)	
$50 000–$149 999	32 (19.9)	10 (18.5)	11 (20.4)	11 (20.8)	
≥$150 000	16 (9.9)	3 (5.6)	4 (7.4)	9 (16.9)	
Health insurance [3]					0.3 [c]
Government	94 (58.4)	35 (64.8)	32 (59.3)	27 (50.9)	
Private	43 (26.7)	11 (20.4)	14 (25.9)	18 (33.9)	
Housing [3]					0.5 [c,e]
House	93 (57.7)	29 (53.7)	30 (55.5)	34 (64.1)	
Apartment	53 (32.9)	19 (35.1)	20 (37.0)	14 (26.4)	
Mobile home	1 (0.6)	0 (0)	1 (1.8)	0 (0)	
Shared housing	2 (1.2)	1 (1.8)	0 (0)	1 (1.89)	
Comorbidities [3]					
Type 2 Diabetes	23 (14.2)	9 (16.6)	8 (14.8)	6 (11.3)	0.7 [c]
Hypertension	7 (4.3)	3 (5.5)	2 (3.7)	2 (3.7)	0.9 [d]
Asthma	22 (13.6)	8 (14.8)	4 (7.4)	10 (18.8)	0.2 [c]
Obstructive sleep apnea	10 (6.2)	5 (9.2)	4 (7.4)	1 (1.8)	0.3 [d]
High cholesterol	21 (13.0)	5 (9.2)	6 (11.1)	10 (18.8)	0.3 [c]
Fatty Liver	20 (12.4)	10 (18.5)	7 (12.9)	3 (5.6)	0.1 [c]
Depression	28 (17.3)	10 (18.5)	9 (16.6)	9 (16.9)	0.9 [c]
Irregular menses	33 (20.5)	9 (16.6)	13 (24.0)	11 (20.7)	0.6 [c]
Anxiety	43 (26.7)	13 (24.0)	14 (25.9)	16 (30.1)	0.8 [c]
Site [3]					0.7 [c]
CHLA	98 (60.8)	32 (59.2)	32 (59.2)	34 (64.1)	
UCLA	20 (12.4)	5 (9.2)	7 (12.9)	8 (15.0)	
CEDARS	22 (13.6)	10 (18.5)	6 (11.1)	6 (11.3)	
Harbour UCLA	21 (13.0)	7 (12.9)	9 (16.6)	5 (9.4)	
Completers [3]					<0.001 [c]

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	Total (*N* = 161)	Clinic (*n* = 54)	App (*n* = 54)	AppCoach (*n* = 53)	*p*
Non-completer	59 (35.6)	12 (22.2)	31 (57.41)	16 (30.1)	
Completer	102 (63.3)	42 (77.7)	23 (42.59)	37 (69.8)	

Note: Data are summarized as

[1]= Median (Interquartile range);

[2]= Mean ± SD;

[3]= Frequency (Percentage) Statistical comparison based on

[a]= Kruskal–Wallis test;

[b]= Analysis of variance (ANOVA);

[c]= Chi-Squared test;

[d]= Fisher's Exact test;

[e]= Statistical comparison only includes categories with sufficient data.

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TABLE 2

Multivariate linear regression model of the association of intervention arm, perceived stress score, binge eating disorder screener-7 score, yale food-addiction score, sex, visit and recruitment site on change in $\%BMI_{p95}$

$\%BMI_{p95}$	**% Change**	**95% CI**	***p***
Intervention			
Clinic	Ref	--	--
App	−6.1	(−13.8, 2.3)	0.1
AppCoach	−6.2	(−13.6, 1.9)	0.1
Perceived stress[a]			
Low	Ref	--	--
Moderate	−0.4	(−4.3, 3.7)	0.9
High	−0.1	(−4.2, 4.1)	0.9
Binge eating[a]			
No	Ref	--	--
Yes	1.8	(0.3, 3.4)	0.02
Food addiction[a]			
No	Ref	--	--
Yes	−3.8	(−7.6,0.3, 1.3)	0.7
Sex			
Male	Ref	--	--
Female	−13.5	(−19.1, −7.0)	<0.0001
Food addiction*sex	2.4	(0.05,4.7)	0.045
Visit			
Baseline	Ref	--	--
12-week	−0.6	(−1.2, −0.05)	0.03
24-week	−1.1	(−1.6, −0.5)	<0.0001
Site			
CHLA	Ref	--	--
UCLA	−12.0	(−20.7, −2.5)	0.02
CEDARS	−15.7	(−24.1, −6.3)	0.001
Harbour UCLA	−5.7	(−16.4, 6.4)	0.3

[a]Baseline values.