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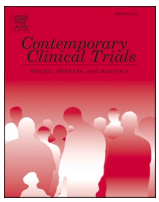

Design of Project STAR: A randomized controlled trial evaluating the impact of an adaptive intervention on long-term weight-loss maintenance

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ABSTRACT

Background: Without provision of additional intervention, most individuals regain weight after the end of weight-loss programs. Extended-care programs have been demonstrated to improve long-term weight-loss maintenance, but effects are modest.

Methods: We proposed to evaluate whether delivering extended-care telephone sessions on an *ADAPTIVE* (provided when individuals are deemed to be at high-risk for weight regain) versus *STATIC* (the once-per-month schedule typically used in extended-care programs) schedule improves weight regain after initial weight loss. Adults with obesity were initially recruited for a 16-week lifestyle weight-loss program, and those who lost ≥5 % of their initial weight were eligible for enrollment in the Project STAR maintenance trial.

Results: A total of 449 individuals (*mean* ± *SD* age = 49.5 ± 11.4 years, BMI = 35.7 ± 4.0 kg/m^2, 83.5 % female, 23.4 % Black or African American, 9.8 % Hispanic) were recruited for the initial weight-loss program and lost an average of 6.4 ± 4.9 % of their initial body weight; 255 were randomized to the maintenance trial. There were no significant differences between participants randomized to the trial versus those who were not in terms of baseline weight, gender, race/ethnicity, education, or marital status, all *ps* > 0.05; however, participants who were randomized to the trial were older, $p = .014$, and reported higher incomes, $p < .001$.

Conclusion: Results from Project STAR will demonstrate whether providing extended-care intervention on an individually adaptable schedule improves long-term weight-loss maintenance. Moreover, the rich longitudinal dataset collected during the trial will serve as a foundation for building future predictive algorithms of weight regain and novel weight-maintenance interventions.

1. Introduction

Comprehensive lifestyle treatments for obesity produce clinically-meaningful weight losses [1]; however, long-term outcomes have remained suboptimal [2]. Without additional intervention, most individuals regain weight after these programs end [1]. Importantly, research has demonstrated that individuals who are able to adhere to weight management behaviors long-term can successfully maintain weight loss [3,4], implicating non-adherence as a primary behavioral mechanism for weight regain [2,5,6]. A key challenge remains regarding the promotion of long-term adherence to beneficial dietary and activity patterns despite an unsupportive environment and physiological influences that promote weight regain (e.g., endocrine adaptations that increase appetite and decrease satiety) [7].

Consequently, obesity has been increasingly conceptualized within a chronic disease "continual care" model, necessitating long-term treatment provision [5,8]. Under this model, existing "extended-care" interventions provide continued treatment after the end of initial intervention [1,9]. Although different theoretical orientations have been used in the provision of these interventions (e.g., problem-solving therapy may be more effective for promoting weight maintenance versus relapse-prevention training [10]), the format used by most of these programs has been fairly standardized, with current guidelines suggesting that these programs should provide intervention contact at least

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once per month, either in-person or via telephone [1]. Meta-analyses of randomized trials have demonstrated that extended-care interventions can produce significant improvements in adherence to behavioral weight management strategies and reduce weight regain compared to no-contact control conditions [9,11]. Although statistically significant, the impact of these interventions has been modest, resulting in 2–3 kg less regain at 18–24 months versus control [9,11]; moreover, there tends to be high individual variability in response to intervention [2].

One challenge to the effectiveness of extended-care programs has been continued participant engagement, often operationalized as session attendance. Attendance has been consistently associated with long-term weight loss maintenance [9,12,13]; however, attendance at monthly extended-care sessions tends to be poor and declines over time [14]. It is possible that the once-per-month, static treatment schedules of existing programs may contribute to these suboptimal outcomes [15]. Under this schedule, a participant experiencing a small lapse (e.g., failing to self-monitor dietary intake for several days) may not receive additional support for several weeks, by which time they may be experiencing a larger lapse (e.g., complete abandonment of self-monitoring and former dietary changes) and weight regain. Critically, this cycle may result in participant disengagement and avoidance of treatment sessions due to feelings of frustration, shame, or embarrassment [16–18]. Conversely, tailoring intervention delivery such that extended-care sessions are provided when individuals are at "high risk" for weight regain (potentially, before weight regain actually occurs) offers potential to disrupt this cycle and improve program engagement, adherence to program goals, and long-term weight maintenance outcomes. Our team previously developed an algorithm for detecting "high risk" periods for weight regain after initial loss using self-monitoring data and the completion of two self-report items each week [19]. In the current study, we proposed to evaluate whether using this algorithm to trigger provision of extended-care reduces weight regain after the end of an initial weight-loss program.

The Support and Tracking to Achieve Results (Project STAR) study is a randomized controlled trial designed to evaluate the impact of an adaptive extended-care intervention on long-term weight-loss maintenance. As we proposed to examine weight *regain*, we aimed to enroll participants who had successfully lost weight; [20,21] therefore, we provided potential participants with a 16-week weight-loss program and randomized participants who lost ≥5 % of their baseline weight (a clinically-significant weight loss [22]) to one of two extended-care programs. Participants randomized to the *ADAPTIVE* condition are provided extended-care sessions when our algorithm deems that they are at "high risk" for weight regain, while participants randomized to the *STATIC* condition are provided with extended-care sessions on the monthly, pre-scheduled format used in gold-standard extended-care programs [9]. As a primary aim, we proposed to test the hypothesis that *ADAPTIVE* participants will experience significantly less weight regain from Month 4 (end of the initial intervention) to Month 24 (end of the maintenance period) compared to *STATIC* participants. As a secondary aim, we proposed to test the hypothesis that a greater proportion of *ADAPTIVE* (versus *STATIC*) participants will maintain clinically significant weight losses (of ≥5 % from baseline) at Month 24. As exploratory aims, we proposed to (1) use daily weight data to model differences in weight trajectories between groups, (2) investigate potential treatment mediators (e.g., treatment sessions attendance and adherence to dietary intake, physical activity, and self-monitoring goals), and (3) use the rich dataset collected via technology-based self-monitoring tools to develop dynamic models of weight loss/regain and to investigate additional proximal predictors of changes in weight and weight-related behaviors, supporting future adaptive intervention development.

2. Methods

The Project STAR trial consists of two distinct phases: (1) a non-randomized, initial intervention period in which all enrolled participants are provided with a gold-standard, 16-week lifestyle weight management program (Months 0 to 4), and (2) a 20-month randomized maintenance trial phase during which eligible participants (i.e., those who lost ≥5 % of their baseline weight during the initial intervention) are randomized into one of two extended-care maintenance programs (Months 4 to 24). The protocol for the initial intervention (along with protocol changes made due to the COVID-19 pandemic) has been published previously [23]; the current manuscript describes protocol for the maintenance trial and provides outcomes from the initial weight-loss intervention. All study procedures were approved by the University of Florida (UF) Institutional Review Board; data and safety are being overseen by a Safety Officer and not a full Data and Safety Monitoring Board.

2.1. Study timeline

Participants were recruited across five cohorts. Recruitment for Cohort 1 began in October 2019, and initial intervention began in January 2020; randomization of eligible participants into the maintenance trial began in May 2020. Cohort 5 participants began initial intervention in October 2022, and eligible participants were randomized into the maintenance trial beginning in February 2023. Final assessments for Cohort 5 will occur in October 2024.

2.2. Participants

Full details regarding recruitment procedures and eligibility criteria for the initial intervention has been published previously [23]. Briefly, individuals residing in north central Florida were recruited via community outreach and UF's Consent2Share program, a database of UF Health patients who had consented to be contacted for research studies [24]. Potential participants were asked to complete an initial telephone screen prior to a study orientation visit, at which informed consent was obtained.

To be eligible for the initial intervention, potential participants must have been adults (aged 18–70 years) with obesity (BMI between 30 and 45 kg/m^2, but weights <180 kg due to limits of study-provided e-scales) who reported owning a smartphone (iPhone 5 s or newer or Android phone running OS 4.4 or newer) with a cellular data plan and who had no medical contraindications for taking part in a lifestyle weight-loss program. Enrollment was limited to one individual per household.

To be eligible for the maintenance trial, initial intervention participants had to have (1) completed the Month 4 assessment, (2) demonstrated a weight loss of ≥5 % of their baseline weight at Month 4, and (3) reported willingness to both use the study smartphone applications and be randomized to either of the maintenance programs.

2.3. Initial weight-loss intervention

All participants were provided with a 16-week weight-loss intervention based on the Diabetes Prevention Program lifestyle intervention [25]. Cohort 1 began in-person; however, due to the COVID-19 pandemic, intervention was transitioned to videoconferencing (via Zoom) starting with session 11(videoconference delivery was used for all remaining cohorts) [23]. Intervention sessions were 60 min and conducted in closed groups of 9 to 18 participants, co-led by two trained interventionists with bachelor's or master's degrees in nutrition, psychology, or related fields. At the first session, participants were provided with study tools for self-monitoring dietary intake, physical activity, and weight (i.e., access to the FatSecret [26] smartphone application, which allowed participants to self-monitor dietary intake and physical activity, and a BodyTrace e-scale [27]) and encouraged to self-monitor daily. Participants were also provided with initial caloric intake goals (of 1200 to 1800 kcal/day, based on baseline weight [1]). During session 5, participants were provided with physical activity goals focused on gradually increasing engagement in moderate-intensity physical

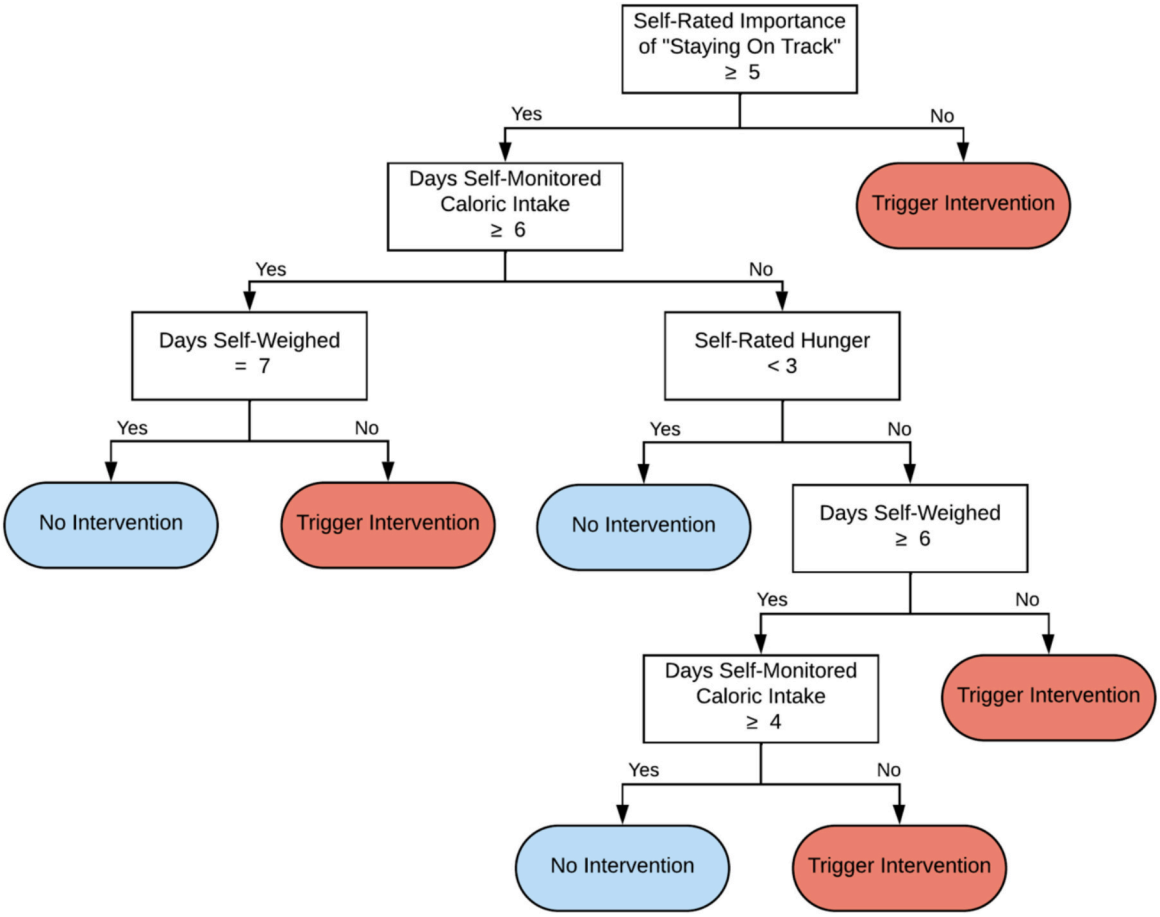

Fig. 1. Algorithm for triggering *ADAPTIVE* intervention delivery.

activity, such as brisk walking, up to 300 min/week [28].

Session content was based in social cognitive theory [29] and self-regulation theory [30] and used behavior-change strategies from cognitive behavioral therapy [31] and problem-solving therapy [31]. Each session began with a round-robin discussion of goals achieved and barriers to goal achievement experienced during the previous week. Next, a discussion of a specific session topic was led by the group interventionists. Sessions ended with participants setting goals for the upcoming week, with interventionist feedback, in a round-robin format. Additional details regarding the initial intervention, including an outline of session topics, have been published previously [23].

2.4. Randomization

Eligible participants were randomized to the maintenance trial by the study statistician using R; a 1:1 allocation scheme was used, stratified by initial weight loss (i.e., whether initial weight loss was $\geq$10 % or $<$ 10 %) due to the known association between initial weight loss and longer-term maintenance [32–34]. Participants were notified of their inclusion/exclusion and, if applicable, maintenance program condition via a phone call from study staff.

2.5. Maintenance programs

All participants (across both randomization conditions) are asked to continue to self-monitor weight, dietary intake, and physical activity daily throughout the 20-month maintenance period. After enrollment in the maintenance trial, all participants are also asked to download a smartphone application developed by our study team (MyTrack+, available on iOS and Android) which syncs with the study-provided e-scale and FatSecret to display summaries of self-monitoring data (e.g., total caloric intake versus caloric intake goal, charts of caloric intake and physical activity over the prior week, and a graph demonstrating weight trajectory over time) [35]. Through MyTrack+, participants also receive pushed notifications twice each week to complete brief self-report questionnaires (see Supplementary Materials). Each Sunday evening, participants are asked to complete two items asking them to rate, on a 1–7 scale, how hungry they were over the past week and how important it was for them to stay on track over the past week, compared to other demands in their life. On another randomly-selected evening each week (Monday through Saturday, with the day randomly selected for each participant each week), all participants are asked to complete a longer, 12-item measure assessing hours of sleep and ratings of other constructs hypothesized to be proximally associated with weight loss [36]. Finally, all participants are provided with telephone-based intervention support over the 20-month maintenance period, although the frequency and timing of this support varies by randomization condition.

2.5.1. Extended-care session format and content

For each extended-care intervention session, participants are contacted directly by their assigned study interventionist via telephone. Based on techniques from problem-solving therapy [31], each call begins with a brief check-in, wherein the interventionist queries participant progress towards their eating, activity, and self-monitoring goals, followed by discussion of any barriers experienced in meeting these goals. To address these barriers, interventionists guide participants through structured problem solving. Each call ends with structured goal setting for the upcoming week. If a participant cannot be reached for a call, interventionists make up to four additional attempts on various days/times (with no more than one attempt/day).

2.5.2. STATIC condition

Participants randomized to the *STATIC* condition receive extended-care intervention calls on a fixed, once-per-month schedule, mirroring the frequency of contact used by existing, gold-standard extended-care programs [1,9]. *STATIC* participants receive up to 20 monthly extended-care telephone sessions, with the date/time of the initial session scheduled shortly after the randomization notification call and subsequent sessions scheduled at the end of each session.

2.5.3. ADAPTIVE condition

Participants randomized to the *ADAPTIVE* condition receive extended-care intervention calls when either (1) our study algorithm (see Fig. 1) indicates that a participant is at "high risk" for weight regain, based on self-monitoring data and responses to Sunday rating scale questions, or (2) the participant requests a session by navigating to a "support" section of the app (this navigation option exists only for participants randomized to the *ADAPTIVE* condition). The study algorithm displayed in Fig. 1 was previously developed by our team to identify high-risk periods for weight regain following initial weight loss [19]. Given our aim to provide individuals with extended-care support as early as possible in a potential lapse cycle (potentially, even before weight regain itself occurs), this algorithm was optimized for sensitivity (i.e., correctly identifying individuals when they actually are at high risk for weight regain) with the trade-off of lower specificity (i.e., incorrectly triggering intervention when individuals are not actually at risk for weight regain). In an initial training dataset, this algorithm demonstrated sensitivity of 75.6 % and specificity of 45.8 %; across two testing datasets, sensitivity was 82.0 % and 81.5 % and specificity was 30.4 % and 33.2 %, respectively [19]. All participants randomized to the *ADAPTIVE* condition receive one initial call to introduce their interventionist and discuss initial goals; subsequent calls are triggered weekly by the algorithm (alerting interventionists of participants at risk of weight regain each Monday morning). Across the 20-month maintenance period, participants can receive between 1 and 85 intervention calls.

2.6. Measures

Assessments occur at Month 0 (baseline), Month 4 (end of initial weight-loss intervention), Month 12, and Month 24. Month 0 assessments were completed in-person for Cohort 1, but subsequent assessments (Months 4, 12, and 24) were completed remotely, as were all assessments for Cohorts 2–5, following protocol changes related to COVID-19 [23]. All self-report questionnaires were completed by participants online via REDCap [37].

2.6.1. Anthropometrics

Baseline height was assessed via self-report across all study cohorts; however, Cohort 1 also had in-person assessments of baseline height, conducted by trained study staff using a Shorrboard stadiometer and standard protocol [38], with participant shoes removed. Height was measured twice, to the nearest 0.1 cm; if the difference was $>$0.5 cm, height was measured a third time. The two closest heights were averaged to calculate the final height.

Weight (primary trial outcome) is being measured at each assessment via study-provided e-scales (BodyTrace, Inc.), which have demonstrated high concordance with weights measured in-person [39,40]. Participants are asked to weigh themselves first thing in the morning, after voiding but before having anything to eat or drink, in no more than light indoor clothing, with shoes removed and pockets emptied [41]. Participants are asked to step on and off the scale three times; the closest two weights are averaged and used as the final assessment weight. Participants are asked to complete this protocol on specific assessment days, as scheduled by study staff.

For Cohorts 2–5, e-scales were mailed to potential participants during the screening process and baseline weight was assessed the morning of the first intervention session (sessions were scheduled in the afternoon and evening). For Cohort 1, baseline weights were initially measured in-person using a professionally calibrated digital scale (Tanita BWB800), with participants in no more than light indoor clothing and with shoes removed and pockets emptied. Weight was measured twice to the nearest 0.1 kg and, if weights varied by 0.2 kg, a third measurement was taken (the closest two measurements were averaged to serve as the final weight). In-person weights were measured in the evening, as individuals arrived for their first intervention session (e-scales were also provided to participants at this session); to ensure consistency in measurements between baseline and later assessment visits (for which participants were asked to weigh themselves on the e-scale first thing in the morning), e-scale weights measured the morning after the first intervention session were used as baseline weights for Cohort 1.

2.6.2. Dietary intake and physical activity

Dietary intake is assessed at each assessment via three 24-h dietary recalls (two reflecting weekday intake and one reflecting weekend intake), conducted via the National Cancer Institute's Automated Self-Administered 24-h Dietary Assessment Tool [42,43]. For Cohort 1, baseline physical activity was initially assessed using ActiGraph GT3X-BT accelerometers [44]; participants were asked to wear accelerometers on their waist throughout all waking hours (minimum of 10 h/day) for one week prior to their first initial intervention session. Due to protocol changes in response to COVID-19 [23], physical activity was assessed at subsequent Cohort 1 assessments and all assessments for Cohorts 2–5 using the self-report International Physical Activity Questionnaire [45]. Finally, self-monitoring data regarding dietary intake and physical activity (i.e., data submitted via the FatSecret app [26]) are collected via a secure application programming interface (API) link with the FatSecret platform [35].

2.6.3. Additional self-report questionnaires

Questionnaires completed at baseline assessed participant demographics, contact information (including residential address), medical and weight-loss history, social norms related to weight status and eating/physical activity, [46] and chronotype [47]. Questionnaires completed at each assessment include weight-loss self-efficacy [48], body image satisfaction [49], use of weight control strategies [50], motivations for eating [51,52], meal planning behavior, sedentary behavior [53], supportive accountability [54], perceived stress [55], health-related quality of life [56,57], and program costs. Participants are additionally asked to complete a program satisfaction questionnaire at Month 24 (with the same questionnaire used for all participants). Finally, data are collected from the two questionnaires delivered weekly via MyTrack+ (see Supplementary Material).

2.7. Retention strategies

Retention strategies developed by Kiernan and colleagues [58,59] were implemented starting at study orientation visits. Moreover, participants were provided with a yearly study newsletter and were compensated $50 for completing each assessment at Months 4, 12, and 24.

2.8. Statistical analyses

2.8.1. Sample size justification

The primary outcome will be participant change in body weight from Month 4 to Month 24. The sample size for the primary aim analyses was based on the ability to detect a "minimal clinically important difference" [60] in weight change by condition. Although there are not existing thresholds for determining clinically significant weight regain, weight losses as small as 2.5 % have been demonstrated to produce clinically-meaningful benefits (e.g., reductions in fasting glucose and HbA1c

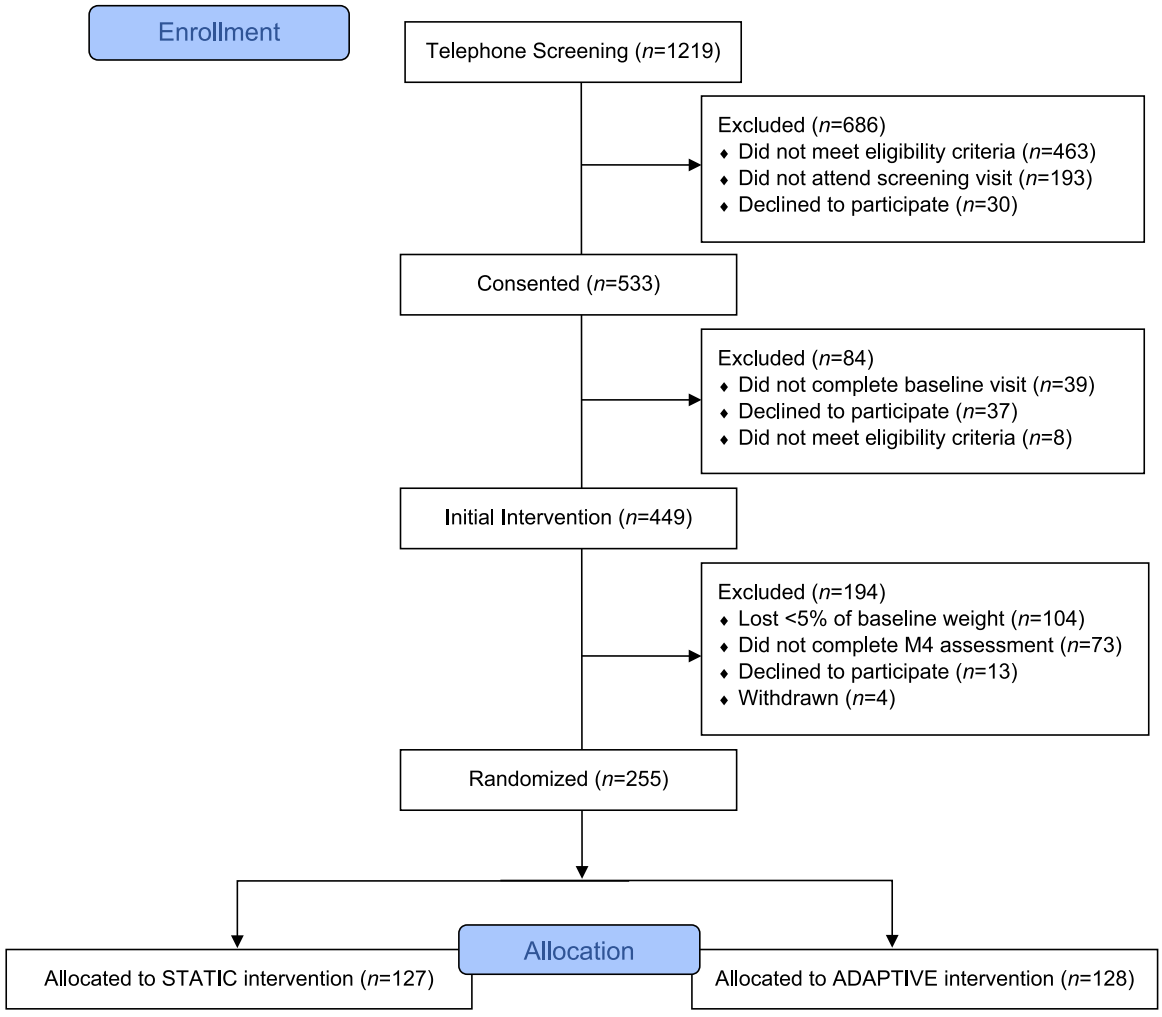

Fig. 2. Participant flow through recruitment, initial intervention, and ultimate trial randomization.

[1]); thus, we estimated the sample size necessary for statistical power of 0.90 to detect a difference in weight change of 2.5 ± 5.5 kg between *ADAPTIVE* and *STATIC* groups from Month 4 to Month 24, resulting in an estimated 206 participants (103 participants per group). Assuming a retention rate of 80 % at Month 24, 258 participants would need to be randomized. Based on previous studies conducted by our team [12,61,62], we estimated that 60 % of participants who completed the initial weight-loss program would be eligible for randomization; thus, we aimed to recruit 430 adults for the initial program.

2.8.2. Primary and secondary analyses

Analyses for the primary and secondary aims will be conducted using an intention-to-treat approach, including all randomized participants. A longitudinal mixed-effects model [63], using maximum likelihood to handle missing data, will be used to test the primary hypothesis that participants randomized to the *ADAPTIVE* condition will experience significantly less weight regain from Month 4 to Month 24 compared to those randomized to the *STATIC* condition. Fixed effects will include randomization condition, time since study start, and initial intervention weight loss (as a binary variable representing whether initial weight loss was ≥10 % or < 10 %, used to stratify randomization). A two-sided z-test for two proportions will be used to test the secondary hypothesis that a greater proportion of *ADAPTIVE* (versus *STATIC*) participants will maintain clinically significant weight losses (of ≥5 % from baseline) at Month 24. Sensitivity analyses will be conducted to assess robustness of results under alternative assumptions related to missing data (including a missing not-at-random approach assuming that individuals who discontinue participation in the study prior to Month 24 regained an average of 0.3 kg/month, up to baseline weight [12,21,64]). Given that there is potential for differential contact between maintenance conditions, and that dose of weight management intervention is known to impact intervention outcomes [61], we will also investigate the impact of the *ADAPTIVE* and *STATIC* conditions on weight regain after controlling for dose of intervention received.

2.8.3. Exploratory analyses

As an exploratory aim, we propose to compare weight change trajectory over the maintenance trial between the two groups using longitudinal mixed-effects modeling [63] and growth curve modeling [65]. Changes in dietary intake, physical activity, and self-monitoring adherence over time will be assessed using similar longitudinal mixed-effects models to the primary aim analysis. Potential treatment mediators (e.g., intervention engagement, operationalized as the proportion of possible extended-care sessions attended, adherence to self-monitoring, and changes in dietary intake/physical activity) will be assessed using bootstrapping to estimate confidence intervals around indirect effects [66]. Finally, building on our previous work [19] and following the pragmatic framework developed by Nahum-Shani and colleagues [67], we propose to build dynamic models of weight loss and weight regain, identifying key tailoring variables and potential intervention options for future just-in-time adaptive interventions for weight loss maintenance.

Table 1
Baseline participant characteristics and demographics, overall and by randomization status.

	All Initial Intervention Participants	Randomized Trial Participants	Participants Not Randomized to the Trial
	(*N* = 449)	(*n* = 255)	(*n* = 194)
	M (*SD*) or *n* (%)	*M* (*SD*) or n (%)	*M* (*SD*) or *n* (%)
Age (years)	49.5 (11.4)	50.6 (11.3)	48.0 (11.3)
Weight (kg)	99.9 (15.2)	99.9 (15.5)	99.9 (14.8)
Baseline BMI (kg/m^2)	35.7 (4.0)	35.6 (4.2)	35.9 (3.9)
Obesity Class			
Class I (BMI 30.0–34.9)	217 (48.3)	129 (50.6)	88 (45.4)
Class II (BMI 35.0–39.9)	151 (33.6)	79 (31.0)	72 (37.1)
Class III (BMI 40.0–45.0)	81 (18.0)	47 (18.4)	34 (17.5)
Gender			
Male	74 (16.5)	46 (18.0)	28 (14.4)
Female	375 (83.5)	209 (82.0)	166 (85.6)
Ethnicity			
Hispanic or Latino	44 (9.8)	25 (9.8)	19 (9.8)
Not Hispanic or Latino	405 (90.2)	230 (90.2)	175 (90.2)
Race*			
American Indian or Alaskan Native	7 (1.6)	4 (1.6)	3 (1.5)
Asian	14 (3.1)	7 (2.7)	7 (3.6)
Black or African American	105 (23.4)	51 (20.0)	54 (27.8)
Native Hawaiian or Other Pacific Islander	2 (0.4)	1 (0.4)	1 (0.5)
White	333 (74.2)	199 (78.0)	134 (69.1)
Not Reported	5 (1.1)	3 (1.2)	2 (1.0)
Education			
High school	16 (3.6)	8 (3.1)	8 (4.1)
Vocational training or some college	71 (15.8)	34 (13.3)	37 (19.1)
Associate degree	55 (12.2)	27 (10.6)	28 (14.4)
College/university degree	132 (29.4)	80 (31.4)	52 (26.8)
Graduate or professional education	175 (39.0)	106 (41.6)	69 (35.6)
Marital Status			
Married	274 (61.0)	170 (66.7)	104 (53.6)
Separated, divorced, or widowed	82 (18.3)	40 (15.7)	42 (21.6)
Never married	69 (15.4)	32 (12.5)	37 (19.1)
Other	24 (5.3)	13 (5.1)	11 (5.7)
Income			
0–25,000	17 (3.8)	8 (3.1)	9 (4.6)
25,001-50,000	86 (19.2)	36 (14.1)	50 (25.8)
50,001-75,000	100 (22.3)	50 (19.6)	50 (25.8)
75,001-100,000	74 (16.5)	47 (18.4)	27 (13.9)
100,001-125,000	64 (14.3)	49 (19.2)	15 (7.7)
125,001+	97 (21.6)	57 (22.4)	40 (20.6)
No response	11 (2.4)	8 (3.1)	3 (1.5)

* Participants could select more than one race category; thus, totals may exceed 100 %.

Table 2
Weight change at Month 4, by participant enrollment and randomization status.

	All Initial Intervention Participants	Randomized Trial Participants	Participants Not Randomized to the Trial
	(*N* = 449)	(*n* = 255)	(*n* = 194)
	M (*SD*)	*M* (*SD*)	*M* (*SD*)
Baseline Weight, kg	99.88 (15.19)	99.89 (15.52)	99.86 (14.79)
Month 4 Weight, kg	93.53 (15.10)	90.39 (14.53)	97.67 (14.86)
Change in Weight Baseline toMonth 4, kg	−6.35 (4.99)	−9.51 (3.67)	−2.19 (3.10)

3. Initial intervention outcomes and trial randomization

3.1. Remote and in-person measure concordance from Cohort 1 baseline

Given that Cohort 1 had both self-report and study-measured height, and weights measured both in-person and via e-scales at baseline, we assessed concordance between these measures. Lin's concordance correlation coefficient between self-report and study-measured height was 0.975, and between in-person measured weight and e-scale weights was 0.997.

3.2. Initial intervention outcomes

Figure 2 displays participant flow through screening, enrollment, and randomization. A total of 449 individuals were enrolled in the initial intervention and 255 were randomized to the maintenance trial. Table 1 provides baseline participant characteristics and demographics. Overall, participants were predominately female; 36.52 % of individuals who enrolled in the initial intervention ($n = 164$) and 33.33 % of participants randomized to the maintenance trial ($n = 85$) were from racial/ethnic groups historically underrepresented in research. There were no significant differences between participants randomized to the maintenance trial versus those who were not in terms of baseline weight, gender, race/ethnicity, education, or marital status, all $ps > 0.05$; however, there were differences in age, $t(447) = 2.5$, $p = .014$, and income, $\chi^2(5) = 22.0$, $p < .001$, such that participants randomized to the maintenance trial were older and reported higher incomes.

Of the 449 participants who began the initial intervention, 419 (93.32 %) had weight assessed at Month 4; participants who did not have weight measured at this assessment were assumed to have regained 0.3 kg/month (0.01 kg/day) from their last measured e-scale weight. Table 2 provides weights at each time point and changes from baseline to Month 4. Overall, participants lost an average (*mean* ± *SD*) of 6.37 ± 4.85 % of their baseline weight at Month 4; participants randomized to the maintenance trial lost an average of 9.53 ± 3.33 % of their baseline weight whereas participants not randomized lost 2.20 ± 3.07 %.

3.3. Trial randomization

Of the 255 participants randomized to the maintenance trial, 127 were randomized to *STATIC* and 128 to *ADAPTIVE*. Randomization was stratified by Month 4 weight loss; 106 participants lost ≥10 % of baseline weight ($n = 54$ randomized to *STATIC* and $n = 52$ to *ADAPTIVE*) and 149 participants lost ≥5 % but <10 % of baseline weight ($n = 73$ randomized to *STATIC* and $n = 76$ to *ADAPTIVE*).

4. Discussion

Project STAR is a randomized controlled trial evaluating the impact

of providing extended-care intervention via telephone on a *STATIC* (once-per month) versus *ADAPTIVE* (when triggered by a study algorithm predicting that an individual is at high risk for weight regain) schedule. Accomplishments to date include the enrollment of 449 adults in an initial weight-loss program (with participants losing an average of 6.4 % of their baseline weight) and randomization of 255 individuals who successfully lost ≥5 % of their baseline weight to the maintenance trial. Overall, the magnitude of weight loss demonstrated by participants in the initial intervention was clinically-meaningful [1] and similar in magnitude to the 6.9 % achieved in the initial 16-week Diabetes Prevention Program lifestyle intervention [68]. This is notable as the intervention period was impacted both by the transition to videoconferencing delivery and the broader COVID-19 pandemic, which substantially impacted many individuals' dietary intake and physical activity patterns [69,70]. Promisingly, this outcome is consistent with previous research suggesting that lifestyle weight management intervention appears robust to alternate delivery formats (e.g., via telephone [1,71] or videoconferencing [23,72,73]) and delivery of intervention during global pandemics [23,72,73].

The sample randomized to the maintenance trial was broadly representative of the larger sample enrolled into the initial intervention. Despite previous literature demonstrating that lifestyle interventions are less beneficial for Hispanic and African American or Black participants [74–76], there was not a significant difference in race/ethnicity between participants randomized and those not randomized to the trial. Participants randomized to the trial were, however, older and reported higher household income than participants who were not randomized, suggesting potential for sampling bias (and consistent with previous literature demonstrating that older adults [68,74] and adults with higher incomes [77,78] may receive greater benefit from weight-loss programs).

Overall, results from the Project STAR trial will demonstrate whether providing extended-care intervention on an individually-adaptive schedule (i.e., at times when individuals are deemed at "high risk" for weight regain [19]) improves weight regain after initial weight loss in adults with obesity compared to the static, once-per-month schedule used in existing gold-standard programs [1,9]. Moreover, the collection of daily self-monitoring data throughout the maintenance period (along with weekly self-report ratings of constructs hypothesized to be proximally associated with dietary intake, physical activity, and weight change [36]) will serve as a foundation upon which future predictive algorithms and novel, individually-adaptive interventions can be developed.

CRediT authorship contribution statement

Kathryn M. Ross: Writing – review & editing, Writing – original draft, Visualization, Supervision, Resources, Methodology, Investigation, Funding acquisition, Conceptualization. **Meena N. Shankar:** Writing – review & editing, Writing – original draft, Project administration, Investigation, Formal analysis, Data curation. **Peihua Qiu:** Writing – review & editing, Software, Methodology, Formal analysis, Data curation. **Zibo Tian:** Writing – review & editing, Visualization, Formal analysis, Data curation. **Taylor N. Swanson:** Writing – review & editing, Writing – original draft, Formal analysis. **Armaan Shetty:** Writing – review & editing, Writing – original draft. **Jaime Ruiz:** Writing – review & editing, Software, Resources, Data curation. **Lisa Anthony:** Writing – review & editing, Software, Resources. **Michael G. Perri:** Writing – review & editing, Methodology, Funding acquisition.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper. The research described in this publication was supported by the National Institute of Diabetes and Digestive and Kidney Diseases of the National Institutes of Health, under award number R01DK119244.

Data availability

Data will be made available on request.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.cct.2024.107707.

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