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Results of a pilot sequential multiple assignment randomized trial using counseling to augment a digital weight loss program

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Abstract

Objective: Adaptive interventions may improve the potency and scalability of behavioral weight loss interventions, but the treatments—or treatment combinations—that should be offered are unknown. A two-stage pilot sequential multiple assignment randomized trial was used to test the timing and dose of human support added to a core digital weight loss program.

Methods: In stage 1, 99 adults with overweight/obesity were randomized at baseline to a kick-off with or without additional human support. In stage 2, "early non-responders" who had not achieved a 2% weight loss were re-randomized after 4 weeks to either biweekly counseling (120 min over 8 weeks) or a one-time check-in (30 min) with a dietitian. "Early responders" continued with the mHealth program alone. Feasibility and acceptability were assessed against pre-specified criteria. Preliminary outcomes (weight loss, self-monitoring and behavioral goal adherence) were explored.

Results: The study met all feasibility and acceptability criteria. The rate of early response was 52.5%. Mean (SE) 3-month percent weight losses were significantly greater in early responders (−6.63% (0.72)) than non-responders (−1.70% (0.43), $p < 0.001$). Outcomes were similar by first- and second-line treatment though more counseling (27.3%) than check-in (12.5%) participants achieved a 5% weight loss.

Conclusions: Identifying early responders may help optimize weight loss interventions, but more research is needed on rescue treatments for early non-responders.

Trial Registration: ClinicalTrial.gov, NCT05929469.

KEYWORDS

adaptive, counseling, digital, obesity, optimization

1 | INTRODUCTION

An estimated 73.1% of adults in the United States meet the clinical criteria for overweight or obesity, with 42.4% meeting the criteria for obesity and 9.2% for severe obesity.[1] Current guidelines for the management of overweight and obesity in adults report that there is the strongest evidence for interventions that are on-site, high-intensity (≥14 individual or group sessions in 6 months), comprehensive, and delivered by a trained interventionist.[2,3] However, not everyone loses weight in these programs[4–6] and existing resources preclude everyone from receiving such "gold standard" treatment.[3,7,8] There is a critical need for "optimized" weight loss interventions that are individually potent but scalable.[9,10]

Intervention optimization involves identifying intervention components that are active, and the dose required for clinically meaningful outcomes.[11] Sequential multiple assignment randomized trials (SMARTs) can be used to build adaptive interventions and answer questions about the optimal timing and sequencing of interventions.[12,13] They are factorial designs in a sequential setting that employ a priori decision rules based on a primary tailoring variable to determine response or non-response at a prespecified time.[12,13] They mark an important departure from traditional studies that provide a fixed treatment given evidence that early weight loss is a good predictor of weight outcomes at study end.[5,14–16] Analyses of Look AHEAD participants randomized to the intensive lifestyle intervention showed that participants who had not lost 2% of initial body weight at Month 1 were 5.6 times more likely to not have lost 10% of initial body weight at Year 1 than those who did lose 2% of initial body weight.[17] Early rescue efforts may improve treatment response[18] but little is known about which treatments—or treatment combinations—should be offered.[13]

Discovering how to best leverage different treatment modalities may be an opportunity for intervention optimization. Although weight losses in mobile health (mHealth) programs are typically less, on average, than traditional programs with human input, mHealth programs can achieve clinically significant weight loss in as many as 25%–40% of participants.[19,20] There is promise in "hybrid" interventions, which combine personalized, specialized care provided by dietitians and more resource-efficient, scalable, digital technologies that are pervasive and well-accepted for nutrition and weight loss.[21–23] They can produce weight losses comparable to or greater than those in interventions with human support, and greater than those in interventions with technology alone.[22,24–26] In the absence of a "one size fits all" approach, there is a need to identify responders and non-responders to different interventions to both understand for whom different interventions are effective, and to differentiate those who do and do not need intensive interventions.[18,21]

There is a compelling need to understand how to best use human support in the embedded treatment sequences of a SMART.[9,27,28] Human support is thought to be an "active ingredient" of "gold standard" treatments that can produce weight losses of 5% in 50%–70% of participants at 12 months,[4–6] but the time, cost, and staffing inputs it requires limit program scalability.[3,7,8] Few studies have isolated and tested different human support components, instead including them in large multicomponent intervention packages.[29]

The overarching goal of the study was to explore the feasibility, acceptability, and preliminary outcomes (self-monitoring adherence, behavioral goal adherence, weight loss) of a two-stage SMART. Specific objectives were to (a) test the feasibility of the SMART design and the acceptability of intervention components, (b) compare 3-month outcomes between early responders and non-responders, and (c) explore outcomes by human support components received.

This study's design both complements and advances the evidence base on interventions for early non-response to mHealth treatments.[18,28,30] To our knowledge, this study will be the first to isolate human involvement in kick-off sessions. Though a common feature of stepped care interventions testing first-line mHealth treatments[18,28,30] and a possible contribution to trial retention and engagement,[31] human support may be a target for intervention optimization. This resource-intensive component may not be necessary in the setting of high baseline motivation for weight loss[32–34] and carries a risk of creating dependency on a coach, unintentionally undermining autonomy and the long-term sustainability of behavior change.[23,28,35] The second line tested different doses of human support, given that past research shows that (a) early non-responders will lose more weight with periods of brief coaching than no additional intervention[18] and (b) greater doses of human support are generally—but not always—better for most participants.[36,37] The Check-In was designed to serve as a "motivational booster" at a critical time point for motivation.[32–34] Though the minutes of Counseling was similar to those of other studies, they differed in their spread across the sessions—with sessions intentionally set at 30 min each to mirror the dose allowed in Medicare's medical nutrition therapy benefit—and use of video calls instead of phone calls given their greater communication bandwidth.[23,38]

2 | MATERIALS AND METHODS

2.1 | Design

PATH to Health was a pilot and feasibility study that employed a two-stage SMART design (Figure 1) to test different doses and timings of human support (Human Enhanced Kick-Off, Check-In, Counseling) added to a core mHealth program (App). The trial was preregistered at ClinicalTrials.gov (NCT05929469).

2.2 | Participant recruitment

The study was conducted in Chapel Hill, NC though participants completed all assessments remotely. To be eligible, participants had to be 18–65 years old, currently living in North Carolina, English-speaking, and owners of a smartphone with a data and texting plan. Individuals were excluded if they had a history of recent weight loss, weight loss surgery, an eating disorder, Type I diabetes, or another

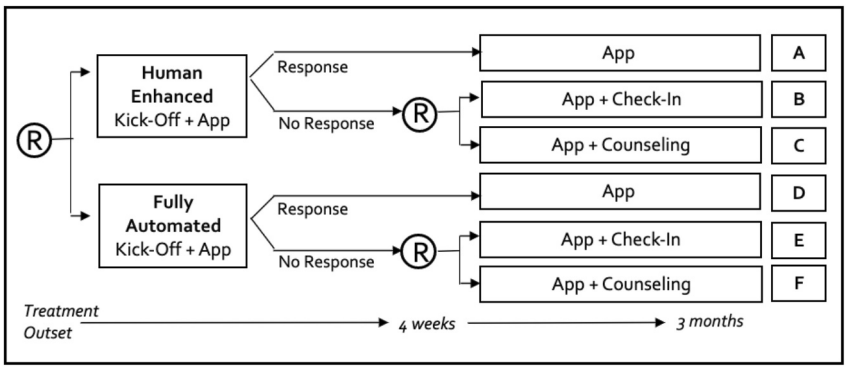

FIGURE 1 Sequential multiple assignment randomized trial design. In this figure, the rectangles represent different first- and second-line treatments with varying doses of human support. The circles with an "R" in them depict randomization points. The letters at the right of the diagram are labels for the different treatment sequences. The study timeline is depicted at the bottom of the figure.

condition that could impact their ability to safely complete the program. Individuals with Type II diabetes were excluded if they were managing their disease with medication.

Participants were recruited using informational listservs, participant registries, and boosted Facebook posts. Recruitment materials directed individuals to an online questionnaire with initial eligibility questions. Eligible individuals were contacted by phone for additional screening and study details. After the call, eligible individuals were sent an electronic Informed Consent form to sign to indicate their voluntary participation in the study.

2.3 | Randomization

As seen in Figure 1, participants were randomized at baseline in a 1:1 ratio to either a Fully Automated or Human Enhanced Kick-Off (Stage 1). A random number table generated in Excel by the project manager was used and uploaded to REDCap to conceal the sequence. Per an a priori *decision rule*, all participants who had not lost at least 2% of their baseline body weight at 4 weeks were deemed *early non-responders*. They were re-randomized via block randomization stratified by Stage 1 treatment in a 1:1 ratio to either (a) Check-In or (b) Counseling (Stage 2), using a randomization table with random blocks of 2 or 4 generated in Excel by one of the co-investigators. *Early responders* who had lost 2% of their baseline weight were not re-randomized and continued with the app alone. Participants were notified of the possible doses and timing of human support prior to study consent, but were not informed of the re-randomization criteria. Due to the nature of the intervention, researcher blinding to participant group assignment was not possible.

2.4 | Interventions

The interventions embedded in the SMART were informed by Self-Determination Theory[39] and the Supportive Accountability Model.[23] The conceptual model of the intervention is shown in Figure 2. All participants received a core 3-month behavioral weight loss program that encouraged nutrient-dense foods, calorie reduction, and increased exercise. It delivered behavior change techniques[40] shown to be effective in weight loss interventions such as goal setting, self-monitoring, feedback on behavior, and feedback on outcome(s) of behavior.[40,41] Participants were asked to self-monitor daily activity with a Fitbit Inspire 3 activity tracker, weight with a Fitbit Aria Air Bluetooth scale, and calories via the Fitbit app, The study smartphone app (PATH) synced with the Fitbit app and showed progress toward personalized study goals for weight, calories (range: 1200–1800 calories, based on starting weight), and active minutes (range: 10–60 min/day, based on starting activity level, and advanced throughout the intervention per goal progress). The PATH app also included weekly lessons, tailored weekly feedback messages, resources, and an option for participants to modify some study goals. Participants received 4-5 text messages per week, which were tailored based on self-monitoring data. The PATH app was used in a prior randomized controlled trial (RCT) and adapted for the target audience of this study.[42]

The difference between first- and second-line treatments was the dose of human support. All human support components (Human Enhanced Kick-Off, Check-In, Counseling) were conducted by Zoom with a dietitian trained in behavioral weight management and motivational interviewing, using a semi-structured protocol, with a primary intervention target of the participant's autonomous motivation. In Stage 1, both groups (Fully Automated, Human Enhanced) watched a 45-min pre-recorded kick-off video that included (a) a study overview, (b) best practices for success, (c) an introduction to self-monitoring components, and (d) an app tour. Human Enhanced participants received an additional 30-min video-conference session prior to study start that was designed to: (a) ensure understanding of the study and study goals, (b) confirm comfort using the study technologies, (c) explore motivations for behavior change and link them to the benefit of behavior change in PATH, and (d) help with initial problem solving, with script tailored to responses on baseline questionnaire about weight loss history and past weight loss strategies. In Stage 2, Check-In participants received one 30-min session with a dietitian during week 5. Counseling participants had 30-min,

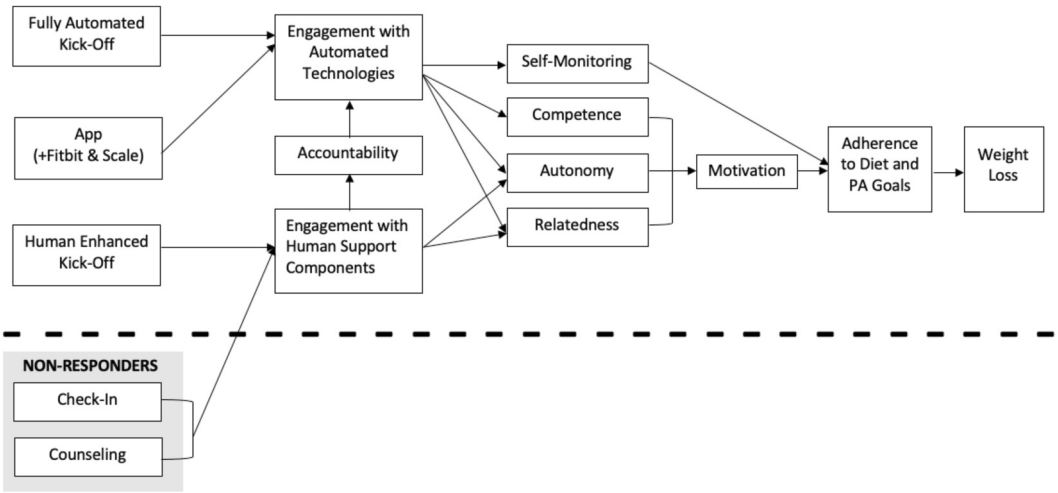

FIGURE 2 Conceptual model of the intervention. This model depicts the behavioral targets of the interventions as well as the proposed behavior change pathways. Both were informed by Self-Determination Theory and the Supportive Accountability Model.

biweekly sessions starting in week 5 for a maximum second-stage dose of 120 min over 8 weeks. Stage 2 human support sessions (Check-In, Counseling) were designed to: (a) check-in with participants about their self-perceived progress in PATH, (b) acknowledge progress with self-monitoring and weight loss goals, with scripts tailored to level of progress, (c) explore motivations for behavior change and link them to the potential benefits of behavior change in PATH, (d) discuss behavioral goals for the second part of the program, and (e) help participants problem-solve.

2.5 | Outcomes

Participants completed remote, objective weight assessments and survey questionnaires at baseline, 1 week, 4 weeks, and 3 months, plus diet assessments at baseline and 3 months. They were compensated for complete assessments ($10 each for Weeks 1 and 4, $25 for Month 3).

The primary outcomes were feasibility and acceptability. Feasibility was defined as the ability of the investigators to implement the SMART procedures and deliver the embedded treatment sequences. Acceptability was defined as the participants' perceptions of the treatment(s). Feasibility and acceptability criteria were specified prior to trial start; the SMART design would be deemed feasible if (a) missing data on the tailoring variable at 4 weeks was less than 10% and (b) the rate of early response was at least 25% and acceptable if (a) attrition was similar across early responders and non-responders, and in total did not exceed 20% at 3 months, (b) at least 75% of participants attended at least 50% of human support sessions, and (c) at least 75% of participants were satisfied with the program. Acceptability criteria were set conservatively to allow for diverse user profiles in hybrid interventions.

The percentage of participants with missing data at 4 weeks was calculated as the number of participants who did not complete the 4-week weight assessment, divided by the number randomized. The rate of early response was calculated as the number of individuals deemed early responders divided by the number randomized. Attrition was calculated as the number of intervention participants who completed the 3-month weight measurement divided by the number randomized. The rate of attendance at human support sessions was calculated as the number of human support sessions (Human Enhanced Kick-Off, Check-In, Counseling) completed, divided by the number of sessions assigned. Program satisfaction was assessed using a single item on the final questionnaire. Participants rated their overall satisfaction with the program on a 4-point Likert scale that ranged from "very dissatisfied" to "very satisfied," in which scores of "3" and "4" indicated satisfaction with the program.

Weights were measured objectively on participants' Bluetooth-enabled Fitbit Aria Air scales using procedures adapted from other RCTs with remote assessments[43]; participants took three consecutive weights and the average of the three weights was recorded. Percent weight change from baseline and the percentage of participants who lost at least 5% of their initial body weight were calculated using these weights. A prespecified protocol was used to determine subsequent treatment in the presence of missing weight data on the tailoring variable: percent weight change at 4 weeks. If an official weight was not received by Day 2 (Tuesday) of Week 5, researchers used weights captured by the study scale in the prior week. If a weight was not found, missingness was counted as early non-response. Similar protocols were used for missing weights for the week 1 and 3 months assessments. Analyses were conducted using all available weights.

Secondary outcomes were days of self-monitoring (diet, activity, weighing) and behavioral goal (diet, active minutes) adherence, which were assessed via the digital technologies (scale, Fitbit tracker, Fitbit app). To be adherent to daily self-monitoring goals, participants had to track at least 800 calories, 100 steps, and a weight. They were adherent if they were at or above their active minutes goal and at or below their calorie goal with complete tracking that day.

Calorie intake at baseline and 3 months was measured using one 24-h recall at each time point, which is consistent with National Cancer Institute (NCI) Diet Assessment Primer guidelines for comparing the change in mean usual intake of two groups between two time points. It was assessed via the Automated Self-Administered 24-h Recall program from NCI.[44] The Paffenbarger Physical Activity Questionnaire captured physical activity at baseline and 3 months as energy expenditure from physical activity per week (kcal/week).[45]

2.6 | Sample size

The sample size of 99 participants was calculated using guidance for pilot SMARTs.[46,47] This sample was necessary so that, with 80% probability and early non-response rate of 70%, a minimum of 10 participants would fall into each subgroup (treatment paths A-F in Figure 1), given 90% retention in the study. The estimated rate of non-response was informed by two similar studies, which showed weight losses <2% at 4 weeks in 70% and 63% of participants, respectively.[48,49] The goal was a sample sufficient to detect an effect size and assess the variance in the sample to inform the design of full-scale efficacy SMART, not one designed to be fully powered for all analyses.

2.7 | Statistical methods

Analyses were conducted with SAS software version 9.4 (Cary, NC). Acceptability and feasibility measures were compared to a priori criteria. Independent sample *t*-tests were used to compare outcomes (percent weight change, self-monitoring adherence, study goal adherence) in early responders versus early non-responders, and by human support received. Specifically, *t*-tests compared outcomes (1) at 4 weeks and 3 months in early responders versus non-responders (A + D v. B + C + E + F in Figure 1), (2) at 4 weeks and 3 months in those randomized to Human Enhanced versus Fully Automated (A + B + C v. D + E + F; A v. D; B + C v. E + F), (3) at 3 months in those randomized to Check-In versus Counseling (B + E v. C + F), and (4) at 3 months in those randomized to Human Enhanced then each type of human support versus Fully Automated then each type of human support (B vs. E; C vs. F). Chi-square tests of independence were used for comparisons of the percentage of participants who lost at least 5% of initial body weight. Significance was set a $p < 0.05$. Adjustments were not made for multiple comparisons as analyses were intended to be hypotheses-generating and not confirmatory.[50]

2.8 | Ethics

The Institutional Review Board at the University of North Carolina at Chapel Hill approved the study (Reference ID: 416262).

3 | RESULTS

Rolling recruitment began in October 2023 and all data were collected by March 2024. Participant flow is depicted in Figure 3 and participant characteristics are shown in Table 1. Overall, participants were 48.2 ± 9.8 years old, 89.9% self-identified as female, 75.0% self-identified as White, and 75.7% had at least a 4-year college degree. At baseline, 75.8% had a BMI that fell in the clinical classification of "Obesity," and the percentage of participants who self-reported diagnoses of high blood pressure and hyperlipidemia were 13.1% and 17.2%, respectively. The percentages of participants with available assessment weights at baseline, week 1, week 4, and 3 months were 100%, 100%, 99.0% and 99.0%, respectively. The 3-month questionnaire that contained the feasibility and acceptability measures was completed by 97.0% of the participants.

3.1 | Feasibility

With only 1.0% missingness for percent weight change at 4 weeks, the study met the a priori feasibility goal of less than 10% missing data on the tailoring variable at 4 weeks. The rate of early response of 52.5% also met the feasibility goal of a rate of at least 25%. Early responders were equally distributed across first-stage treatments ($n = 26$/treatment).

3.2 | Acceptability

The study met the a priori acceptability criteria for total attrition that did not exceed 20% at 3 months given that 97.0% of randomized participants had an official weight measurement and 99.0% ($n = 99$) had weights for analysis at 3 months. Overall rates of missing weights were similar between early responders (100% completed and analyzed) and non-responders (93.6% completed, 97.9% analyzed).

Participants were assigned to an average of 1.68 sessions with a behaviorally trained dietitian during the 3-month study. Of those who were assigned to at least one session ($n = 73$), 95.9% attended at least 50% of the sessions they were assigned to receive, which was higher than the acceptability goal of at least 75%. There was 100% completion of Human Enhanced sessions in Stage 1; 87.5% of Check-Ins and 88.0% of assigned Counseling sessions were completed in Stage 2. Over 75% of Counseling participants attended all 4 sessions (78.2%). The percent of Check-In and Counseling sessions completed did not vary by Stage 1 treatment (Fully Automated (91.7%, 86.4%) and Human Enhanced (83.3%, 89.6%)).

Of those with complete program evaluations ($n = 96$), 87.5% were satisfied with the program, which was above the a priori acceptability criteria of at least 75%. Mean program satisfaction (on a scale of 1–4) was 3.40 (95% CI: 3.25, 3.54). The percentage of individuals who were satisfied in each treatment sub-group was: 85.4% in Fully Automated, 89.6% in Human Enhanced, 90.2% in early responders, 84.4% in early non-responders, 86.4% in Counseling, and 82.6% in Check-In.

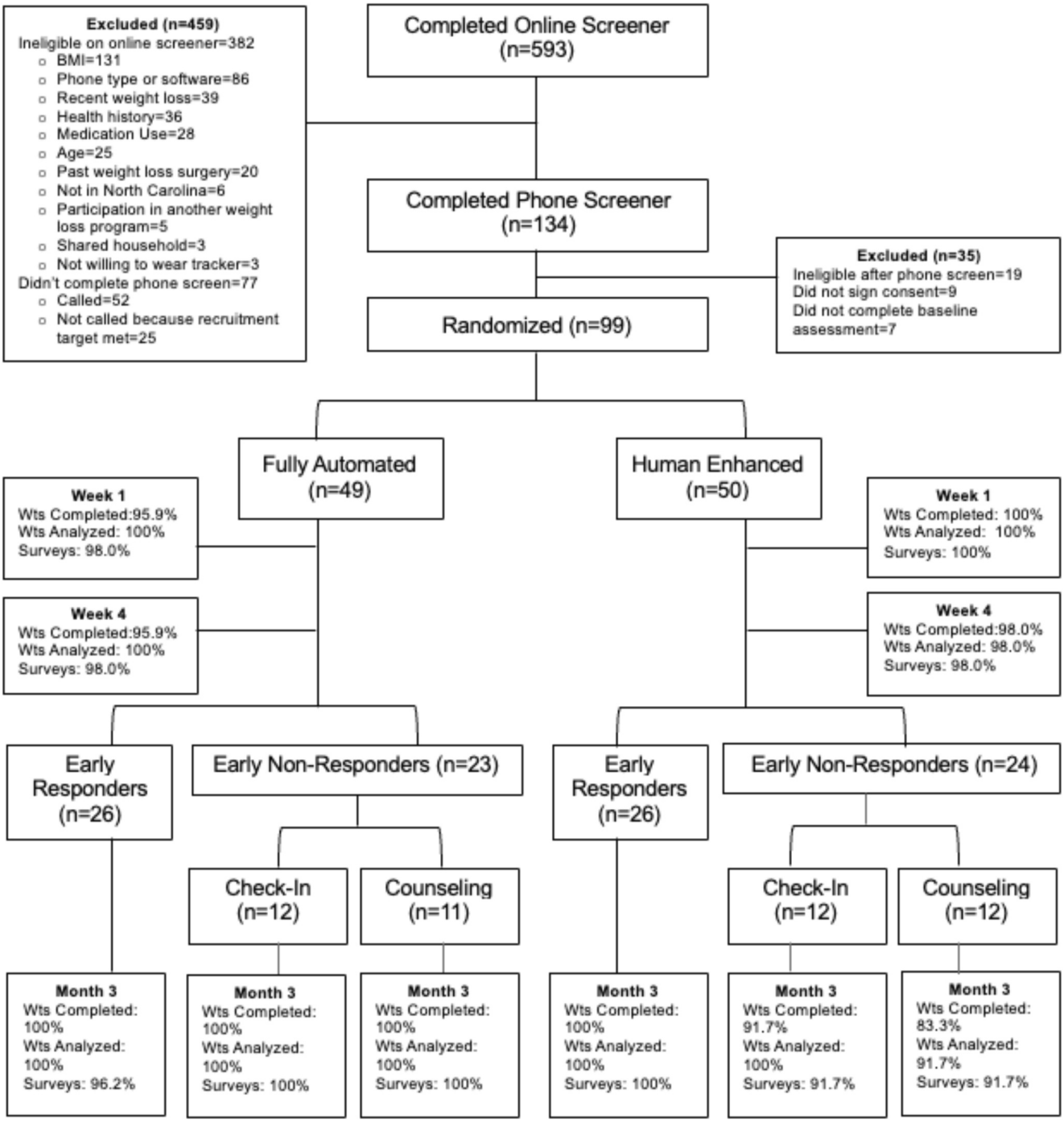

FIGURE 3 Flow of participants through the intervention. In this figure, "weights" are abbreviated as "wts." The percentages for "wts completed" refer to the percentage of official weight measurements completed by participants. This assessment included three back-to-back weights on a participant's study scale. "Wts analyzed" includes any weight obtained using pre-specified procedures for missing weights. These weights were also collected objectively, and were taken from backend data from the participant's study scale.

3.3 | Outcomes, by early response status

Table 2 details the study outcomes. Mean (SE) percent weight loss at 3 months was −4.34% (0.50) in all participants (n = 98); 39.80% (n = 39) of participants lost at least 5% of their initial body weight at 3 months. On average, percent weight loss was significantly greater in early responders (−6.63% (0.71)) than in early non-responders (−1.70% (0.43), $p < 0.001$). More early responders (57.69%) also achieved a 5% weight loss than early non-responders (19.57%, $p < 0.001$). The difference in percent weight change in early responders and non-responders was statistically significant from baseline to 4 weeks, but not 4 weeks to 3 months. Early responders met their daily calorie self-monitoring goals, calorie goals, and active minute goals on statistically significantly more days

TABLE 1 Participant characteristics.

	Total sample (n = 99)	Early responders (n = 52)	Early non-responders (n = 47)
Age (years)	48.2 ± 9.8	49.0 ± 9.3	47.3 ± 10.3
Sex			
Female	89 (89.9%)	44 (84.6%)	45 (95.7%)
Hispanic, Latino/a/x, or Spanish origin[a]			
No	87 (91.6%)	46 (90.2%)	41 (93.2%)
Yes	6 (6.3%)	5 (8.8%)	1 (2.3%)
Some other race, ethnicity, or origin	2 (2.1%)	0	2 (4.5%)
Race[b]			
White	72 (75.0%)	39 (76.5%)	33 (73.3%)
Black or African American	18 (18.8%)	7 (13.7%)	11 (24.5%)
Other or multiple races	6 (6.2%)	5 (9.8%)	1 (2.2%)
Education			
High school, GED, technical school, vocational training, or less college 1–3 years	7 (7.1%)	3 (5.8%)	4 (8.5%)
college 1–3 years	17 (17.2%)	7 (13.5%)	10 (21.3%)
College degree (4 years)	34 (34.3%)	22 (42.3%)	12 (25.5%)
Master's or doctoral degree	41 (41.4%)	20 (38.4%)	21 (44.7%)
Income[c]			
<$25,000	2 (2.2%)	0 (0.0%)	2 (4.5%)
$25,000–$49,999	5 (5.4%)	3 (6.3%)	2 (4.5%)
$50,000–$74,999	15 (16.3%)	8 (16.7%)	7 (15.9%)
$75,000–$99,999	16 (17.4%)	6 (12.5%)	10 (22.8%)
$100,000 or more	54 (58.7%)	31 (64.5%)	23 (52.3%)
Weight (kg)	92.5 ± 14.4	90.8 ± 13.7	94.4 ± 15.0
BMI (kg/m^2)	33.6 (4.3)	32.7 (4.0)	34.7 (4.5)
Overweight (25.0–29.9)	24 (24.2%)	20 (38.4%)	4 (8.5%)
Obesity class I (30–34.9)	41 (41.4%)	18 (34.6%)	23 (48.9%)
Obesity class II (35.0–39.9)	24 (24.2%)	11 (21.2%)	13 (27.7%)
Obesity class III (40.0–50.0)	10 (19.2%)	3 (5.8%)	7 (14.9%)
High blood pressure			
Yes	13 (13.1%)	7 (13.5%)	6 (12.8%)
Hyperlipidemia			
Yes	17 (17.2%)	9 (17.3%)	8 (17.0%)
Type II diabetes			
Yes	1 (1.0%)	1 (1.9%)	0
Diet (calories/day)	2144.4 ± 803.91	2217.4 ± 827.8	2060.6 ± 777.5
Activity (calories/week)	1073.6 ± 979.6	1060.9 ± 951.5	1087.7 ± 1020.0

Note: Data are presented as n (%) or mean ± SD.

[a]n = 95 in the full sample, n = 51 in the sample of Early Responders, and n = 44 in the sample of Early Non-Responders because 4 chose "Prefer Not to Answer"; Participants who responded yes to this question self-identified as Mexican (n = 5) or Another Hispanic, Latino/a/x, or Spanish origin (n = 1).

[b]n = 96 in the full sample, n = 51 for Early Responders, and n = 45 for Early Non-Responders because 3 chose "Prefer Not to Answer"; Participants in the "Other or Multiple Races" category self-identified as: Asian (n = 2), both Asian and White (n = 1), Some other race, ethnicity, or origin (n = 1; "Brown"), or they preferred to self-describe (n = 2; "Mestizo" and "Hispanic").

[c]n = 92 in the full sample, n = 48 in the sample of Early Responders, and n = 44 in the sample of Early Non-Responders because 7 chose "Prefer Not to Answer."

TABLE 2 Main outcomes by early response status.

	Everyone (n = 99)	Early responders (n = 52)	Early non-responders (n = 47)	p-value
Weight[a]				
Percent weight change, baseline-week 4[a]	−2.16 (0.23)	−3.86 (0.23)	−0.23 (0.17)	<0.001
Weight change (kg), baseline-week 4[a]	−1.94 (0.21)	−3.46 (0.19)	−0.22 (0.17)	<0.001
Percent weight change, week 4-month 3[b]	−2.26 (0.40)	−2.89 (0.65)	−1.52 (0.37)	0.074
Weight change (kg), week 4-month 3[b]	−2.10 (0.39)	−2.62 (0.64)	−1.44 (0.37)	0.115
Percent weight change, baseline-month 3[a]	−4.34 (0.49)	−6.63 (0.71)	−1.70 (0.43)	<0.001
Weight change (kg), baseline-month 3[a]	−3.99 (0.49)	−6.08 (0.72)	−1.62 (0.43)	<0.001
BMI change (kg/m^2), baseline-month 3[a]	−1.36 (0.17)	−2.10 (0.25)	−0.53 (0.16)	<0.001
Percent who lost 5% of initial body weight[a]	39.80% (39)	57.69% (30)	19.57% (9)	<0.001
Self-monitoring adherence				
Days tracker worn, week 4-month 3	47.78 (1.33)	49.58 (1.48)	45.79 (2.25)	0.163
Days weighed, week 4-month 3	41.86 (1.63)	44.54 (2.07)	38.89 (2.51)	0.084
Days with complete calories, week 4-month 3	28.56 (2.07)	33.15 (2.62)	23.53 (3.13)	0.020
Days tracker worn, baseline–month 3	74.52 (1.53)	76.98 (2.66)	71.79 (2.66)	0.099
Days weighed, baseline–month 3	66.48 (2.06)	70.10 (2.61)	62.49 (3.19)	0.066
Days with complete calories, baseline–month 3	48.83 (2.79)	55.54 (3.40)	41.40 (4.29)	0.011
Study goal adherence				
Days under calorie goal, week 4-month 3	15.24 (1.28)	18.08 (1.79)	12.11 (1.74)	0.019
Days met active minutes goal, week 4-month 3	15.55 (1.31)	19.44 (2.01)	11.23 (1.41)	0.001
Days under calorie goal, baseline–month 3	25.57 (1.81)	30.08 (2.49)	20.57 (2.46)	0.008
Days met active minutes goal, baseline–month 3	29.07 (1.94)	35.65 (2.86)	21.79 (2.16)	<0.001
Intermediate outcomes				
Change in diet (kcal/day)[c]	−598.57 (87.81)	−644.6 (117.70)	−542.1 (133.00)	0.565
Change in physical activity (kcal/week)[d]	188.67 (210.47)	279.50 (357.20)	85.74 (198.20)	0.637

Note: All values are listed as Mean (SE), with the exception of the percentage who lost 5% of starting body weight, which is listed as %(n). The n for each column is indicated at the top, with exceptions noted with superscripts. The p-value indicates the significance of the t-test or Chi-square test comparing outcomes in Early Responders v. Early Non-Responders. All values represent 3-month outcomes, unless otherwise noted.

[a]For these analyses, n = 98 for All Participants and n = 46 for Early Non-Responders.

[b]For these analyses, n = 97 for All Participants and n = 45 for Early Non-Responders.

[c]For this analysis, n = 89 for All Participants, n = 49 for Early Responders, and n = 40 for Early Non-Responders.

[d]For these analyses, n = 96 for All Participants, n = 51 for Early Responders, and n = 45 for Early Non-Responders.

than early non-responders over the 3-month study and in the last 8 weeks.

3.4 | Exploratory analyses of outcomes, by human support received

Outcomes for each possible treatment sequence are presented in Table 3. Mean percent weight changes at 4 weeks and 3 months were similar in those initially randomized to Fully Automated (−2.22% (0.33), −4.57% (0.77)) and Human Enhanced (−2.10% (0.34), −4.06% (0.61)). There was a trend for a greater achievement of a 5% weight loss in Fully Automated (46.9%) than Human-Enhanced (32.7%), though the difference did not reach statistical significance. Otherwise, between-group differences in outcomes at 4 weeks and 3 months after first-line treatment were not clinically or statistically significant.

Mean percent weight changes at 3 months were −1.25% (0.59) in Check-In and −2.20% (0.62) in Counseling. The percentage of participants who achieved a 5% weight loss was 12.5% in Check-In and 27.27% in Counseling. No between-group differences in other outcomes, by second-line treatment, reached statistical significance. In exploratory analyses in both the sub-sample of early non-responders who received Check-In and the sub-sample who received Counseling, mean outcomes were similar among those who received Fully Automated and Human Enhanced.

TABLE 3 Main study outcomes by treatment sequence.

			Early non-responders (n = 47)			
	Responders (n = 52)		Check-in (n = 24)		Counseling (n = 23)	
	Human enhanced and app, alone (n = 26) (A)	Fully automated and app, alone (n = 26) (D)	Human enhanced and check-in (n = 12) (B)	Fully automated and check-in (n = 12) (E)	Human enhanced and counseling (n = 12) (C)	Fully automated and counseling (n = 11) (F)
Baseline to Week 4 (28 days)						
Percent weight change (%)	−3.78 (0.34)	−3.95 (0.31)	0.05 (0.37)[a]	−0.40 (0.24)	−0.42 (0.40)	−0.11 (0.37)
Weight change (kg)	−3.37 (0.31)	−3.55 (0.24)	0.01 (0.34)[a]	−0.37 (0.22)	−0.33 (0.43)	−0.16 (0.36)
Days tracker worn	27.27 (0.35)	27.54 (0.17)	26.67 (0.50)	29.92 (0.61)	24.50 (1.99)	25.91 (1.22)
Days weighed	26.38 (0.44)	24.73 (1.14)	23.75 (1.50)	22.92 (1.85)	22.50 (1.69)	25.36 (1.00)
Days with complete calories	24.12 (0.89)	20.65 (1.68)	19.17 (2.36)	19.75 (1.97)	14.33 (3.22)	18.27 (3.18)
Days under calorie goal	12.58 (1.10)	11.42 (1.38)	7.83 (1.31)	9.42 (1.71)	6.00 (1.67)	10.82 (2.61)
Days met active minutes goal	16.42 (1.30)	16.00 (1.59)	11.83 (1.87)	9.17 (2.29)	9.00 (2.03)	12.36 (1.97)
Week 4 to 3 Months (56 days)						
Percent weight change (%)	−2.41 (0.68)	−3.37 (1.13)	−1.43 (0.69)[a]	−1.04 (0.76)	−1.97 (0.67)[a]	−1.71 (0.90)
Weight change (kg)	−2.07 (0.59)	−3.18 (1.15)	−1.23 (0.64)[a]	−1.05 (0.82)	−1.99 (0.73)[a]	−1.50 (0.83)
Days tracker worn	48.96 (2.41)	50.19 (1.75)	44.08 (5.88)	45.25 (4.03)	46.92 (4.56)	47.00 (3.57)
Days weighed	44.77 (2.70)	44.31 (3.20)	39.33 (5.73)	38.83 (5.55)	33.75 (5.01)	44.09 (3.50)
Days with complete calories	32.73 (3.26)	33.58 (4.17)	20.67 (6.65)	25.83 (5.99)	21.92 (6.34)	25.91 (6.81)
Days under calorie goal	17.85 (2.15)	18.31 (2.90)	10.92 (3.37)	11.67 (3.32)	11.17 (3.50)	14.91 (4.08)
Days met active minutes goal	18.04 (2.74)	20.85 (2.96)	10.75 (2.98)	8.58 (1.62)	11.92 (3.30)	13.91 (3.28)
Baseline to 3 Months (84 days)						
Percent weight change (%)	−6.07 (0.87)	−7.19 (1.12)	−1.08 (0.76)	−1.42 (0.94)	−2.57 (0.84)[a]	−1.82 (0.95)
Weight change (kg)	−5.44 (0.81)	−6.72 (1.20)	−0.96 (0.70)	−1.42 (0.99)	−2.54 (0.94)[a]	−1.66 (0.86)
Percent who lost 5% of initial body weight	46.15% (12)	69.23% (18)	8.33% (1)	16.67% (2)	27.27% (3)	27.27% (3)
Days tracker worn	76.23 (2.68)	77.73 (1.81)	70.75 (6.29)	72.17 (4.42)	71.42 (6.33)	72.91 (4.43)
Days weighed	71.15 (3.05)	69.04 (4.29)	63.08 (6.96)	61.75 (7.29)	56.25 (6.48)	69.45 (4.30)
Days with complete calories	56.85 (3.94)	54.23 (5.60)	39.83 (8.58)	45.58 (7.76)	36.25 (9.21)	44.18 (9.66)

(Continues)

TABLE 3 (Continued)

	Responders (n = 52)		Early non-responders (n = 47)			
			Check-in (n = 24)		Counseling (n = 23)	
	Human enhanced and app, alone (n = 26) (A)	Fully automated and app, alone (n = 26) (D)	Human enhanced and check-in (n = 12) (B)	Fully automated and check-in (n = 12) (E)	Human enhanced and counseling (n = 12) (C)	Fully automated and counseling (n = 11) (F)
Days under calorie goal	30.42 (2.93)	29.73 (4.08)	18.75 (3.56)	21.08 (4.87)	17.17 (5.06)	25.73 (6.13)
Days met active minutes goal	34.46 (3.81)	36.85 (4.32)	22.58 (4.20)	17.75 (3.43)	20.92 (4.80)	26.27 (4.96)

Note: All values are listed as Mean (SE), with the exception of the percentage who lost 5% of starting body weight, which is listed as %(n). The letters listed next to each treatment sequence refer to the path depicted in Figure 1 and referenced in the text.

[a]n = 11 for this analysis.

4 | DISCUSSION

This pilot and feasibility study is a step toward creating optimized adaptive treatment sequences and a greater understanding of digital behavioral weight loss programs with or without human support. The findings support the feasibility of the SMART design and acceptability of the embedded treatments. Over 50% of participants achieved a 2% weight loss at 4 weeks through the use of a primarily automated smartphone intervention with integrated smart technologies and tailored messaging, with no differences in the rate of response in those who received a one-on-one session with a dietitian as a part of their study kick-off and those who did not. Early responders achieved a 6.6% weight loss from baseline to 3 months, on average, which was significantly more than early non-responders, who achieved less than a 2% weight loss on average. Mean weight loss was similar among early non-responders randomized to Check-In and Counseling, though there was a clinically meaningful difference in the percentage of participants who achieved a 5% weight loss, with more Counseling participants meeting this goal.

The study met all pre-specified acceptability and feasibility criteria. Study protocols allowed for objective assessment of early response in 99% of participants. The actual rate of early non-response (47.5%) was lower than expected (70%), which resulted in fewer participants in Counseling and Check-In; however, low attrition allowed for outcome data from at least 10 participants per subgroup, which was the goal stated in the power calculation. Overall program satisfaction was high, even among early non-responders (84%)—though only 20% of them achieved a 5% weight loss—and among those who received no human support (88%).

There were clear differences in proximal and distal outcomes between early responders and non-responders, which is in line with evidence that early response is related to treatment outcomes[5,14–16] and that differences in outcomes remain between early responders and non-responders after early non-responders are offered "rescue" or "stepped up" treatments.[18,51–53] Interventions provided to early responders had a maximum human support dose of 30 min, yet 57.7% of early responders lost 5% of their starting weight. Though the pilot SMART was not powered for these analyses, this provides a strong signal that low-burden automated approaches may be enough for some participants to achieve short-term weight outcomes, which is significant for intervention optimization efforts that aim to balance individual-level potency with population-level efficiency.

The study kick-off may be a target for optimization. There was no difference in weight outcomes at 4 weeks or 3 months between Fully Automated and Human Enhanced participants, and there was a trend for a greater achievement of a 5% weight loss in Fully Automated (46.9%) than Human-Enhanced (32.7%). This is notable given that Fully Automated participants who received a pre-recorded kick-off video received a lower dose of support than typically seen in digital behavioral weight loss interventions, which generally use in-person assessments and/or orientations to the study. The study design does not allow us to determine if the kick-off video itself had an effect on intermediate or end outcomes, but future research could explore whether these sessions are an active part of the intervention and whether human support in an intervention might unintentionally undermine autonomy or the long-term sustainability of behavior change.[23,28,35]

Individuals who did not achieve a 5% weight loss by study end should be the focus of future analyses. In this analysis, this group included 60% of the total sample (42% of early responders, 80% of early non-responders). In particular, there is a need for a greater understanding of rescue treatments, including human support. The difference in this study in the percentage of participants who achieved a 5% weight loss in Counseling (27%) and Check-In (12.5%) may be a signal of improved outcomes with greater doses of human support, and such a difference could be impactful on a population level. However, between-group differences in other outcomes were small and none reached statistical significance. It is possible that the different doses did not have a differential impact on weight outcomes, that neither second-line dose of human support was enough to impact outcomes since "gold standard" treatment proposes ≥14 sessions in 6 months,[3,7,8] that the counseling sessions did not target the correct behavioral mediators or have their intended effect, or

that variability in intervention uptake—including human and tech components—impacted findings.

This emerging evidence base suggests that some human support for early non-responders is better than no human support,[18,52] but has not clarified whether greater doses of human support will yield better outcomes. Notably, there has been variability in the type and timing of human support offered to early non-responders, which has ranged from acceptance-based therapy (started in week 3 or week 7),[53] to group sessions (started in week 15),[51] to 1 individual session and 2 follow-up calls (started in week 4).[18] More research is needed to better understand whether the human support is optimally targeting behaviors important for weight outcomes, and whether evidence-based behavioral strategies are equally effective in early non-responders as other participants in weight research. Evidence suggests greater heterogeneity and more barriers to weight loss in early non-responders[52] that are likely driving heterogeneity in outcomes. As more studies aim to rescue early non-responders, it may be beneficial to have clinically meaningful definitions for response—such as a 5% weight loss—and targets for rates of response to better determine the cost/benefit ratio of more resource-intensive, second- or third-line treatments.

Findings should be interpreted in the context of this pilot and feasibility study, which was not powered for between-group comparisons. It did not have a control group in the second-line treatment, which means we cannot conclude that the possible effects of Check-In or Counseling are different than what would be observed with no further intervention. Comparisons of early responders and non-responders may be additionally biased given that participants were not randomized to these groups, so groups could be different in observed and unobserved characteristics. The 3-month time frame is a limitation, especially since percent weight losses in the last 8 weeks were not significantly different in early responders and non-responders and longer-term studies have shown that average weight losses of responders may decrease over time.[53] Study generalizability is limited by its primarily female and well-educated sample. This is a consideration for future research as Facebook was used to reach a more diverse sample across North Carolina and recruitment of groups underrepresented in behavioral weight loss research was prioritized in later recruitment waves. Ensuring that recruitment materials and methods are appropriate for all populations could help strengthen the generalizability of a future, fully powered SMART.

Overall, this study helped establish the feasibility and acceptability of a two-stage pilot SMART and its embedded treatments. The difference in outcomes between early responders and non-responders highlights the heterogeneity in individuals and the treatments they may need to manage a disease with as complex an etiology as obesity. The study also provided some insight on human support as a target for intervention optimization, though more work is needed to understand optimal doses of human support in first- and second-line treatments.

AUTHOR CONTRIBUTIONS

All authors contributed to the study concept and design. CEM, BTN, and DFT provided study supervision. CEM analyzed the data. All authors were involved in writing the paper and had final approval of the submitted version.

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De-identified participants will be available upon request to the corresponding author in compliance with applicable privacy laws, data protection, and requirements for consent and anonymization. Proposals will be reviewed for scientific overlap and merit. Once the proposal has been approved, data can be transferred securely after the signing of a data access agreement. The study was partially funded by the Academy of Nutrition and Dietetics Foundation through the Amy Joye Memorial Research Grant.

CONFLICT OF INTEREST STATEMENT

All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: DFT is a member of the Scientific Advisory Board for WW and Wondr Health. The other authors declare no conflicts of interest.

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