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Preventing Weight Regain After Glucagon-Like Peptide-1 Therapy Discontinuation: A Pilot Randomized Controlled Trial

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ABSTRACT

Objective: Glucagon-like peptide-1 receptor agonists (GLP-1 RAs) are effective treatments for obesity, but discontinuation is common due to cost, insurance coverage limitations, side effects, patient preference, and other factors. Weight regain often occurs rapidly after cessation, yet few evidence-based strategies exist to support weight maintenance during this transition. This pilot randomized trial examined whether a digital wellness application or medically tailored meals (MTM) could mitigate weight gain during the first 4 months after GLP-1 cessation.

Methods: In this pilot randomized trial, adults with prior GLP-1-induced weight loss were randomized to usual care, wellness application, or MTM at the time of GLP-1 cessation. Surveys assessed adherence and satisfaction (primary outcome) as well as exploratory outcomes, diet quality, and perceived health. Weight (exploratory) was measured monthly using validated Bluetooth scales.

Results: Participants ($n = 39$) were randomized to control ($N = 14$), digital wellness application ($N = 12$), or MTM ($N = 13$) and had a mean baseline BMI 31.4 (SD 6.3) kg/m^2. Diet quality, perceived health, adherence, and satisfaction did not significantly differ by group, though some estimates suggested possible trends favoring the wellness application. Relative to control, both the wellness application and MTM groups had less total weight gain: Wellness application −7.16% (95% CI: −12.27, −2.04) and MTM −7.17% (−12.20, −2.14).

Conclusions: These findings suggest that structured support may attenuate early weight gain after GLP-1 cessation. Larger, more diverse trials with longer follow-up and clinical outcomes are needed to confirm results and clarify mechanisms.

1 | Introduction

Over 73% of US adults have overweight or obesity and 50%–70% are attempting to lose weight each year [1, 2]. GLP-1 receptor agonists have been approved for the treatment of type 2 diabetes since 2005, and several agents, including liraglutide and semaglutide, subsequently received regulatory approval for obesity management beginning in 2014, with demonstrated weight loss of 8%–17% depending on the medication type [3]. With the increased awareness of the drug class's effectiveness in healthcare and the popular media, demand and costs have skyrocketed, leading some insurers to halt coverage to people without T2D; as of 2025, only about 19% of the population is

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covered for weight loss [4]. This is problematic for patients losing coverage and those who could benefit, as after bariatric surgery, GLP1-s are among the most effective long-term weight maintenance strategies [3, 5].

Longitudinal studies show there is steep weight regain in the first 3–4 months after abrupt GLP-1 discontinuation and most patients regain at least half of their lost weight within a year of cessation [5, 6]. While treatment with GLP1s is an effective long-term weight management strategy and discontinuations are not recommended, payers question the utility of GLP-1 for weight management as they are hesitant to cover costs long-term. Additionally, many patients would also prefer not to take medications in perpetuity and may struggle with lifelong adherence due to adverse side effects, high out-of-pocket costs, or having reached one's goal weight [7, 8]; this is highlighted by analyses showing that 20%–50% of patients discontinue a GLP-1 within a year of starting the medication. These challenges present an opportunity to test interventions, such as meal replacements and lifestyle behavioral programs, to support weight maintenance *after* successful weight loss with GLP-1 [9].

Long-term weight maintenance is influenced by interacting physiological, behavioral, social, and environmental factors. Weight loss induces compensatory biological adaptations that increase hunger and decrease satiety and energy expenditure, while environmental food cues, access to healthy foods, and self-management behaviors also contribute substantially to weight regain risk [10]. Meal replacements and lifestyle behavior change programs have a clinically meaningful effect on weight loss, are cheaper than GLP-1s, and have a long history of supporting patients' weight management efforts [11].

Medically tailored meals (MTM) are a form of meal replacement. MTMs are nutrient-dense dietitian-developed prepared meals provided to patients with chronic diseases (e.g., uncontrolled diabetes, chronic kidney disease) that can be positively impacted by nutrition intervention. Although MTM were initially developed for people with complex diet-related chronic diseases, their underlying principles of structured nutrition support and reduced food-preparation burden may also be relevant for obesity treatment and weight-loss maintenance, and are similar to meal replacement programs, which have benefited patients with obesity for decades [11]. Patients are typically prescribed 10 home-delivered MTM per week as meal replacement (~$372 per person per month). No researchers have tested MTM for weight maintenance, but MTM has been shown to produce a marginal effect on weight loss, weight maintenance, and improve diet quality and A1C, in people with obesity and/or T2D [12, 13].

Noom is a subscription digital wellness application that translates behavioral science principles into a tailored weight management plan that helps patients manage internal and external cues to overeating, encourages healthier choices, and provides access to several physical and mental wellbeing activities (e.g., exercises, meditation). There are several peer-reviewed articles published on the effectiveness of Noom [14–22], including one longitudinal study that found −5.2% weight loss was maintained at 52-month follow-up [21] and another that found 57% of weight loss was maintained after 2 years [23]. Noom and other digital wellness applications typically cost ~$17–70/month, which may result in cost savings if this strategy proves effective. To our knowledge, no studies have tested these strategies for helping people maintain weight loss after ending GLP-1s or compared them to each other. The interventions were selected because they address complementary mechanisms associated with post-weight-loss maintenance. The digital wellness application focuses on self-monitoring, behavior change skills, and management of social and environmental eating cues, whereas MTM modifies the food environment by reducing the meal planning burden and increasing access to portion-controlled, nutrient-dense meals. These approaches target behavioral and environmental factors that may interact with physiological drivers of post-discontinuation weight regain.

The purpose of this study was to compare adherence to and satisfaction with two weight management strategies, one using the digital wellness application (intervention 1) and one using MTM (intervention 2), versus usual care during the first 4 months after cessation of GLP-1 RA treatment (primary outcomes). Secondary outcomes included diet quality and percentage weight loss maintained across groups.

2 | Methods

2.1 | Study Design

This study was conducted from 3/2024 to 8/2025. This was a randomized, controlled, fully remote pilot trial with participants ($N = 39$) randomized to receive 4 months of usual care (control, $n = 14$), a monthly digital wellness application subscription (intervention 1, $n = 12$), or medically tailored meals (MTM) (intervention 2, $n = 13$). All participants completed questionnaires pre- and post-intervention (beginning of Month 1, end of Month 4) and used a Bluetooth scale to weigh-in from home pre-intervention and every 30 days thereafter until study end. This study was reviewed and approved by the University of Texas Southwestern Medical Center Human Research Protection Program (STU-2023-1168).

2.2 | Recruitment and Screening

Participants were recruited through obesity medicine clinics in Dallas and El Paso, Texas and StudyFinder, a web-based platform used by universities and health systems to connect people with local studies that meet their chronic condition criteria. Eligibility was assessed using the electronic health record (EHR) when data were available through the University of Texas system and/or a brief REDCap questionnaire. *Inclusion criteria were*: (1) Age 18 or older; (2) ability to read, write, and speak English; (3) ability to provide informed consent; (4) greater than 10% GLP-1 induced weight loss; (5) less than 30 days since GLP-1 cessation; and (6) willingness to participate. *Exclusion criteria were*: (1) major psychiatric illness or substance use disorder that could impair ability to participate; (2) presence of a medical condition or dietary restriction precluding eating study meals or weight loss (e.g., medical condition requiring liquid diet, pregnancy, eating disorder); (3) participation in a study or program involving MTM or Noom within the previous 12 months.

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2.3 | Procedures

The study was conducted remotely. At the initial remote encounter, participants met with a study team member to verify information provided in the eligibility screener and completed a virtual consent and baseline questionnaire in REDCap prior to randomization. All participants were mailed a FitBit Aria 2 Bluetooth scale for weight measurement. After completing baseline questionnaires and weight measurement, participants were randomized using random number generation with equal group allocation in Microsoft Excel. The file was uploaded into REDCap by a team member uninvolved in enrollment or data collection. The team was unaware of the assignment until the participant consented and REDCap indicated the assignment. Complete masking was infeasible given the nature of the interventions: the study team and participants knew if the participant received MTM, a wellness application subscription, or usual care. The outcome assessor was masked to the group until the analyses were completed. Once groups were assigned, the team set up a virtual meeting with the participant using the participants' preferred video conferencing platform. During this meeting, the team assisted the participant with creating a profile on the MTM website and placing their first order or downloading the digital wellness application and creating a profile. At the end of month four (post-intervention), participants were sent the follow-up questionnaire by email or text. Participants were requested to weigh-in using the Bluetooth scale at least monthly. Upon completion of follow-up, participants were mailed a ClinCard MasterCard with a $40 USD balance as remuneration.

2.4 | Intervention Descriptions

2.4.1 | *Usual Care (Control) Group*

Usual care for weight loss maintenance is highly variable and may include nutrition, exercise, and lifestyle counseling. Implementation depends on the healthcare provider's resources and in some cases may include 1–2 office or remote visits with a clinician or registered dietitian. In this study "usual care" was left to each provider's discretion. Participants randomized to "usual care" received no specific intervention from the study team and care was any care performed according to clinical standards in their respective referring practice, consistent with typical variability in usual patient care.

2.4.2 | *Digital Wellness Application Intervention*

Noom is a digital application that provides evidence-based behavioral strategies for weight loss and maintenance, such as self-monitoring of diet, exercise, and weight. The application provides education on the physiological, psychological, social, and environmental factors that influence eating behavior and tools that increase self-efficacy for dealing with those stimuli. For example, there are in-app lessons that define social triggers, explain the influence triggers have on motivation to eat, and ask the user to identify their own triggers and a plan for managing triggers should they come up. The app then prompts users to report back on how they managed or struggled to manage a trigger and respond accordingly. Participants were prescribed to use the application for at least 15 min per day, according to the manufacturer's recommendations, time that included interactive lessons, food logging, and weigh-ins.

2.4.3 | *Medically Tailored Meals (MTM) Intervention*

MTM are nutrient-dense, dietitian-developed meals provided to patients with diet-related diseases (e.g., uncontrolled type 2 diabetes, chronic kidney disease). Participants in the MTM group selected 10 of their preferred "weight wellness" meals per week (40 meals per month) from a list of over 70 meals with a variety of flavors and ingredients available on RFoodX's website [24]. Selected meals were delivered to their homes for 4 months. Most meals have at least two servings of vegetables and all meals have fewer calories (breakfast 130–310 kcal, lunch/dinner: 160–460 kcal), and lower saturated fat (breakfast 0–5 g, lunch/dinner: 1–7 g), sodium (breakfast 330–620 mg, lunch/dinner: 80–600 mg) and comparable or lower sugar (breakfast 2–10 g, lunch/dinner: 4–11 g) than conventional prepared meals [25, 26]. Intervention costs, including Noom subscriptions, medically tailored meals and associated delivery costs, were covered by study funds and provided at no cost to participants.

2.5 | Measures

Weight was measured at least monthly using a FitBit Aria 2 Bluetooth scale pre- and post-intervention to calculate the percentage of body weight change (current weight − original weight/original weight × 100). Data were electronically transmitted and acquired through Fitabase. Participants were instructed to weigh themselves monthly and received a text, email, or call reminder from the study team to do so; however, weigh-in frequency varied by participant (some participants weighed themselves more often, while some forgot or skipped some months entirely). When multiple measures of weight were taken on the same day, a participant's first weight of the day was chosen for analysis. The analytic baseline weight was defined as the first weight measurement after consent; Month 1, 2, 3, and 4 target dates were defined as 30, 60, 90, and 120 days after the analytic baseline, respectively. For each target date, the closest available weight within ± 15 days was assigned to that month.

Participants completed study-specific questionnaires at baseline and at the end of the study using REDCap via their preferred device. The questionnaire included demographics as well as the Mini-EAT (eating assessment tool), which is a brief, validated 9-item dietary screener that assesses overall diet quality by capturing usual intake patterns across key food groups, including fruits, vegetables, whole and refined grains, fish, legumes, dairy, and sweets. It has demonstrated strong validity and reliability, showing agreement with Healthy Eating Index (HEI-2015) scores ($r \approx 0.71$) when compared with a comprehensive food frequency questionnaire and maintaining consistent predictive performance after item reduction and cross-validation [27].

A single item on perceived health quality (PHQ) was used as a concise and validated measure of overall health status, capturing a broad construct that reflects physical, mental, and functional health. Similarly, a single item on perceived diet quality (PDQ) was used to offer a low burden, global assessment of dietary patterns as it has demonstrated construct validity through

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associations with dietary behaviors and cardiometabolic health outcomes [28, 29].

Adherence was measured in the control group (e.g., adherence to provider recommendations) and the intervention groups (e.g., 15-min application use per day, 10 MTM per week) using the Perceived Behavior subscale (6-items) from the validated Treatment Adherence Perception Questionnaire (TAPQ, e.g., "How often did you forget to do one of your recommended actions?" with response options "I did not follow any recommended actions" [0%] to "I perfectly followed all recommended actions" [100%]) [30]. Additionally, participants in the MTM group were asked, "How many medically tailored meals (MTM) did you eat each week, on average?" with an open-ended response option with numeric validation and participants in the digital wellness application group were asked, "How many days per week, on average, did you use the Noom application?" with a dropdown response option ranging from zero to seven. Satisfaction was measured using the Treatment Satisfaction Questionnaire for Medication, which was adapted to capture satisfaction with usual care and the interventions understudy. For example, "How satisfied or dissatisfied are you with the medication to prevent or treat your condition?" it was changed to, "How satisfied or dissatisfied are you with using [MTM/Noom/your current efforts]?" [31, 32].

2.6 | Statistical Analysis

Consistent with recommendations for pilot trials, the study was designed to estimate intervention effects and assess feasibility outcomes rather than provide definitive tests of efficacy. The sample size was determined by available funding and recruitment capacity and was not powered to detect small-to-moderate between-group differences. This was an exploratory pilot randomized controlled trial; analyses emphasized model-based effect estimates with 95% confidence intervals (CI). Descriptive statistics (e.g., means, percentages) were used to summarize baseline characteristics by randomized trial arm.

For the three outcomes collected at baseline and follow-up (Mini-EAT, PDQ, PHQ scores), each was analyzed using a baseline-adjusted linear regression (ANCOVA) model with the follow-up score as the dependent variable, randomized trial arm as the primary independent variable, and the corresponding baseline score included as a covariate.

The single measure (follow-up only) of both TAPQ Perceived Behavior and TSQM domain (separately: Global Satisfaction, Convenience, Effectiveness) scores were analyzed using a linear regression model with randomized trial arm as a three-level predictor. Because only two participants reported any side effects, the TSQM Side Effects domain was summarized descriptively and not modeled inferentially.

Percent weight change at each follow-up timepoint was calculated relative to baseline weight. Participants with an observed baseline weight and at least one observed post-baseline weight were included to leverage all available data; non-missing percent weight change measures were analyzed using a linear mixed-effects regression with fixed effects for randomized arm, time (month since baseline), a randomization arm-by-time interaction, and a participant-level random intercept to account for within-person repeated measure correlation. Model-based arm means and arm-versus-control contrasts were estimated at each observed follow-up month. Total weight change was defined as the model-estimated percent weight change at Month 4 relative to baseline. Monthly weight change slopes and slope contrasts were estimated from the same mixed-effects model. Complete-case analyses were included as a sensitivity test.

Analyses were conducted in R v4.5.2 using the emmeans package for adjusted estimates and contrasts; lme4 and lmerTest for mixed-effects modeling. Significance was assessed through nominal p values with a threshold of $p < 0.05$.

3 | Results

3.1 | Participant Characteristics

Overall, 39 people were randomized to control ($N = 14$), digital wellness application ($N = 12$), or MTM ($N = 13$) and 34 participants completed a final study weigh-in (see Figure 1 for a CONSORT diagram). All participants were within 30 days of stopping GLP-1 medication. At baseline, participants had a mean (SD) age of 49.9 (11.8) years, mean weight of 85.7 (17.5) kg, mean BMI of 31.4 (6.3) kg/m^2, and a mean weight loss on GLP-1 medication of 18.1% (6.7). Participants identified as female (82.1%), 31.6% as African American or Black, 5.3% as Asian, 20.5% as Hispanic or Latino(a), 5.3% as Multiethnic or more than one race, and 57.9% as White. Most participants were employed in full- or part-time work (71.1%) and had a college degree or higher (69.2%). Several participants were retired (15.8%), unemployed and looking for work (7.9%), or homemakers (5.3%). Among those who reported income, all resided in a household with an annual income $\geq$ \$30,000 (100%). Further details can be found in Table 1. No adverse events or harms were reported.

3.2 | Treatment Perceptions and Satisfaction

Follow-up TAPQ perceived behavior scores did not significantly differ between intervention arms and control. Mean TAPQ scores were 53.9 for control, 35.7 for the digital wellness application, and 49.9 for MTM; compared with control, the estimated difference was −18.2 points for the digital wellness application (95% CI: −40.6 to 4.3, $p = 0.11$) and −3.9 points for MTM (95% CI: −25.5 to 17.6, $p = 0.71$). Treatment satisfaction scores also did not significantly differ by intervention arm across TSQM effectiveness, convenience, or global satisfaction domains. Across these domains, all digital wellness applications and MTM versus control confidence intervals crossed the null (Table 2 and Figure 2). Furthermore, participants receiving medically tailored meals (MTM) reported consuming an average of 8.08 meals per week (SD = 3.37). Participants assigned to the digital behavioral app reported using the app an average of 2.80 days per week (SD = 1.99).

3.3 | Body-Weight Change

Weight gain differed by intervention arm over follow-up. In the mixed-effects regression model, participants in the control group gained an estimated 10.75% (95% CI: 7.03–14.47) body

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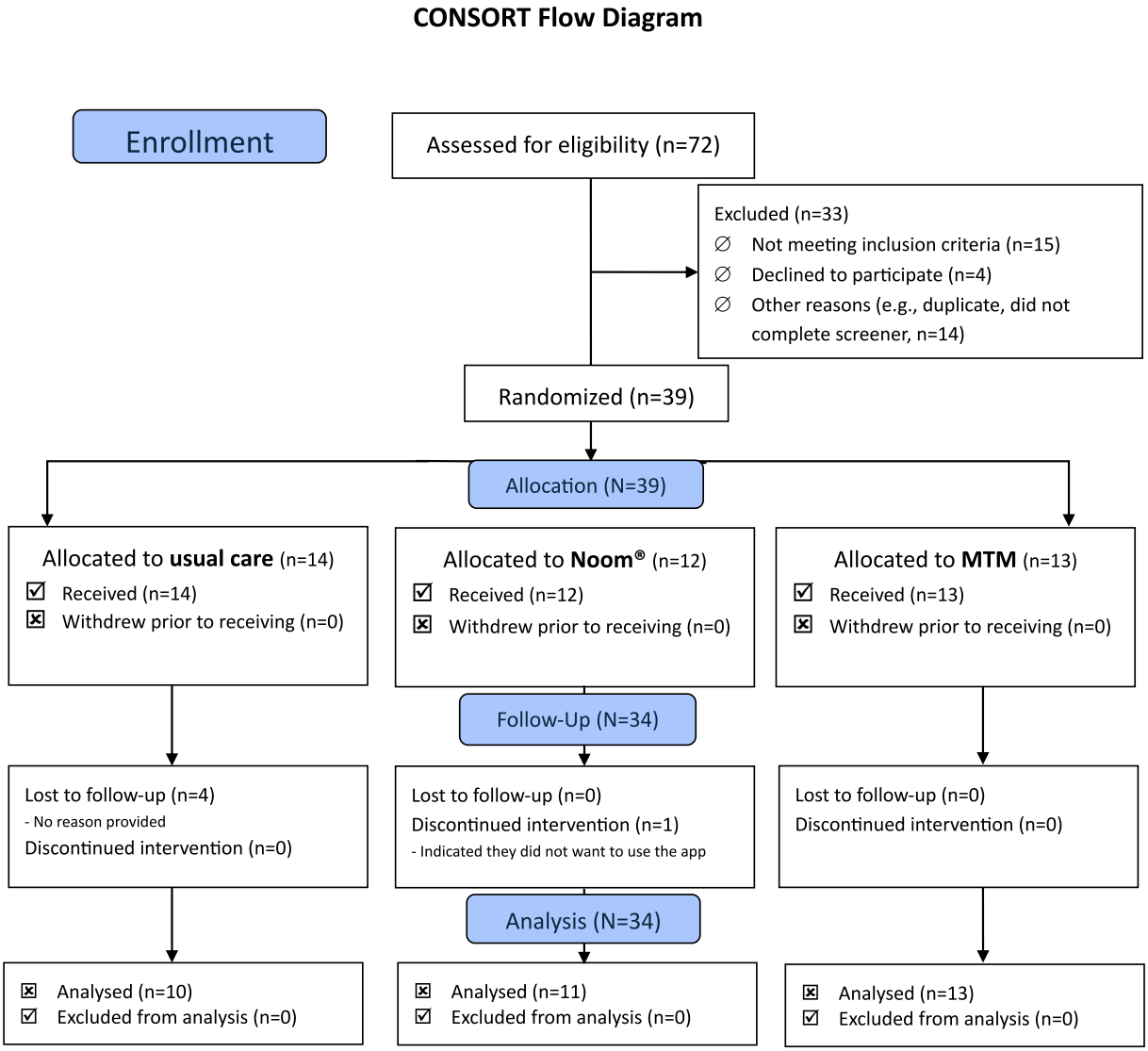


FIGURE 1 | CONSORT flow diagram.

weight, compared with 3.60% (95% CI: 0.08–7.11) in the wellness application group and 3.58% (95% CI: 0.19–6.96) in the MTM group. Relative to control, both intervention groups were associated with lower total weight gain (wellness application: −7.16%, 95% CI: −12.27 to −2.04, $p = 0.007$; MTM: −7.17%, 95% CI: −12.20 to −2.14, $p = 0.006$). Monthly weight gain also differed. The control group gained 2.94% per month (95% CI: 1.82–4.07), compared with 0.42% per month (95% CI: −0.61 to 1.45) in the wellness application group and 0.61% per month (95% CI: −0.50 to 1.71) in the MTM group. Relative to control, both wellness application and MTM were associated with significantly attenuated weight gain: digital wellness application −2.52% per month (95% CI: −4.05 to −1.00, $p = 0.002$) and MTM −2.34% per month (95% CI: −3.91 to −0.76, $p = 0.004$) (Table 2 and Figure 3).

In sensitivity analysis restricted to participants with complete pre-randomization GLP-1 weight-loss data, adjustment for percent weight lost while on GLP-1 and baseline weight slightly attenuated the estimated total weight gain differences, but both intervention contrasts remained statistically significant (wellness application vs. control: −5.83%, 95% CI: −10.64 to −1.02, $p = 0.019$; MTM vs. control: −6.29%, 95% CI: −11.02 to −1.55, $p = 0.010$). Monthly gain estimates remained consistent with the primary model with slight increases in the magnitudes of effect (wellness application vs. control: −2.58% per month, 95% CI: −4.16 to −1.01, $p = 0.002$; MTM vs. control: −2.81% per month, 95% CI: −4.39 to −1.22, $p < 0.001$) (Table S1).

3.4 | Diet Quality and Perceived Health

Baseline-adjusted follow-up Mini-EAT scores did not significantly differ between intervention arms and control. Adjusted mean Mini-EAT scores were 62.9 for control, 66.8 for wellness application, and 63.9 for MTM. Compared with control, the adjusted difference was 3.9 points for the wellness application (95% CI: −1.7 to 9.5, $p = 0.17$) and 1.0 point for MTM (95% CI: −4.3 to 6.3, $p = 0.71$).

Perceived diet and health quality also did not significantly differ by intervention arm. For PDQ, adjusted mean scores were 2.87 for control, 2.87 for the wellness application, and 3.31 for MTM,

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TABLE 1 | Baseline characteristics by randomized arm in the GLP-1 RA cessation support pilot trial.

Characteristic	Control (n = 14)	Noom (n = 12)	MTM (n = 13)	Total (N = 39)
Demographic and household characteristics				
Age, y	49.9 (11.0)	51.8 (11.1)	48.3 (14.0)	49.9 (11.9)
Sex				
Female	14 (100.0%)	7 (58.3%)	11 (84.6%)	32 (82.1%)
Male	0 (0.0%)	5 (41.7%)	2 (15.4%)	7 (17.9%)
Race/ethnicity				
White race	7 (53.8%)	6 (50.0%)	9 (69.2%)	22 (57.9%)
African American or Black race	5 (38.5%)	4 (33.3%)	3 (23.1%)	12 (31.6%)
Hispanic/Latino ethnicity	3 (21.4%)	2 (16.7%)	3 (23.1%)	8 (20.5%)
Asian race	0 (0.0%)	2 (16.7%)	0 (0.0%)	2 (5.3%)
Multiethnic or more than one race	1 (7.7%)	0 (0.0%)	1 (7.7%)	2 (5.3%)
Employment				
Employed (full-time or part-time)	11 (78.6%)	7 (58.3%)	9 (75.0%)	27 (71.1%)
Unemployed	1 (7.1%)	2 (16.7%)	0 (0.0%)	3 (7.9%)
Receiving disability payments	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Retired	2 (14.3%)	2 (16.7%)	2 (16.7%)	6 (15.8%)
Homemaker	0 (0.0%)	1 (8.3%)	1 (8.3%)	2 (5.3%)
College graduate or higher	7 (50.0%)	11 (91.7%)	9 (69.2%)	27 (69.2%)
Household income $\geq$ $30,000	12 (100.0%)	12 (100.0%)	11 (100.0%)	35 (100.0%)
Always had health insurance or medical coverage	13 (92.9%)	10 (83.3%)	12 (92.3%)	35 (89.7%)
Forgone medical care in past 2 years	4 (28.6%)	3 (25.0%)	3 (23.1%)	10 (25.6%)
Children in household	10 (71.4%)	7 (58.3%)	6 (46.2%)	23 (59.0%)
Household size, no.	3.1 (1.4)	2.9 (1.2)	2.2 (0.9)	2.8 (1.2)
Baseline clinical and questionnaire measures				
Weight, kg	76.5 (15.9)	91.4 (15.3)	87.9 (18.8)	85.7 (17.5)
Weight loss while on GLP-1, %	21.2 (8.5)	17.7 (5.1)	15.6 (5.4)	18.1 (6.7)
BMI, kg/m^2	28.8 (5.1)	32.0 (6.8)	33.0 (6.4)	31.4 (6.2)
Type of GLP-1 RA prior to study				
Cagrilintide and semaglutide	4 (28.6%)	4 (28.6%)	6 (42.9%)	14 (35.9%)
Semaglutide	8 (42.1%)	7 (36.8%)	4 (21.1%)	19 (48.7%)
Tirzepatide	1 (25.0%)	0 (0.0%)	3 (75.0%)	4 (10.3%)
Unknown	1 (50.0%)	1 (50.0%)	0 (0.0%)	2 (5.1%)
Mini-EAT score	62.5 (6.2)	62.7 (8.3)	61.2 (8.7)	62.1 (7.6)
PDQ (1 = excellent, 5 = poor)	3.2 (0.6)	3.2 (0.8)	3.2 (0.6)	3.2 (0.6)
PHQ (1 = excellent, 5 = poor)	3.4 (0.5)	2.6 (0.7)	3.2 (0.7)	3.1 (0.7)

Note: Values are mean (SD) for continuous variables and n (%) for categorical variables. Percentages use non-missing denominators; "prefer not to answer" responses were treated as missing.
Abbreviations: BMI, body mass index; GLP-1, glucagon-like peptide-1 receptor agonist; Mini-EAT, Mini-Eating Assessment Tool; MTM, medically tailored meal; PDQ, perceived diet quality; PHQ, perceived health quality.

with adjusted differences versus control of −0.01 for the wellness application (95% CI: −0.61 to 0.59, p = 0.98) and 0.43 for MTM (95% CI: −0.14 to 1.00, p = 0.13). For PHQ, adjusted mean scores were 2.65 for control, 2.77 for the wellness application, and 2.85 for MTM, with adjusted differences versus control of 0.12 for the wellness application (95% CI: −0.50 to 0.73, p = 0.71) and 0.20 for MTM (95% CI: −0.32 to 0.72, p = 0.45) (Table 2 and Figure 2).

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TABLE 2 | Model-based adjusted estimates for exploratory outcomes by randomized arm in the GLP-1 RA cessation support pilot trial.

Outcome	Control estimate (95% CI)	Noom estimate (95% CI)	MTM estimate (95% CI)	Noom versus control difference (95% CI)	*p*	MTM versus control difference (95% CI)	*p*
Baseline-adjusted follow-up outcomes							
Mini-EAT score	62.9 (59.1 to 66.7)	66.8 (62.7 to 70.8)	63.9 (60.2 to 67.5)	3.9 (−1.7 to 9.5)	0.17	1.0 (−4.3 to 6.3)	0.71
PDQ (lower = better)	2.87 (2.46 to 3.29)	2.87 (2.43 to 3.30)	3.31 (2.91 to 3.70)	−0.01 (−0.61 to 0.59)	0.98	0.43 (−0.14 to 1.00)	0.13
PHQ (lower = better)	2.65 (2.26 to 3.04)	2.77 (2.32 to 3.21)	2.85 (2.48 to 3.22)	0.12 (−0.50 to 0.73)	0.71	0.20 (−0.32 to 0.72)	0.45
Follow-up-only outcomes							
TAPQ perceived behavior, 0–100	53.9 (37.0 to 70.7)	35.7 (20.8 to 50.5)	49.9 (36.5 to 63.4)	−18.2 (40.6 to 4.3)	0.11	−3.9 (−25.5 to 17.6)	0.71
TSQM effectiveness, 0–100	47.0 (34.7 to 59.2)	55.0 (42.2 to 67.8)	41.7 (29.9 to 53.4)	8.0 (−9.7 to 25.8)	0.36	−5.3 (−22.3 to 11.7)	0.53
TSQM convenience, 0–100	55.1 (41.1 to 69.0)	60.0 (45.4 to 74.6)	60.6 (47.3 to 74.0)	4.9 (−15.3 to 25.2)	0.62	5.6 (−13.7 to 24.9)	0.56
TSQM global satisfaction, 0–100	56.1 (41.4 to 70.7)	59.2 (43.8 to 74.5)	45.1 (31.1 to 59.2)	3.1 (−18.1 to 24.3)	0.77	−10.9 (−31.2 to 9.3)	0.28
Longitudinal weight outcome							
Weight change total, %	**10.75 (7.03 to 14.47)**	**3.60 (0.08 to 7.11)**	**3.58 (0.19 to 6.96)**	**−7.16 (−12.27 to −2.04)**	**0.007**	**−7.17 (−12.20 to −2.14)**	**0.006**
Weight change slope, %/month	**2.94 (1.82 to 4.07)**	**0.42 (−0.61 to 1.45)**	**0.61 (−0.50 to 1.71)**	**−2.52 (−4.05 to −1.00)**	**0.002**	**−2.34 (−3.91 to −0.76)**	**0.004**

Note: Values are model-estimated follow-up means with 95% CIs. Bolded values are statistically significant. Mini-EAT, PDQ, and PHQ were analyzed using baseline-adjusted linear regression; TAPQ and TSQM domains were analyzed using (follow-up-only) linear regression. Weight outcome is reported as monthly percent weight-change slopes from a linear mixed-effects model with randomized arm, month since baseline, and arm-by-month interaction; contrasts are slope differences versus control. Higher values indicate more favorable Mini-EAT, TAPQ, and TSQM scores; lower PDQ and PHQ values are better; a lower weight-change slope indicates less gain. TSQM side-effects scores were not modeled because only two participants reported side effects.

Abbreviations: CI, confidence interval; GLP-1, glucagon-like peptide-1 receptor agonist; Mini-EAT, Mini-Eating Assessment Tool; MTM, medically tailored meal; PDQ, perceived diet quality; PHQ, perceived health quality; TAPQ, Treatment Adherence Perception Questionnaire; TSQM, Treatment Satisfaction Questionnaire for Medication.

4 | Discussion

In the first randomized pilot trial to test medically tailored meals (MTM) and a digital wellness application for weight maintenance after GLP-1 cessation, both the wellness application and MTM interventions were associated with slower weight gain after GLP-1 cessation compared with usual care. Over 4 months, participants in the control group gained an estimated 10.75% body weight, whereas gain was markedly lower in the wellness application (3.60%) and MTM (3.58%) groups. The trajectory of weight gain also differed between groups in mixed-effects regression modeling; the control group gained an estimated 2.94% of body weight per month, with slower rates in the wellness application (0.42% per month) and MTM (0.61% per month) groups. Sensitivity analyses adjusting for pre-randomization weight loss while on GLP-1 and baseline weight slightly attenuated total weight gain contrasts, but both the wellness application and MTM remained statistically significantly associated with less weight gain than control. Monthly weight-change slope differences remained consistent with the primary analysis in both intervention groups. These findings suggest that structured non-pharmacologic support may help buffer the physiological and behavioral pressures that drive weight gain after GLP-1 cessation. Even a modest slowing in gain could be helpful given that the early post-cessation window is a critical period for intervention. This finding suggests that the weight gain expected after stopping GLP-1 RA may be attenuated with concerted nutritional and/or behavioral support.

Statistically significant differences in diet quality or perceived health across the groups were not observed. The diet quality estimates (e.g., Mini-EAT scores) for the wellness application group were numerically higher than the control and MTM groups, suggesting a trend toward better dietary composition. However, the confidence intervals were wide and crossed the null. These results are hypothesis generating. It is also possible that behavioral changes take longer to register in self-report

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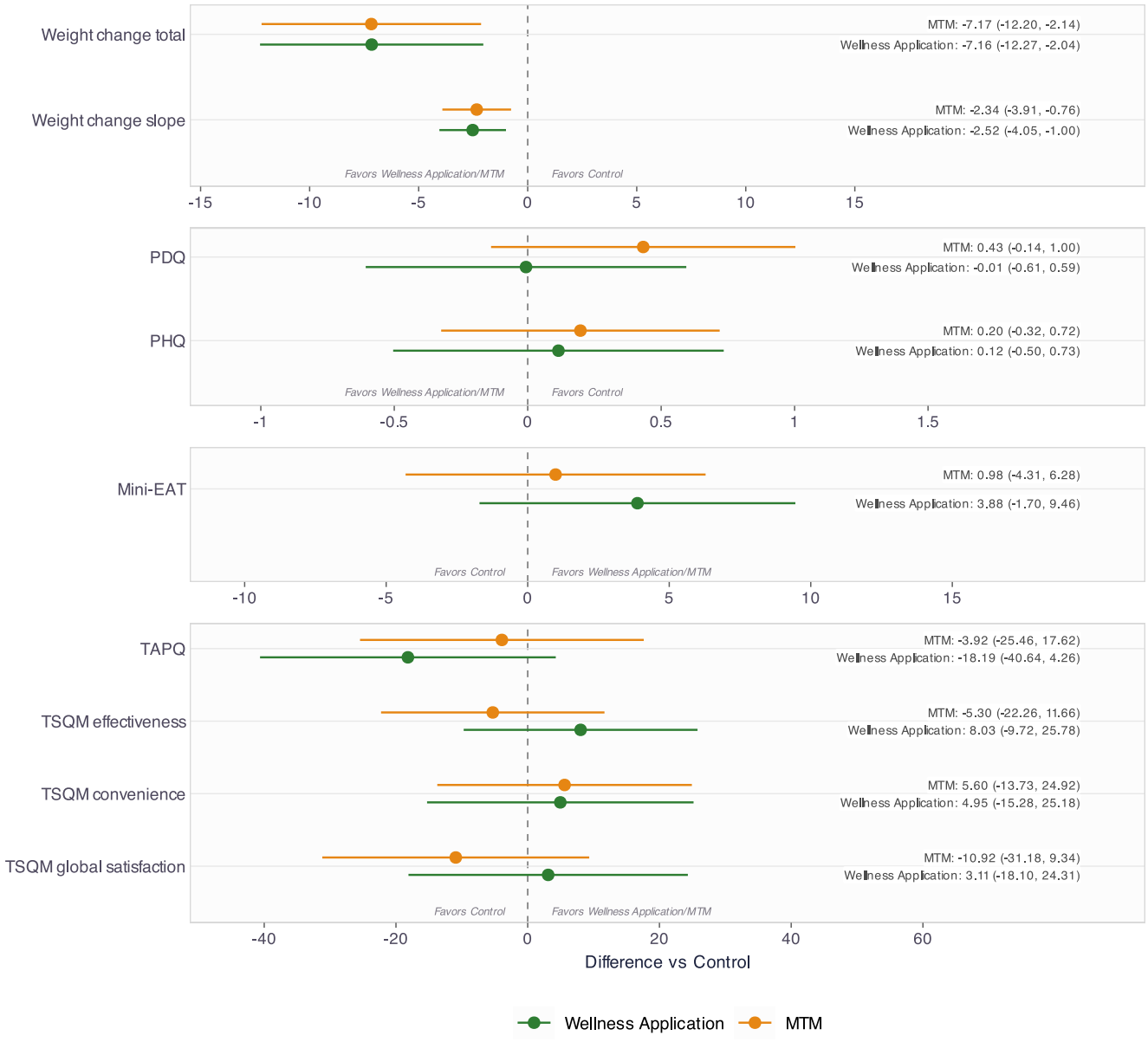


FIGURE 2 | Model-based contrasts versus control for weight and exploratory outcomes. Points show Noom-versus-control and MTM-versus-control estimates; horizontal bars show 95% CIs. For weight, estimates are differences in monthly percentage weight-change slopes. For Mini-EAT, PDQ, and PHQ, estimates are baseline-adjusted follow-up differences. For the TAPQ and TSQM domains, estimates are "follow-up-only" differences. CI, confidence interval; Mini-EAT, Mini-Eating Assessment Tool; MTM, medically tailored meal; PDQ, perceived diet quality; PHQ, perceived health quality; TAPQ, Treatment Adherence Perception Questionnaire; TSQM, Treatment Satisfaction Questionnaire for Medication.

tools, require larger sample sizes to yield significant effects, or that the measures used did not fully capture relevant changes.

A similar pattern emerged for perceived behavior and treatment satisfaction, with no clear differences by arm. The wellness application group showed numerically lower perceived adherence than the control group, but there was substantial uncertainty with wide CIs; however, this contrast is notable given the stronger weight-related findings in that group and it may reflect the different demands of the intervention. The wellness application asks users to engage daily, track behaviors, and reflect on habits, which has been associated with weight loss and maintenance in prior studies [16, 23, 33]. This requires effort and consistency. In contrast, MTM reduces effort. MTM are pre-prepared, portions are set, and decisions are simplified. The wellness application (Noom) approach asks participants to build skills within their environment, while MTM changes the environment itself. These differences may shape both experience and effect. Some participants may benefit more from MTM's structure and reduced time burdens, while others benefit more from building self-regulation skills. In a recent survey of US adults, 82.7% of respondents expressed interest in alternative, lower-cost weight management strategies to support discontinuing GLP-1s, of which MTM and nutrition support programs were identified as particularly important [34]. Though the cost-effectiveness of MTM use for obesity has yet to be

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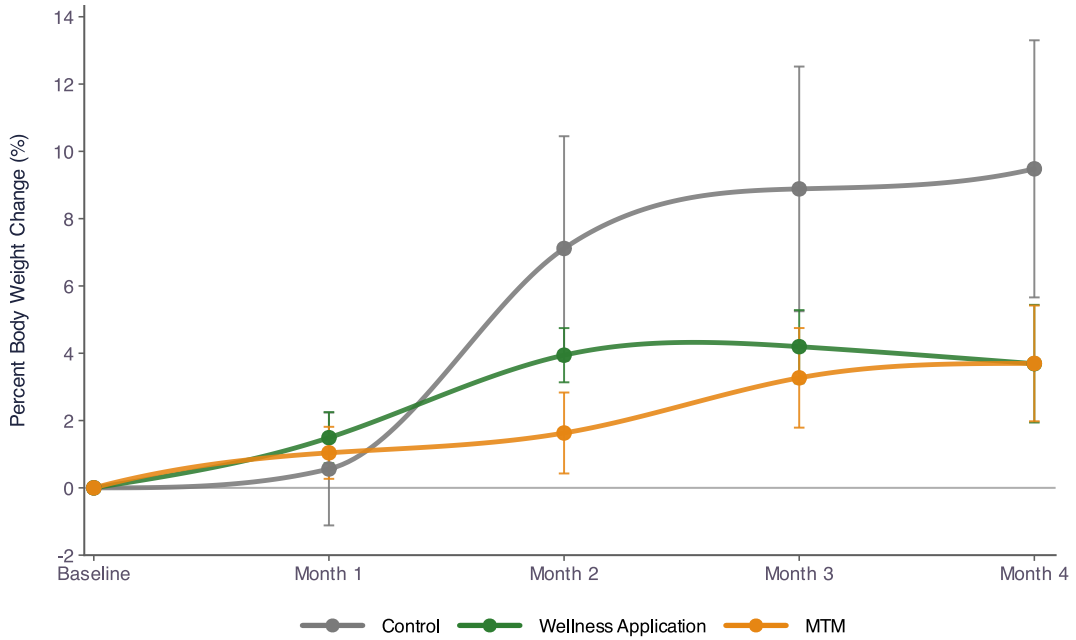


FIGURE 3 | Percent body weight change trajectories by randomized arm. Points show observed arm-specific mean percent body weight change among participants with baseline weight and ≥ 1 post-baseline weight measurement. Error bars represent $\pm$ 1 standard error. Curves interpolate observed arm means for visualization.

assessed, preliminary evaluations of healthcare costs for the wellness application demonstrated a potential cost savings of $1219.06 per user after 2 years [35]. Future trials could test how these pathways influence adherence, satisfaction, healthcare utilization, cost, and outcomes both independently and in combination.

The divergence between weight outcomes and questionnaire data raises important questions. Clinical changes may emerge before participants perceive or report shifts in diet or health. Objective measures, collected repeatedly, may be more sensitive to early changes than self-reporting. Questionnaires are also subject to reporting bias, scale limitations, and variable interpretation. It is also possible that these interventions influence weight through mechanisms that are not well captured by the instruments used here. These findings point to the value of including objective clinical measures in future studies. Biomarkers such as HbA1c, lipids, and blood pressure may provide a more complete picture of dietary and physiological changes. Measures of body composition or waist circumference could also add insight into how these interventions affect fat distribution and metabolic risk, beyond changes in overall weight. Longer follow-up may help clarify whether perceived changes eventually align with clinical trends.

Strengths of this study include its status as, to our knowledge, the first randomized trial to evaluate MTM or a commercial digital wellness application specifically for weight maintenance after GLP-1 cessation, addressing a timely and clinically relevant gap. Additional strengths are its randomized design, preregistration, and use of objective, repeated measures of body weight transmitted via Bluetooth scales and acquired through Fitabase, reducing both recall and social desirability bias common in self-report weight data. The interventions were low-burden, scalable, and aligned with Food is Medicine principles, offering potential cost-effective alternatives or adjuncts to long-term pharmacotherapy.

This study has important limitations. The study was not powered for definitive efficacy testing. Consequently, non-significant findings for adherence, satisfaction, diet quality, and perceived health may reflect limited statistical power rather than absence of intervention effects. Additionally, the study population was not diverse across key dimensions. Similar to most GLP-1 trials and users, most participants were female, relatively well educated, and had stable income. These factors may influence engagement with digital tools and access to food resources that support weight maintenance. Due to recruitment challenges, our target sample of 60 people was not reached within the grant timeline/period of availability of funds. Remote recruitment proved less effective than anticipated. In contrast, in-person "warm handoffs" and direct phone outreach appeared more promising but could not be used consistently given a lack of funding for these strategies. Future studies should plan for a larger and more diverse recruitment base, including additional sites. It may also be important to allocate additional resources for clinical staff time to support in-person introductions or direct patient outreach, which may improve enrollment and engagement. Another limitation is that the short follow-up limits our ability to draw conclusions about long-term weight maintenance. Future studies should follow participants for at least 1 year to assess whether effects can be replicated and persist over a longer period. Furthermore, usual care was not standardized and varied according to provider practices. Although this approach improves external validity by reflecting real-world care, it may have introduced heterogeneity in participant experiences and adherence expectations. Lastly, adherence was assessed using a validated self-report instrument to enable comparison across intervention and usual-care arms.

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More objective intervention-specific measures, such as application engagement logs, meal consumption tracking through remote monitoring, or attendance at follow-up clinical encounters, may provide more precise estimates of adherence and should be incorporated into future trials.

These findings should be interpreted within the context of the limited but growing literature on weight maintenance following GLP-1 discontinuation. Most existing studies have focused on documenting weight regain after cessation rather than testing strategies to mitigate it. For example, the STEP 1 extension study demonstrated substantial regain of lost weight and attenuation of cardiometabolic benefits within 1 year of semaglutide withdrawal, highlighting the challenges of maintaining treatment-related weight loss after cessation [5]. Emerging evidence from a randomized trial evaluating exercise, liraglutide, or the combination of both suggests that participants who received exercise support demonstrated more favorable weight maintenance after GLP-1 treatment ended than those receiving liraglutide alone, suggesting that behavioral interventions may help offset the physiologic and behavioral drivers of regain [36]. Ongoing trials have also begun evaluating alternative approaches, including medication tapering combined with lifestyle support and gradual dose reduction before complete cessation, although studies are not yet completed [37]. Taken together, the existing literature suggests that discontinuation of GLP-1 therapy represents a particularly vulnerable transition period and that active maintenance strategies may be needed to sustain treatment benefits.

The present study extends this emerging body of evidence by providing randomized pilot data of scalable behavioral and nutrition-focused interventions specifically designed to support weight maintenance following GLP-1 discontinuation. These results point to the period immediately after stopping medication as a critical window for support. Structured interventions during this time may help stabilize weight and ease the transition off therapy. However, larger and longer trials are needed to confirm these findings, understand how these approaches work, and identify which patients are most likely to benefit from each strategy. Additionally, no pre-specified adherence benchmark was established because the primary purpose of this pilot study was to evaluate acceptability and obtain preliminary adherence estimates. Future efficacy trials should define intervention-specific adherence thresholds a priori and examine whether adherence mediates weight-maintenance outcomes.

Author Contributions

K.H.-H. conceptualized the study and secured funding to carry out the study. I.L. contributed to the study design, analytic plan, and recruited participants. K.H.-H. led manuscript preparation. K.H.-H. and A.V. conducted data analyses. C.H. collected data and supported participants. J.P.A. provided clinical recruitment support. C.H. and A.V. created tables and figures. All authors critically reviewed the manuscript and provided valuable feedback and edits.

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Ethics Statement

This study was reviewed and approved by the University of Texas Southwestern Medical Center Human Research Protection Program (STU-2023-1168).

Consent

Written consent to participate was obtained from the study team and securely stored for all participants. The study was pre-registered on ClinicalTrials.gov (Identifier: NCT06273163, Url: https://clinicaltrials.gov/study/NCT06273163). The trial was registered on 02/15/2024, prior to enrollment of the first participant on 03/05/2024.

Conflicts of Interest

Unrelated to this work, K.H.-H. is a Program Advisor (paid consultant) on The Special Supplemental Nutrition Program for Women, Infants, and Children Community Innovation and Outreach program (WIC CIAO) on behalf of the Center for Nutrition and Health Impact. After this study was completed and submitted for publication, K.H.-H. received grant funding from Noom, Inc. a digital wellness company to conduct a larger and longer follow-up study that is currently preparing for recruitment. Noom, Inc. did not have any influence on the design, conduct, reporting, or interpretation of the research presented in this manuscript. I.L. has received research funding (paid to the institution) and/or products from Novo Nordisk, Boehringer-Ingelheim, Dexcom, Roche, Pfizer, and Lilly. I.L. received research related consulting fees (paid to the institution) from NovoNordisk. I.L. received advisory/consulting fees and/or other support from: Aadvarak Therapeutics, Abbvie, Adarx, Altasciences, Alveus Therapeutics, Amgen, Antag Therapeutics, Arrowhead Pharmaceuticals, Astra Zeneca, Baim Institute, Bain Capital, Bayer, Betagenon AB, Bioio Inc., Biomea, Boehringer-Ingelheim, Boston Scientific, Carmot, Corxel, Cytoki Pharma, Eli Lilly, Genentech, Janssen/J&J, Juvena, Kailera Therapeutics, Keros Therapeutic Inc., Mediflix, Metsera, Neurocrine, Novo Nordisk, Penguin Bio, Pfizer, Regeneron, Response Pharmaceutical, Roche, Sanofi, Shionogi, Sparrow, Skye Bioscience, Source Bio, Structure Therapeutics, SUMMIT, Tenvie, TERNS Pharma, Verdiva Bio, Viking Therapeutics, and Zealand Pharma.

Data Availability Statement

Data are available upon reasonable request to the corresponding author (kelseanna.hollis-hansen@utsouthwestern.edu). Data requests will require a data use agreement. The R code used for data management and analyses can be found open access at https://github.com/axvonder/KHH-GLP-1-cessation-MTM-analysis.

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Supporting Information

Additional supporting information can be found online in the Supporting Information section.

Table S1: Sensitivity analysis of longitudinal weight change.

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