Clinical Interventions in Aging

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ORIGINAL RESEARCH

Intervening on Calorie Intake or Eating Timing in Older Adults: Lessons Learned in the Healthy Aging and Late-Life Outcomes Randomized Controlled Pilot Trial

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Purpose: The Healthy Aging and Late Life Outcomes Pilot (HALLO-P) trial was designed to pilot in-person and remotely delivered caloric restriction (CR and RCR respectively) and time restricted eating (TRE) in preparation for a long-term multi-site clinical trial. Herein, we describe the development and execution of these behavioral interventions with a focus on lessons learned and post-study questionnaire data.

Patients and Methods: Participants were community-dwelling older (60+ yrs) adults with obesity or overweight with an indication for weight loss. Participants were randomized to 9 months of group-based CR, RCR, or TRE supported by self-monitoring technologies [ie, a tablet application paired with an activity monitor (all) and wireless scale (CR and RCR)]. Intervention staff recorded attendance at sessions and noted intervention-related lessons learned as they arose. Upon completion of the study period, participants were asked to complete a series of Likert-type and open-ended questions related to their experiences in the trial.

Results: Participants (N = 90; 67.19 ± 4.91 years) attended 84.4% of sessions on average, engaged with study technologies 96.4% of days, and provided daily weights on >4 days per week across the study (CR and RCR only). Participants reported high satisfaction with the program, with RCR participants being significantly more likely than TRE participants to report being satisfied with their program overall (100% vs 75%, $p < 0.01$), intending to continue their dietary change post-intervention (97% vs 63%, $p < 0.01$), and being willing to sustain their dietary approach and engage with study technologies over a 5-year period (88% vs 61%, $p < 0.01$). Open-ended feedback underscored the value of the group-based structure of the program and remote delivery to reduce travel burden, the need for reduced burden associated with food logging, and the need to identify methods for enhancing perceived value of TRE among older adults.

Conclusion: An intervention designed to promote CR, primarily delivered remotely and supported by self-monitoring technology, is both feasible and acceptable to many older adults.

Keywords: aging, technology, behavior, obesity, pilot

Introduction

One's diet, including the timing, quantity, and composition of foods consumed, has powerful effects on health. For example, diet directly affects body composition, makes key nutrients available to vital bodily functions, and affects systemic inflammation.[1,2] Diet also affects health indirectly via interactions with activity and sleep behaviors.[3–5] Of particular interest to the scientific community is the potential for dietary caloric restriction (CR), independent of weight loss and other factors, and alternative strategies such as time restricted eating (TRE) to enhance longevity in humans.[6–18]

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Herein we present the design of the behavioral interventions underlying the *Healthy Aging and Late Life Outcomes-Pilot* (HALLO-P) trial involving CR and TRE, focusing on lessons learned and participant feedback, which are valuable data for researchers and healthcare providers designing their own dietary behavioral interventions.

The benefits of CR—especially among older adults with obesity—are myriad and include reductions in markers of inflammation, blood pressure, and fasting glucose; better insulin sensitivity; and faster gait speed.[19–32] Benefits of CR are associated with reductions in body mass. For instance, in the Look AHEAD study, 5145 adults aged 45–76 with overweight or obesity and type 2 diabetes were randomized to receive either an intensive lifestyle intervention (ILI) that included CR or an enhanced usual care control condition comprising diabetes support and education (DSE). Participants engaged in the program over 9–11 years. Those in ILI demonstrated remission of diabetes and reduced rates of multimorbidity and frailty compared to DSE as well as enhanced function and health-related quality of life; findings that were more associated with changes in weight than with changes in activity levels.[33–38] Many benefits of CR on health and longevity are also expected to occur independent of changes in body mass, and may be mediated by cellular and molecular mechanisms associated with energy homeostasis, regulation of cellular growth, autophagy, and the reduction of oxidative damage and inflammation.[6–17]

In addition to health benefits associated with CR, TRE may also be associated with favorable metabolic adaptations and longevity. TRE in yeast, worms, and rodents, results in extended lifespan and healthspan.[39–41] Should similar effects present in older adults, TRE would represent a highly attractive intervention, forgoing the powerful behavioral challenge of restricting and modifying caloric intake.[42] To date, limited data on TRE exist in the context of interventions (1) targeting older adults, (2) lasting longer than 12 weeks, and (3) delivered in the absence of CR.

Investigating the long-term impact of either CR or TRE naturally requires dietary behavior change and maintenance, a demanding task that is influenced by factors as diverse as evolutionary needs to obtain and preserve energy, social and built environments that cue cravings for energy-dense foods,[43] limited awareness of energy intake (a core aspect of successful self-regulation),[44] and interactions with other daily time-use behaviors (eg, sleep, exercise) that can drive hedonic or compensatory eating.[45,46] Herein, we describe the development of dietary behavior change interventions in the HALLO-P trial (clinicaltrials.gov registration #NCT05424042), focusing on lessons learned and post-study exit questionnaire data. HALLO-P was designed to pilot in-person CR and remotely delivered CR (RCR) and in-person time restricted eating (TRE) in preparation for a first-of-its-kind long-term multi-site clinical trial investigating the impact of dietary behavior change on biomarkers of longevity in older adults.

Materials and Methods

Participants

Participants were community-dwelling older adults (aged 60+ years) with obesity (ie, body mass index [BMI] of 30–40 kg/m^2) or who were overweight (BMI of 27–30 kg/m^2) with an indication for weight loss, such as hypertension, hyperlipidemia, elevated waist girth, and controlled diabetes. Individuals were excluded due to any contraindication to dietary and activity behavior change, a history of eating or nutritional disorders, presence of a severe chronic illness that may affect participation, or an inability to perform key self-monitoring behaviors required by the interventions (eg, weighing daily, completing food logs) as determined by a 1-week behavioral run-in. Participants were randomized according to a blocked randomization scheme, stratified on sex, developed by the study statistician. The randomization protocol and the randomization process were prepared and executed by investigators from the Biostatistics and Design Team through the secure web-based data management system so that eligibility was automatically confirmed. Randomization occurred across 4 waves. During the first 3 waves, participants were randomized 1:1:1 to CR, RCR, or TRE. Due to an interest in collecting additional information on RCR and TRE, which the research team had less experience with, the final wave was randomized 1:1 to either RCR or TRE. All study procedures were approved by the Wake Forest School of Medicine Institutional Review Board (IRB #00072563) and all participants provided signed informed consent in accordance with the 1964 helsinki declaration. The research team aimed to recruit N = 90 participants. Notably, as a pilot study, we followed the recommendations of Leon et al,[47] focusing our design on an evaluation of feasibility. The design of the overall HALLO-P study was centered on evaluating benchmarks and width of confidence intervals around feasibility criteria like adherence and loss to follow-up. Our total sample size of 90 was sufficient for evaluating the feasibility of the protocol.

Interventions

Behavioral Framework

The design of the interventions was informed by social cognitive theory[48] and principles of group dynamics,[49] and further refined using concepts from self-determination theory (eg, a focus on intrinsic motivation, social connection, and autonomy)[50] and contemporary dual process theories (eg, through consideration of interacting conscious and subconscious processes).[51] The intervention framework builds upon an approach utilized by our group across several large randomized controlled weight loss and physical activity trials of older adults.[52–55] Core aspects of this program include: (1) group sessions (three times per month for 24 weeks and then once per month for 16 weeks; see Supplemental Tables 1 and 2 for topics) that were led by a registered dietitian and behavioral interventionist and designed to allow for social bonding and education to facilitate knowledge and self-regulation skill development; (2) individual contacts (once per month) with a behavioral interventionist and/or registered dietitian to facilitate goal review and revision; and (3) provision of a set of study technologies designed to foster ongoing social connection and the development of real-time awareness of one's current behaviors and their alignment with study diet and movement goals.

The technology toolkit included a study-provisioned tablet computer, a consumer activity monitor, and the intervention-specific *Companion App* (Figure 1), that iterated upon a platform designed hand-in-hand with older adults[52,56–58] to provide real-time feedback on dietary and movement goals, immediately cue goal achievement to support self-efficacy via mastery, and facilitate real-time communication between participants and privately with interventionists. The Companion App functions as a progressive web app—hosted on secure cloud servers managed by Wake Forest School of Medicine—to allow for functionality across devices. As described below, participants in CR and RCR were provided with a "smart scale" for use at home to monitor changes in weight. All participants received the same activity program designed to sustain or enhance participation in lifestyle activity and to counteract potential increases in sedentary time with dietary behavior change. Data from Fitbit were retrieved via the Fitbit web API and visualized within the Companion App. The timeline bar (see feedback at the bottom of Figure 1) visualized patterns of movement

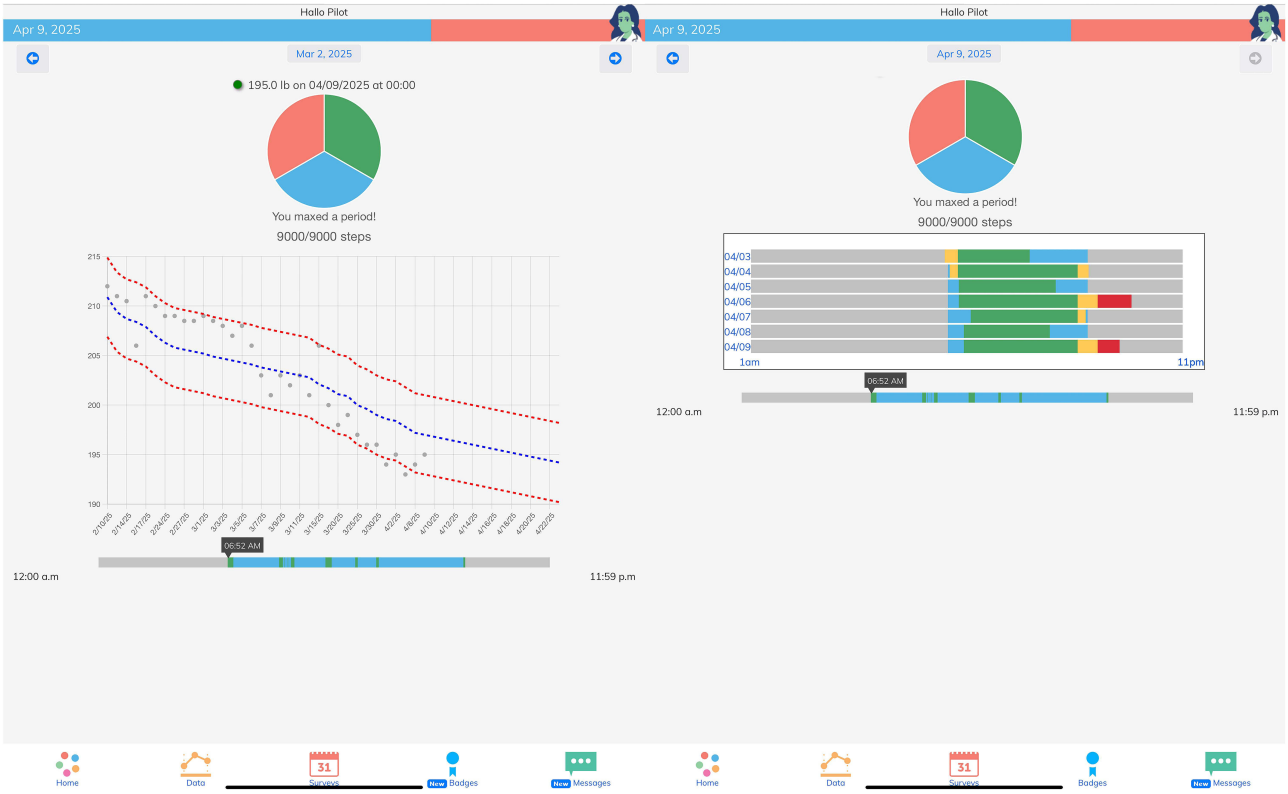

Figure 1 Example HALLO-P Companion App Screens for caloric restriction groups (left) and time restricted eating (right).

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(displayed in green) and non-movement (displayed in blue) across the day. Participants were tasked with reviewing this feedback throughout the day, attempting to minimize periods of prolonged sitting. Progress toward the daily step goal was also reinforced via a daily "periodic step goal" plot, displayed at the top of Figure 1. Here, progress toward the overall daily step goal was displayed numerically and progress was visually depicted in a pie chart that sub-divided the goal into three periods (before noon, between noon and 5:30pm and after 5:30 pm). For instance, a goal of 6000 daily steps could be broken into a 2000-step morning, midday, and evening goal. Participants were cued via in-app notifications paired with goal-specific "mastery badges" when they achieved overall or periodic daily step goals.

Caloric Restriction

The primary difference between the CR and RCR conditions was the mode of delivery. CR participants attended their group sessions at a central location whereas those randomized to RCR attended sessions via videoconference. During the intervention, participants learned key food logging skills (eg, estimating portion size, selecting components of a recipe, looking up nutrition information when dining out) and were tasked with recording all food and beverage intake in the Fitbit application in real time, when possible. The Fitbit application summarizes daily macronutrient profiles, and the study dietitian leveraged these data to set and revise goals related to CR, diet quality, and protein intake. CR goals were formulated using doubly labeled water (DLW) to estimate total daily energy expenditure (TDEE) under the assumption participants were in energy balance at baseline and TDEE would equal energy intake. Each participant's CR goal was set at 80% of this value, rounded to the nearest 50 kcals with a minimum goal of 1100 kcals for women and 1300 kcals for men. These data were displayed on a "Zone of Adherence" plot,[59] which was constructed using the NIDDK body weight planner[60] by inputting key participant characteristics (body weight, sex, age, height, a fixed physical activity level [PAL] of 1.5) and the individual's calorie target, with a trajectory of change of 280 days (40 weeks). A zone around this projected weight loss was created by adding and subtracting four pounds from each day's target weight. Throughout the program, daily weights obtained from the "smart scale" were plotted against the Zone of adherence, as well as in a notification bar given at the top of the app (Figure 1), and this feedback was used to refine weekly CR goals. Here, weights below the top boundary were paired with a green notification icon. In addition to the calorie goal, participants aimed to eat approximately 90 g/d of protein and up to 1200 mg/d of calcium and 800 IU/d of vitamin D, and supplementation was encouraged if these targets could not be met.

Time Restricted Eating

Those randomized to receive TRE were asked to record the start and end time of each day's eating events within their *Companion App* using two methods. Participants were encouraged to use "Started Eating" and "Stopped Eating" buttons within the "Surveys" section of the application, which recorded timestamps corresponding to the beginning and end of the eating event. If a participant forgot to record an event or was inaccurate in their start or stop times, the participant or interventionist had the ability to edit the duration of each eating event, and these adjustments were recorded by the app. Each day's total eating duration (ie, the start time for the first bout through the end time of the final bout) was plotted on a "Feedogram"[61] against the participant's daily eating window goal (see the right panel in Figure 1). Eating periods that fell within 30 minutes of the start or end of the targeted eating window were coded in yellow, and those exceeding 30 minutes from the start or end of the target window were coded in red.

Measures

Lessons Learned

Throughout the conduct of the interventions, the study interventionists investigators noted key lessons learned as they arose related to intervention delivery, participant reception of intervention content, and use of study technologies. We believe providing these lessons learned is critical for advancing the science of dietary behavior change, and so we provide an inventory of these lessons learned and subsequent modifications that were made to our protocol.

Participant Feedback

Upon completion of the 9-month study period, participants were asked to complete a series of Likert-type and open-ended questions related to their experiences in the trial, reactions to study-provided technologies, and their willingness to

engage in a full-scale study that would last 5 years (for examples, see "Closeout Survey for In-Person CR" and "Technology Feedback" in the Supplement Material 1).

Analyses

To characterize participants and to describe Likert-type feedback items, we present descriptive statistics [mean ± SD for continuous variables, n (%) for count variables]. To explore whether there were differences in the percent of participants in the randomized groups responding positively (ie, responses of "moderately" or "very much") to Likert-type feedback items, we conducted a series of exact tests for 3 × 2 contingency tables, with significant overall tests followed by post-hoc pairwise exact tests between groups. Significance of all tests was established at $p < 0.01$, to balance the small and exploratory nature of the analyses with the number of comparisons being conducted. Additionally, select open-ended items of relevance to the design of a future HALLO trial were grouped by theme (characterized by one member of the research team [JF]), and select quotes are provided in-text.

Results

Participant Characteristics

Baseline participant characteristics are displayed in Table 1. Participants (N = 90) were recruited across 4 waves between July 2022 and September 2023. Participants were 67.19 ± 4.91 years of age on average, had an average BMI of 31.71 ± 2.87 kg/m^2, 62% were female, 83.3% were White, and 98% were not Hispanic.

Intervention Compliance

Median participant attendance to group sessions is depicted in Table 2. Median attendance across available sessions (ie, excluding days wherein a clinic closure, for example, prevented attendance) was 84.4%, or 84.1% per protocol. The RCR condition achieved the highest attendance (87.5% per protocol), followed by CR (79.7% per protocol), and TRE (76.6% per protocol).

As described in Table 3, participants in the CR and RCR conditions provided weights via the cellular-enabled smart scale on 66.7% of days over the first three months of the intervention (or 4.7 days per week; participants were encouraged to weigh approximately daily) and 62.2% of days over the remaining 6 months of the intervention (or 4.4 days per week; participants were encouraged to weigh at least weekly). Participants randomized to TRE reported eating times on a median of 91.7% of days (25th percentile: 84.2%; 75th percentile: 96.3%).

Table 1 HALLO-P Participant Characteristics

Characteristics	CR (n=22)	RCR (n=34)	TRE (n=34)	Overall (n=90)
Age, M (SD), years	66.55 (4.96)	68.71 (4.56)	66.09 (4.96)	67.19 (4.91)
Sex, N (%)				
Male	9 (40.9)	13 (38.2)	12 (35.3)	34 (37.8)
Female	13 (59.1)	21 (61.8)	22 (64.7)	56 (62.2)
Race, N (%)				
African American/Black	4 (18.2)	5 (14.7)	5 (14.7)	14 (15.6)
Caucasian/White	18 (81.8)	29 (85.3)	28 (82.4)	75 (83.3)
Other	0 (0.0)	0 (0.0)	1 (2.9)	1 (1.1)
Any Underrepresented Group, N (%)	4 (18.2)	5 (14.7)	6 (17.6)	15 (16.7)
Hispanic Ethnicity, N (%)	0 (0.0)	0 (0.0)	2 (5.9)	2 (2.2)
BMI, M (SD), kg/m²	31.37 (2.94)	31.69 (2.87)	31.95 (2.88)	31.71 (2.87)
History of Arthritis, No. (%)	11 (50.0)	26 (76.5)	22 (64.7)	59 (65.6)
History of Hypertension, No. (%)	12 (54.5)	19 (55.9)	17 (50.0)	48 (53.3)
History of High Cholesterol, No. (%)	13 (59.1)	15 (44.1)	19 (55.9)	47 (52.2)
History of Depression, No. (%)	4 (18.2)	13 (38.2)	10 (29.4)	27 (30.0)
History of Smoking, No. (%)	6 (27.3)	5 (14.7)	7 (20.6)	18 (20.0)

Abbreviations: CR, In-person caloric restriction; RCR, remotely delivered caloric restriction; TRE, time-restricted eating.

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Table 2 Percent Attendance

Condition	Attendance at Possible Sessions	Attendance Per Protocol
CR	82.6 (66.7, 90.3)	79.7 (56.3, 87.5)
RCR	87.5 (75.0, 93.8)	87.5 (75.0, 93.8)
TRE	79.7 (62.5, 93.5)	76.6 (28.1, 90.6)
Overall	84.4 (70.3, 93.8)	84.1 (59.4, 93.5)

Notes: median (20^{th} percentile, 80^{th} percentile).
Abbreviations: CR, Caloric Restriction; RCR, Remote Caloric Restriction; TRE, Time Restricted Eating.

Table 3 Percent of days Wherein Daily Weights Were Provided

Condition	1–90 Days	91–180 Days	181+ Days
CR	70.0 (53.3, 77.8)	62.2 (28.9, 71.1)	62.2 (28.9, 71.1)
RCR	65.6 (56.7, 74.4)	63.3 (53.3, 73.3)	61.7 (50.0, 70.0)
Overall	66.7 (53.3, 75.6)	62.2 (50.0, 73.3)	62.2 (42.2, 71.1)

Notes. median (20^{th} percentile, 80^{th} percentile).
Abbreviations: CR, Caloric Restriction; RCR, Remote Caloric Restriction; TRE, Time Restricted Eating.

Table 4 depicts the median percent of days on which the *Companion App* was opened at least once. Participants opened the app on 96.4% of days across all conditions. The RCR condition opened the app on the highest percent of days (97.8%), followed by CR (96.1%) and TRE (93.4%).

Participant Feedback

Participant feedback to Likert-type items is summarized in Tables 5 and 6 and Figure 2. Across all conditions, feedback to questions related to experiences within the HALLO-P study (Table 5) were positive (ie, at least 75% of CR, 68% of RCR, and 60.7% of TRE participants responding positively on each item). There was a statistically significant difference between groups ($p = 0.002$) in how satisfied participants were with the dietary approach used in their intervention, which was driven by a greater percent of RCR vs TRE participants reporting satisfaction (97% vs 64% $p = 0.002$). Likewise, there was a significant difference between groups in overall level of satisfaction with the intervention ($p = 0.004$), which was again driven by more RCR participants reporting satisfaction relative to TRE (100% vs 75%, $p = 0.002$). It is also notable that RCR participants were more likely to report satisfaction than were CR participants, but this did not reach statistical significance (100% vs 85%, $p = 0.046$). There was also a significant group difference in the number of participants reporting they intended to continue their dietary program following the intervention ($p = 0.001$), which was

Table 4 Percent of days Where the Companion App Was Used at Least Once

Condition	App Use
CR	96.1 (89.6, 99.3)
RCR	97.8 (93.5, 100.0)
TRE	93.4 (63.9, 99.0)
Overall	96.4 (87.0, 99.6)

Notes. median (20^{th} percentile, 80^{th} percentile).
Abbreviations: CR, Caloric Restriction; RCR, Remote Caloric Restriction; TRE, Time Restricted Eating.

Table 5 Participant Feedback Relative to Their Time in the HALLO-P Study

Number Reporting "Moderate" or "Very Much So"	CR (N=20)	RCR (N=34)	TRE (N=28)	p^a
Did you feel the HALLO-P time restricted eating/caloric restriction intervention made you healthier?	18 (90.0%)	29 (85.3%)	19 (67.9%)	0.080
How satisfied were you eating in the 8-hour window/with the approach used to cut back the calories you consumed each day?	17 (85.0%)	33[b] (97.1%)	18 (64.3%)	0.002
How satisfied were you with the physical activity/stepping part of the intervention?	17 (85.0%)	33 (97.1%)	24 (85.7%)	0.179
How helpful were your group leaders in helping you adhere to your HALLO-P 8-hour eating window/calorie goal?	17 (85.0%)	33 (97.1%)	25 (89.3%)	0.245
How helpful were your fellow group members in helping you adhere to your HALLO-P 8-hour eating/calorie window goal?	16 (80.0%)	23 (67.6%)	17 (60.7%)	0.391
Do you think the HALLO-P intervention helped you to lose weight?	15 (75.0%)	27 (79.4%)	-	0.744
How satisfied were you with the HALLO-P remote video conferencing treatment approach?	-	32 (94.1%)	-	
Overall, how satisfied were you with your experience?	17 (85.0%)	34[b] (100%)	21 (75%)	0.004
How likely are you to continue eating within an 8-hour window/following your calorie goal after the intervention ends?	19 (95.0%)	33[b] (97.1%)	18 (64.3%)	0.001

Notes. [a]Exact test overall *p* value. [b]RCR vs TRE pairwise exact test p < 0.01.
Abbreviations: CR, Caloric Restriction; RCR, Remote Caloric Restriction; TRE, Time Restricted Eating.

Table 6 Participant Feedback Relative to Willingness to Participate in a 5-year Study

Number Reporting "Moderate" or "Very Much So"	CR (N=20)	RCR (N=34)	TRE (N=28)	p^a
Would you be willing to commit to an intervention study like this for a period of 5 years?	17 (85.0%)	24 (70.6%)	15 (53.6%)	0.073
If you did commit, how confident are you that you would be able to maintain eating in the 8-hour window on most days of the week/maintain this calorie goal for 5 years?	18 (90.0%)	31[b] (91.2%)	17 (60.7%)	0.007
If you did commit, how confident are you that you would be able to maintain the physical activity/stepping part for 5 years?	19 (95.0%)	31 (91.2%)	22 (78.6%)	0.259
If you did commit, would you be willing to continue monitoring your diet and activity using the "companion app", watch, and scale for a week each month for 5 years?	15 (75.0%)	30[b] (88.2%)	17 (60.7%)	0.002
If you did commit, would you be willing to attend clinic visits every 6 months over the course of 5 years?	16 (80.0%)	30 (88.2%)	21 (75.0%)	0.149
If you did commit, would you be willing to meet or have a Zoom call with a coach monthly for 5 years?	16 (80.0%)	31 (91.2%)	21 (75.0%)	0.038
If you did commit, would you be open to participating in group events every 6 months with other participants to socialize and hear from investigators about new research in this field of study?	18 (90.0%)	30 (88.2%)	22 (78.6%)	0.352

Notes. [a]Exact test overall *p* value. [b]RCR vs TRE pairwise exact test p < 0.01.
Abbreviations: CR, Caloric Restriction; RCR, Remote Caloric Restriction; TRE, Time Restricted Eating.

again driven a higher percent of positive responses in RCR vs TRE (97% vs 64%, $p = 0.002$). It is also notable that CR participants more frequently responded positively to this item relative to TRE, but this did not reach statistical significance (95% vs 64%, $p = 0.016$).

Regarding long-term participation in a study like HALLO-P (Table 6), 17 (85%) CR, 24 (71%) RCR, and 15 (54%) TRE participants noted they would be willing to engage in a study like HALLO-P for 5 years. There was a difference between groups in participants' confidence in sustaining the dietary approach over 5 years (p = 0.007). Participants enrolled in RCR (91%) were more likely to report confidence than were TRE participants (61%; $p = 0.006$). CR participants were also more likely to report confidence (90%) relative to TRE, though this did not reach statistical significance ($p = 0.046$). Finally, there was a significant difference between groups in the percent of participants reporting willingness to use study technologies over a 5-year period ($p = 0.002$), which was driven by a higher percent of positive responses in RCR (97%) vs TRE (61%; $p = 0.001$).

Table 7 contains common themes that emerged in response to select open-ended questions relevant to the design of a future trial. When asked about features of the program they liked the best, TRE participants most often noted appreciation for the impact of the intervention on their health or health behaviors (eg, "Got me into habit of eating during certain times" or "I feel it made me healthier and I'm hoping I can continue") and for the knowledge they gained (eg, "[the] nutrition advice was good"). Participants also noted appreciation for the connection afforded by interventionists and the peer group (eg, "interaction with group members and leaders"). This was the most preferred feature of the program for both CR and RCR participants, who likewise appreciated the knowledge and awareness developed during

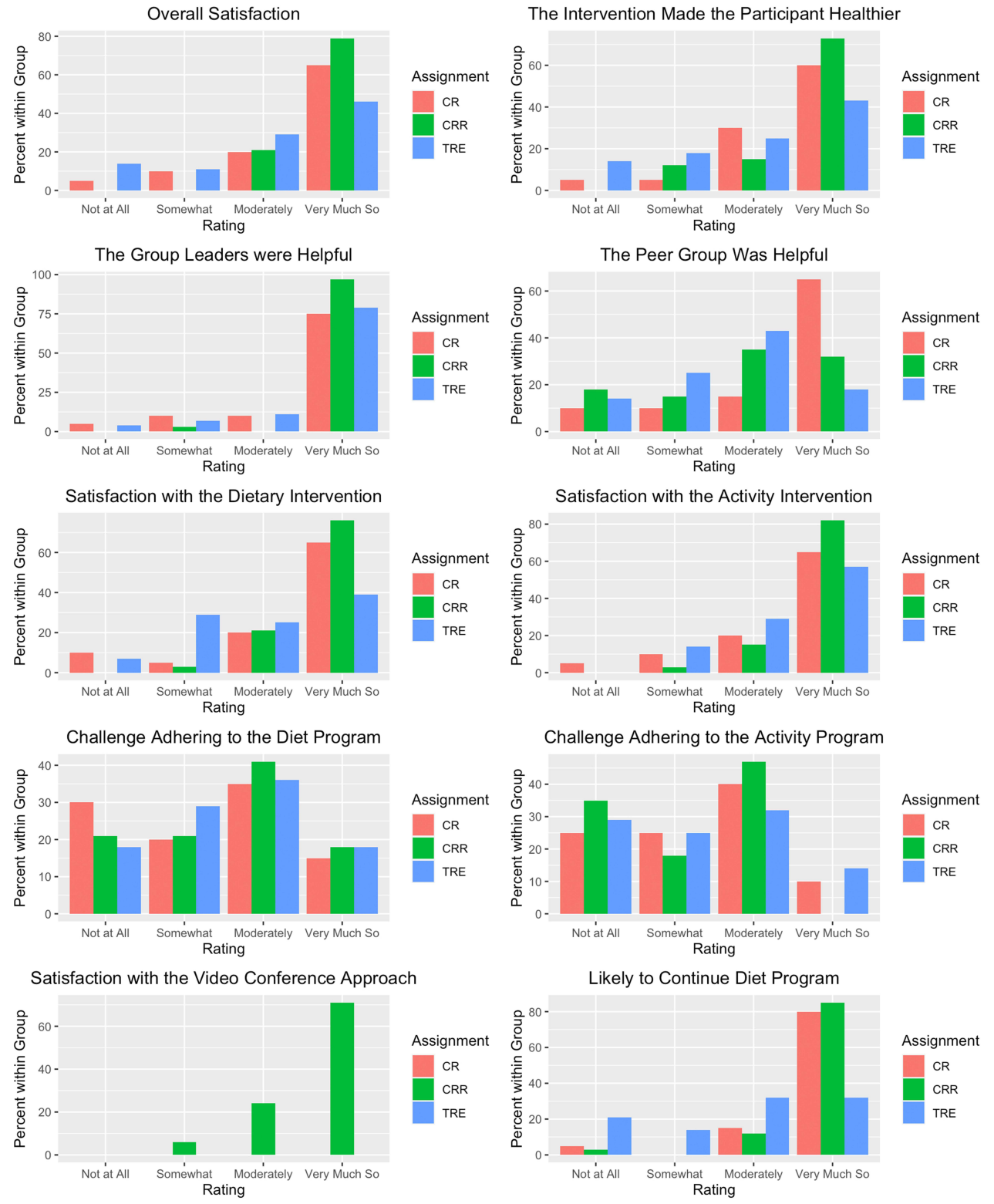

Figure 2 Participant Responses to Likert-type Feedback Questions.

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Table 7 Themes Emerging in Response to Select Open-Ended Feedback Questions Relevant to the Design of a Future HALLO Intervention

	TRE (n)	CR (n)	RCR (n)
What did you like most about the HALLO-P intervention?			
Accountability	1	4	7
Effects on health and behavior	12	0	3
Goals and/or feedback	1	2	8
Group-specific behavioral targets	6	1	1
Knowledge and/or awareness	12	7	13
Social support from group and/or leaders	9	10	16
Staff assistance/customer service	0	1	1
Technology and tools	0	2	3
What did you like least about the HALLO-P intervention?			
Adherence demands	0	0	1
Classes uninteresting, uninformative, or unmotivating	3	2	0
Did not achieve a desired outcome	3	0	0
Group-specific behavioral targets	8	0	0
Issues with study delivery/pilot procedures	0	1	1
Meeting format	0	0	4
One on one sessions	0	0	1
Other	0	0	2
Peer group and/or leaders	0	1	2
Self-monitoring	1	2	8
Session timing and/or schedule	3	5	3
Social consequences associated with intervention	1	0	0
Study technologies and/or tools	2	2	1
Testing study procedures	3	2	3
Too long	1	0	0
No perceivable health benefit	1	0	0
[If you indicated you are 'not at all' willing to participate in the HALLO-P intervention for 5 years] why do you feel this way?			
Burden	4	0	2
Cost associated with participating in the study	1	1	0
Low value for targeted behavior	3	0	0
No interest	0	0	1
Targeted behavior is unsustainable	1	0	0
Unable to or uninterested in participating in a long study	3	2	2

the program (eg, CR: "The dietary information/counseling provided by the dietitians/group leaders - they were awesome and so knowledgeable!", RCR: "Calorie information and guidance helping me to [lose] weight".).

Regarding features of interventions participants liked least, those in TRE most often reported disliking the programmatic focus on a reduced eating window (eg, "Felt very pressured due to the eating window. Not hungry, but always watching the clock"). CR participants most often reported issues related to scheduling or timing of intervention sessions, including a desire for more sessions (eg, "not as satisfying as the group sessions fell off") or that sessions were challenging to attend (eg, "sometimes tough to go to the all the meetings"). For RCR participants, the self-monitoring aspect of the intervention arose as their least favorite aspect (eg, "Daily entering [of foods] into Fitbit and daily weight").

Finally, participants were asked whether they were interested in participating in a 5-year intervention, and if they indicated they were not at all interested in participating, they were asked why. Two (10%) CR, 6 (18%) RCR, and 10 (36%) TRE participants fell into this latter category. For TRE participants, the most common responses related to burden associated with a 5-year study was the in-person sessions (eg, "Not at all if I had to come [to in-person sessions] every

week"). TRE participants also noted a low perceived value of a restricted eating window (eg, "I don't feel it is healthy to be on TRE of 8 hours daily") or general lack of availability or interest in a 5-year program (eg, "Not enough time for me to devote to a five-year study. Preparing to retire and travel".). This was also a top reason for both CR (n = 2) and RCR (n = 2) participants (eg, CR: "Too long"; RCR: "Too long – no more than 2 years".).

Lessons Learned

Challenge 1: Coaching to CR Vs Weight Loss

As a CR intervention, we initially placed considerable emphasis on both goal-setting and didactic content related to the benefits of CR, independent of weight loss. This contributed to confusion on behalf of participants driven by several potential sources of ambiguity. First, where daily calorie goals were derived from DLW data, participants relied on daily food logs to monitor goal progress. Successfully self-regulating challenging behaviors, such as caloric intake, requires access to high-fidelity, consistent self-monitoring tools.[44] Unfortunately, daily self-reported calories tend to be much lower than consumed calories (often 20–30% or more),[62–64] and this may be due to a variety of factors including but not limited to poor or incomplete recall, inaccurate accounting of the ingredients in a dish or portion size, psychosocial factors such as fear or negative evaluation or weight-loss history, and more.[64–66]

Considerations for Future Work

To provide a more objective goal setting structure for adherence to CR, the interventionists refocused goal setting activities on changes in WL for the final two waves—supported via the "Zone of Adherence" feedback within the Companion App. This approach provides a framework for monitoring progress that has high fidelity and acts as a foundation for regular CR goal recalibration.

Challenge 2: Addressing the Influence of Physical Activity

As described above, participants monitored adherence to their CR goals indirectly using a body weight "Zone of Adherence" plot, which depicted a tailored trajectory of change in body weight. A PAL range of 1.40–1.69 is often used to describe a sedentary-to-lightly-active lifestyle,[67] and we selected a PAL of 1.5 for sample who were selected to be low-active at baseline. In conducting the trial, the influence of heterogeneous baseline activity levels and changes in activity levels during the trial on one's ability to fall within the "Zone of Adherence" became apparent. Figure 3 displays three example weight plots generated using the NIDDK body weight planner for a 70-year-old male weighing 200 lbs, standing 59 inches tall, with an energy intake target of 1800 calories, and a PAL of either 1.2, 1.4, or 1.6. At 100 days, the model of an individual with a PAL of 1.2 predicts a weight loss of approximately 6 lbs, 14 lbs for a PAL of 1.4, and 21 lbs for a PAL of 1.6. Consequently, a person who engages in little activity (ie, with a true PAL less than 1.5) would likely fail to achieve their targeted CR goal and thus would fail to align with their projected weight plot, potentially resulting in frustration toward one's progress in the program. Conversely, a highly active individual may align with their projected weight plot despite eating more calories than prescribed.

Considerations for Future Work

Future iterations of the intervention will implement a tailored PAL (eg, estimated via accelerometry) to better match the initial weight plot to the activity levels of the individual. Moreover, regularly revisiting changes in PAL to calibrate the "Zone of Adherence" plot may help to ensure that any changes in weight are primarily driven by changes in energy intake rather than activity behavior.

Challenge 3: Many Older Adults Engage in TRE

Key to examining whether engaging in TRE affects key markers of health and longevity is meaningfully changing the time window over which participants eat. Our protocol targeted an 8-hour daily eating window beginning no later than 11:00 am. To be eligible, we required participants to eat for at least 11 hours daily, which was verified by tasking participants with logging the content and timing of daily eating events each day during a one-week behavioral run-in prior to randomization. In total, we excluded 45 of 135 potentially eligible individuals during pre-randomization screening and the leading cause of exclusion (n = 17; 38%) was that participants did not eat over a sufficiently long window. This aligns with a recent randomized pilot trial by Anton et al wherein the top reason older adults failed pre-

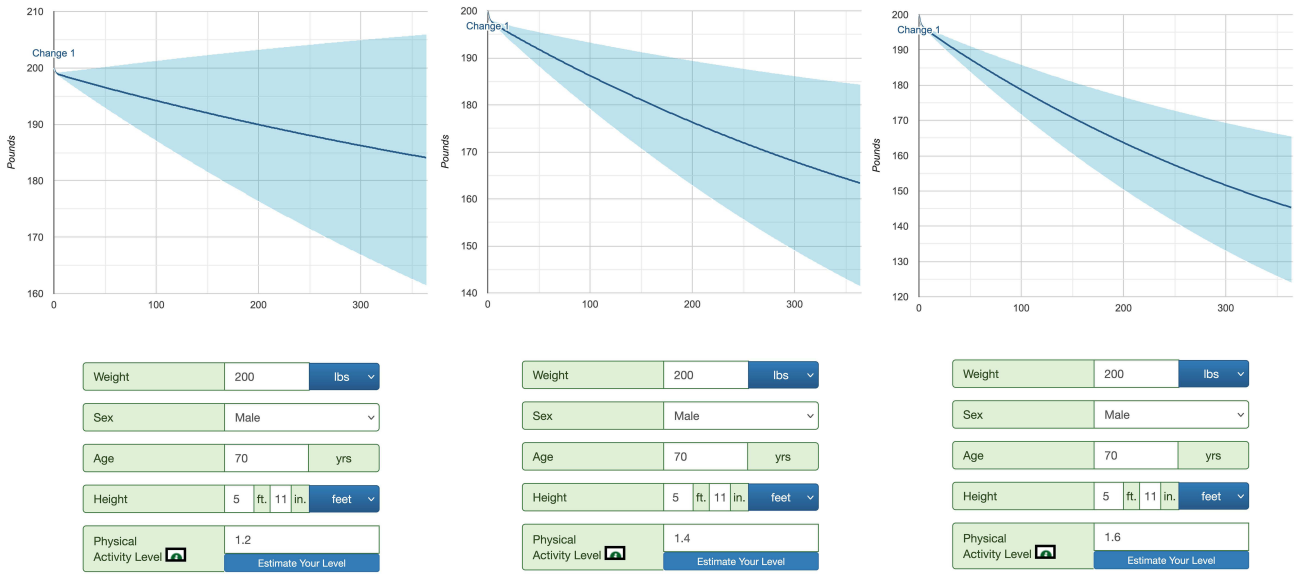

Figure 3 Example weight plots generated by the NIDDK body weight planner for a 200 lb male, aged 70, standing 59 inches, with an energy intake of 1800 kcals and a physical activity level of 1.2 (left), 1.4 (center), or 1.6 (right) over 100 days.

screening was due to an insufficiently long daily eating window.[68] While we are unable to determine the drivers of restricted eating among those who were screened out of our study, and therefore cannot rule out that some older individuals may be engaging in TRE purposefully, we also suspect that interacting factors such as changing health states leading to reduced appetite or disrupted/irregular sleep patterns are responsible for a reduced eating window.

Considerations for Future Work

Those considering implementing TRE for older adults would benefit from planning for greater recruitment costs due to current behaviors relative to other dietary interventions such as CR.

Challenge 4: Finding Value in TRE

Many contemporary behavioral theories, such as social cognitive theory,[48] self-determination theory,[50] and emerging dual-process theories,[51] are at least partially rooted in expectancy-value theory. In brief, this approach suggests that individuals will tend to engage in behaviors that they expect to result in deeply valued outcomes, and outcomes that are more proximal than distal in time are likely to be felt as more valuable and persuasive.[69] A challenge encountered in promoting TRE among older adults is that there are few highly valued benefits that are felt strongly in the near term. The desire to improve appearance is among the strongest motivators for dietary behavior change and weight loss among adults and older adults (though there are at times poorer behavioral outcomes tied to such desires),[70,71] and progress toward weight loss goals can be reflected objectively. Changes in weight, for instance, are reflected in the way that clothes fit or the ease with which one can move. By contrast, there are few immediate motivating outcomes to be promised with TRE, as many potential benefits are invisible (eg, better glucose regulation) or to be realized in the future (eg, potentially enhanced longevity). We observed that some participants ultimately came to feel TRE improved factors such as feelings of energy, while others found the stimulus to be insufficiently beneficial to overcome the loss of social opportunities afforded by a longer eating window (eg, dining with friends and family in the evening).

Considerations for Future Work

It will be critical that those interested in implementing long-term TRE among older adults develop methods for helping older adults to identify and savor near-term changes in valued outcomes associated with their participation in TRE. Though potentially more costly, early individual counseling leveraging techniques such as motivational interviewing may offer one method for helping older adults to identify beneficial changes.

Discussion

Herein we described the design of three behavioral interventions piloted in HALLO-P: in-person or remotely delivered caloric restriction interventions (CR & RCR) and an in-person time restricted eating intervention (TRE). We also described participant responses to these interventions and lessons learned in their delivery. Our intention is to share these lessons with others so that they may leverage and iterate upon our successes while avoiding the barriers that we confronted. Although adherence to the interventions was generally favorable, the lowest levels were observed in TRE and highest in RCR. For instance, on average, participants attended 80% (TRE) to 88% (RCR) of classes offered and engaged with the Companion App toolset on 93% (TRE) to 98% (RCR) of days, respectively. It was also encouraging that daily weights were available for approximately two-thirds of the total days requested both in CR and RCR. Likert-type responses from a post-study questionnaire indicated that participants found the activity and CR interventions to be satisfying and valuable, with highest ratings generally given for RCR. For instance, relative to CR and TRE, RCR participants more commonly reported satisfaction with the program as a whole. Moreover, relative to TRE, RCR participants were more likely to report satisfaction with the dietary aspect of the intervention, were more likely to report an intention to continue the dietary behavior change upon completion of the program, were more willing to do so for a 5-year intervention period and were more willing to use technologies over this same extended period. Additionally, all but one RCR participant reported being satisfied with the videoconference approach used for intervention delivery, further supporting the suitability of this approach in future dietary behavioral interventions.

These findings are in-line with prior research on remotely delivered behavioral interventions wherein center-based interventions more strongly affect outcomes in the short term but home-based programming may be superior for long-term adherence.[72] Given our position that social support is critical for long-term behavior change,[48,50] there may be a need for additional emphasis on peer bond formation in remotely delivered programs. For instance, taking cues from pedagogy and partnering participants for guided discussion at the beginning of each session (eg, within breakout rooms) may be one option for more rapidly developing rapport among peers online.[73]

Open-ended responses by CR and RCR participants supported the program's social group-based skill development and education approach, as participants emphasized the value of peer/leader support, and the knowledge and awareness gained through participation as favored features of the program. By contrast, the need to attend frequent in-person sessions (CR) emerged as a challenge, further supporting the value of a remotely delivered intervention. Among those in the RCR condition, regular food logging was a commonly cited challenge, and it is notable that many participants engaged in food logging across the entire 9-month intervention. A more periodic approach wherein food logging is used initially to develop awareness of one's eating habits and then later to recalibrate perceptions of caloric intake and portion size may reduce the self-monitoring burden associated with CR interventions.

Participants assigned to TRE engaged the least in intervention procedures and were the least likely to provide favorable responses to Likert-type feedback, though it is notable that a majority did rate the intervention positively. Open-ended feedback and feedback provided by intervention leaders highlighted that some participants had difficulty identifying deeply valued outcomes that were changing beneficially in response to the intervention. Whereas those participating in CR have objective evidence of success (ie, weight loss) that is typically viewed as socially favorable and is closely tied with highly valued outcomes (eg, one's ability to move around the home more easily, reductions in pain), those participating in TRE had fewer easily observed benefits associated with their new behavior change. Rather, participants more readily reported strong social (eg, inability to eat with friends and family) and experiential (eg, hunger early in the day or at night) challenges that reduced enthusiasm for long-term participation.

The HALLO-P intervention team also identified four key lessons learned that will inform future iterations of the HALLO-P experience: (1) anchoring coaching on the basis of weight loss as opposed to CR; (2) dealing directly with heterogeneity in baseline physical activity levels and changes over time since it has a strong effect on expected trajectories of weight loss with CR; (3) for TRE studies, dealing with the challenge that many older adults naturally engage in reduced eating windows and (4) struggle to find changes in short term, valued outcomes associated with TRE.

Strengths and Limitations

The HALLO-P study has several strengths, including the use of a randomized design and the ability to contrast participant perceptions related to several theory-based behavioral interventions: CR, RCR, and TRE. Participants were not required to own a smartphone or have in-home internet and were able to engage with a set of novel digital health technologies designed to drive real-time self-monitoring and social connection. Finally, strengths specific to this manuscript include the ability to share feedback and lessons learned from both participants and intervention staff to inform the development of future interventions targeting CR and TRE.

There are also several important limitations to note. First, a majority of participants were White and only 2% self-reported Hispanic ethnicity, limiting generalizability of our findings. While this is reflective of the catchment area for the trial, it does suggest there is value in additional user-centered refinement work refining aspects of the intervention (eg, the usability of study technologies or the content of intervention materials). Second, as a pilot trial focused on refining intervention and study procedures, the final sample size was relatively small, and the intervention duration was of insufficient length to examine behavioral maintenance. Similarly, we were unable to implement more time-intensive refinement procedures (eg, to test methods for building greater value for TRE in older adults).

Conclusions

The content, volume, and timing of one's diet can powerfully affect health and quality of life in aging and limited data to date have investigated the impact of extended CR or TRE on markers of aging in older adults. Results of HALLO-P suggest that (1) an intervention designed to promote CR, (2) primarily delivered remotely and (3) supported by self-monitoring technology, is both feasible and acceptable to many older adults. Our results further suggest that such an approach may benefit from using burdensome self-monitoring activities such as food logging in a periodic fashion, including activities designed to promote social connection more rapidly, and leveraging ongoing objective measures of physical activity to set and recalibrate weight loss projections over time.

Data Sharing Statement

The data presented herein will be made available upon reasonable request via contact to the research team.

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Disclosure

The authors have no conflicts of interest to declare for this work.

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