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Does intervention sequence impact self-regulatory and behavioral outcomes in an adaptive trial among adults with prediabetes?

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ABSTRACT

Background: Lifestyle interventions can promote improvement in dietary intake and physical activity (PA), on average, by strengthening motivation, self-regulatory efforts, and commitment to behavioral change. However, maintenance of behavioral change is challenging, and slow responders during treatment often experience less overall success. Adaptive intervention sequences tailored to treatment response may be more effective in sustaining behavioral change.

Methods: Adults ≥ 21 years old with prediabetes (n = 187) were stratified at week five to the standard Group Lifestyle Balance (GLB) intervention, if they achieved > 2.5% weight loss, or to the augmented intervention GLB Plus (GLB+) at week five, if they did not. At month five, each person in a matched pair was randomly assigned to GLB or GLB + for the extended intervention phase (months 5-12) followed by no study conduct (months 13-18). The primary comparison of interest was the change in outcomes between the standard (GLB followed by GLB) and augmented (GLB + followed by GLB+) intervention sequences post-intervention at 12 – and 18-months using linear mixed effect models.

Results: The augmented GLB + intervention sequence reported a decline in the change in self-efficacy for reducing fat intake, self-efficacy for 'sticking to' healthy eating and exercise, and hopeful thought and planning compared to the standard GLB intervention sequence (all $P < 0.0167$) at 18-months. However, there were no significant differences between these intervention sequences at 18-months in the change in dietary intake or minutes of PA (all $P > 0.05$).

Conclusions: No significant change in behavioral measures across intervention sequences occurred at study end. An 18-month decline in self-efficacy regarding diet and PA and hopeful thought and planning among slow responders following no intervention for six months indicates greater extended care is likely needed.

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The type of extended care that is most effective for slow treatment responders requires additional research.

Introduction

Weight loss is the dominant determinant of reduced risk for type 2 diabetes in adults with prediabetes (Hamman et al., 2006). Early weight loss success during behavioral interventions targeting weight reduction is predictive of post-treatment success (Unick et al., 2017). Prior research among women with obesity, for example, found that those who lost ≥ 1.5 pounds/week (≥ 0.68 kg) within the first month of intervention were approximately five times more likely to achieve and maintain 10% weight loss at 18-months compared to participants with slower rates of initial weight loss (Nackers et al., 2010). Thus, greater weight loss during the first month of treatment is associated with greater long-term weight loss success.

Despite the impact of early weight loss, maintenance of weight loss remains challenging, as individuals often regain weight during the first year following treatment, but the rate of weight regain tends to slow over time (Coughlin et al., 2016). Extended care, in which obesity is treated as a chronic disease and continued intervention support is provided, reinforces behavioral intervention strategies (Middleton et al., 2012). However, little is known regarding the type and sequence of intervention strategies needed to reinforce and sustain behaviors to support weight loss maintenance (WLM) following initial treatment, especially for slow weight loss responders. We are aware of only one study that examined the sequence (attain a stable body weight before attempting to lose weight) of intervention training on weight outcomes. In this trial, the sequence of skill-building mattered. Participants who first received training in 'stability skills' for maintaining a stable weight (e.g. appropriate food portions without feeling deprived) was more effective in maintaining weight loss at 18-months than training participants first in a standard behavioral weight loss program (e.g. reduced energy intake and calorie counting) (Kiernan et al., 2013).

Successful WLM depends on key self-regulatory processes, including a belief that weight management is possible, perceived self-efficacy to change behavior, commitment to the goal, and the development and ongoing implementation of self-regulatory skills (Annesi, 2016; Reyes et al., 2012; Spreckley et al., 2021). Successful behavioral change reinforces motivation and increases satisfaction with consistently engaging in lifestyle behaviors. Thus, slow responders during a standard behavioral weight loss program who do not receive reinforcement from early success may benefit from an alternate intervention which augments self-regulatory skills and practices; additional research is needed, however, to evaluate the efficacy of augmented self-regulatory training for slow responders.

In the current study, the impact of an alternate intervention designed for slow weight loss responders was evaluated. An adaptive research design was employed in which stratification to treatment type was based on weight loss progress defined *a priori* (> 2.5% weight loss) following the first month of intervention. Early responders remained in the standard behavioral weight loss intervention (entitled Group Lifestyle Balance or GLB) following the first month of treatment, while slow responders were stratified to

the alternate intervention (entitled GLB Plus or GLB+) following the first month of treatment. Weight loss following the weekly, intensive intervention phase at 4-months was published and demonstrated equivalent mean weight loss between GLB and GLB + assuming 2.5% weight loss at week five (Miller et al., 2022).

Following initial weight loss, prior research demonstrated that extended care is needed to promote WLM (Middleton et al., 2012). Therefore, the current study offered additional intervention sessions for both GLB and GLB + but sessions were held less frequently during the extended intervention phase. We anticipated that slow responders would require ongoing self-regulatory training and support offered in GLB + during the extended phase, while early responders who received GLB during the intensive intervention phase would be able to sustain lifestyle behaviors with the standard intervention during the extended phase (Unick et al., 2019). Thus, intervention sequences were created to evaluate the impact of standard (GLB/GLB intervention sequence) vs. augmented self-regulatory training (GLB+/GLB + intervention sequence) on psychosocial and behavioral measures. A 6-month no contact phase followed 12 months of intervention to evaluate the sustained impact of intervention sequence. We hypothesized that there would be no significant difference in outcomes between the GLB/GLB and GLB +/GLB + intervention sequences at 12 – and 18-months. The weight loss findings are published elsewhere (Miller et al., 2024) and demonstrated that weight loss following the first month of treatment predicted weight loss at 12 – and 18-months regardless of intervention sequence. The aims of the current analyses were to evaluate the impact of intervention sequence on self-regulatory and behavioral measures.

Methods

Participant population and recruitment

The study was conducted at a U.S. midwestern university, and participants were employees ≥ 21 years old with prediabetes and overweight or obesity (body mass index ≥ 25 kg/m^2 in non-Asians or ≥ 23 kg/m^2 in Asians). Participants met the criteria for prediabetes based on a fasting glucose of 100–125 mg/dL or A1c of 5.7-6.4% (American Diabetes Association Professional Practice Committee, 2024) and reported being able to engage in moderate PA (Thomas et al., 1992). Recruitment occurred from January 2018 through April 2021 through electronic advertisements and flyers and electronic mail advertisements and postcards distributed to employees. Study eligibility was confirmed through an in-person screening appointment following a telephone screening interview, and individuals provided written informed consent.

Research design

A stratified design was employed at week five in which participants were assigned to treatment group. Enrolled participants completed baseline data collection and initiated the standard, group-based intervention. In-person sessions were offered prior to the SARS-CoV-2 pandemic; videoconferencing sessions were offered following pandemic onset in March 2020. All participants initially completed four weeks of the standard GLB intervention. Prior research showed failure to achieve > 2.5% weight loss following the first month of intervention predicted failure to achieve ≥ 5% weight loss at follow-up

Table 1. Research Design.

Weeks 1-4: Initial Treatment	Weeks 5-16: Lose > 2.5% weight at week 5?	Months 5-12: Randomization by Matched Pair	Months 12–18 No contact	Intervention Sequence
GLB core (all participants)	**Yes:** remain in GLB at week 5	GLB or GLB+	Maintain behavioral strategies	GLB/GLB GLB/GLB+
	No: switch to GLB+ at week 5	GLB or GLB+		GLB+/GLB GLB+/GLB+

Data collection occurred at baseline, 4-months following the weekly, intensive intervention phase, 12-months following the extended intervention phase, and 18-months at study end.

(Miller et al., 2015). Thus, participants who achieved ≤ 2.5% weight loss at week five were stratified to the GLB + intervention at week five. Participants who achieved > 2.5% weight loss remained in GLB at week five (Table 1). Both interventions included an additional 12 weekly sessions. Following the intensive 16-week intervention phase, percent weight change was determined. Same-sex pairs of participants within GLB or GLB + were matched based on percent weight change, and each member of the pair was randomly assigned to GLB or GLB + using a standard uniform generator for the extended intervention phase during months 5-12. This phase transitioned to fewer sessions with two semi-monthly and seven monthly group-based sessions for 12 total months of intervention (25 total sessions of 60-minute duration). Some participants remained in the same intervention they were stratified to at week five (e.g. GLB/GLB and GLB+/GLB+) following randomization, while other participants were randomized to the alternate intervention (e.g. GLB/GLB + and GLB+/GLB). Thus, four intervention sequences were created (Table 1) to determine the impact of the standard compared to the augmented intervention sequence on outcomes.

Following 12 months of intervention, participants entered a 6-month no contact phase to evaluate the impact of intervention sequence on behavioral maintenance. Data collection occurred by study staff who were aware of treatment group assignment, as they determined weight loss for treatment stratification at week five.

Standard compared to the augmented lifestyle intervention

The GLB standard intervention was modified for group delivery from the Diabetes Prevention Program (DPP) intervention described elsewhere (Diabetes Prevention Program Research Group, 2002). Intervention goals were consistent with those of the original DPP: achieve ≥ 7% weight loss, engage in ≥ 150 minutes/week of moderate intensity PA, and consume < 25% of energy from total fat. Participants received their individual calorie and fat goals as well as fundamental knowledge and skills regarding how to decrease energy and fat intake while increasing PA during the first intervention month. Strategies to achieve the calorie and fat intervention goals were identified by participants and self-set (Table 2). Subsequent sessions focused on increasing knowledge and skills to promote weight loss and addressed the psychological, social, and motivational challenges encountered. Semi-monthly and monthly GLB sessions followed the weekly intervention phase to reinforce core behavioral skills and provide ongoing support and accountability.

The GLB + intervention included the same weight loss and behavioral goals as the GLB intervention (Table 2). However, content varied across interventions starting at

Table 2. Components of the intervention description and replication (TIDieR) checklist for each intervention (Hoffmann et al., 2014).

TIDieR Component	Group Lifestyle Balance Intervention	Group Lifestyle Balance Plus Intervention
Why	Focused on self-regulation to promote ≥ 150 minutes/week of physical activity and < 25% of energy intake from fat to promote weight loss	Focused on self-regulatory models of behavioral change consistent with Goal Setting Theory & Hope Theory to promote ≥ 150 minutes/week of physical activity and < 25% of energy intake from fat to promote weight loss
What	Participants received a workbook with key content for each session & activities to complete	Participants received a workbook with key content for each session & activities to complete
What	Weekly weights obtained; identified common obstacles to weight management; self-set goals established; review of goals completed at session beginning; self-monitored weight, dietary intake, & physical activity with feedback from the health coach	Weekly weights obtained; individual action plans established each session; review of action plans completed at session beginning; problem-solving, action planning, & coping planning occurred to identify relevant/likely pathways to achieve goals & overcome personal obstacles to change; emphasized positive agency for change & mindful decision making consistent with core values; self-monitored weight, dietary intake, & physical activity with feedback from the health coach; recognized goal progress
Who provided	Intervention sessions delivered by health coaches with training in nutrition or health behavior	Intervention sessions delivered by health coaches with training in nutrition or clinical psychology
How	In person, group-based sessions delivered prior to the SARS-CoV-2 pandemic; group-based video conferencing sessions employed following pandemic onset	In person, group-based sessions delivered prior to the SARS-CoV-2 pandemic; group-based video conferencing sessions employed following pandemic onset
Where	Implemented at a university worksite in the midwestern US	Implemented at a university worksite in the midwestern US
When & How much	60-minute sessions delivered weekly for 16 weeks; bimonthly for 1 month; monthly for 7 months	60-minute sessions delivered weekly for 16 weeks; bimonthly for 1 month; monthly for 7 months; 3 bimonthly telephone coaching calls occurred during months 6–12
Tailoring	Participants who achieved > 2.5% weight loss at week 5 remained in this intervention at week 5	Participants who did not achieve > 2.5% weight loss at week 5 were stratified to this intervention at week 5
Modifications	Sessions transitioned to videoconferencing sessions at pandemic onset	Sessions transitioned to videoconferencing sessions at pandemic onset
How well	At least 20% of sessions were audio recorded to assess fidelity by the Principal Investigator using a predefined checklist; additional training provided for health coaches as needed (0.13% of sessions included departures from the intervention as planned)	At least 20% of sessions were audio recorded to assess fidelity by the Principal Investigator using a predefined checklist; additional training provided for health coaches as needed (0.20% of sessions included departures from the intervention as planned)

week five. GLB + was grounded in an integrated self-regulatory conceptual framework based on Goal Setting Theory (Locke & Latham, 1990) and Hope Theory (Snyder, 1994) and is described more fully elsewhere (Miller et al., 2023). Briefly, GLB + guided participants in tying goals to personal values and specific plans for implementing change consistent with Hope Theory. Participants were encouraged to create individual, specific routes (i.e. pathways) to achieve goals and strengthen beliefs (i.e. agency) to initiate and sustain movement toward goals (Locke & Latham, 1990; Schwarzer, 2008; Snyder, 1994). Some plans may not succeed due to obstacles; thus, participants were encouraged to identify several goal pathways to circumvent possible obstacles to promote goal attainment. Goals with moderate levels of difficulty that were specific yet attainable were emphasized consistent with Goal Setting Theory. Linking goals to

personal values and engaging in mindful decision making for lifestyle change also were promoted throughout GLB + . Finally, goals, pathways thinking, and agency thinking reciprocally influence each other so that high agency leads to the formation of new pathways and motivates the generation of alternative pathways when faced with obstacles or setbacks, and the ability to generate pathways increases a sense of agency (Snyder, 1994). Following the weekly intervention phase, GLB + included group-based, semi-monthly or monthly contacts to reinforce behavioral and self-regulatory strategies. Sessions reinforced the practices of goal setting, problem-solving, and positive agency addressed during the weekly sessions. Three telephone coaching calls also were included to assess individual goal progress and to increase support, accountability, and problem-solving skills for goal attainment. The calls concluded with the establishment of a self-selected goal(s), identification of potential obstacles, and creation of specific pathways for goal attainment and minimizing obstacles.

Participants were unaware of differences between the interventions. They were informed that smaller groups were formed at week five for better tailoring and personalization of the intervention and that randomization occurred at month five for program evaluation. It was explained that a purpose of the study was to evaluate two versions of the program. Coaches also were unaware of the content and membership differences between treatment groups. All personnel were unaware of treatment stratification and random assignment until it occurred.

GLB coaches completed a two-day training in intervention delivery. GLB + coaches completed individual training conducted by the principal investigator. At least 20% of the group sessions were audio recorded to assess intervention fidelity. A checklist with key elements and topics of intervention sessions was completed by the principal investigator to identify departures from the protocol.

Outcome measures

Outcome measures targeted self-efficacy expectations, self-regulation, goal commitment, and hope regarding goal attainment, consistent with the conceptual framework for GLB + (Miller et al., 2023). Self-efficacy for eating a lower fat diet and engaging in PA was assessed using the Self-Efficacy for Eating and Exercise Behaviors Scales (Sallis et al., 1988). Five subscales were included: 'reducing calorie intake,' 'reducing fat intake,' 'sticking to healthy eating,' 'sticking to exercise,' and 'making time for exercise.' A 5-point response scale ranged from 'I know I cannot' to 'I know I can.' Cronbach's α, an estimate of internal consistency, ranged from 0.83–0.85 for the exercise subscales and 0.85–0.93 for the dietary subscales. Test-retest reliability coefficients were 0.68 for the exercise subscales and ranged from 0.43–0.64 for the dietary subscales previously (Sallis et al., 1988).

The Weight Efficacy Lifestyle Questionnaire (WEL) assessed participants confidence regarding the ability to successfully resist the desire to eat in various situations (Clark et al., 1991). Five subscales addressed high-risk situations such as when high-calorie food is available, when experiencing negative or positive emotions or physical discomfort, or when under social pressure. A 10-point response scale ranged from 'not confident at all that I can resist the desire to eat' to 'very confident that I can resist the desire to eat.' A total WEL score indicates global self-efficacy judgements about eating

behavior. The WEL was highly correlated with other measures of self-efficacy and affect and was sensitive to change following treatment in previous research (Clark et al., 1991).

The Self-Regulation for PA-12 Scale assessed participants use of self-regulation strategies, including self-monitoring, goal setting, eliciting social support, reinforcement, time management, and relapse prevention to support the adoption and maintenance of PA. The 5-point response options ranged from 'never' to 'very often,' and higher scores indicated greater use of self-regulatory strategies. Scale scores were related to self-efficacy for PA ($r = 0.56$) and self-reported PA ($r = 0.60$) previously (Umstattd et al., 2009).

Goal commitment was assessed using 7 items (Cronbach's $\alpha = 0.80$) to indicate how strongly the respondent was pursuing the goal of weight loss (e.g. 'I think this is a good goal to shoot for.'). The 5-point response options ranged from 'strongly disagree' to 'strongly agree,' and higher scores indicated stronger goal commitment (Seijts & Latham, 2000).

Hopeful thought and planning were assessed using the State Hope Scale (Cronbach's $\alpha = 0.93$). This scale assesses goal-directed determination, or agency, and goal-directed planning, or pathways. Higher levels of hopeful thought include both positive agency and effective planning. The 8-point response options ranged from 'definitely false' to 'definitely true' (Snyder et al., 1996).

Dietary intake during the previous year was assessed using the previously validated 127-item full-length Block 2014 Food Frequency Questionnaire (NutritionQuest, Berkeley, CA). The self-administered food frequency questionnaire and a food portion visual were provided for respondents to indicate the size of food portions consumed and frequency of consumption (e.g. 'never' to 'daily'), providing a daily estimate of energy and nutrient intake.

A Fitbit Flex 2 accelerometer (San Francisco, CA) was provided to each participant during data collection periods to assess minutes spent in PA across seven days of wear. Participants were instructed to wear the device on their non-dominant wrist during all waking hours except during swimming and bathing. A log was provided for participants to report PA that occurred (e.g. swimming) when the device was not recording. Prior research found the Fitbit device has similar accuracy for PA assessment compared to research grade accelerometers (Imboden et al., 2018; Lee et al., 2014).

Statistical analyses

Between-group differences in demographic characteristics at baseline were assessed using Wilcoxon rank sum test for continuous responses and Fisher's exact test for categorical responses. For each psychosocial and behavioral variable, a mixed effect linear model was fit with the (four) treatment sequence groups, assessment timepoints, and their interaction as fixed effects and participants as random effects. All within – and between-group change score comparisons were conducted using the fitted model. Given the sample size, the primary comparison of interest was the standard GLB/GLB intervention sequence compared to the novel GLB+/GLB + intervention sequence, and of secondary interest was the GLB/GLB + intervention sequence compared to the GLB+/GLB intervention sequence (Table 1). Separate models by sex also were estimated across the four intervention sequences in secondary analyses.

For the PA analyses, continuous step counts from the Fitbit device were extracted from the manufacturer's website (Small Steps Labs, Berkeley, CA). Participants were

included in the PA analyses if they had ≥ 4 days with ≥ 1,000 steps/day during the 7-day collection period. Fitbit uses proprietary algorithms to categorize intensity. However, it is estimated that they use the following guidelines for classifying PA intensity: lightly active (1.5-2.9 metabolic equivalents or METS), fairly active (3.0-5.9 METS), and very active (≥ 6.0 METS) (Jette et al., 1990). Lightly, fairly, and very active PA minutes were summed across the 7 days. Active PA minutes were recorded only when accumulated in ≥ 10-minute bouts.

For the current analyses with four intervention sequences, three independent sample t-tests comparing subgroups with sample sizes of 50 each, effect size of 0.66, and alpha of 0.0167 had 80% power to detect differences in mean outcome measures. All analyses were completed using JMP version 15 (Carey, NC, 2019). A P-value < 0.0167 was used for statistical significance to account for the Bonferroni correction of three comparisons of between – and within-group change scores at follow-up timepoints.

Results

The number of people screened for study eligibility, enrolled in the study, and completing the interventions is reported elsewhere (Miller et al., 2024). In brief, 589 people were assessed for study eligibility, 232 people initiated the intervention, 190 people were randomized to treatment group at month five, and 110 people completed the 18-month visit. There was no significant difference in study attrition across intervention sequences following randomization. Fifty-two of enrolled participants did not complete the 18-month data collection visit due to pandemic-related restrictions in 2020. There were no significant differences between groups in demographic characteristics except intervention sequence GLB+/GLB included more females than intervention sequence GLB/GLB + ($P < 0.05$; Table 3).

Change in outcomes between GLB/GLB and GLB+/GLB+

Between-group comparisons of GLB and GLB + at baseline and 4-months following the intensive, weekly intervention phase are reported elsewhere (Miller et al., 2023). For the purpose of context, they are briefly noted here. There were no significant differences in baseline self-regulatory outcomes between groups; however, GLB + reported greater energy and fat and lower carbohydrate intake at baseline. Both GLB and GLB + reported significant gains in self-efficacy for weight management, PA self-regulation, and hopeful thought and significant reductions in energy and fat intake at 4-months in the mixed model analyses.

In the current analyses, intervention sequence GLB/GLB reported an increase in self-efficacy for 'sticking to exercise' at 18-months compared to intervention sequence GLB +/GLB+, who reported a decline in self-efficacy during this time ($P < 0.01$), and the between-group difference was significant (Table 4). There also was a significant difference between these intervention sequences in self-efficacy for 'reducing fat intake,' 'sticking to healthy eating,' and total hope scores at 18-months (all $P < 0.01$), with GLB/GLB reporting an increase or relatively stable score compared to a decrease in score in GLB +/GLB + . There was no significant difference in the change in measures across intervention sequences for the other self-efficacy measures, goal commitment, measures of dietary intake, or minutes of PA.

Table 3. Participant characteristics at baseline across four intervention sequences[a].

Characteristic	GLB/GLB (n = 48)	GLB+/GLB+ (n = 63)	*P*-value	GLB/GLB+ (n = 31)	GLB+/GLB (n = 45)	*P*-value
	Mean (±SD)			**Mean (±SD)**		
Age (years)	52.15 (±10.19)	48.79 (±10.14)	0.0984	53.71 (±9.79)	54.69 (±9.21)	0.9451
Body mass index (kg/m^2)	35.55 (±5.96)	37.77 (±8.74)	0.4030	35.50 (±5.70)	36.63 (±8.90)	0.9242
	n (%)			**n (%)**		
Female	32 (66.67)	51 (80.95)	0.1220	17 (54.84)	37 (82.22)	0.0193
Married	30 (62.50)	40 (63.49)	0.8441	23 (74.19)	31 (70.45)	0.7979
Occupation			0.6410			0.8504
Professional	24 (52.17)	38 (63.33)		18 (60.00)	29 (65.91)	
Clinical	8 (17.39)	7 (11.67)		3 (10.00)	4 (9.09)	
Clerical	8 (17.39)	10 (16.67)		6 (20.00)	9 (20.45)	
Technical	5 (10.87)	5 (8.33)		2 (6.67)	2 (4.55)	
Other	1 (2.17)	0 (0.0)		1 (3.33)	0 (0.0)	
Education			0.4148			0.5362
High school or GED or vocational training	4 (8.33)	3 (4.76)		1 (3.23)	0 (0.0)	
Some college or bachelor's degree	26 (54.17)	29 (46.03)		12 (38.71)	20 (45.45)	
Postgraduate training or degree	18 (37.50)	31 (49.21)		18 (58.06)	24 (54.55)	
Race			0.0669			0.9012
Non-Hispanic white	43 (89.58)	47 (74.60)		26 (83.87)	34 (75.56)	
Non-Hispanic black	2 (4.17)	12 (19.05)		3 (9.68)	5 (11.11)	
Asian	3 (6.25)	4 (6.35)		2 (6.45)	3 (6.67)	
More than 1 race	0 (0.0)	0 (0.0)		0 (0.0)	1 (2.22)	
Not reported	0 (0.0)	0 (0.0)		0 (0.0)	2 (4.44)	
Ethnicity			1.00			0.3732
Hispanic	0 (0.0)	0 (0.0)		1 (3.23)	4 (8.89)	

[a]Values may not sum for the sample due to missing data.

In terms of within-group effects, GLB/GLB participants reported a decline in self-efficacy for 'sticking to exercise' at 12-months and those in GLB+/GLB + reported a decline in PA self-regulation and self-efficacy for weight management at 18-months (all $P < 0.01$). Participants in both intervention sequences reported a decline in commitment to losing weight at 12-months (all $P < 0.01$). Measures of self-efficacy for reducing calorie intake, making time for exercise, dietary measures, and minutes of PA were relatively stable at 18-months.

Change in outcomes between GLB/GLB + and GLB+/GLB

There were no significant differences in the change in self-regulatory, dietary or PA measures across these intervention sequences at 12 – and 18-months except for a decline in percent of energy from protein at 12-months and PA minutes at 18-months in intervention sequence GLB/GLB + (all $P < 0.01$; Table 4). GLB+/GLB reported a decline in goal commitment to losing weight at 12 months ($P < 0.001$).

Interaction effects by sex

There were few interaction effects by sex across the four intervention sequences except for self-efficacy for weight management (WEL score) and self-efficacy for 'making time for exercise' for females (data not shown). The change for females in self-efficacy for

Table 4. Comparison of the least squares mean (±SE) change in measures at 12 – and 18-months across four intervention sequences.

Self-Regulatory Measures	GLB/GLB[a]	GLB+/GLB + [b]	*P*-value [c]	GLB/GLB + [d]	GLB+/GLB [e]	*P*-value [c]
Self-efficacy: Reducing Calorie Intake						
Change: 4–12 months	−1.16 (±0.56)	−0.39 (±0.52)	0.3119	−1.23 (±0.72)	0.53 (±0.61)	0.0620
Change: 12–18 months	0.37 (±0.66)	−0.93 (±0.57)	0.1358	−1.78 (±0.86)	−1.15 (±0.73)	0.5792
Self-efficacy: Reducing Fat Intake						
Change: 4–12 months	−1.89 (±1.08)	0.93 (±0.99)	0.0560	−1.17 (±1.36)	1.10 (±1.18)	0.2072
Change: 12–18 months	1.40 (±1.26)	−3.01 (±1.10)**	0.0088	−1.17 (±1.64)	−3.37 (±1.41)	0.3094
Self-efficacy: Sticking to Healthy Eating						
Change: 4–12 months	−0.92 (±0.54)	0.31 (±0.49)	0.0949	−0.37 (±0.68)	0.76 (±0.58)	0.2057
Change: 12–18 months	−0.08 (±0.64)	−2.61 (±0.56)***	0.0031	−1.50 (±0.83)	−1.05 (±0.70)	0.6796
Self-efficacy: Sticking to Exercise						
Change: 4–12 months	−2.98 (±1.16)**	0.75 (±1.06)	0.0179	−3.02 (±1.47)	−0.43 (±1.26)	0.1817
Change: 12–18 months	2.78 (±1.36)	−1.79 (±1.18)	0.0117	−3.01 (±1.78)	−0.58 (±1.52)	0.2979
Self-efficacy: Making Time for Exercise						
Change: 4–12 months	−1.25 (±0.64)	0.38 (±0.58)	0.0609	−1.84 (±0.82)	0.21 (±0.69)	0.0546
Change: 12–18 months	0.59 (±0.75)	−0.77 (±0.65)	0.1719	−1.85 (±0.98)	−0.67 (±0.83)	0.3608
Physical Activity Self-regulation Skills						
Change: 4–12 months	−0.89 (±1.41)	0.74 (±1.29)	0.3956	−1.53 (±1.79)	−2.00 (±1.52)	0.8411
Change: 12–18 months	−2.51 (±1.66)	−6.39 (±1.45)***	0.0800	−3.03 (±2.17)	−0.17 (±1.85)	0.3083
Self-efficacy: Weight Management						
Change: 4–12 months	−7.07 (±3.72)	0.51 (±3.39)	0.1332	−4.37 (±4.78)	0.58 (±4.04)	0.4300
Change: 12–18 months	1.78 (±4.39)	−10.38 (±3.81)**	0.0372	−4.32 (±5.81)	2.07 (±4.88)	0.4001
Goal Commitment to Losing Weight						
Change: 4–12 months	−1.55 (±0.54)**	−1.47 (±0.49)**	0.9109	−1.51 (±0.68)	−1.69 (±0.58)**	0.8391
Change: 12–18 months	−0.26 (±0.64)	−1.07 (±0.56)	0.3402	−0.31 (±0.82)	−1.43 (±0.70)	0.3059
Total Hope Score						
Change: 4–12 months	−0.50 (±0.78)	−0.57 (±0.72)	0.9468	−1.57 (±1.01)	0.73 (±0.85)	0.0831
Change: 12–18 months	0.99 (±0.93)	−2.13 (±0.82)**	0.0119	−1.67 (±1.23)	−2.64 (±1.03)	0.5479
Dietary Measures						
Energy (kcal)						
Change: 4–12 months	117 (±71)	25 (±65)	0.3383	−149 (±90)	3 (±79)	0.2040
Change: 12–18 months	22 (±84)	−20 (±74)	0.7083	67 (±110)	3 (±96)	0.6584
Total fat (% energy)						
Change: 4–12 months	1.45 (±0.84)	0.54 (±0.76)	0.4242	1.33 (±1.06)	0.79 (±0.92)	0.6975
Change: 12–18 months	−0.37 (±0.99)	1.22 (±0.86)	0.2261	−0.95 (±1.29)	−0.20 (±1.13)	0.6596
Protein (% energy)						
Change: 4–12 months	−0.22 (±0.36)	−0.10 (±0.33)	0.8014	−1.31 (±0.46)**	−0.32 (±0.40)	0.1040
Change: 12–18 months	−0.24 (±0.43)	−0.12 (±0.38)	0.8298	0.08 (±0.56)	0.09 (±0.49)	0.9880

Carbohydrate (% energy)						
Change: 4–12 months	−1.45 (±0.90)	−0.76 (±0.82)	0.5720	0.62 (±1.15)	−0.62 (±1.00)	0.4163
Change: 12–18 months	0.42 (±1.06)	−1.17 (±0.93)	0.2612	0.55 (±1.40)	0.27 (±1.22)	0.8800
Fiber (grams)						
Change: 4–12 months	0.54 (±1.07)	0.47 (±0.97)	0.9622	−0.06 (±1.36)	1.64 (±1.18)	0.3451
Change: 12–18 months	−0.08 (±1.26)	−0.48 (±1.10)	0.8107	0.25 (±1.65)	−1.23 (±1.44)	0.4983
Total sugars (grams)						
Change: 4–12 months	−3.66 (±5.23)	2.72 (±4.02)	0.5270	−6.88 (±5.62)	0.24 (±4.89)	0.3397
Change: 12–18 months	3.66 (±5.23)	−2.37 (±4.58)	0.8521	2.76 (±6.86)	2.04 (±5.97)	0.9369
Moderate Intensity Physical Activity (total minutes across 7 days)						
Change: 4–12 months	21.07(±27.63)	9.86 (±24.85)	0.7632	−37.43 (±35.18)	−2.02 (±31.76)	0.4554
Change: 12–18 months	−50.66 (±33.92)	−42.87 (±29.58)	0.8627	−92.99 (±46.60)*	−15.97 (±38.47)	0.2032

[a]Intervention sequence Group Lifestyle Balance (GLB) from baseline to 4-months (n = 48) and GLB from 5 – to 18-months (n = 29). Some participants did not complete the 18-month assessment due to pandemic-related restrictions in 2020.

[b]Intervention sequence Group Lifestyle Balance Plus (GLB+) from baseline to 4-months (n = 62) and GLB + from 5 – to 18-months (n = 41)

[c]Comparison of the mean change between the two intervention sequences. A *p*-value < 0.0167 used to indicate statistical significance to account for the Bonferroni correction of three between – and within-group comparisons.

[d]Intervention sequence GLB from baseline to 4-months (n = 31) and GLB + from 5 – to 18-months (n = 17)

[e]Intervention sequence GLB + from baseline to 4-months (n = 45) and GLB from 5 – to 18-months (n = 23)

***P*-value < 0.01; ****P*-value < 0.001

'making time for exercise' decreased in GLB/GLB while there was little change in self-efficacy in GLB+/GLB + ($P = 0.0114$) at 12-months. The change for females in WEL in GLB/GLB increased while the change in GLB+/GLB + decreased ($P = 0.0118$) at 18-months.

No serious events occurred in any treatment group that were related to the interventions.

Discussion

The aim of the current study was to investigate the impact of sequence of behavioral lifestyle interventions on self-regulatory, dietary, and PA measures among adults with prediabetes at a university worksite. The novel GLB + intervention was developed to improve self-regulatory skills, goal setting, and goal pursuit among slow weight loss responders in adults at-risk for type 2 diabetes. We examined whether initial and continued training in these skills during the intensive and extended intervention phases (GLB +/GLB + intervention sequence) facilitated greater improvement in measures compared to initial and continued training in the standard intervention (GLB/GLB intervention sequence) prior to 6 months of no contact. The GLB+/GLB + intervention sequence reported declines in self-efficacy and hope at 18-months compared to the GLB/GLB intervention sequence; however, dietary and PA behaviors remained stable.

Participants were stratified to intervention based on early weight loss success at week five; therefore, early success for GLB participants likely served as reinforcement of the self-regulatory effort extended to promote success. Thus, some people with prediabetes who join a standard lifestyle intervention for weight loss experience initial success in changing behavior. Commitment to the goal of losing weight, however, declined for participants in GLB/GLB (early responders) at 12-months. These participants may have believed that the weight loss achieved was satisfactory (even if they did not lose as much weight as hoped at study enrollment), and commitment to engage in additional self-regulatory efforts to promote WLM was lower. Despite the 12-month decline in goal commitment, behavioral measures did not significantly deteriorate at 18-months. Thus, an intensive weekly intervention followed by semi-monthly and monthly 'booster' sessions was sufficient to facilitate lifestyle change for these early responders.

In contrast, slow responders were stratified to GLB + at week five, and some continued in GLB + following randomization at month five. The GLB+/GLB + intervention sequence reported a significant decline in commitment to the goal of losing weight at 12-months when participants knew they would not receive further study contact. Also, a decline in perceived self-efficacy for 'reducing fat intake,' 'sticking to healthy eating,' and weight management and in PA self-regulation skills at 18-months was observed following 6 months of no contact. The significant decline in hope at 18-months is particularly concerning in these participants who initially experienced a slow response. Participants may need to set smaller, more achievable goals over time as obstacles are encountered and experience goal attainment to bolster confidence and hope in sustaining lifestyle behaviors. Furthermore, a recent systematic review of qualitative studies among people who attempted to achieve WLM for ≥ 1 year found that support systems provided a sense of belonging and motivation for goal pursuit (Spreckley et al., 2021). In addition, the review found that prioritizing WLM and regularly adjusting dietary and PA goals

according to expected and unexpected life events enhanced adherence and commitment to WLM. The current findings suggest slow responders may need extended care beyond the 12-month period to enhance self-efficacy and continued commitment toward goals for WLM. In addition, more frequent assessment (e.g. weekly or monthly) of goal commitment, self-efficacy, and self-regulatory efforts during the extended intervention phase would allow for the determination of stability of the intervention effect and provision of just-in-time intervention support when significant declines are observed.

However, little research has examined the optimal content and delivery type of extended care needed for slow responders. Across behavioral weight loss programs, (Wing et al., 1996) found that weekly, year-long telephone calls by staff without intervention training was not effective in promoting WLM. (Perri et al., 1987) demonstrated no effect of peer-led maintenance groups on weight regain compared to no-contact. Another study by (Perri et al., 1984) provided evidence that a therapy-based extended care program had greater WLM compared to a contact-only group. A recent trial in which participants who lost < 2.5% of baseline weight at session four were randomized to receive either portion-controlled meals (to assist self-regulation of food intake) as part of a therapist-led standard behavioral weight loss program or receive an alternate therapist-led acceptance-based behavioral treatment (to develop new skills) found no significant between-group difference in weight loss at 18-months (Sherwood et al., 2022). Thus, therapist-led contact seems necessary in promoting WLM. However, the type of intervention that is most effective in promoting WLM, especially among slow responders to treatment, requires further investigation.

Pharmacotherapy may be effective as a form of stepped care for slow responders, especially for WLM (US Preventive Services Task Force, 2018). Weight loss medication (compared to placebo), implemented as stepped care for suboptimal response among patients with obesity and binge eating disorder, resulted in significantly greater reductions in both binge eating and weight in a recent trial (Grilo et al., 2020). Whether slow weight loss responders with prediabetes benefit from pharmacotherapy as stepped care requires further research. However, self-regulatory training to eat a healthful diet and engage in PA is recommended as part of a multicomponent program for long-term WLM and optimal health (Wadden et al., 2020). Currently, the optimal sequence for prescribing weight loss medication, if at all, in combination with lifestyle counseling is unknown. Additional research regarding the optimal treatment sequence for stepped care for slow responders is urgently needed.

There were no significant between-group differences in the change in measures across participants who received components of both the standard and augmented interventions in the current study. Participants in the GLB+/GLB intervention sequence reported a significant decline in commitment to the goal of losing weight at 12-months, reinforcing the finding that participants with early suboptimal response likely need ongoing support to bolster their self-efficacy beliefs and weight loss efforts. Participants may decide to 'give up' in terms of goal commitment instead of pursuing the goal without ongoing support. Further, the combination of GLB + followed by GLB during the extended intervention phase (i.e. GLB+/GLB) weakened the consistency of the GLB + behavioral messages and strategies with little carryover effect. Slow responders may need to remain in GLB + during the extended intervention phase to strengthen skill building and goal commitment.

Intervention stratification at session five depended on early weight loss success. Predictors of early success are needed to better tailor intervention content and focus for slow responders. The GLB + intervention in the current study was based on self-regulatory, theoretical models of change (Locke & Latham, 1990; Snyder, 1994), as prior research has not consistently identified predictors of early success (Carrraca et al., 2018). Greater research regarding characteristics of slow responders is needed for potentially more effective intervention tailoring. Furthermore, different types of extended care may be needed for different subgroups of participants. The variables on which to segment participants for intervention tailoring requires in-depth investigation as participant needs vary widely. How to provide extended care in a sustainable, cost-effective manner also requires further research.

Strengths and limitations

While this is one of the few studies to examine the impact of intervention sequence on outcomes, some limitations should be noted. The sample included more women (66%) than men and generalizing findings to a broader population of men with prediabetes requires further investigation. This study is noteworthy since both men and women were enrolled, as many prior weight loss studies were conducted among women only (Kiernan et al., 2013; Perri et al., 2001). Due to time lost during pandemic restrictions, 52 participants did not complete the final 18-month visit. Thus, precision of the estimates and power are diminished for comparisons involving the final visit, which reduces the ability to detect long-term differences. Study measures consisted primarily of self-reported instruments and may be subject to bias from social desirability. The assessment of dietary intake asked participants to self-report usual intake which is subject to recall bias.

Conclusion

In summary, early weight loss success can be initially beneficial in sustaining motivation and self-regulatory beliefs regarding dietary intake and PA. Yet, self-efficacy for eating a healthy diet, implementing self-regulation skills for PA, and being hopeful significantly declined among slow responders compared to early responders at 18-months. However, there was no significant difference at 18-months in the change in dietary and PA behaviors between early and slow responders. Extended care beyond the 12-months of intervention provided in this study is likely needed to bolster training, support, and accountability, especially among slow responders (Middleton et al., 2012). The content and type of intervention support that is effective and sustainable among adults with prediabetes requires additional research to reduce the incidence of type 2 diabetes, as empirically-based clinical guidelines currently are not available (Bray et al., 2018). Furthermore, identification of predictors of early and long-term success is needed to better tailor extended care for slow responders. Efforts should be made to enhance early weight loss during behavioral treatment and develop empirically-based guidelines for stepped care for slow responders.

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Data deposition

The datasets used during the current study are available from the corresponding author upon reasonable request.

Disclosure statement

No potential conflict of interest was reported by the author(s).

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Ethics approval & consent to participate

The study was conducted in accordance with the Declaration of Helsinki and was approved by an Institutional Review Board. See details under Methods.

Study participants provide written informed consent under approval number 2016H0392 by the Ohio State University Institutional Review Board.

Trial registration

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