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An iterative mindset approach as an adjunct to the national diabetes prevention program: a randomized trial assessing retention, engagement and weight loss

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Abstract

Background Retention and engagement continue to be a challenge for the National Diabetes Prevention Program lifestyle change program (LCP). This challenge is especially stark for persons living in medically-underserved, economically-disadvantaged communities. In the current work, we sought to investigate if a digital solution—an adjunct habit formation app (Fresh Tri®) grounded in neuroscience theory around iteration (i.e., changing one's approach to a problem when encountering challenges)—could improve these metrics, as well as weight loss, in these populations.

Methods We conducted a randomized study using a three-level, nested hierarchical structure, with 364 participants (212 intervention; 152 control) across 33 sites from February 1, 2021–October 13, 2022. We examined retention, engagement (number of sessions attended) and $\geq 5\%$ body weight loss for participants in the intervention condition (standard LCP curriculum plus the Fresh Tri iterative mindset app) compared to the control condition (standard LCP curriculum) and also to a nationally representative group (National DPP LCP data from the United States Centers for Disease Control and Prevention (CDC)).

Results Intervention participants reported higher retention than controls at 6 months (79.7% vs. 67.1%; OR = 2.06; 95% CI = 1.15–3.68; $P=.01$) and 12 months (78.3% vs. 53.1%; OR = 3.14; 95% CI = 1.11–8.88; $P=.03$). Engagement at 6 and 12 months was not statistically different. Compared to the National DPP LCP participants overall, both the intervention and control arms had higher retention ($P<.001$) and engagement (intervention $P<.001$; control $P=.02$) at 6 months. We found no differences in $\geq 5\%$ body weight loss between intervention and control groups at 6 months (26% vs. 27%; OR = 0.99; 95% CI = 0.57–1.73; $P=.97$, $P=.90$), but a statistically significant higher proportion of those in the intervention arm having $\geq 5\%$ weight loss after 12 months (41.3% vs. 30.6%, OR = 1.72; 95% CI = 1.01–2.92; $P=.05$).

Conclusions Overall, these results show promise for the applicability of a digital habit formation app, based on an iterative mindset, as an adjunct to the LCP for retention and weight loss.

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Trial registration This clinical trial (ClinicalTrials.gov Identifier: NCT06656273) was retrospectively registered on October 18, 2024.

Keywords Mindset, Habit formation, Retention, Engagement, Digital health, Weight loss, Iteration

Background

Diabetes remains a persistent, global public health challenge. In the United States, 29.7 million adults have been diagnosed with type 2 diabetes mellitus while 97.6 million meet clinical criteria for prediabetes [8]. The societal consequences of diabetes are increased morbidity and mortality [8], as well as indirect impacts such as productivity losses and excess healthcare spending [1, 27]. Prediabetes, similarly, places a significant strain on individuals and systems. Those with elevated glucose levels have a higher risk for worse health outcomes [10], including higher rates of cardiovascular [22], renal [36], and ophthalmic diseases [38]. Perhaps most concerning, individuals from racial and ethnic minority groups suffer from nearly twice the rate of diabetes [7] and have significantly worse outcomes than their non-Hispanic (NH) White counterparts, [4, 14, 18, 25] including higher risk of end stage renal disease for NH Black individuals [13] and higher rates of renal and cardiovascular disease for Hispanic individuals [30].

Intensive lifestyle change programs have been successful in preventing and delaying onset of type 2 diabetes [37] and have become the first-line treatment choice [16]. The National Diabetes Prevention Program (National DPP) lifestyle change program (LCP)—widely considered to be the gold standard [2, 15, 19]—has brought evidence-based lifestyle modification to hundreds of thousands of participants across the U.S [7, 12, 16]. However, despite the National DPP's success, the program has not been adopted widely by, nor demonstrated as strong an effect, for persons who live in locations with higher rates of poverty and limited access to healthcare services [5]. National DPP providers have also faced challenges in recruiting and retaining participants from lower income, rural, and racial/ethnic minority populations [5, 35]. Among those within these populations who do enroll, rates of retention, engagement, and weight loss are lower than those of higher income and NH White individuals [34]. To further understand and address these challenges, we investigated the effect of using a novel methodology called the Iterative Mindset Method™ (IMM) to create positive and sustainable health behaviors and habits, delivered via a mobile app and used as an adjunct to the standard LCP.

In the current work, we assess an innovative digital solution—namely, the IMM delivered through the Fresh Tri app—to address the issues of retention, engagement and weight loss in the National DPP, especially for vulnerable populations. The IMM is a try-and-tweak mental

strategy for the development of lasting habits and behavior change [3]. The IMM combines the use of three key strategies, including assessment (i.e., viewing failure as a part of learning), practice (consistently repeating a behavior enough to elicit the neuroplasticity required to develop lasting habits) and iteration (i.e., adapting new strategies to overcome obstacles and sustain practice).

In this study, we evaluate whether a digital app that seeks to strengthen users' iterative mindset can improve retention, engagement and weight loss for individuals enrolled in the National DPP's lifestyle change program (LCP). Because the IMM does not rely on traditional goals and tracking approaches to weight loss, we did not assess measures such as food, activity or weight tracking (although the LCP does ask participants to track their weight and physical activity). We assessed the downstream outcomes measures - retention, engagement and weight loss, rather than the interim activities (e.g., tracking).

We specifically focus on communities that scored above average on the COVID-19 Community Vulnerability Index (CCVI). These populations are identified by calculating relative vulnerability across seven main themes: (1) socioeconomic status; (2) minority status and language; (3) household and transportation; (4) epidemiological factors; (5) healthcare system factors; (6) high-risk environments; and (7) population density. Each individual theme is scored from zero (low vulnerability) to 1 (high vulnerability). Individual theme scores are aggregated into a single vulnerability score (from 0 to 1) by census tract, county, or state. Many of these types of vulnerabilities have been shown to be barriers to retention and engagement ([5, 33, 35]).

In summary, our overall goal in the current work is to test whether the Fresh Tri LCP can help improve retention, engagement and weight loss, in populations who score higher than average on the CCVI. We do this using a randomized control design.

Methods

An independent ethical review board, WCG IRB, reviewed and approved this study protocol (<https://www.wcgirb.com/>, #1300367). Trial design and implementation adhere to CONSORT guidelines [20]. We incorporated a two-arm, three-level cluster study, whereby participants were nested within classes, and classes were nested within sites. We randomized groups of individuals, or clusters, rather than individual participants, in order to minimize contamination between intervention

and control groups that may occur when individuals within the same cluster receive different treatments and to reduce disruption to management of the classes. In this study, a cluster was an LCP class at a given site.

We employed a per protocol approach for sample size and a modified intent-to-treat (mITT) data analysis, rather than a full ITT approach, because the intervention in this study was an adjunct to the existing DPP LCP, rather than an independent treatment. Because there are a number of reasons related to the LCP—and not the study intervention—why a participant might drop out of the study or not adhere to the protocol (e.g., concerns with their coach, issues with the general LCP curriculum, etc.), we believed that powering the study for and analyzing only those that were actually eligible for and able to receive the intervention as designed was appropriate. This approach allowed us to evaluate the app's added value within the intended implementation context, rather than the overall program effect regardless of exposure.

We randomized arm allocation at the site level using the RAND function in Excel. The first class at each site enrolled in the study was randomly assigned to either the intervention or control arm. If additional classes were enrolled from a particular site, we alternated the subsequent class to the other study arm to make the demographic characteristics more similar in the two arms. We assigned classes to either the control arm (standard curriculum), or the intervention arm (standard curriculum plus Fresh Tri).

We had three primary outcomes assessed at 6 months: retention, a binary variable indicating whether a participant remained enrolled in the LCP; engagement, the number of LCP sessions attended by a participant; and weight loss, a binary variable indicating whether the individual achieved $\geq 5\%$ body weight loss. While the original study design included a 6-month study period, we were able to access follow-up data for retention, engagement and weight loss on a subset of participants at 12 months following study entry.

Intervention and control arms

The study intervention was using the Fresh Tri app as a companion tool to a standard LCP curriculum (either PreventT2 or the 2012 curriculum). The LCP curriculum and standard delivery method was not altered for those in the intervention arm, with use of the Fresh Tri app being additive to the program.

We designed Fresh Tri in coordination with CDC and LCP sites as a behavior change and habit formation app to enhance the LCP. The app operationalizes behavior change techniques including habit formation, behavioral experiments, behavioral practice, framing/reframing, problem solving/coping, planning, social support, reattribution, and positive self-talk, as part of

the Iterative Mindset Method™ [3], Fresh Tri's proprietary behavior change methodology. This methodology includes a dynamic, non-linear cycle of behavioral practice (the effort put into adopting a behavior and building a habit), assessment (reflection on personal barriers, learnings, and progress) and iteration (adjusting or refining a behavior change strategy as needed). LCP Lifestyle Coaches monitored participant progress and communicated with participants through Fresh Tri using chat-based messages.

LCP participants in the intervention arm were granted free access to the Fresh Tri app. A representative from Fresh Tri conducted a brief (15–20 min) training on the app for these participants during their initial LCP session. LCP Lifestyle Coaches were instructed to encourage participants to use Fresh Tri in between their LCP sessions in order to learn and practice an iterative approach to their habit formation, stay in practice and receive motivational support. The coaches monitored participant progress and communicated with participants through Fresh Tri using chat-based messages.

The control arm included individuals who signed up for the standard LCP curriculum at participating NDPP sites. The curriculum includes sessions that focus on physical activity, diet, and behavior change, and was delivered by lifestyle coaches. Control arm participants were not given access to the Fresh Tri app and were not given any additional tools beyond what was offered to them through the standard program.

Consent

During enrollment, intervention arm participants signed informed consent (including Health Insurance Portability and Accountability Act, or HIPAA, authorization) electronically or on hard copy. Control group participants signed a HIPAA waiver for data collected in the study, but did not sign an informed consent to receive an intervention because they only received the standard LCP for which they had signed up. We advised all LCP registrants in both intervention and control arms of their right to decline participation in the study without losing any benefits from the standard LCP.

Sample size

We calculated sample size employing a per protocol analysis approach, using study parameters of 0.05 alpha, 0.02 beta, and 90% power for all three outcomes. Mean reference values were based upon prior literature as follows: retention at 6 months ($\mu = 55\%$ retained; $\sigma = 11.1$; [5]) number of sessions attended in 6 months, or engagement ($\mu = 14$ sessions; $\sigma = 6.75$; [12]); $\geq 5\%$ body weight loss at 6 months ($\mu = 35\%$ achieved body weight loss goal; $\sigma = 7.5\%$; [12]). We assumed attrition of 30% to account for dropout and 30% non-compliance with the treatment

protocol. These rates were estimated based on previous literature considering factors such as intervention intensity and participant characteristics [5]. After adjusting for attrition and compliance, we predicted a sample size of 216 participants per arm to power the study. To account for additional unknown risks, we inflated this to a maximum enrollment sample size of 275 per group.

Site recruitment

Recruitment efforts included an email campaign and an informational webinar series for potential study sites across the U.S. from the registry of CDC-recognized LCP sites, with emphasis on enrolling sites serving people in geographically, socially, and economically disadvantaged communities. We enrolled classes at LCP sites from 17 states in urban, suburban, and rural settings, primarily at YMCAs, academic institutions, community health organizations, and small, privately-run entities. We recruited between February 1 and October 13, 2021, with follow-up through October 13, 2022. We required coaches who were leading the intervention delivery to attend a training on using Fresh Tri. Three sites (with 5 total classes and 35 participants) were excluded from the study before enrollment because these sites did not sign a study agreement. One other site was excluded (with two intervention classes, totaling 12 participants, and two control classes, totaling 13 participants) after enrollment when it was discovered that this site was not following the standard DPP curriculum.

Participant recruitment

We recruited potential participants from the pool of individuals already enrolled in an LCP class at prospective study sites. Inclusion criteria for participants in the study were: (1) eligibility for and enrollment in an LCP at a site selected for this study during the enrollment period; (2) possession of a smartphone or other device able to run the Fresh Tri app; (3) registration in the Fresh Tri app; and (4) ability to read English at fifth-grade level or higher (determined by the LCP sites). Inclusion criteria 2 and 3 applied to intervention arm participants only. We found that requiring use of a digital app did not deter enrollment in the study, with almost all LCP participants, who otherwise wished to enroll in the study, being able to use a smart phone or other device to register for and use Fresh Tri. We excluded participants from analysis post-enrollment, due to not meeting LCP participant criteria (at the discretion of the sites), based on National DPP enrollment standards. These disqualifying instances included missing required study data, based on one or more of the following reasons: (1) prediabetes status not confirmed based on glucose test, risk test, or gestational diabetes mellitus score; (2) physical activity never recorded for that participant; (3) weight not recorded for

both the first and last LCP sessions; (4) did not attend at least two LCP sessions (see Fig. 1 for enrollment flow). We excluded one participant because they effectively withdrew their informed consent by indicating that they no longer wanted to be in the study or use the app, making them, similarly, ineligible for the study.

For an LCP class to be eligible to participate as an intervention class, at least 80% of the class had to agree to participate in the study and successfully register in the Fresh Tri app. No monetary incentives were given to participants for enrolling; however, each participant received a \$20 gift card as compensation if they completed the post-survey, which participants did not learn about until after they had completed the study. We compensated sites up to \$150 per enrolled participant for the following activities: (1) \$50 for each completed participant intake survey; (2) \$50 per participant in the intervention arm whose coach was trained to use the app; (3) \$50 for each completed participant post-survey at 6 months or earlier drop out. Compensations 1 and 3 were paid for both intervention and control classes, whereas compensation 2 was paid only for intervention classes.

We screened a total of 485 participants, but 35 were members of classes at sites that did not ultimately enroll in the study. Therefore, final enrollment for the study included 450 participants (55 classes), of whom 257 were in the intervention arm (27 classes, 9.5 participants per class) and 193 were in the control arm (28 classes, 6.9 participants per class). We excluded from the analysis 45 intervention and 41 control participants (see Fig. 1 for reasons and numbers). The final analysis sample for the 6-month study period thus included 212 intervention (25 classes) and 152 control (26 classes) participants (see Table 1; Fig. 1).

Measurements

We analyzed three primary outcomes: retention (yes/no), engagement (# of sessions attended), and achievement of $\geq 5\%$ weight loss (yes/no) and compared these between intervention and control conditions. These outcomes were selected because of their known association with diabetes risk reduction [17, 23] and because LCP sites are typically reimbursed by payers based on these metrics [28]. We obtained CCVI data to understand the degree of vulnerability of the study site communities. For further comparison, we obtained these outcome measures for all other National DPP LCP participants who received the program via distance learning (e.g., video-conferencing; [9]) during a similar time period and whose data were reported to CDC's Diabetes Prevention Recognition Program ("National DPP Comparison Data").

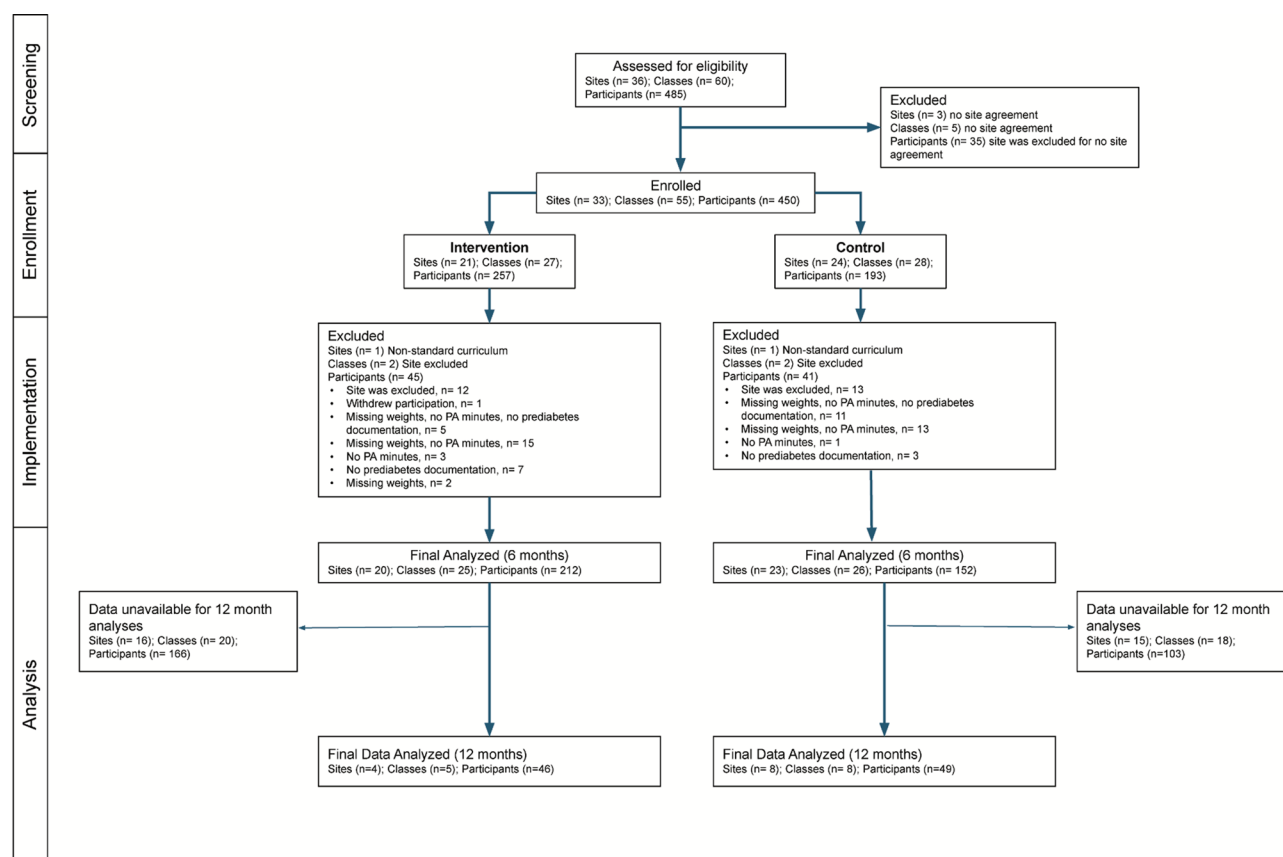


Fig. 1 CONSORT diagram for enrollment cascade. Figure 1 outlines the sequential process of enrollment of sites, classes, and participants, including the reasoning for any exclusions or removed data. Abbreviations: PA= physical activity

Data collection

LCP coaches collected the previously described measurements and the sociodemographic data required for organizations to maintain recognition as National DPP LCP providers. Site data administrators submitted these data to Fresh Tri on a monthly basis. Data collection went from enrollment of the first participant on February 1, 2021, and 6-month program completion by the final enrolled class on April 13, 2022. Although we initially designed the study to be 6 months in duration, we had the opportunity to collect data for an additional 6 months for a subset (13) of our enrolled classes (5 intervention and 8 control), covering approximately 25% of the total study population. These sites agreed to supply the 12-month data in exchange for an additional \$150 per class. Due to our rolling enrollment design, sites that provided this additional data consisted of classes that were still actively completing their 6-month study period toward the end of the study overall.

Analysis strategy

This clustered trial had three levels, whereby a person was nested within classes, and classes were nested within sites. We first compared participant characteristics (age,

sex, race/ethnicity, and CCVI) between study arms at baseline. Descriptive statistics included mean and standard deviation for continuous variables and count and percentages for categorical variables (see Table 1). For primary hypotheses, to evaluate intervention effects, we used mixed-effect models. Specifically, we used a generalized linear mixed-effect model with a logistic link to analyze achieving 6-month retention (yes/no) and $\geq 5\%$ body weight loss (yes/no), and we used a generalized linear mixed-effect model with a Poisson link for count data to analyze engagement (# of sessions attended). Results for engagement are expressed as a rate ratio (RR). Results for the two binary outcomes are expressed as odds ratios (OR). We adjusted all mixed-effect models for CCVI and included random intercepts of sites and random intercepts for classes within the sites. All statistical analyses were conducted using SAS 9.4 (SAS Institute), and statistical significance was assessed at the two-sided 5% level.

The primary analysis followed a modified intention-to-treat (mITT) approach. The analytic population included all enrolled participants except those who were subsequently determined to be ineligible for participation under the National DPP enrollment criteria, and one participant who withdrew informed consent. No

Table 1 Comparison of baseline characteristics between treatment arms

	Intervention	Control	P-value
Class, n	25	26	
Participant, n	212	152	
Baseline			
Age (years), mean (SD)	56.39 (12.96)	56.36 (13.05)	0.98
Missing	12	15	
Sex			
Male, n (%)	45 (22.06%)	27 (19.7%)	0.59
Female, n (%)	156 (77.61%)	110 (80.29%)	
Missing	11	15	
Race/ethnicity			
Non-Hispanic White, n (%)	92 (48.94%)	67 (57.26%)	.16 ^a
Racial/ethnic minority groups, n (%)	96 (51.06%)	50 (42.74%)	
Non-Hispanic Black	46 (24.47%)	18 (15.38%)	
Hispanic	11 (5.85%)	9 (7.69%)	
Other	39 (20.74%)	23 (19.66%)	
Missing	24	35	
COVID-19 Community Vulnerability Index, Mean (SD)	0.69 (0.21)	0.64 (0.21)	0.03

^aThis P-value is a comparison between the category of non-Hispanic White and the category of racial-ethnic minority groups (including non-Hispanic Black, Hispanic, and Other)

P-values were calculated using Fisher's exact test and independent t-test. Missing values for baseline characteristics were those not reported by the participant

participants were excluded on the basis of non-adherence, intervention exposure, or post-enrollment outcomes. Importantly, the resulting analytic population was identical to that which would have been analyzed under a standard intent-to-treat framework, as the excluded participants were not eligible to participate in either the intervention or comparison groups. Thus, exclusions were independent of treatment assignment and outcome and were prespecified based on eligibility criteria rather than protocol compliance. The study's findings, therefore, are robust to the choice of analysis set.

Results

Baseline characteristics

Participants in the intervention and control arms were similar in terms of age and sex (see Table 1). More than half of participants in the intervention arm were from racial and ethnic minority groups (NH Black, Hispanic, and Other), non-significantly higher than in the control arm (51% vs. 43%, $P=.16$) and significantly higher than the National DPP Comparison Data (51% vs. 42%, $P=.01$). The CCVI was significantly higher in the intervention arm compared to the control arm (0.69 vs. 0.64, $P=.03$, national average = 0.5). Baseline age, sex, and race did not differ significantly between participants who completed

Table 2 Baseline demographic characteristics between participants with and without 12-month follow-up

	Completed 12-month follow-up	Did not complete 12-month follow-up	P-value
Participant, n	95	269	
Baseline			
Age (years), mean (SD)	58.4 (13.4)	55.7 (11.6)	0.07
Sex			
Female, n (%)	73 (76.8)	193 (71.8)	0.34
Race/ethnicity			
Non-Hispanic White, n (%)	41 (43.2)	118 (43.9)	0.31
Non-Hispanic Black	16 (16.8)	48 (17.8)	
Hispanic	2 (2.1)	18 (6.7)	
Other	36 (37.9)	85 (31.6)	
Missing	24	35	
COVID-19 Community Vulnerability Index, Mean (SD)	0.7 (0.2)	0.6 (0.2)	<0.0001

P-values were calculated using Fisher's exact test and independent t-test

the 12-month follow-up and those who did not (Table 2). Mean baseline CCVI was higher among participants who completed the 12-month (0.7) follow-up than among those who did not (0.6; $p < .0001$).

Retention at 6 and 12 months

At 6 months, intervention classes had a statistically significant higher retention of participants than control classes (79.7% vs. 67.1%, OR = 2.06; 95% CI = 1.15–3.68; $P=.01$) (Table 3; Fig. 2). After controlling for CCVI using a mixed-effect logistic regression model, retention effects remained statistically significant with the intervention arm demonstrating a 108% increased odds of being retained at 6 months compared to the control arm (OR = 2.08; 95% CI = 1.16–3.73; $P=.01$) (Table 3). When compared to the National DPP Comparison Data, both the intervention and control arms were significantly more likely to be retained at 6 months ($P<.001$) (Fig. 3). At 12 months, we analyzed available data ($n=95$, 26% of 6 month sample) and found that retention in the intervention arm compared to the control arm remained significant (OR = 3.14; 95% CI = 1.11, 8.88; $P=.03$), with the intervention arm ($n=46$) retaining 36 (78.3%) participants while the control arm ($n=49$) retained 26 (53.1%). When controlling for CCVI, however, we did not find a significant intervention effect on the odds of retention at 12 months (OR = 2.29; 95% CI = 0.55–9.61; $P=.25$) (Table 3).

Engagement at 6 and 12 months

Engagement, measured by the number of sessions attended by a participant, at 6 months was similar between the intervention and control arms (14.4 ± 4.5 sessions vs. 13.2 ± 5.0 sessions; RR = 1.08; 95%

Table 3 Unadjusted and adjusted mixed effect model results of primary and secondary outcomes

	Unadjusted Models						Adjusted Models					
	Retention at 6 months (n = 364)		Engagement 0–6 months (n = 364)		≥ 5% Body weight loss at 6 months (n = 364)		Retention at 6 months (n = 364)		Engagement 0–6 months (n = 364)		≥ 5% Body weight loss at 6 months (n = 364)	
	OR (95% CI)	P	RR (95% CI)	P	OR (95% CI)	P	OR (95% CI)	P	RR (95% CI)	P	OR (95% CI)	P
Intervention	2.06 (1.15, 3.68)	0.01	1.08 (0.98, 1.18)	0.14	0.99 (0.57, 1.73)	0.97	2.08 (1.16, 3.73)	0.01	1.08 (0.98, 1.19)	0.12	1.02 (0.59, 1.78)	0.94
Control	ref		ref		ref		ref		ref		ref	
	Retention at 12 months (n = 95)		Engagement 0–12 months (n = 101)		≥ 5% Body weight loss at 12 months (n = 95)		Retention at 12 months (n = 95)		Engagement 0–12 months (n = 101)		≥ 5% Body weight loss at 12 months (n = 95)	
	OR (95% CI)	P	RR (95% CI)	P	OR (95% CI)	P	OR (95% CI)	P	RR (95% CI)	P	OR (95% CI)	P
	OR (95% CI)	P	RR (95% CI)	P	OR (95% CI)	P	OR (95% CI)	P	RR (95% CI)	P	OR (95% CI)	P
Intervention	3.14 (1.11, 8.88)	0.03	1.17 (0.99, 1.38)	0.06	1.72 (1.01, 2.92)	0.05	2.29 (0.55, 9.61)	0.25	1.19 (0.94, 1.50)	0.15	1.76 (0.35, 8.85)	0.49
Control	ref		ref		ref		ref		ref		ref	

All models adjusted for CCVI. Engagement is defined as the total number of sessions attended from 0–6 months or 0–12 months

Abbreviations: OR, Odds Ratio; RR, Rate Ratio; CI, Confidence Interval; ref, reference; p, p-value

CI=0.98–1.18; $P=.14$) (Table 3; Fig. 2). After controlling for CCVI, engagement for the intervention and control arms remained similar ($RR=1.08$; 95% CI=0.98–1.19; $P=.12$) (Table 3). Compared to the National DPP Comparison Data (12.1 ± 5.4 sessions), however, both the intervention and control arms demonstrated statistically significant higher engagement ($P<.001$ and $P=.02$, respectively) at 6 months (Fig. 3). At 12 months, there was not a difference in engagement between the intervention ($n=46$) and control ($n=49$) arms (20.5 ± 5.9 sessions vs. 16.6 ± 6.1 sessions; $RR=1.17$; 95% CI=0.99–1.38; $P=.06$). After adjusting for CCVI, this result remained non-significant ($RR=1.19$; 95% CI=0.94–1.50; $P=.15$) (Table 3).

Weight loss at 6 and 12 months

At 6 months, the proportion of participants achieving $\geq 5\%$ body weight loss was equivalent between intervention and control arms (26% vs. 27%; $OR=0.99$; 95% CI=0.57–1.73; $P=.97$) (Table 3; Fig. 2). After adjusting the model for CCVI, we also found similarity between the groups ($OR=1.02$; 95% CI=0.59–1.78; $P=.94$) (Table 3). A similar proportion within the National DPP Comparison Data (24.9%) achieved $\geq 5\%$ body weight as the intervention and control arms at 6 months ($P=.73$ and $P=.57$, respectively) (Fig. 3). At 12 months, the proportion of those achieving $\geq 5\%$ body weight loss was significantly higher in the intervention arm (41.3%) compared to the control arm (30.6%) ($OR=1.72$; 95% CI=1.01–2.92; $P=.05$). The mixed-effect logistic regression model, adjusted for CCVI, however, demonstrated a non-significant difference in the odds of achieving $\geq 5\%$ body weight loss between groups at 12 months ($OR=1.76$; 95% CI=0.35–8.85; $P=.49$) (Table 3).

Adverse events

We did not observe any adverse events in this study.

Discussion

The National DPP LCP has shown promising results in reducing rates of conversion from prediabetes to type 2 diabetes mellitus [24]. Despite this, retention and engagement, which are known drivers of weight loss and reduction in diabetes risk and therefore integral to programmatic success [5, 33, 34, 35] have been hard to achieve, particularly in persons who live in communities with higher rates of poverty and decreased access to medical and social services [5, 35]. Accordingly, there have been strong recommendations to develop creative strategies for improving retention and engagement [6, 39].

To reach this aim, Fresh Tri, LLC collaborated with the CDC to create Fresh Tri LCP, a habit formation app based on the Iterative Mindset Method, to be used as an adjunct to the standard LCP curriculum with the goal of improving retention, engagement, and $\geq 5\%$ body weight loss. We hypothesized that intervention participants, when introduced to an iterative approach to lifestyle change and habit formation through Fresh Tri, would demonstrate higher rates of retention and engagement and better weight management, compared to participants in the control condition. We found that the intervention had a significant positive effect on retention at 6 and 12 months. The absolute differences in retention for the intervention arm compared to the control arm were 12.6% at 6 months and 25.2% at 12 months. Effects for engagement, while numerically different at 6 and 12 months, failed to reach statistical significance. The

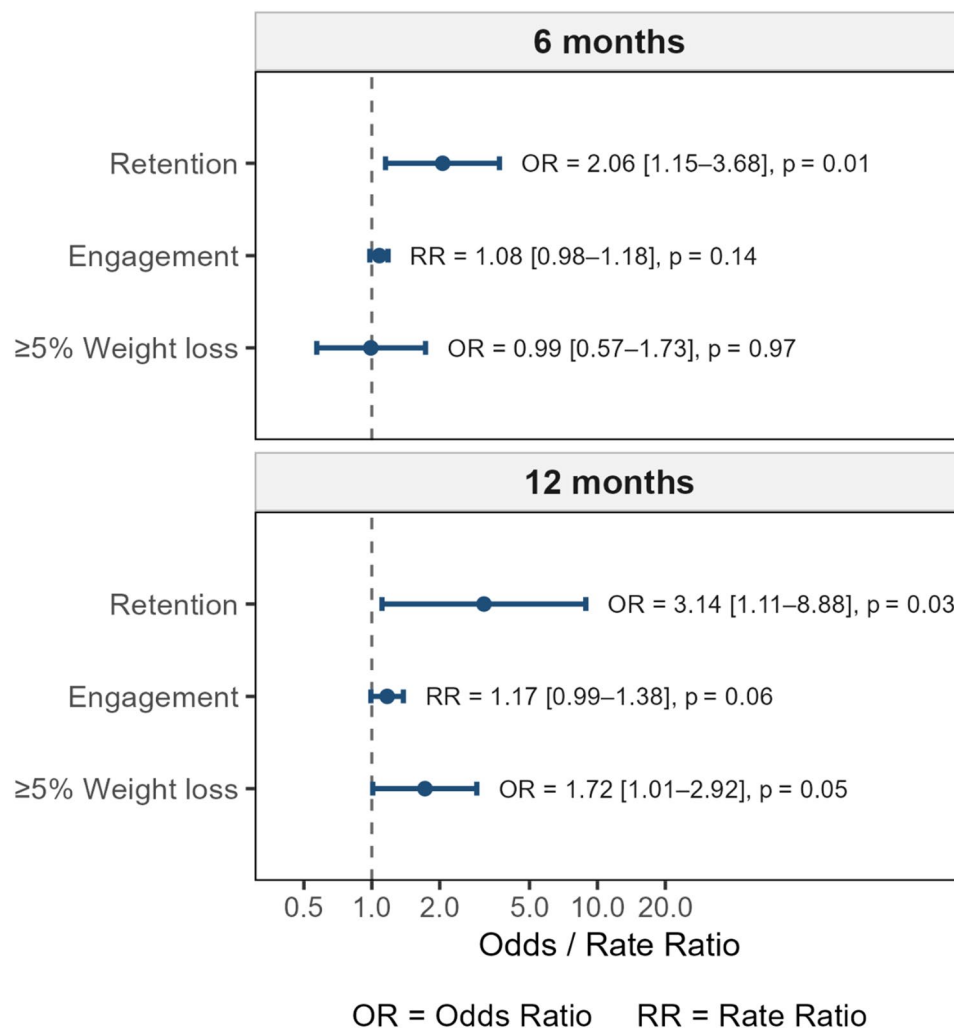


Fig. 2 Unadjusted odds and rate ratios for program outcomes at 6 and 12 months. Panels show the intervention effects on (1) Retention, (2) Engagement (session attendance), and (3) $\geq 5\%$ Weight Loss. Points represent point estimates for the Intervention group relative to the Control group, with horizontal bars indicating 95% confidence intervals. Dashed vertical line represents the null value (OR=1.0). All estimates are from unadjusted mixed-effect models comparing intervention and control participants at each timepoint (6 months and 12 months)

outcome of $\geq 5\%$ weight loss was equivalent between the intervention and control arms at 6 months. However, by 12 months, the intervention arm had significantly higher weight loss, showing a progression towards greater weight loss over time. Additional, larger studies using a 12-month study period could elucidate whether weight loss in the LCP does improve over time using Fresh Tri.

Our findings have practical implications for the utility of using a digital intervention to help individuals practice an iterative approach for the prevention of Type 2 Diabetes. This study demonstrates that a digital application can be included in the delivery of the LCP without much difficulty for the coaches or participants. The results are particularly relevant to future National DPP success for vulnerable populations due to successful recruitment of individuals from LCP sites within zip codes that score higher than average on the CCVI, with intervention arm

sites having a statistically significant higher CCVI (0.69) as compared to control (0.64).

Limitations

Despite applications and implications, there are limitations worth noting. For example, several challenges resulted from the COVID-19 pandemic, which was ongoing throughout the study. National DPP sites, which had previously offered the LCP in-person, were forced to switch to distance-learning delivery. This rapid shift contributed to decreased site and participant enrollment and the need for protocol adaptations.

This challenge to enrollment led to our not being able to achieve the final analyzed sample size needed to fully power the study. The predicted sample size for full power was 216 per arm, and we ended up with 212 analyzed participants in the intervention arm and only 152 in the

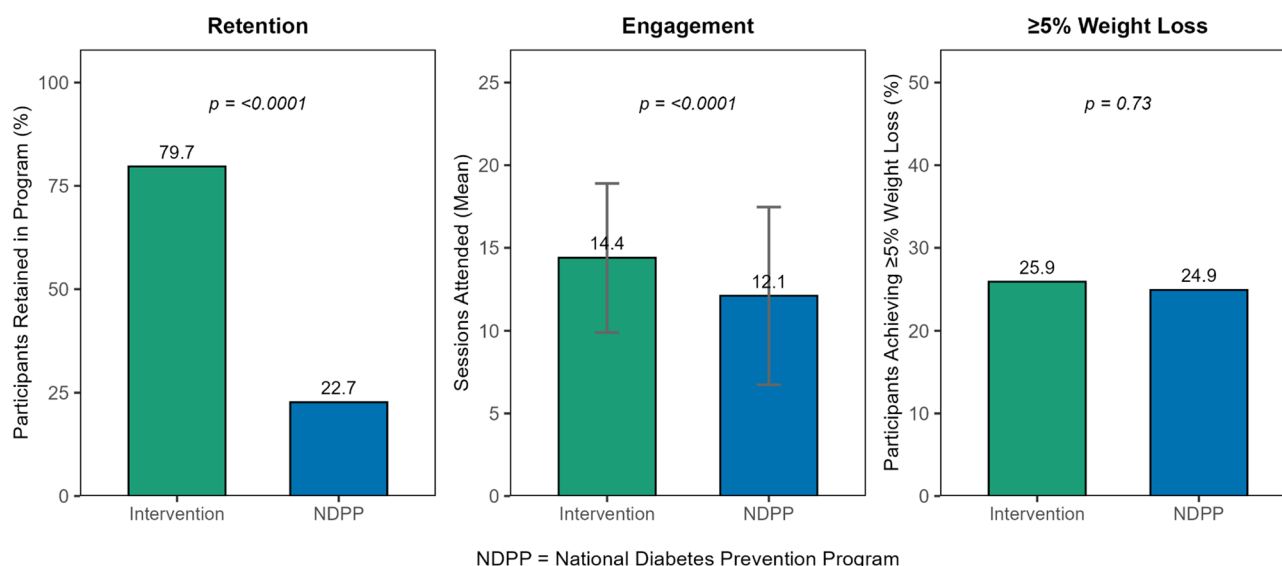


Fig. 3 Comparison of participant outcomes between the local Lifestyle Change Program (Intervention) and the National Diabetes Prevention Program (NDPP) at 6 months. Panels show (A) Participants Retained in Program (%), (B) Sessions Attended (Mean $\pm$ SD), and (C) Participants Achieving $\geq 5\%$ Weight Loss (%). Bars represent proportions or means for the Intervention and NDPP groups. Error bars indicate standard deviations for session attendance. P-values correspond to between-group comparisons at 6 months. All comparisons are unadjusted two-sample tests (chi-square for proportions, t-test for means)

control arm. Consequently, the observed results should be interpreted with caution, as they may be more susceptible to random variation.

An additional limitation includes the larger number of enrolled participants in the intervention classes than the control classes. This may have been in part because intervention participants had the added incentive to join the study to gain free access to Fresh Tri. This concern is addressed, in part, by similar results when comparing the intervention condition to a national representative sample of LCP participants alleviating most concerns about intervention selection bias [26]. The difference in sample sizes between the intervention and control arms could provide a separate limitation if the lower proportion of eligible members of control classes who joined the study caused the characteristics and demographics of the control arm to be dissimilar from the intervention arm. We did not collect data on the demographics of eligible LCP class members who did not choose to join the study, so do not have insight into this difference.

Given that the inclusion criteria requiring smartphone access was only applied to the intervention arm (and not the control arm), this represents a possible limitation. As smartphone access may be tied to socioeconomic status, this could have introduced selection bias into the study. However, smartphone access is quite ubiquitous, and baseline characteristics were similar between the two groups. In fact, CCVI was significantly higher in the intervention group.

Another potential limitation of this study is that multiplicity adjustments for Type 1 error were not applied

across the three primary outcomes. This decision reflects the study's design as an early-phase, pragmatic evaluation focused on estimating effect sizes and feasibility rather than providing a single confirmatory test of efficacy. As such, analyses emphasized estimation and precision over dichotomous significance testing, which is consistent with recommended practices for exploratory and non-regulatory behavioral or digital health intervention trials [11, 31, 32]. Nonetheless, recognizing that the lack of multiplicity adjustment may increase the likelihood of Type 1 error, a Bonferroni-adjusted post hoc sensitivity analysis was performed, in which the retention outcome still remained statistically significant at 6 months (OR = 2.08; 95% CI = 1.16–3.73; $P=.03$), suggesting that the finding is robust even under stricter error-control assumptions.

Furthermore, the conclusions from the 12-month data are limited because the sample size for that analysis was only ~25% of total study enrollment. Because only a subset of participants contributed 12-month data, these analyses were exploratory and underpowered, although we did see statistically-significant differences in retention and $\geq 5\%$ body weight loss at 12 months, even in this limited-sized sample. Although baseline demographic characteristics were largely comparable between participants with and without 12-month follow-up, CCVI was significantly higher among those completing follow-up, indicating a potential influence of site-level or structural factors, but also that the 12-month cohort was even more indicative of the underserved communities we were seeking to study. The 12-month findings, while indicating

trends beyond 6 months, warrant confirmation in future studies with prospectively planned long-term follow-up.

Finally, another potential issue was that participants may have used other behavior change apps in addition to Fresh Tri. We learned that many of our study sites encouraged or required the use of other apps. In addition to adding noise and complexity for the participants, having them use potentially contradictory methodologies to Fresh Tri's approach, could have dampened the observed impact of the intervention. Fresh Tri's proprietary Iterative Mindset Method [3] which uses iteration to protect individuals from failure and keep them in-effort, diverges significantly from the goals-and-tracking approach of other behavior change apps that tie participants' feelings of success, narrowly, to achievement of a specific goal [21, 29]. Overall, although we recruited participants from a broad range of geographies (17 states) and settings (urban, suburban, and rural), using a randomized cluster design, more work is needed to address limitations and replicate findings. We hope this initial introduction of an iterative mindset approach serves as a catalyst for such future inquiry.

Conclusion

This study demonstrated statistically significant higher retention and weight loss for LCP participants who used the Fresh Tri app, at sites in communities with above average CCVIs. Historically, the National DPP has struggled to engage and retain individuals from these communities. Our findings suggest that using an iterative mindset approach via a digital health software could lead to important impacts on the health of individuals with prediabetes in these communities. Furthermore, because higher retention typically leads to higher weight loss [12]—which we observed in the 12-month follow-up data in this study—and therefore higher reimbursement [28], an iterative mindset approach might help increase reimbursement rates for LCP sites. Future research could focus on investigating the Fresh Tri app as a stand-alone intervention to better understand the direct effects of this digitally-delivered, novel habit-building methodology.

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Author contributions

JWL, MJC, YM, ZWB, KIW and KB contributed to the study conception and design. Material preparation, data collection and analysis were performed by JWL, ZWB, AMS, ASG and KB. The first draft of the manuscript was written by JWL, and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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Data availability

Data, other than data containing participants' personal health information or other regulated private information or data that is proprietary to Fresh Tri, is available upon request from Joshua Leichter at jleichter@freshtri.com. The software code used in the Fresh Tri app utilized in this study is proprietary to Fresh Tri and will not be shared.

Declarations

Ethics approval and consent to participate

An independent ethical review board, WCG (WIRB-Copernicus Group) IRB, reviewed and approved this study protocol (<https://www.wcgirb.com/>, #1300367) and the study was performed in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards. Informed consent was obtained from all individual participants included in the study.

Consent for publication

Not Applicable.

Permission to adapt or reuse any copyrighted material

In this study, the Fresh Tri app was used by participants in the intervention arm. The Fresh Tri app is protected by copyright laws as well as trade secrets, with all rights thereto owned by Fresh Tri, LLC, which conducted the study and permitted the use of the Fresh Tri app in the study.

Competing interests

JWL and KB are employees of Fresh Tri, LLC, which conducted the study and is the developer of the app used in the intervention arm. ZWB is a former consultant, and ASG, KIW and AMS are former employees of Fresh Tri, LLC. MJC and YM are employees of CDC, which funded this study under contract with Fresh Tri, LLC.

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