One-Year Clinical Outcomes of an Artificial Intelligence-Based Digital Diabetes Prevention Program

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ABSTRACT

BACKGROUND: The CDC recognizes more than 1,520 National Diabetes Prevention Program (DPP) providers to reduce the risk of developing type 2 diabetes, yet fewer than 1 in 40 eligible individuals have enrolled in a DPP. This study investigated the efficacy of a scalable, digital DPP to achieve weight loss and engagement over one year in a large population of eligible participants.

METHODS: We enrolled 610 participants in the Artificial Intelligence-based Lark digital DPP that were identified as eligible for a National DPP based on CDC criteria for high risk of developing type 2 diabetes. Participants downloaded the Lark DPP to their smartphones and were shipped a digitally connected weight scale. They then participated in the Lark DPP CDC Prevent T2 curriculum and were measured for weight loss via connected weight scale and engagement in coaching conversations within the Lark DPP for one year.

RESULTS: Our analysis of the Lark DPP shows weight loss at one year as a percentage of baseline body weight was 4.2% ($p<0.0002$). 40% of participants achieved weight loss of at least 5%, and average weight loss was 10 lb (4.5 kg). This compares to previous published studies of in-person DPPs demonstrating 27% of participants achieving weight loss of at least 5%[13] and average weight loss of 5.1 lb (2.3 kg)[22] at 12 months. Over the one year, Lark DPP participants recorded an average of 182 weight measurements per participant and logged an average of 280 meals per participant.

CONCLUSIONS: This one-year study of 610 participants in Lark's digital DPP with CDC Full Recognition demonstrates Lark's ability to engage and achieve long-term, clinically significant weight loss to help reduce the risk of developing type 2 diabetes.

BACKGROUND

Diabetes is among the most costly medical conditions in the United States, with an estimated annual cost of $327 billion in direct and indirect expenditures. An estimated 1 in 9 adults in the United States has diabetes, and healthcare spending for each individual with the condition costs 2.3 times the amount for an individual without diabetes.[1,2]

Type 2 diabetes, which accounts for 90 to 95% of all diabetes cases, is commonly preceded by prediabetes.[3] More than 84 million US adults, or 33%, have prediabetes and 29% of people with prediabetes have been shown to develop type 2 diabetes within three years.[4] Prediabetes and type 2 diabetes are largely due to modifiable risk factors, including obesity and physical inactivity, and in many cases are considered preventable through sustained changes to these risk factors.[1]

Given type 2 diabetes prevalence, cost, and preventability, the Centers for Disease Control and Prevention (CDC) and National Institutes of Health (NIH) have made extensive efforts to prevent or delay the onset of type 2 diabetes among those at high risk. The National Diabetes Prevention Program (DPP), established in 2010, is a lifestyle intervention program that focuses on weight loss and physical activity as a means to lower the risk of developing type 2 diabetes for those with prediabetes.

As of February 2020, more than 1,520 CDC-recognized DPPs were listed as active,[5] yet fewer than 1 in 40 eligible US adults participate in such a program, meaning approximately 82 million qualified US adults have yet to participate in a DPP.[6] Currently, more than 88% of all DPPs are in-person only programs, where all content is delivered in-person by a certified educator.[5] This in-person format limits the ability to efficiently and economically scale programs to meet this currently unserved eligible population. A scalable solution capable of reaching and engaging large populations of qualified individuals may better meet current and future population needs.

The Lark DPP is a digital platform that leverages conversational artificial intelligence (AI) to deliver an interactive version of the CDC's Prevent T2 curriculum. Unlike traditional in-person programs, the Lark DPP is available anytime via a participant's smartphone and offers unlimited interactions on demand. The Lark DPP is among the less than 1% of DPP providers which have a digital delivery approach and have met engagement and clinical outcomes required to achieve Full Recognition status in the National Diabetes Recognition Program.

In this study, we evaluate one-year outcomes for weight loss and overall engagement in 610 qualified DPP participants enrolled in the Lark DPP.

METHODS

STUDY PARTICIPANTS

Participants were identified as eligible for the Lark DPP based on CDC criteria for being at high risk for type 2 diabetes.[7] Eligible participants were recruited via digital awareness campaigns, through a large managed services organization, and through direct physician referrals. Eligible participants who opted in received a link via text message to download the Lark DPP to their smartphones. Participants were shipped a digitally connected weight scale that automatically syncs with their Lark program.

INTERVENTION

The Lark DPP is a digital program that provides automated and personalized coaching using conversational AI. It is available to participants on demand and via push notifications on iPhones and Android smartphones. The Lark DPP presents the CDC Prevent T2 curriculum via a series of 26 standardized weekly missions, with each mission consisting of daily check-ins, and each mission aligning to a weekly topic from the Prevent T2 curriculum.

The curriculum emphasizes weight loss, physical activity, and healthy eating habits, with lessons focusing on specific topics such as grocery shopping, motivation, breaking up sedentary time, and cardiovascular health. In addition to the Prevent T2 curriculum, educational content within the Lark DPP includes information on the relationships between lifestyle behaviors and health, as well as tips to help participants make healthy choices. Additional elements of the Lark DPP include setting weight loss and physical activity goals and tracking progress toward them, and an intuitive meal logging system using natural language processing.

The coaching encourages participants to develop healthy habits through established behavior change strategies such as cognitive behavioral therapy, designed to build self-efficacy for sustained health outcomes. Participants receive in-the-moment feedback when they log meals or physical activity, step on the scale, or indicate they are experiencing negative feelings or stress. Lark is also capable of gathering data from Android devices connected to Google Fit and iOS devices connected to Health Kit.

The Lark DPP provides daily and weekly summaries on diet quality, weight loss, physical activity, and sleep trends. Lark's conversational AI allows consistent, personalized coaching that improves as participants continue to use the program.

MEASURES

The primary efficacy outcome was overall weight loss at one year as a percentage of baseline body weight. To determine weight loss, a starting weight was established for each participant as measured by the first participant-validated weight measurement within the first 30 days from the start of the Lark DPP. The final weight measurement was defined as the average of up to three final weight measurements taken not more than 15 days from the one year anniversary (365 days) from initial enrollment in the Lark DPP. The difference between the starting weight and the final weight measurements constituted the overall weight loss at one year.

Measures of program engagement consisted of the number of conversations with the Lark DPP's conversational AI, number of meals logged, number of weight measurements recorded, and number of missions successfully completed.

RESULTS

DEMOGRAPHICS

A total of 610 participants recorded a baseline and final weight. Basic demographic data were self-reported as a part of the onboarding process. 506 (83%) participants were female, 102 (17%) were male, and 6 (1%) participants did not state gender. The mean age at baseline was 47 years with a standard deviation of 10 years. Racial distribution characteristics of participants closely mirrored United States national distribution statistics (Table 1).[8]

Table 1: *Racial and Ethnic Distribution*

	Study Racial and Ethnic Distribution	Average US Racial and Ethnic Distribution[9]
White	64.5%	56.1%
Hispanic or Latino*	18.1%	16.3%
African American*	10.2%	12.6%
Asian	2.8%	4.8%
American Indian or Alaska Native*	1.2%	0.9%
Native Hawaiian or Other Pacific Islander*	1.0%	0.2%
Other or Two or More Races	2.3%	9.1%

*Demographic group with higher-than-average T2D prevalence

WEIGHT LOSS

Weight loss is a key measure of DPP effectiveness, as obesity has close ties to insulin sensitivity, blood glucose control, and risk for and progression of prediabetes and type 2 diabetes.[7,10] Critically, sustained weight loss at one year has also been shown to improve these measures and reduce risk of developing type 2 diabetes.[7,9] Mean starting weight of study participants was 223 lb (± 47 lb) and average starting body mass index (BMI) was 36.6 kg/m² (± 7.1 kg/m²). Average final weight was 213 lb (±46 lb), and average final BMI was 35 kg/m² (± 6.9 kg/m²) (Figure 1 and Figure 2).

Mean weight loss at one year as a percentage of baseline body weight was 4.2% (p<0.0002). 40% of participants achieved weight loss of at least 5%.

Mean starting BMI was 36.6 kg/m² (+/-7.1 kg/m²). All participants had a baseline BMI above normal.[11] Initially, 105 (17%) participants were classified as overweight, 177 (29%) were class 1 obese, 142 (23%) were class 2 obese, and 186 (30%) were class 3 obese (Table 3). After one year, 26 participants (4%) met criteria for normal BMI, 139 (23%) of participants were classified as overweight, 166 (27%) were class 1 obese, 146 (24%) were class 2 obese, and 133 (22%) were class 3 obese (Table 3). The BMI of 187 participants (31%) decreased by at least one BMI category from baseline to final.

Figure 1: *Weight Loss*

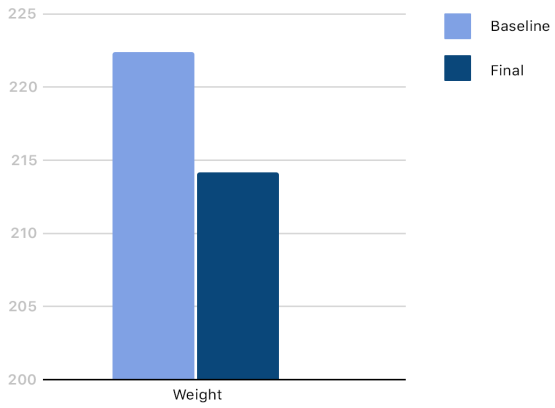

Figure 2: *Change in BMI*

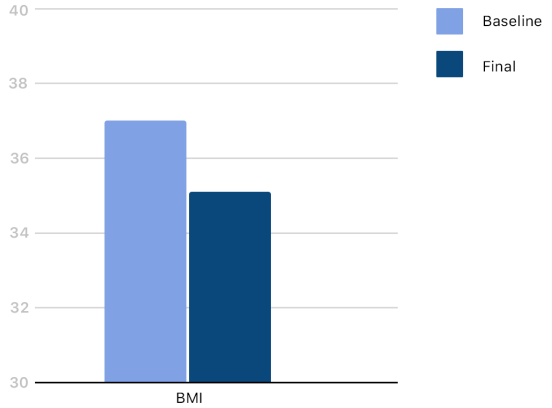

Table 2: *Weight Loss Outcomes*

	Baseline	Final	Change	% Body Weight Loss	p value
Average Weight	223 (101.4 kg)	213 lbs (96.8 kg)	10 lbs (4.5 kg)	4.2%	p<0.0002

ENGAGEMENT

The total number of coaching conversations during the one-year study duration was 239,981, or an average of 393 individual personalized coaching conversations per participant. Participants recorded 111,158 weight measurements, or an average of 182 per participant, and logged a total of 170,759 meals, or an average of 280 per participant. The total number of missions completed was 7,466, or an average number of 12 per participant. (Table 4)

DISCUSSION

CLINICAL EFFICACY

The average weight loss in this one-year study was 10 lb (4.5 kg), with an average of 4.2% of body weight lost after one year. Weight loss is used as a primary clinical proxy for DPP program effectiveness, as obesity has close ties to insulin sensitivity, blood glucose control, and risk for and progression of prediabetes and type 2 diabetes.

Critically, sustained weight loss at one year significantly improves these measures and reduces the risk of type 2 diabetes.[12] In fact, prior research correlates each kilogram lost with a 16% lower risk for type 2 diabetes.[13] In addition, weight loss was the most important predictor of diabetes incidence in this study, and those who lost at least 5 kg had a 0.42 hazard ratio of being diagnosed with diabetes during the follow-up period. Among those who achieved at least a 5% weight loss in the landmark National DPP study, diabetes risk decreased by 58%.[14] Out of the 610 Lark DPP participants, 246 (40%) reached or exceeded this 5% benchmark, suggesting that Lark DPP can significantly decrease diabetes risk.

Table 3: *BMI Shifts Over Study Period (1 Year)**

Initial BMI	Final BMI					
	Normal	Overweight	Obese I	Obese II	Obese III	Total
Overweight	23	78	4	0	0	105
Obese I	1	53	110	12	1	177
Obese II	0	6	43	86	7	142
Obese III	2	2	9	48	125	186
Total	26	139	166	146	133	

*Weight BMI categories are: 18.5-24.9 (normal), 25-29.9 (overweight), 30-34.9 (obese I), 35-39.9 (obese II), and >=40 (obese III)

Table 4: *Engagement Statistics*

	Total	Average (Per Participant)
Conversations	239,981	393
Meals Logged	170,759	280
Weight Measurements	111,158	182
Missions Completed	7,466	12

The reduction in at least one BMI category among 187 of 610 participants (31%) has further positive implications, as the relative risk of developing type 2 diabetes compared to someone of normal weight is 1.5 (overweight), 2.5 (class 1 obese), 3.6 (class 2 obese), or 5.1 (class 3 obese).[15] In addition, weight loss or reductions in BMI of this magnitude have implications for cost savings. For example, one study found that workers with a BMI of at least 27 and less than 30 kg/m² had $1440 lower annual medical expenditures than workers with a BMI of at least 30 kg/m². A separate analysis estimated reductions in annual healthcare expenditures of $56.18, $853.15, and $3,401.82 for a 10% reduction in BMI for patients with a starting BMI of 30, 35, or 40 kg/m².[17]

In this study, 60/505 (11.88%) of participants went from obese to non-obese based on their decreased BMI. Healthcare cost savings for someone who is non-obese compared to obese are estimated at $1,440 annually. Taking the CDC estimate of adult obesity at 39.8% in 2015-2016, a company with 10,000 employees whose obese employees used the Lark DPP could potentially save over $600,000 annually.

SCALABILITY

As a digital solution, the Lark DPP is highly scalable. Taken together with the weight loss results of this study, the ability to scale rapidly suggests that using an AI-driven digital DPP is a viable strategy for increasing access to and enrollment in the DPP. This is critically important because of the scope of prediabetes, which has increased in recent decades in the U.S.[18,19] while at the same time there have been poor participation rates in the National DPP. Fewer than 1 in 20 (4.2%) of eligible individuals ever receive a referral to a lifestyle intervention program, and fewer than 1 in 25 (2.4%) ever participate.[6] Thus, over 97% of Americans at risk of developing diabetes are not participating in a program.

Barriers to enrollment in traditional DPPs include cost and lack of coverage, lack of transportation, difficulty with schedules, and the need for child care.[20] A fully digital solution, Lark decreases or eliminates each of these barriers.

Not only is scaling the Lark DPP logistically feasible, but due to the AI nature of the program, continued expansion and use in fact yielded improved results. A previous study of the Lark DPP with a smaller population (N=70) and shorter duration (15 weeks) resulted in weight loss of 2.38% in a similar population of overweight individuals at high risk for developing type 2 diabetes.[21] As population size and study duration increase, the AI that powers Lark has improved, which lead to improved outcomes, and without encountering operational problems which arise in traditional DPP program expansion.

Notably, despite the Lark digital DPP being highly scalable, the weight loss of 4.2% in this study is comparable to, or greater than, the amount in previously published studies reporting on interventions with live-coach lead sessions. For example, a meta-analysis of 22 studies, all of which evaluated programs with live-coach components, found an average 12-month weight loss of 5.1 lb (2.32kg)[22] as compared to 4.5 kg in this study. In a separate study, 27% of participants who received lifestyle counseling in individual or group sessions lost at least 5% of original body weight,[13] compared to 40% in this study.

CONCLUSIONS

With the burden of diabetes and prediabetes

only increasing, an effective and scalable long-term solution is essential to addressing the economic and productivity costs of this epidemic. Participating in a lifestyle intervention program that assists at-risk individuals with losing weight is a highly effective approach to lowering risk for type 2 diabetes, but enrollment in such programs is limited to fewer than 3% of those who qualify.[6] The significant amount of weight loss among Lark DPP participants in this study demonstrates that a fully digital solution powered by AI can be highly clinically effective without being encumbered by operational challenges associated with scaling people-lead programs, such as hiring and training staff, matching patients with appropriate DPP providers, scheduling educational sessions, and finding appropriate treatment spaces. This study of 610 participants in Lark's CDC-recognized DPP demonstrates that Lark is a scalable and effective solution for engaging and achieving long-term, clinically significant weight loss with an artificial intelligence-based digital DPP.

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