Lark for Diabetes Study Shows Positive Outcomes for People with Type 2 Diabetes

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The diabetes epidemic is one of the most pervasive health crises in the U.S., and recently became its most costly. The overall demand for better healthcare services for the U.S. diabetic population far exceeds existing capabilities. In this paper we describe how a digital, infinitely scalable, stand-alone solution can drive population benefits among people with type 2 diabetes. Our analysis focuses on early results of the Lark Diabetes Management Program (Lark DMP) and seeks to evaluate the potential impact Lark's platform, leveraging Conversational Artificial Intelligence, has on improving A1c for those with type 2 diabetes (DM2).

1. Background

More than 30 million people in the U.S., or 9.4% of the population, have diabetes. Among adults age 18 or over, the proportion increases to 12.2%. The majority of diabetes cases, or 90% to 95%, are type 2.[1] Only 1 in 8 patients with DM2 meet targets for blood sugar control as assessed by glycated hemoglobin (A1c), cholesterol, and blood pressure.[2] People with DM2 are also highly likely to have one or more conditions that increase risk for complications. Examples include high prevalence of hypertension (73.6%), overweight or obesity (87.5%), and smoking (15.9%).

The high prevalence of diabetes, along with expensive clinical factors, such as prescription drugs, hospitalizations, emergency room visits, and treatment for complications and comorbidities, have contributed to this chronic disease becoming the most costly medical condition in the U.S., with an estimated annual spend of $327 billion, which includes both direct medical costs of $237 billion and lost or reduced productivity in the labor force of $90 billion. This cost accounts for almost 1 out of every 4 dollars spent on healthcare in the U.S. in total. On an individual basis, this translates into approximately $16,750 spent annually per person with diabetes, which is 2.3 times higher than spending for individuals without diabetes.[3]

Further complicating the challenge of managing the diabetes crisis is the lack of clinical resources necessary to effectively manage such a large population. It is estimated that by 2025 there will be a shortage of roughly 2,700 endocrinologists who provide specialty care for those with DM2.[4] As a result of this increasing shortage of specialists, primary care physicians have been increasingly expected to treat and manage patients with DM2.[5]

The reliance on primary care physicians also stretches thin an already overleveraged resource. Like specialists, there is a growing shortage of primary care physicians, estimated to be anywhere from 7,300 to 43,100 physicians short of patient needs by 2030.[6] In addition, the time

primary care physicians spend per patient visit is very limited, with 3 out of 4 doctors reporting spending 20 or fewer minutes with patients on average.[7]

Given the challenges described above to effectively manage population health for those with DM2, this paper seeks to investigate the possibility of using technology to empower people with DM2 to effectively manage their diabetes through adoption of sustainable health habits and better lifestyle management.

2. Design

This study was a retrospective, longitudinal cohort study among participants in Lark's Diabetes Management program.

2.1 Cohort Selection

Participants were members who confirmed that they had been diagnosed with DM2 and who enrolled in the Lark program between August 19, 2018 and January 14, 2019. This study is a subgroup analysis of members who self-reported a baseline A1c measurement of at least 6.5%, and an additional follow up A1c measurement within 2 months to 6 months after the baseline A1c measurement.

2.2 Intervention

Lark's DMP is a digital disease management platform focused on building sustainable health habits to improve outcomes through improved self-efficacy in managing DM2, leveraging conversational artificial intelligence (AI) to provide real-time feedback and guidance to members with specific recommendations and education related to their individual DM2 data, with all interactions taking place directly through their smartphone. Lark's DMP is based on evidence-based clinical care guidelines, including the Diabetes Accreditation Management Program, Joslin Clinical Guidelines, and the ADA's Standards of Medical Care in Diabetes. Lark additionally uses cognitive behavior therapy techniques to build self-management skills in individuals in the DM2 program. Lark's DMP addresses diabetes care issues such as:

- Medication adherence
- Medical appointment reminders and tracking (A1c testing, eye exams, etc.)
- Personalized diabetes specific nutrition counseling
- Weight monitoring and counseling
- Glucose monitoring and counseling (including testing supplies fulfillment and resupply)
- Physical activity and sleep monitoring and counseling
- Emotional support and mental health counseling

The Lark DMP is able to passively gather data collected from connected devices, such as a bluetooth or cellular enabled glucometer, low powered sensors on the phone, and data provided directly by the member, such as meals logged in the platform. Lark uses this information to provide real-time insights, feedback, and suggestions to the member through conversational AI that helps a member understand direct consequences of their daily lifestyle choices.

As an example, Lark is able to take activity data from low power sensors on the phone showing less activity than usual, a high carb meal logged by the member, and a glucose reading ingested automatically from a connected glucometer an hour after the meal is logged of 190mg/dl. Analyzing this data, the Lark DMP is able to see that as a result of low activity and high carbohydrate intake, the member's glucose is higher than recommended by clinical guidelines, and shares this information directly with the member through the conversational AI within the platform. In addition to educating the member on how these health choices likely contributed towards an out of recommended glucose range, Lark recommends specific interventions, such as increased activity and/or healthier meals, for later in the day to help get back in a recommended glucose

Table 1: *Demographic descriptions*

Demographic Variable	Distribution
Age	51.3 (10.7 SD)
Gender	74% Female, 14% Male, 14% Unknown/NA
Ethnicity	27% White, 18% Black, 5% Asian, 50% Other/Unknown

range. In addition to these real time data driven insights, Lark provides ongoing educational content through daily check-ins to help educate and empower members to better manage their DM2 through healthy lifestyle choices and behaviors.

2.3 Data Collection

The primary outcome is change in A1c measurements over roughly three months in the Lark DMP. The baseline and follow-up A1c measurements were reported by members directly within the Lark DM2. Members are asked for the date and result of their most recent A1c measurement upon their enrollment in the Lark program. Lark is then programmed to automatically ask a member for a follow up measurement three months after the timing of the initial A1c measurement. In the event the member does not have an updated A1c measurement to report, Lark follows up on at least a monthly basis until a new measurement is reported. Members' baseline and follow up A1c measurements were then used to determine the cohort change in A1c values. P-value calculations were performed using a standard 2 sided t-test.

3. Results

Data were analyzed from members enrolled in Lark's DM2 program who reported both an initial and follow up A1c. The data set included 3 males (14%), 16 females (73%), and 3 members (14%) who did not declare their gender for a total population size of 22. The cohort had an average age of 51.3 (+/- 10.7).

The initial average A1c was 8.4% (+/- 1.7%) and final A1c was 7.4% (+/- 1.3%), reflecting an average decrease in A1c of 1.1% (+/- 1.3%). The range for timing between the initial and follow up A1c measurements was between 2 and 6 months, with the average between 3 and 4 months. The earliest confirmation of an A1c measurement was at three months in the Lark program (91 days) while the latest was a bit over six months into the Lark DMP (163 days), with the median at just under 4 months (113.5 days). We observed a significant ($p < 0.001$) reduction in A1c scores for our sample with a two-sided test against a null of no change. This represents a statistically measurable effect on A1c by the Lark program despite the low expected power due to the relatively small sample size observed.

Engagement data analyzed for this cohort included the number of counseling sessions (a complete conversation between members and Lark's conversational AI), the number of meals manually logged by members, and the number of glucose readings captured by Lark, either by a member manually logging the data or through a glucometer connected through the member's smartphone to the Lark DMP. Members averaged 170 counseling sessions, 215 meals logged, and 56 glucose readings from the time they enrolled in the Lark DMP up to the time they reported their

Table 2: *Change in A1c*

Starting A1c	Final A1c	***A1c Reduction***	t-value	***p-value (two sided)***
8.4% (1.7% SD)	7.4% (1.3%)	***1.1% (1.3%)***	t = 3.93 (N=22)	***0.0008***

Table 3: *Engagement Metrics*

Engagement Measure	Mean	Median	Total	Standard Deviation
Counseling sessions	170	174	3,759	110
Meals logged	215	199	4,738	125
Glucose readings*	56	31	1,133	60

*Note: One member had a continuous glucose monitor, so was excluded from "Glucose reading" calculations on Table 3. If included, total number of glucose readings increase to 12,444.

second A1c measurement.

4. Discussion

This paper describes a one-arm retrospective study in which people with DM2 reduced their A1c by 1.1% (p-value of 0.0008) through the use of a conversational AI program, the Lark DMP. While each patient with DM2 may have individualized goals for A1c and other health outcomes as established by their doctors, achieving or approaching target A1c levels has been shown as an effective proxy for glycemic control and relative health and wellbeing, as well as a meaningful determinant of likely costs for care.[8]

A brief summary of peer-reviewed studies shows a broad range of benefits for the DM2 population stemming from a reduction in A1c when starting above the recommended diabetic threshold, such as an expected reduction in the probability of diabetes related complications in both commercially insured and Medicare populations (43% and 28%, respectively, for a 1% drop in A1c) and anticipated 3-year savings of over $2,700 per individual with an initial A1c above 7.0%. [9]

A population level study showed that any decrease in A1c for an out of control population, when compared to an increase in that same population, results in 24% year 1 savings and 17% year 2 savings, or $2,503 and $1,690 respectively,[10] and yet another study showed that a 45% reduction in risk of cardiovascular death for an A1c reduction of just 0.8%.[11]

In addition to the decrease in A1c, the Lark DMP was able to direct engage in an average of 170 counseling sessions per member between the time the first and final A1c measurements were reported. With each counseling session lasting approximately 4 minutes, this translates into more than 11 hours (680 minutes) in direct, one-on-one, personalized health feedback and counseling. In addition, an average of 215 meals were logged and evaluated per member, providing significant nutritional education and guidance. When compared to a visit with a primary care physician lasting less than 20 minutes, the Lark DMP as a technical platform is not constrained in the volume or frequency of interaction with people with DM2 in the same way as traditional clinical resources.

With significant health benefits and cost savings attributed to a reduction in A1c among the DM2 population with a starting A1c above target levels, the results outlined in this analysis show compelling evidence of likely population level benefits through the health benefits gained through the Lark DM2 program. As a purely digital solution, Lark is also positioned to address the significant clinical resource constraints that exist in current DM2 care models, which leaves a significant percentage of the more than 27 million individuals with DM2 undermanaged clinical care.

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