A Pilot Study to Evaluate the Utility of an Interconnected Diabetes Management Solution in People with T2D

INTRODUCTION

- Self-care is crucial for successful diabetes management¹
- Use of digital applications ('apps', installed on mobile devices such as mobile phones/tablets) to monitor patient health and inform/guide treatment decisions is becoming more widespread²
- Successful interventions delivered using mobile apps include behavior change techniques that prompt self-monitoring and feedback on performance³, however, these apps tend to be 'one size fits all'
- Apps that incorporate human coaching for lifestyle modification offer a new approach to facilitate Type 2 diabetes (T2D) self-management⁴
- Existing diabetes apps address many aspects of diabetes management (e.g. tracking healthy eating, physical activity and medical adherence⁵)
- The Interconnected Diabetes Management Solution (IDMS) presented here combines coaching from a Certified Diabetes Educator (the 'guide'), with a mobile app

OBJECTIVE

This study evaluated the utility of an investigational IDMS, using remote behavioral coaching from a guide and a mobile app

METHODS

 Participants (IDMS 'members') completed a 12-week, single-arm, open-label, observational study to assess the effects of the IDMS (Figure 1)

Figure 1. Study Design



BGMS, blood glucose monitoring system; IDMS, I iOS, mobile operating system; SMBG, self-monitoring of blood glucose; T2D, Type 2 diabetes

- Site visit 1 (Week 0)
- Informed consent obtained Inclusion criteria assessed: confirmed T2D and
- HbA, 7–11% Medical history and demographic information obtained
- Blood tests and anthropometric measurements conducted
- Guide assigned
- App downloaded to member's phone and use of app explained
- Glucose monitoring equipment shipped to member: CONTOUR[®]NEXT ONE blood glucose meter, strips, control solution, lancing devices and lancets
- Welcome call with guide (20–30 minutes) to discuss: - Member's background, diabetes history, typical routines and lifestyle, and current self-care behavior The guide-member relationship

- Guides did not offer any advice to members regarding medication adjustments
- Guides set individualized tasks for members to motivate changes in health behaviors (**Figure 2**)
- Telephone calls: two during 'onboarding' and ≥1 additional call
- The primary member-guide dialogue was via messaging

Leslie Klaff, MD, PhD¹; Thomas Maier, MD²; James Richardson, MPharm, MBA²; Scott Pardo, PhD, PStat^{®3}

¹Rainier Clinical Research Center, Renton WA, USA; ²Ascensia Diabetes Care, Global Medical Affairs, Basel, Switzerland; ³Ascensia Diabetes Care, Global Clinical Affairs, Valhalla, USA

	Study period	
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	Weeks 0–12 • Perform SMBG tests and sync to app • Coaching phone calls	Week 12 Visit 2 • Medical history, baseline anthropomorphic
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- Members used the IDMS at home for 12 weeks, in addition to their routine diabetes management
- Self-monitoring of blood glucose (SMBG) with the CONTOUR[®]NEXT ONE blood glucose monitoring system (BGMS) was individualized and guidedirected
- App and calls allowed member-guide communication and monitoring of guide-directed tasks (short, time-limited behavioral interventions to improve testing, food choice, activity, stress and sleep: Figure 2)
- Site visit 2 (Week 12)
- Blood tests, anthropometric measurements and an update on medication changes Feedback was provided via four validated questionnaires
- Adverse events reported to guides and/or during site visits were recorded by the investigator



RESULTS

Baseline characteristics of participating members are reported in Table 1

Table 1: Baseline characteristics, n=58			
Characteristic	Proportion (%) or mean value		
Male	62%		
Age (years)	62		
Caucasian race	88%		
%-НЬА _{1с}	8.44		
Hypertension	50%		
Obesity (BMI ≥30 kg/m²)	60%		
Cardiovascular disease	10%		
Hyperlipidemia	48%		
Neuropathy	28%		
Retinopathy	12%		
T2D diagnosed for >10 years	71%		

BMI, body mass index; T2D, Type 2 diabetes

- At baseline, all members (n=58) were in receipt of \geq 1 anti-diabetic medication: on insulin, n=36; not on insulin, n=22
- In this study, few members had their medication adjusted by their health care professional
- Changes in medication
- Any diabetes medication change (n=13)
- No diabetes medication change (n=45) - Change in dose of diabetes medication (n=7) Dose decrease (n=5)
- No dose increase during study (n=56)
- HbA

 After 12 weeks of the IDMS, the mean %-HbA, (± standard error of mean) significantly decreased from 8.44 (0.08) at baseline, to 8.01 (0.08) at Week 12: -0.43%, p<0.0007 (**Figure 3**)

Figure 3. Change in HbA, over 12 weeks with the IDMS



ror bar: standard error of the mean. IDMS, Interconnected Diabetes Management Solution

- Analysis of a sub-population of individuals with no change to their diabetes medication(s) (n=45) revealed a significant decrease in HbA, from 0-12 weeks (p=0.0016), from a mean value of 8.31% at visit 1 to 7.91% at visit 2
- There was a negative correlation between the Basics task completion rate and proportion of blood glucose (BG) readings >250 mg/dL (p=0.0362)
- Adverse events
- A total of 59 adverse events (AEs) were recorded. with the majority classified as hypoglycemia
- A total of 40/41 hypoglycemic adverse events were resolved by nutritional supplement, and 1/41 hypoglycemic event was treated with medical intervention
- No AEs resulted in hospitalization and all AEs were

deemed unrelated to the IDMS by the investigator

DISCUSSION

- In this study
- Use of the investigational IDMS (comprising remote behavioral coaching from a certified diabetes educator and a mobile app) resulted in significant improvements in HbA
- Few members changed medication or received a lower dose of medication
- Mean HbA, significantly decreased, independent of changes to medications – suggesting improved selfcare and glycemic control
- The relationship between Basics task completion rate and proportion of BG readings >250 mg/dL suggest a glycemic benefit with more frequent testing

CONCLUSION

The data from this study suggest improved self-care and glycemic control with an investigational IDMS

References

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