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Personalized Digital Health Information to Substantiate Human-Delivered Exercise Support for Adults with Type 1 Diabetes

Garrett I. Ash, PhD[1,2], **Laura M. Nally, MD**[2], **Matthew Stults-Kolehmainen, PhD**[3,4], **Melissa De Los Santos, MS**[4], **Sangchoon Jeon, PhD**[2], **Cynthia Brandt, MD**[1,2], **Barbara I Gulanski, MD**[1,2], **Elias K. Spanakis, MD**[5,6], **Julien S. Baker, PhD**[7], **Stuart A. Weinzimer, MD**[2,*], **Lisa M. Fucito, PhD**[2,*]

[1]Veterans Affairs Connecticut Healthcare System, West Haven, CT, USA

[2]Yale University, New Haven, CT, USA

[3]Yale-New Haven Hospital, New Haven, CT, USA

[4]Columbia University, New York, NY, USA

[5]Veterans Affairs Maryland Healthcare System, Baltimore, MD, USA

[6]University of Maryland, Baltimore, MD

[7]Hong Kong Baptist University, Kowloon Tong, Hong Kong

Abstract

Objective: Pilot-test personalized digital health information to substantiate human-delivered exercise support for adults with type 1 diabetes (T1D).

Design: Single-group, 2-week baseline observation then 10-week intervention with follow-up observation.

Setting: Community-based sample participating remotely with physician oversight

Participants: Volunteers 18–65 years old with T1D screened for medical readiness for exercise intervention offerings. N=20 enrolled, N=17 completing all outcomes with 88%−91% biosensor adherence.

Intervention: Feedback on personalized data from continuous glucose monitoring (CGM), its intersection with other ecological datasets (exercise, mood, sleep), and other informational and motivational elements (exercise videos, text-based exercise coach, self-monitoring diary).

Main Outcome Measures: Feasibility (use metrics, assessment completion), safety (mild and severe hypoglycemia, diabetic ketoacidosis), acceptability (system usability scale, single items, interview themes), standard clinical and psychosocial assessments.

Results: Participants increased exercise from a median of 0 (IQR 0, 21) to 64 (20, 129) minutes per week (p=.001, d=0.71) with no severe hypoglycemia or ketoacidosis. Body mass

Correspondence: Garrett I. Ash, PhD, VA Connecticut Healthcare System (11-ACSLG), Building 35A, Rm 235, 950 Campbell Avenue,West Haven, CT 06516, Phone: 203-444-3079, Fax: 203-937-3829, garrett.ash@yale.edu.
*Co-senior authors

index increased (29.5±5.1 to 29.8±5.4 kg/m^2, p= .02, d= 0.57). Highest satisfaction ratings were for CGM use (89%) and data on exercise and its intersection with CGM and sleep (94%). Satisfaction was primarily due to improved exercise management behavioral skills, although derived motivation was transient.

Conclusions: The intervention was feasible, safe, and acceptable. However, there is a need for more intensive, sustained support. Future interventions should perform analytics upon the digital health information and molecular biomarkers (e.g., genomics) to make exercise support tools that are more personalized, automated, and intensive than our present offerings.

Keywords

Diabetes Mellitus; Type 1; Exercise; Behavior and Behavior Mechanisms; Mobile phone

INTRODUCTION

Type 1 Diabetes (T1D) affects 1.6 million Americans and is associated with micro and macro-vascular complications including cardiovascular disease.[1] Standard treatment approaches to maintain blood glucose levels within a target range (70 – 180 mg/dL) include frequent glucose monitoring by fingersticks and continuous glucose monitoring (CGM), and adherence to complex dietary and insulin regimens.[2] People with T1D must constantly adjust these factors to mitigate blood glucose fluctuations that occur with meals, exercise, and mental and physical stress. These fluctuations can lead to a profound fear of hypoglycemic episodes.[3,4] T1D can also complicate weight management since efforts to maintain glycemic balance often result in overeating[4] or overestimating insulin doses, which has anabolic effects associated with greater risk of obesity.[5] Attention must also be paid to lipid and blood pressure measurements[2] due to the high relative cardiovascular mortality risks (~2 to 12-fold higher) for individuals with T1D.[6]

Research has prioritized interventions improving glycemic control (psychoeducation,[7,8] diabetes devices,[9] and digital platforms[10]) in T1D with minimal focus on overall cardiovascular risk (i.e., glycemic control plus other cardiovascular risk factors noted above). A recent systematic review concluded that exercise is linked to positive health outcomes in T1D that heavily impact cardiovascular risk (aerobic capacity, lipid profile, glycemic control).[11] Unfortunately, most people with T1D do not practice regular exercise.[12,13]

Exercise is logistically challenging because it may cause hypo- or hyperglycemia which must be counteracted by intricate adjustments to insulin and diet.[3,4,14] Some partial predictors of glycemic response include exercise characteristics (intensity, muscle groups), individual characteristics (e.g., endogenous insulin sensitivity), and physiological context (pre-exercise blood glucose level, insulin- and carbohydrates-on-board, and concentration of counter regulatory hormones)[15]. Nonetheless, these factors can be difficult or impossible to measure during daily living and furthermore do not fully account for the variation, leaving people with T1D feeling logistically burdened, frustrated, and fearful of hypoglycemia when trying to establish regular exercise routines.[3,4,14]

Such unpredictability of exercise response (by blood glucose and many other health variables) has raised demand for genomic tests that predict exercise response and can be used to personalize exercise prescription, but such development is currently hindered by problems including nonreproducible results, lack of gene function validation, and selection bias in the genes examined.[16] Thus, one recently proposed alternative is digital phenotyping: tracking biometrics with high frequency and duration to develop a unique signature that informs personalized interventions.[17]

A prime example is continuous glucose monitoring (CGM), increasingly becoming standard of care for T1D that can help support people to achieve safe glucose levels during exercise.[2] By measuring glucose every few minutes CGM identifies trends and trajectories, not just "snapshot" values, helping the user identify relationships among the timing of exercise (eg, morning vs afternoon, after vs before mealtime insulin bolus), acute hypo- or hyperglycemia, and overall time spent in the optimal glucose range.[18] The intersection of CGM datasets with exercise can also improve confidence and motivation for lifestyle change[19–21] but comprehensive interventions translating this information into safe and sustainable exercise behavior for users with T1D are lacking. The goal of personalized exercise prescription will be optimization of digital phenotyping combined with genomic predictors of exercise response once the scientific limitations of exercise genomics are overcome.

This study intervention uses personalized data from CGM intersected with other ecological datasets (smartwatch exercise monitoring, mood and sleep diaries) and integrated with motivational elements to promote behavioral skills, and uses feedback on health outcomes resulting from these skills as additional information and motivation [i.e., information-motivation-behavioral skills (IMBS) approach[22]]. The purpose of this study was to evaluate the feasibility, safety, user satisfaction (i.e., acceptability), and estimate the probable magnitude of the pre-post effect on exercise behavior and other exploratory outcomes (clinical, psychosocial) pertinent to self-management of T1D. We hypothesized that the intervention would be feasible and safe, participants would review it favorably while making suggestions for improvement, and we would observe evidence for its efficacy.

METHODS

Participants.

Adults with T1D were recruited to participate between November 2019 and August 2020 by a combination of social media advertising, snowball sampling, in-person, and other approaches previously described.[23] The inclusion criteria were: 18–65 years old with ≥6mo diagnosis of T1D or other absolute insulin deficiency diabetes, inadequate baseline exercise patterns (<3 exercise sessions/wk),[2,24] English literacy, current user of a smartphone and CGM. Exclusion criteria were chronic disease or physical disability requiring exercise adjustments outside the scope of the mobile intervention.

Study Design.

The study was a pre-post single-group design (Figure 1). Participants completed a 2-week baseline period that included clinical and psychosocial assessments plus observation (CGM,

insulin use, exercise, hip accelerometry) followed by a 10-week intervention with all baseline measures repeated during the last two weeks. A physician (author S.W. or L.N.) reviewed CGM and clinical events every 2 weeks.

Intervention Overview.

We delivered the intervention through a customized mobile digital application adapted from a commercial product (GlucoseZone™, Fitscript^{LLC}, New Haven, CT). Its components (Table 1) were chosen to satisfy the information and motivation components of the IMBS model and include feedback on health outcomes resulting from behavioral skills.[22]

Intervention Component #1: Exercise videos.

All exercise videos were taken from GlucoseZone's publicly available commercial version (www.glucosezone.com), which has been in circulation since 2018 with ~13,700 users globally. The video instructors hold a bachelor's- or master's-level degree in an exercise-related field along with internal training and in-person experience coaching exercise for diabetes. Each video is 20–50 minutes long and includes English guidance to complete an exercise routine interspersed with tips for diabetes management around exercise and description of exercise benefits for diabetes that serve as motivation. The routines are designed to be doable from a home setting. Participants could select routines requiring no equipment, a $10 set of resistance bands (Fit Simplify) loaned by the research team, their own dumbbells or household items like frozen water bottles. The participants could choose video series that progress in difficulty and duration or select single videos from a library filtered by difficulty level, duration, type of exercise (aerobic or resistance), muscle groups, and mobility limitations (knee-friendly, shoulder-friendly, chair-based). Flexibility and balance exercises were also included. Most routines were interval-based in accordance with consensus recommendations for glucose-stabilizing exercises, though participants could also select more continuous exercises to achieve a glucose-lowering effect.

Intervention Component #2: Text-based exercise coach.

Participants could send text messages through the app with exercise questions and receive a response from one of the certified exercise instructors.

Intervention Component #3: Self-monitoring of exercise and barriers.

Participants received an automated SMS each morning at self-reported expected waketime with a link to a secure webform (Qualtrics, Provo, UT). **A)** Exercise completed without video guidance (eg, outdoor activities, ballgames) was logged by type, start/stop time, and a Borg Rating of Perceived Exertion.[25] For video-guided exercise, this information was captured by the application usage log and a post-survey of perceived exertion. **B)** If the participant had not exercised the previous day, the form asked them to rank-order the prior day's barriers to exercise. Choices included moods (lacked positive feelings, had negative feelings, lacked energy, fatigue), fear of hypoglycemia, app malfunction, lack of time/planning, or other. **C)** Hypothetical correlates of exercise behavior were assessed including prior evening's fear of nocturnal hypoglycemia (5-point scale),[4] prior night's sleep quality (10-point numerical scale as per the Pittsburgh Sleep Diary),[26] and fear of

hypoglycemia for the coming day (5-point scale).[4] **D)** Safety information, including each episode of hypoglycemia from the previous day [time of day, symptoms, and mild (self-treatable) versus severe (needed external assistance to treat)]; and any adverse health events (hospitalization, emergency room visit, diabetic ketoacidosis, acute illness, other), gathered every two weeks for purposes of physician monitoring. **E)** Separate from the morning diaries, each video (component #1) queried the profile of mood states (positive feelings, negative feelings, energy, fatigue) by 1-item subscales.[27]

Intervention Component #4: Monthly motivational enhancement therapy session including biosensor feedback.

Participants wore their own CGM to capture 24hr blood glucose and the Apple Watch 3 to capture exercise heart rate (mean absolute relative difference to electrocardiography ~3%).[28] These devices were integrated with video usage logs and self-monitoring data to produce a visual report and quantitative comparisons (Figure 2). The report was reviewed by the principal investigator (G.A. trained by L.F., a clinical psychologist) with participants in an open-ended discussion inviting responses from participants (e.g., “what do you think about this information?”). Subsequent conversation focused on exercise levels, goals, and barriers conducted in the nonconfrontational/empathic style of motivational enhancement therapy which is intended to minimize participant resistance and emphasizes personal responsibility for change.[29]

Assessments.

Exercise was quantified from video usage logs and diaries, converted to metabolic equivalent-minutes by Ainsworth intensities,[30] and verified by Apple Watch heart rate readings [as a percentage of age-predicted maximum (207 – 0.7*age)]. The (relatively infrequent) exercise performed during the 2-week baseline period was recalled day-by-day at the end of baseline, a method we have demonstrated to be reliable (r= 0.79–0.97) and convergently valid with weekly logs (r = 0.65–0.80).[31] We also captured hip accelerometry over waking hours during 7 days of baseline and final intervention week (Figure 1) (Actigraph GT9X, Pensicola, FL), classifying ≥2020 counts/min as moderate-to-vigorous physical activity,[32] although the videos dictated many static exercises (e.g., core exercise) that would not be accelerometer-registered. Methods for our clinical assessments (Table 2) are detailed in our earlier manuscript.[23] Psychosocial instruments were also taken (Supplement #1).

Satisfaction Survey

Satisfaction Survey included the system usability scale[33] for each technical component (10 Likert-style items assessing aspects such as ease of use and degree of technical support needed) and a single Likert-style item for each biosensor feedback component of the monthly discussions. Participants also completed a semi-structured interview with the principal investigator asking what initially made them interested in the study and what they did and did not like about specific components. These were audio recorded, de-identified, and transcribed for analysis.

Analysis.

Feasibility metrics were usage of each component and assessment completion. Safety metrics were self-reported occurrence of mild hypoglycemia, severe hypoglycemia, and diabetic ketoacidosis. Acceptability metrics were percentage above normative system usability scale average for technology products (70 / 100) and percentage satisfied or very satisfied for discussion components (i.e., 4 or 5 out of 5).

Outcomes were compared between the baseline and follow-up by intention-to-treat, using Cohen's d and paired t-tests after verifying normality and log-transforming where needed. Exercise and physical activity behavior variables were positively skewed even after transformation since this lowly active population had a substantial number of "0" cases (Figure 3), so were analyzed by the non-parametric Wilcoxon signed-rank test. Analyses were performed in SPSS 24.0 for Windows (Armonk, NY).

Interviews were analyzed using qualitative description[34] using Atlas.ti™ 7 software (Berlin, Germany) by a single coder (M.D.). The coder read all transcripts, established initial codes inductively from a subset, then coded all others and grouped codes and quotes into themes.

ETHICAL CONSIDERATIONS

The study was approved by the Yale University Institutional Review Board, in accordance with the Declaration of Helsinki. All participants completed an approved copy of the informed consent document prior to study procedures. Study compensation was US $100.38 prorated by mobile diary completion (average $91.75).

RESULTS

Participants

Participants (11F, 9M) were 42.3±15.0 years old with 20.5±15.3 years of diabetes. Most had T1D (90%) and 10% had Latent Autoimmune Diabetes of Adulthood. Some demographic advantages appeared overrepresented compared to the general T1D population[9] including education (70% bachelor's or higher), household income (85% ≥ $50k per year, 50% ≥ $80k per year), Non-Hispanic white race/ethnicity (95%, with 5% Hispanic white), and usage of a continuous subcutaneous insulin infusion pump (85%). The remaining 15% (i.e., 3 participants) used multiple daily injections, among whom 2 complied with the Bluetooth InPen (Companion Medical) during the study and the 3rd preferred to log manually using the InPen's mobile application. Their CGMs included the Dexcom G6 (40%), G5 (10%), G4 (5%), Medtronic 670G (35%), and Abbott Freestyle Libre (10%). On average they had indications of cardiovascular risk including inadequate physical activity, overweight to obese body mass index, prehypertension, and above-target A1c (Table 2). CGM profile also indicated sub-optimal control (>25% above target range, <70% in range).[2] They rated their sleep quality above average.

Feasibility.

Participants exercised a median of 31 (IQR 12, 58) minutes per week with the videos and 28 (6, 69) minutes per week without video guidance. Participants rarely texted the

coaches (average <1x/month) but 85% of them attended both monthly calls. Completion of assessments, diaries, and accelerometer wear were ≥85% (Table 2).

Safety.

There was no ketoacidosis or severe hypoglycemia. Mild hypoglycemia was self-reported a median of 1.5 (IQR 1.1, 4.0) times per week.

Efficacy outcomes.

Participants significantly increased their exercise (Figure 3) and body mass index (Table 2). They tended to slightly decrease blood pressure, A1c, mean sensor glucose and to slightly increase waist circumference and quality of sleep. Total daily insulin dose was not different.

Acceptability surveys.

Among the 18 / 20 participants who completed the survey, 67% said they were satisfied or very satisfied with the intervention and 83% said they would recommend the program to a friend or family member with T1D. Virtually all survey respondents reported above-average satisfaction with their CGM devices (Table 3). Otherwise, the most satisfying components were discussion of specific subsets of the biosensor/diary data at the monthly calls, mostly those involving exercise or its intersection with another biosensor/diary variable. Other technical devices besides the CGM were rated less highly. Discussion of diary variables were rated lower (unless combined with biosensor data as mentioned above) and daily usage of the diaries was unsatisfying. Texting with the coach was unsatisfying on the rare occasions it was utilized.

Acceptability Interviews

Theme 1: Exercise management behavioral skills.—Participants said they learned skills including reducing pre-exercise insulin doses, using exercise to account for overconsumption of carbohydrates, tailoring the timing and type of exercise to optimize glycemic control, and adjusting insulin-to-carbohydrate ratio for exercise-induced insulin sensitivity changes. Many participants stated these skills would help them exercise even more in the future even though time/planning limited how much they achieved during the intervention. A participant who exercised just 1x per month (female, 20 years old) said, “I did notice after doing exercise sessions the glucose went down, so the exercise does work.” Another participant who exercised 1–2x per week (male, 50 years old) said, “this program is helping me feel more comfortable in the exercise space, more comfortable doing the programs and more comfortable exercising, and I can see and feel results by doing it, if I can just get into the habit of doing it more.”

Theme 2: Motivation.—Although some participants enrolled because of desiring to learn more skills (c.f. theme 1), the most common reason for enrollment was wanting more accountability and “background motivation” to exercise. Some reported having adequate exercise on some days or even some weeks of the year but not others, and they enrolled in the intervention to achieve greater consistency. By the end of the intervention, some reported this need for motivation was met by the monthly motivational enhancement therapy sessions

with the principal investigator, more so reviewing the big data (Figure 2) than interacting with the principal investigator. Many others, however, reported the motivation was transient and could be sustained with more frequent feedback and inferences from specific subsets of the big data (e.g., drawing causality between specific exercises and improvements to insulin sensitivity and glycemic control).

DISCUSSION

Principal Findings

The purpose of this study was to pilot an intervention leveraging personalized digital health information to substantiate human-delivered, client-centered exercise support for T1D. The intervention was safe and feasible, a substantial majority of participants found it satisfying and recommendable, and data indicate potential to moderately increase exercise levels if it were tested in a larger trial with a randomized controlled design. Nonetheless, this moderate increase (from a median of 0 to 64 minutes per week) would clearly fall beneath recommended levels of 150 minutes per week[2]. These findings indicate that the current intervention holds some promise but needs refining before conducting a larger trial.

Guidance for such refinement was obtained from the participants through a satisfaction survey and interview. The most appealing component was discussion of data about exercise and its intersection with health outcomes, including personal data from CGM and ecological momentary assessment of sleep and mood variables. They rated these data discussions higher than many popular commercial products they were using (insulin device, Apple Watch, exercise videos tailored to T1D) and similarly to general CGM use, which has recently revolutionized diabetes care.[2,18–21]

When asked why they liked the data discussions, participants stated that they improved their exercise management behavioral skills related to T1D. Nonetheless, some failed to increase regular exercise due to lack of motivation. Many noted that the data discussions improved their motivation only transiently and they would like to see more sophisticated inferences. For example, recommended insulin-to-carbohydrate ratios could be fluidly calculated from exercise-CGM relationships rather than a static number set at quarterly clinician visits.

Implications for Future Interventions

These findings suggest that the collection and use of personal digital health information was feasible and appealing, but the motivational tools require improvement. The participants suggested they would be best served by an application that could draw causality between specific exercises and improvements to insulin sensitivity and glycemic control. One way to achieve this goal would be expanding the array of biological variables that are accounted for, ideally without increasing the sensor burden per participant. For example, CGM patterns may be explained not only by the exercise heart rate we captured but also more direct indicators of sympathetic activation like cortisol and epinephrine. To avoid needing a high number of sensors to measure every such variable, we could utilize genomic tests indicative of pathway upregulation (e.g., glucocorticoid receptor polymorphisms associated

with greater cortisol sensitivity[35]), to provide participants with more definitive and validated insights on predicting their exercise response.

Second, machine learning can anticipate behavioral inclinations based on historical sensor data. For instance, physical activity sensor patterns predict social anxiety.[36] Application of similar machine learning models to our data may reveal that integrated signatures of physical activity, CGM, mood, and sleep predict vulnerability to missing a day of exercise, to which we could accordingly time and tailor the delivery of behavioral support (i.e., just-in-time adaptive intervention).[37] For example, if high blood glucose variability is a vulnerable state predictor, the just-in-time message meeting its occurrence would read: “Sometimes blood glucose can go up and down. You can still be active using the strategies you and your provider have discussed.” Expanding these machine learning algorithms to incorporate genomic factors, such as those demonstrating associations with exercise behavior,[38] is another exciting frontier.

Comparison to Previous Work

Aligned with other exercise programs for T1D, the direction of effect sizes indicated potential for benefit to glycemic control and blood pressure but not body weight or adiposity.[11] Management of exercise often requires carbohydrate correction of blood glucose, complicating weight management.[39] Unfortunately, we lacked a true body composition assessment technique, such as a valid skinfold model or dual-energy x-ray absorptiometry, to determine whether the increased BMI was due to increased adipose tissue or fat-free mass.

Limitations

While this study was designed to identify insights that can guide refinement of the intervention, limitations due to sample size and design diminished testing efficacy and maintenance. Specifically, the single-group pre-post design does not control for time-related threats to internal validity, such as the COVID-19 pandemic and participants’ prior motivation to change. Additionally, the sample was biased toward individuals with demographic advantage and users of CGM technology. CGM use has quadrupled over the past decade due to its heavy clinical endorsement, but its adoption has lagged behind in non-white populations.[40] Finally, only one motivation enhancement therapist was utilized, who also happened to be the principal investigator; which may have limited the generalizability of our findings and generated some bias by participants to give favorable reviews.

Conclusions

This study personalized data from biosensors to substantiate human-delivered, client-centered exercise support for T1D. Despite limitations, the moderate beneficial effect on exercise behavior and small-to-moderate beneficial effects on glycemic control and blood pressure support potential for efficacy if the strategies to intensify the intervention taken from the acceptability interviews can be incorporated. Promising means to do so include incorporation of genomic biomarkers, advanced analytics, or the combination of these two powerful personalized technologies.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Conflicts of Interest and Source of Funding

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Clinical Trial Registration and Data Availability

The trial was publicly registered on clinicaltrials.gov (NCT04204733). Individual deidentified participant data (including data dictionaries) will be shared. This includes individual participant data that underlie the results reported in any aspect of a published article (text, tables, figures, and appendices). Other documents that will be available include the study protocol, statistical analysis plan, informed consent form, analytic code. The data will be available immediately following publication with no end date. Data will be shared with researchers who provide a methodologically sound proposal to achieve aims in the approved proposal. Proposals should be directed to Dr. Garrett Ash at Yale University (garrett.ash@yale.edu). To gain access, data requesters will need to sign a data access agreement.

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Clinical Relevance:

Being able to view their individual data, combined with human coaching was a feasible and appealing way to support exercise for people with type 1 diabetes, suggesting a strong desire for personalized data (e.g., genomics) in this population.

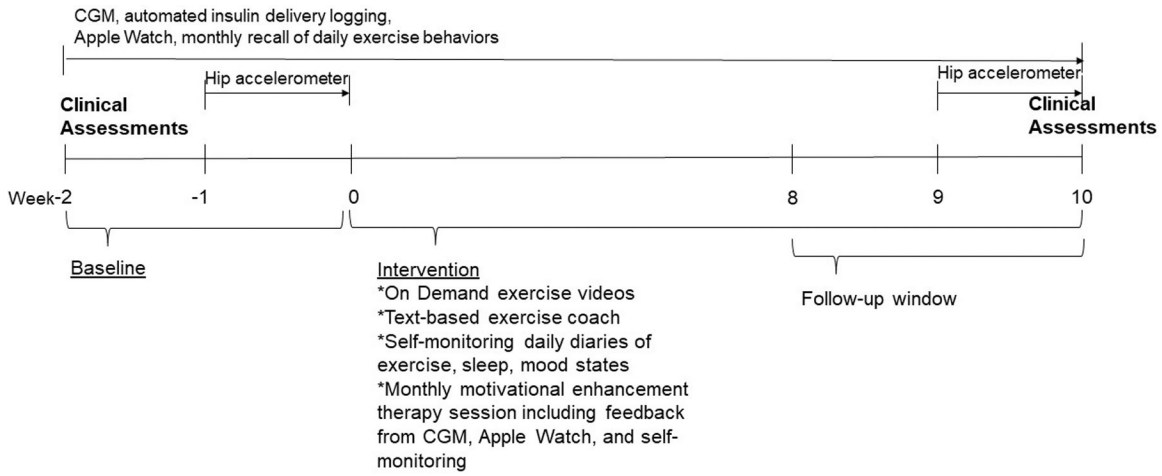
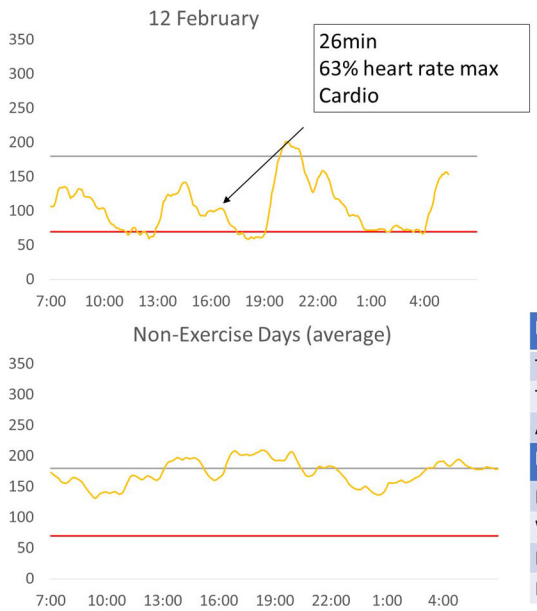
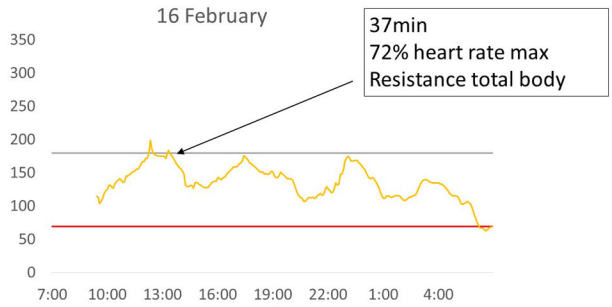


Figure 1.
Study Design.





Blood Glucose	Exercise Days	Non-Exercise Days
Time in range (%)	77	69
Time High (%)	13	23
Average (mg/dL)	127	142
Mood and Sleep	**Exercise Days**	**Non-Exercise Days**
Positive Affect	2.0	3.0
Worry of hypoglycemia	2.0	1.2
Previous night sleep quality	7.1	7.7
Next night sleep quality	8.0	7.1

Figure 2.

Example of personalized big data at monthly motivational enhancement therapy sessions. Blood glucose data also contained % time low (<70 mg/dL) and variability (coefficient of variation). Prior to depicting this intersection of variables, the report contained exercise (total minutes, total days, average intensity by heart rate / perceived exertion / workout video difficulty) and continuous blood glucose summary statistics in isolation, compared to clinical targets (150 minutes exercise per week, blood glucose mean <156 mg/dL, time in range >70%, time above range <25%, time below range <4%). The report ended with tables of mood states before/after exercise and diary-reported exercise barriers ranked by frequency.

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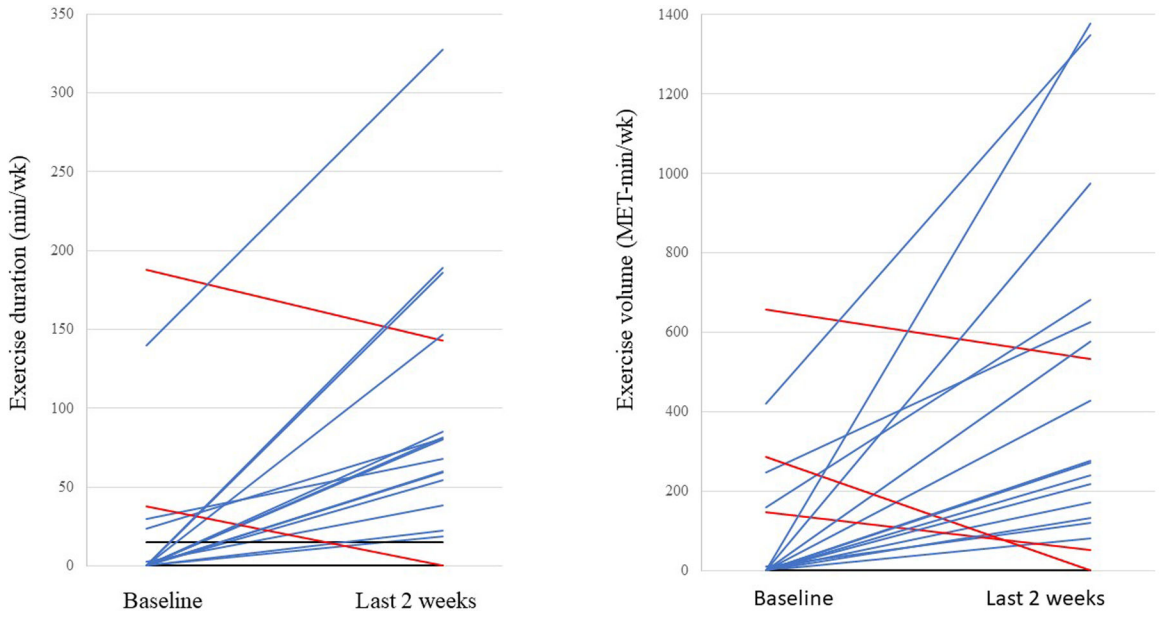

Figure 3.

Exercise duration (left) and volume (right) of each participant during baseline and last 2 weeks of intervention. Participants who increased are colored blue (n = 15 duration / 15 volume), unchanged colored black (n = 3 / 2) and decreased colored red (n = 2 / 3).

Table 1.

Components of IMBS-based exercise intervention for T1D.

Component	Informational Aspects	Motivational Aspects
Exercise videos (on-demand from smartphone) led by GlucoseZone instructor	*Exercise techniques *Exercise benefits for T1D	*Visual display of expected health impact[†]
Text-based exercise coach	*Exercise advice	*Personalization of messages
Self-monitoring of exercise, barriers to exercise, mood, and sleep	*Common barriers to exercise[‡]	*Self-monitoring
Monthly motivational enhancement therapy session including biosensor feedback led by principal investigator	*Reports of CGM and exercise data *Advice to change	*Presentation of data to draw inferences about CGM-exercise relationship *Person-centered therapy

[†]Eg, diagram of areas where muscle insulin sensitivity improves for a specific exercise.

[‡]Choices included the profile of mood states (lacked positive feelings, had negative feelings, lacked energy, fatigue), fear of hypoglycemia, app malfunction, lack of time/planning, or other.

Table 2.

Efficacy Outcomes and data completion

Metric	Baseline	Last 2 weeks	*P*	Cohen's d	Data completion
EXERCISE					
Logged exercise duration (min/wk) *†	4 (0, 41)	64 (20, 129)	.001	0.71	100% logs captured
Logged exercise volume (MET-min/wk) †	0 (0, 156)	256 (91, 614)	.003	0.91	
Accelerometer-measured moderate-to-vigorous physical activity in bouts ≥10min (min/wk) †	0 (0, 89)	21 (0, 88)	.13	0.25	90% returned, worn 6.8±0.5 out of 7 days for 14.7±1.5 waking hours per day
CLINICAL					
Body mass index (kg/m^2)	29.5±5.1	29.8±5.4	.02	0.57	85% completed
Waist circumference (cm)	92.1±14.7	94.0±15.6	.10	0.39	
Systolic blood pressure (mmHg)	123±16	119±16	.06	−0.45	
Diastolic blood pressure (mmHg)	77±9	76±6	.35	−0.21	
HbA1c (%)	7.2±1.1	7.0±0.9	.07	−0.42	
Mean continuous glucose (mg/dL)	159±40	154±39	.09	−0.41	95% returned, worn 90.4±8.8% of time
Glucose time <70 mg/dL (%)	2.3±2.7	2.7±3.6	.52	0.15	
Glucose time 70–180 mg/dL (%)	68.9±22.4	70.2±23.4	.72	0.08	
Glucose time >180 mg/dL	28.7±23.6	27.1±24.8	.65	−0.11	
Glucose variability (coefficient of variation, %)	30.9±6.3	29.5±6.3	.18	−0.32	
Insulin use (U/kg)	0.64±0.23	0.65±0.28	.71	0.09	90% logs captured
Sleep quality diary (0–10)	6.8±1.4	7.2±1.5	.10	0.41	91.4±14.1% completed

*Verified by exercise video usage and exercise heart rate on Apple Watch 3 (**62.2±9.5% age-predicted maximum**) including static exercises not registered by accelerometer.

†Positively skewed, so log-transformed, tested non-parametrically (Wilcoxon signed-rank test) and reported as median (25th %'ile, 75th %'ile). Others were normally distributed, tested parametrically (paired t-test), and reported as mean±SD.

Table 3.

Satisfaction results

Component	Proportion reporting above-average* satisfaction	Mean Score (SD) out of 100	N†
Discussions of exercise and blood glucose	**94%**	**88 (16)**	**17**
Discussions of exercise	**94%**	**87 (16)**	**17**
Discussions of exercise and sleep	**94%**	**81 (24)**	**17**
Continuous glucose monitor	89%	85 (13)	18
Discussions of glucose	**82%**	**79 (18)**	**17**
Discussions of exercise and mood	**82%**	**75 (25)**	**17**
Apple Watch	78%	72 (21)	18
Videos	72%	69 (18)	18
Insulin Device	67%	77 (17)	18
Discussions of mood	**65%**	**68 (23)**	**17**
Discussions of sleep	**59%**	**68 (25)**	**17**
Discussions of exercise barriers	**53%**	**65 (27)**	**17**
Texting with coach	33%	57 (19)	18
Diaries	0%	26 (11)	18

Bolded indicates discussion topic assessed by single item. Others assessed by system usability scale.

† Participants skipped items they did not use, and 2 participants declined to complete the survey.

* Defined as ≥70 out of 100 (above worldwide average for a technology product, “satisfied” or “very satisfied” for a discussion component)