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Ash, Garrett I. PhD; Nally, Laura M. MD; Stults-Kolehmainen, Matthew PhD; De Los Santos, Melissa MS; Jeon, Sangchoon PhD; Brandt, Cynthia MD; Gulanski, Barbara I. MD; Spanakis, Elias K. MD; Baker, Julien S. PhD; Weinzimer, Stuart A. MD; Fucito, Lisa M. PhD. Personalized Digital Health Information to Substantiate Human-Delivered Exercise Support for Adults With Type 1 Diabetes. *Clinical Journal of Sport Medicine* ():10.1097/JSM.0000000000001078, January 27, 2023. | DOI: 10.1097/JSM.0000000000001078. Access at: <https://oce.ovid.com/article/00042752-9900000000-00091/HTML>

Personalized Big Data for Type 1 Diabetes Exercise Support

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This work is a preprint (pre-peer review).

Please cite as: Ash GI, Nally L, Stults-Kolehmainen M, De Los Santos M, Jeon S, Brandt C, Gulanski BI, Spanakis E, Baker JS, Weinzimer SA*, Fucito LM*. (2021). Personalized big data for type 1 diabetes exercise support. *SporRxiv*. <https://doi.org/10.31236/osf.io/34vdc>

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All authors have read and approved this version of the manuscript. This article was last modified on March 23, 2021. Author Laura Nally @drnallypants can be reached on Twitter .

Conflicts of Interest and Source of Funding

The study was funded by the Michael and Rosemary Ryan Pediatric Diabetes Research Fund. G.I.A. is supported by a fellowship from the Office of Academic Affiliations at the United States Veterans Health Administration. E.K.S. was partially supported by the VA MERIT award (#1I01CX001825) from the United States Department of Veterans Affairs Clinical Sciences Research and Development Service.

E.K.S. has received unrestricted research support from Dexcom (to Baltimore VA Medical Center and to University of Maryland) for the conduction of clinical trials, which (Dexcom) did not support the work monetarily or in kind. S.A.W serves as a Speaker for Medtronic and as Consultant for Zealand Pharmaceuticals; neither of these entities supported the above study. For the remaining authors none were declared.

Clinical Trial Registration and Data Availability

The trial was publicly registered on [clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT04204733) (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.

Acknowledgments

The authors thank Madilyn Augustine, Jenna Burton, Irene Chernova, Anthony Cifre, Jack LaVigne, Allison McNeilly, Natalia Roberts, David Robledo, Marisa Rodgers, Chanelle

Simmons, Kathleen Tackos, and Asiya Way for their contributions to the implementation of the study. The authors thank Dr. David Korfhagen for transcribing the interviews.

Abstract word count: 250 / 250

Manuscript word count (not counting figures, tables, references): 2,968 / 3,000

1 ABSTRACT

2 **Objective:** Evaluate feasibility, safety, acceptability, and estimate efficacy of an exercise
3 promotion intervention for adults with type 1 diabetes (T1D) and sub-optimal baseline exercise
4 patterns.

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

7 **Setting:** Community-based sample participating remotely with physician oversight

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

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

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

17 **Results:** Participants increased exercise from a median of 0 (IQR 0, 41) to 64 (20, 129) minutes
18 per week ($p=.004$, $d=0.71$) with no severe hypoglycemia or ketoacidosis. Body mass index
19 increased (29.5 ± 5.1 to 29.8 ± 5.4 kg/m², $p=.02$, $d=0.57$). Highest satisfaction ratings were for
20 CGM use (89%) and data on exercise and its intersection with CGM and sleep (94%).

21 Satisfaction was primarily due to improved exercise management behavioral skills, although
22 derived motivation was transient.

23

Conclusions: The use of personalized big data from biosensors to substantiate human-delivered, client-centered exercise support for T1D is feasible and acceptable for interventions involving big data collection. However, there is a need for more intensive, sustained support. The big data could support informatics-based, automated motivational tools.

Keywords: Diabetes Mellitus, Type 1; Exercise; Behavior and Behavior Mechanisms; Mobile phone

Clinical Relevance: A mobile application using personalized readings from wearable devices to support beginner's exercise with type 1 diabetes was tested to solicit user feedback.

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 overeating⁴ 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 measurements² 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 platforms¹⁰) 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 depending on individual circumstances (magnitude and timing of most recent meal and insulin dose, any hypoglycemia in the past 24 hours, etc), which must be counteracted by intricate adjustments to insulin and diet.^{3,4,14}

Continuous glucose monitoring (CGM), increasingly becoming standard of care for T1D 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 hyper-glycemia, and overall time spent in the optimal glucose range.¹⁵ The intersection of big CGM datasets with exercise can also improve confidence and motivation for lifestyle change¹⁶⁻¹⁸ but comprehensive interventions translating this information into safe and sustainable exercise behavior for users with T1D are lacking.

Therefore, this study intervention uses big 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) approach¹⁹]. 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.

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 fully described in a separate manuscript.²⁰ The inclusion criteria were: 18-65 years old with ≥ 6 mo diagnosis of T1D or other absolute insulin deficiency diabetes, inadequate baseline exercise patterns (< 3 exercise sessions/wk),^{2,21} 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.¹⁹

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.		

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.²² 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),²³ 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.²⁴

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%).²⁵ 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.²⁶

Assessments. Exercise was quantified from video usage logs and diaries, converted to metabolic equivalent-minutes by Ainsworth intensities,²⁷ and verified by Apple Watch heart rate readings

[as a percentage of age-predicted maximum ($207 - 0.7 \times \text{age}$)]. 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 ($r = 0.65-0.80$).²⁸ 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,²⁹ 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.²⁰

Satisfaction Survey included the system usability scale³⁰ 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. Analyses were performed in SPSS 24.0 for Windows (Armonk, NY).

Interviews were analyzed using qualitative description³¹ using Atlas.tiTM 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 (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 population⁹ 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 $\geq 85\%$ (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 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.

Table 2. Efficacy Outcomes and data completion						
Metric	Baseline	Last 2 weeks	<i>P</i> ‡	Cohen’s d	Data completion	
EXERCISE						
Logged exercise duration (min/wk)*†	0 (0, 21)	64 (20, 129)	.004	0.71	100% logs captured	
Logged exercise volume (MET-min/wk)	0 (0, 156)	256 (91, 614)	.001	0.91		
Accelerometer-measured moderate-to-vigorous physical activity in bouts ≥10min (min/wk)†	0 (0, 89)	18 (0, 88)	.27	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/m²)	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. †Negatively skewed, so log-transformed for analysis and reported as median (25 th %’ile, 75 th %’ile). Others were normally distributed and reported as mean±SD.						

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216 Acceptability surveys. Among the 18 / 20 participants who completed the survey, 67% said they

217 were satisfied or very satisfied with the intervention and 83% said they would recommend the

218 program to a friend or family member with T1D. Virtually all survey respondents reported

219 above-average satisfaction with their CGM devices (Table 3). Otherwise, the most satisfying

220 components were discussion of specific subsets of the biosensor/diary data at the monthly calls,

221 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.

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)			

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 big data from biosensors 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 4 to 64 minutes per week) would clearly fall beneath recommended levels of 150 minutes per week².

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 big data from CGM and ecological momentary assessment of sleep and mood variables. They rated these big 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.^{2,15-18}

When asked why they liked the big 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 big 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 big data was feasible and appealing, but more frequent motivational tools should be developed and enlisted. One such possibility is a just-in-time adaptive intervention, in which big data are used to machine-learn predictors of a vulnerable state and tailor encouragement accordingly.³² 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.” A second possibility is personalized assessment of

exercise's causal impact upon CGM after adjustment for covariates measured as frequently as the CGM including insulin-on-board, Apple Watch steps at sub-exercise intensity, and carbohydrates self-reported into insulin delivery device (mathematical examples and graphics separately published³³). This could provide automated personalized feedback to encourage exercise that is improving glucose levels or modifying exercise that is not (e.g., switch from resistance to aerobic). In addition, it provides a digital phenotype³⁴ that could be aligned with other big data sources (e.g. genomics) that may explain and predict the health response to exercise.

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.³⁵

Limitations

While this study was designed to identify insights that can guide refinement of the intervention, limitations due to sample size and design precluded testing efficacy and maintenance. 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.³⁶ 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 big 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.

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Figure 1. Study design

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.