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"It changed everything we do": A mixed methods study of youth and parent experiences with a pilot exercise education intervention following new diagnosis of type 1 diabetes

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ABSTRACT

Aims: This pilot study delivered a comprehensive exercise education intervention to youth with new-onset type 1 diabetes (T1D) and their parents to increase knowledge and confidence with physical activity (PA) shortly after diagnosis.

Methods: Youth initiated continuous glucose monitoring (CGM) and PA trackers within 1 month of diagnosis. Youth and their parents received the 4-session intervention over 12 months. Participants completed self-report questionnaires at baseline, 6- and 12-months. Surveys were analyzed using linear mixed effects models. Semi-structured interviews and focus groups explored experiences with the exercise education intervention. Groups and interviews were audio-recorded, transcribed, and analyzed using content analysis.

Results: A total of 16 parents (aged 46 ± 7 years; 88 % female; 67 % non-Hispanic White) and 17 youth (aged 14 ± 2 years; 41 % female; 65 % non-Hispanic White) participated. Worry about hypoglycemia did not worsen throughout the study duration. Parents and youth reported increased knowledge and confidence in managing T1D safely and preventing hypoglycemia during PA following receiving the tailored exercise education intervention.

Conclusion: This study assessed a novel structured exercise education program for youth and their parents shortly following T1D diagnosis. These results support the broad translation and acceptability of a structured exercise education program in new-onset T1D.

1. Introduction

Due to cardiovascular health benefits, increases in insulin sensitivity, and improved glycemic outcomes,[1] regular physical activity (PA) is strongly encouraged for individuals with type 1 diabetes (T1D) by both the American Diabetes Association (ADA)[2] and the International Society for Pediatric and Adolescent Diabetes (ISPAD).[3] Exercise consensus guidelines recommend youth with T1D should aim to achieve at least 60 min of moderate-to-vigorous PA daily.[3] Regular PA in children and adolescents has been shown to improve HbA1c, bone mineral density, blood lipid profiles, and body composition.[4]

Unfortunately, few youth with T1D meet PA guidelines due to several barriers,[5,6] including fear of hypoglycemia (FoH); worry about loss of control over glucose levels; challenges with scheduling time for PA; low fitness levels; and perceived stigma.[7–11] A synthesis of qualitative studies on barriers to PA in youth with T1D noted themes including:

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level of motivation to engage in PA; limited support from family, peers, and others; limited education and knowledge of how to address and prevent hypoglycemia; and communication between stakeholders (e.g., family, teachers, diabetes care team).[12]

The new-onset period is a major life adjustment for many youth and their families.[13–16] Families receive a large amount of education on insulin administration, carbohydrate counting, and glucose monitoring to manage T1D.[13,16,17] Youth with T1D must adjust to managing diabetes in their daily lives and adjust to using devices such as continuous glucose monitoring (CGM) and/or insulin pumps.[18,19] PA education has not traditionally been included in standard new-onset educational content, perhaps due to concerns about contributing to additional burden by increasing required education during a period of significant adjustment and distress.[14,15]

Previous interventions promoting PA in youth with T1D have demonstrated feasibility, acceptability, and evidence of numerous physical health benefits.[20–24] Given that FoH and concerns about glucose management are common reasons that youth and their parents may have hesitations around engaging in PA, the new-onset period represents a unique opportunity to introduce key concepts that could help youth resume activities following diagnosis with a greater level of confidence, and to foster greater confidence in preventing and managing hypoglycemia. However, little is known about the potential impact of structured exercise and PA education in the new-onset period following diabetes diagnosis. Therefore, the goal of this mixed methods pilot study was to determine the feasibility and acceptability of delivering a structured exercise and PA education intervention to youth with new-onset T1D and their parents/caregivers. We also explored the acceptability of starting newly diagnosed youth with T1D on wearable technology (CGM and PA trackers) shortly after diagnosis. This paper reports on the parental and youth experiences in receiving exercise and PA education shortly after diagnosis.

2. Materials and methods

2.1. Participants

Eligible youth were part of the larger pragmatic 4T (Teamwork, Targets, Technology, and Tight Control) study for newly diagnosed youth with T1D. The main 4T protocol has been described elsewhere in detail.[25–27] As part of the 4T protocol, all youth diagnosed with T1D between July 2018 and June 2020 and seen at the Stanford/Lucile Packard Children's Hospital were approached to initiate use of CGM (Dexcom G6, Dexcom Inc., San Diego, CA) within the first month of diagnosis. Those who opted to initiate CGM then attended a visit with a Certified Diabetes Care and Education Specialist (CDCES) to start using CGM, and attended a follow-up visit via telehealth with a nurse practitioner one week after CGM initiation. For eligible youth in the main 4T cohort, the 4T Exercise study offered exercise education to participants and their parents/caregivers and a PA tracker (Garmin vívosmart 4, Garmin Ltd., Olathe, KS) during the 12-month study duration. The 4T Exercise Study inclusion criteria included: clinical T1D diagnosis; 11- < 21 years of age; and English-speaking. Exclusion criteria included: diabetes diagnosis other than T1D; diagnosis of T1D >1 month prior to the initial visit; and/or individuals planning to receive T1D care at another clinic.

2.2. Procedures

2.2.1. 4T Exercise study intervention

The 4T Exercise study was approved by the Stanford Institutional Review Board (NCT04336969). Informed parental consent and youth assent were obtained. Parents and youth were asked to complete four exercise education sessions during the 12-month study. Sessions were offered separately or together for parents and youth. The education content was developed based on exercise consensus guidelines and published T1D and exercise literature. Sessions were led by a person with diabetes (PWD) who is a Certified Exercise Physiologist (CEP) and CDCES (D.P.Z.). Additional stakeholders included the 4T CDCES team at Stanford's Lucile Packard Children's Hospital that reviewed and provided feedback and iterations to the education content. Each education session was approximately 45 min to 1 h in duration and was conducted using secure tele-health video communication (Zoom Video Communications Inc.; San Jose, CA) via Stanford Children's Electronic Health Record platform (MyChart by Epic Systems Corporation; Verona, WI). Exercise education modules were scheduled around the following time windows, with flexibility in module dates: 1–3 months, 4–6 months, 7–9 months, and 10–12 months post-diagnosis. The exercise education content that was covered included, but not limited to: Module 1) benefits of exercise, PA guidelines, terminology, challenges around PA; Module 2) safe starting glycemia for PA, exercise time of day, reducing dysglycemia around PA; Module 3) carbohydrate intake around PA, planned versus unplanned PA, insulin dosing adjustments for PA; and Module 4) factors impacting glycemia around PA, competition stress, and tailoring insulin modalities (e.g., open loop versus hybrid closed loop) for PA (Fig. 1).

2.2.2. Mixed-methods study design

Qualitative and quantitative data were collected to explore the experience of receiving targeted exercise education following T1D diagnosis. Participants (youth with T1D and parents/caregivers) completed electronic self-report surveys (detailed in Section 2.3) at baseline (pre), 6- (mid), and 12-month (post) time points. Following the completion of exercise modules and 12 months in the 4T Exercise program, a convenience sample of youth and their parents who had previously consented to be contacted for focus groups were approached via telephone and electronic communication and invited to take part in focus groups using a semi-structured interview guide (detailed in Section 2.4). Due to scheduling constraints, interviews were conducted as well as focus groups. Youth and parents were each provided a $50 USD gift card for their participation.

2.3. Measures

2.3.1. Demographic and medical information

Demographic information about youth and parent participants were collected as part of the larger 4T study and included age, self-reported race/ethnicity, sex, insurance type, diabetes duration, and HbA1c at diagnosis.

2.3.2. International Physical Activity Questionnaire – Short Form (IPAQ-SF)

The IPAQ is a commonly used self-report PA questionnaire.[28] The 7-item short form asks about engagement in four distinct categories over the past seven days: vigorous-intensity PA, moderate-intensity PA, walking, and sitting. The IPAQ-SF was administered to youth participants who provided the number of days, number of hours, and number of minutes spent in each category. Respondents could answer "not sure" if they did not know the answer. Scores for vigorous, moderate, and walking PA were converted into metabolic equivalents of task (METs) in minutes of activity per week. An average MET score was calculated.

2.3.3. Hypoglycemia Fear Survey – II Worry Subscale (HFS-W)

The HFS-II measures FoH with two subscales: Behavior (HFS-B) and Worry (HFS-W).[29] The 18-item Worry subscale was administered to youth (HFS-II) and parents (HFS-P) and describes worries the person with diabetes may have regarding episodes of hypoglycemia. Items were rated on a 5-point Likert scale (0 = never; 4 = always). Subscale scores and total scores were summed. Higher scores indicate more FoH.

2.3.4. Study feedback survey

A brief program satisfaction survey was developed for the 4T and 4T

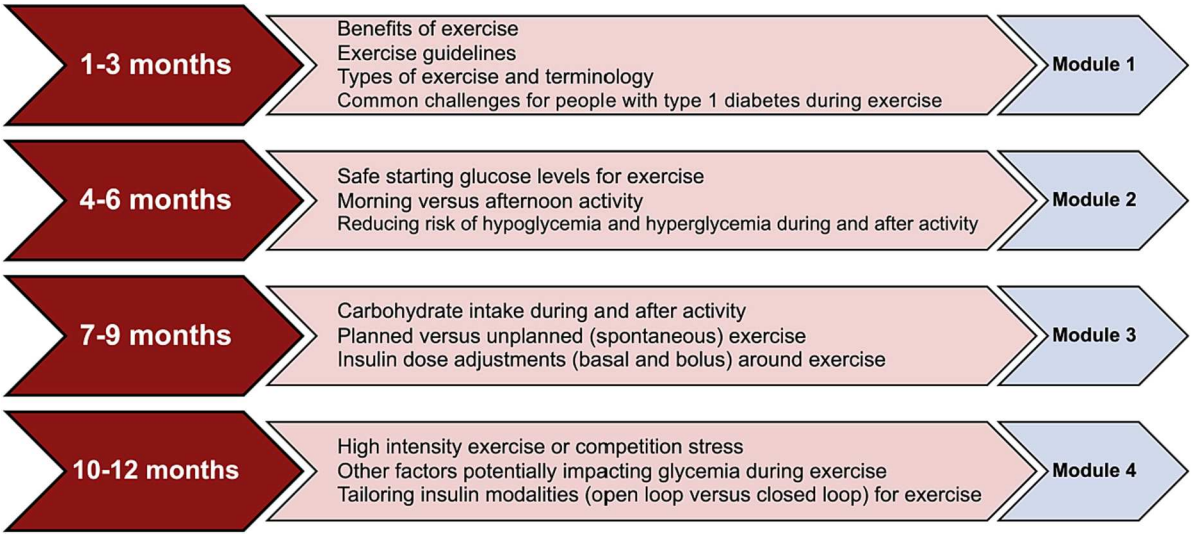

Fig. 1. 4T Exercise Study Module Content.

Exercise study. Participants in the 4T Exercise program were asked to self-report changes in their confidence with exercise because of participating in the exercise education program and to provide feedback on preferred frequency, length, and format of sessions. This survey was sent to 4T Exercise participants electronically via REDCap following the end of study (12-month) period.

2.4. Qualitative data collection

Semi-structured interviews and focus groups were conducted with the goal of obtaining feedback and experiences, benefits, and challenges with starting PA trackers and exercise education shortly after T1D diagnosis. To ensure consistency between interviews and focus groups, interviewers used a semi-structured interview guide that was developed and reviewed by the multidisciplinary 4T study team. Focus groups and interviews were conducted by two female clinical researcher staff members with training in focus group moderation (J.A.H. [MPH, RD] and F.K.B. [MS, CDCES]). J.A.H. and F.K.B. were known to study participants as clinical staff members of the 4T Exercise study team. They had limited prior interactions with participants and did not lead any of the exercise intervention sessions. Focus groups and interviews were held over a HIPAA-compliant videoconference platform (Zoom Video Communications Inc., San Jose, CA) with only youth, parent/caregiver, and researchers present. Focus groups and interviews were audio-recorded and transcribed. Transcripts were checked for quality and de-identified prior to analysis.

2.5. Data analysis

Qualitative data was analyzed using content analysis.[30,31] A team of four coders met weekly to first develop an initial codebook based on open-coding the first set of transcripts. The codebook was refined through a combination of bottom-up (informed by the data) and top-down (informed by study aims) approaches. Then, each transcript was assigned to two coders who applied codes independently and met to discuss codes. A third coder assisted with discussing codes and resolving discrepancies between the codes. The final coding was then entered into NVivo qualitative data analysis software, version 1.7.1.[32]

Descriptive statistics were used to calculate demographics, summarize study feedback survey results, and self-report measures. Linear mixed regression models were used to assess unadjusted and adjusted differences in survey scores at three timepoints in the study: baseline (pre), 6-months (mid), and 12-months/study end (post). This modeling approach is robust in case of non-responses and produces unbiased results provided that the missing data occurs at random, which is assumed here.[33] The unadjusted models consist of a fixed effect for timing (pre/mid/post) with pre- as the reference category and a random effect for participants. Due to the limited sample size, the adjusted models account for potential confounders (i.e., insurance type, age at onset, sex, and ethnicity), one at a time. For the IPAQ-SF survey, a logarithmic link function was used to better capture the distributional characteristics of MET-minutes. Point estimates with 95 % Wald confidence intervals are reported. All analyses were conducted in the R statistical computing framework for macOS, version 4.3.

3. Results

3.1. Self-report measure results

3.1.1. Participant demographics and characteristics

Fig. 2 shows the 4T Exercise pilot study CONSORT diagram. Table 1 summarizes participant demographics and medical information. A total of 17 youth and 16 parents participated in focus groups. Table 2 presents means, 95 % confidence intervals (CI), and results from unadjusted linear mixed effects models examining changes from baseline to 6- and 12-months in FoH (HFS-II and HFS-P Worry) and PA (IPAQ-SF). Based on unadjusted models from baseline to study cessation, FoH did not worsen for parents and youth and PA levels tended to increase in youth, although these findings were not statistically significant. Adjusted models did not significantly change the results.

3.1.2. Study feedback survey

Fig. 3 presents results from the feedback survey that parents completed following their participation in exercise education ($n = 21$). Most respondents ($n = 13$) felt that meetings were frequent enough while some ($n = 5$) would have liked more frequent meetings. Most ($n = 12$) also would have liked to start exercise education within a month of T1D diagnosis; a smaller number would have preferred starting 2–3 months after diagnosis. In terms of format, only 4 respondents said they would have preferred in-person sessions while others either would have preferred virtual sessions or did not have a preference. More respondents (n = 12) would have preferred sessions with the child and parent separate; 7 respondents would have preferred joint sessions. Finally, the top reasons that parents found sessions helpful were: 1) to learn about the different types of PA and their impact on glucose levels; 2) to learn about insulin adjustment strategies for exercise; 3) to

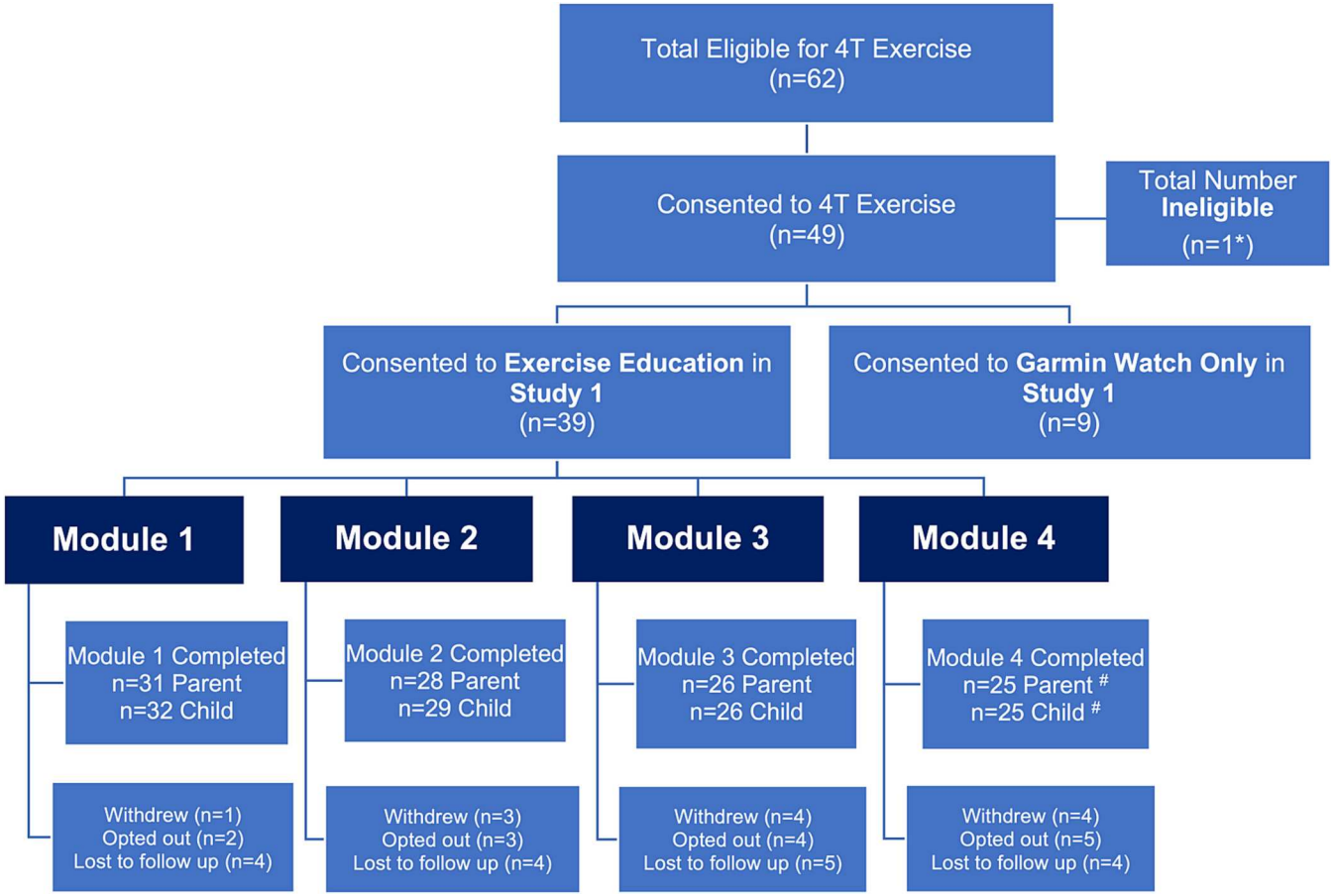

Fig. 2. CONSORT (Consolidated Standards of Reporting Trials) Diagram of All 4T Exercise Study Pilot Participants.
* Denotes one participant consented and then deemed ineligible by Principal Investigator (D.P.Z.) following clinical diagnosis other than T1D
# Denotes one participant (parent and youth) still in progress and need to complete Module 4
A total of 222 modules have been completed for the 4T Exercise Study Pilot.

Table 1
Baseline characteristics of 4T Exercise focus group participants.

	Youth ($n = 17$)	Parent ($n = 16$)
Age at Diagnosis, mean ± SD	14.2 ± 2.4	46.0 ± 6.7
Race/Ethnicity, n (%)		
Non-Hispanic White	11 (64.7 %)	11 (68.8 %)
Non-Hispanic Black	0 (0 %)	0 (0 %)
Hispanic	1 (5.9 %)	2 (12.5 %)
Asian or Pacific Islander	4 (23.5 %)	3 (18.8 %)
American Indian or Alaska Native	0 (0 %)	0 (0 %)
Other	1 (5.9 %)	0 (0 %)
Sex, n (%)		
Male	9 (52.9 %)	2 (12.5 %)
Female	7 (41.2 %)	14 (87.5 %)
Trans-Male	1 (5.6 %)	0 (0 %)
HbA1c at Diagnosis, % mean ± SD	12.2 ± 2.6	–
Insurance Type, n (%)		
Private	14 (82.4 %)	–
Public	3 (17.6 %)	–
Unknown	0 (0 %)	–
Exercise Education Initiation, median (IQR) days	112 (80, 176)	–
CGM Initiation, median (IQR) days	11 (8, 30)	–
Garmin Initiation, median (IQR) days	28 (12, 42)	–

Table 2
Means, standard deviations (SDs) and unadjusted linear mixed effects models assessing change in FoH (HFS) and physical activity (IPAQ-SF)*.

	Mean (SD)	Beta (95 % CI)	*p*-Value
IPAQ-SF – MET Minutes			
Baseline (pre)	4709 (3758)	–	–
6-Months (mid)	5149 (4958)	1.2 (0.80 to 1.81)	0.38
12-Months (post)	5070 (5180)	1.33 (0.90 to 1.96)	0.16
HFS-II Worry			
Baseline (pre)	16 (9)	–	–
6-Months (mid)	15 (10)	−0.96 (−5.4 to 3.5)	0.66
12-Months (post)	15 (6)	−0.86 (−5.5 to 3.8)	0.71
HFS-P Worry			
Baseline (pre)	19 (13)	–	–
6-Months (mid)	18 (11)	−1.4 (−5.5 to 2.6)	0.47
12-Months (post)	18 (13)	−0.80 (−5.3 to 3.7)	0.72

Note: Baseline (pre) $N = 32$; 6-Months (mid) $N = 30$; 12-Months (post) $N = 22$). IPAQ-SF=International Physical Activity Questionnaire Short Form; MET = Metabolic Equivalent of Task; HFS-II=Hypoglycemia Fear Survey-II (Child); HFS-P=Hypoglycemia Fear Survey-Parent.

understand the impact of exercise and other factors on glycemia; and 4) to learn how to manage post-exercise hypoglycemia and hyperglycemia.

3.2. Qualitative results

Eight focus groups (two participants per group) and 19 interviews were conducted and lasted from 10 to 56 min in length (31 ± 13 min).

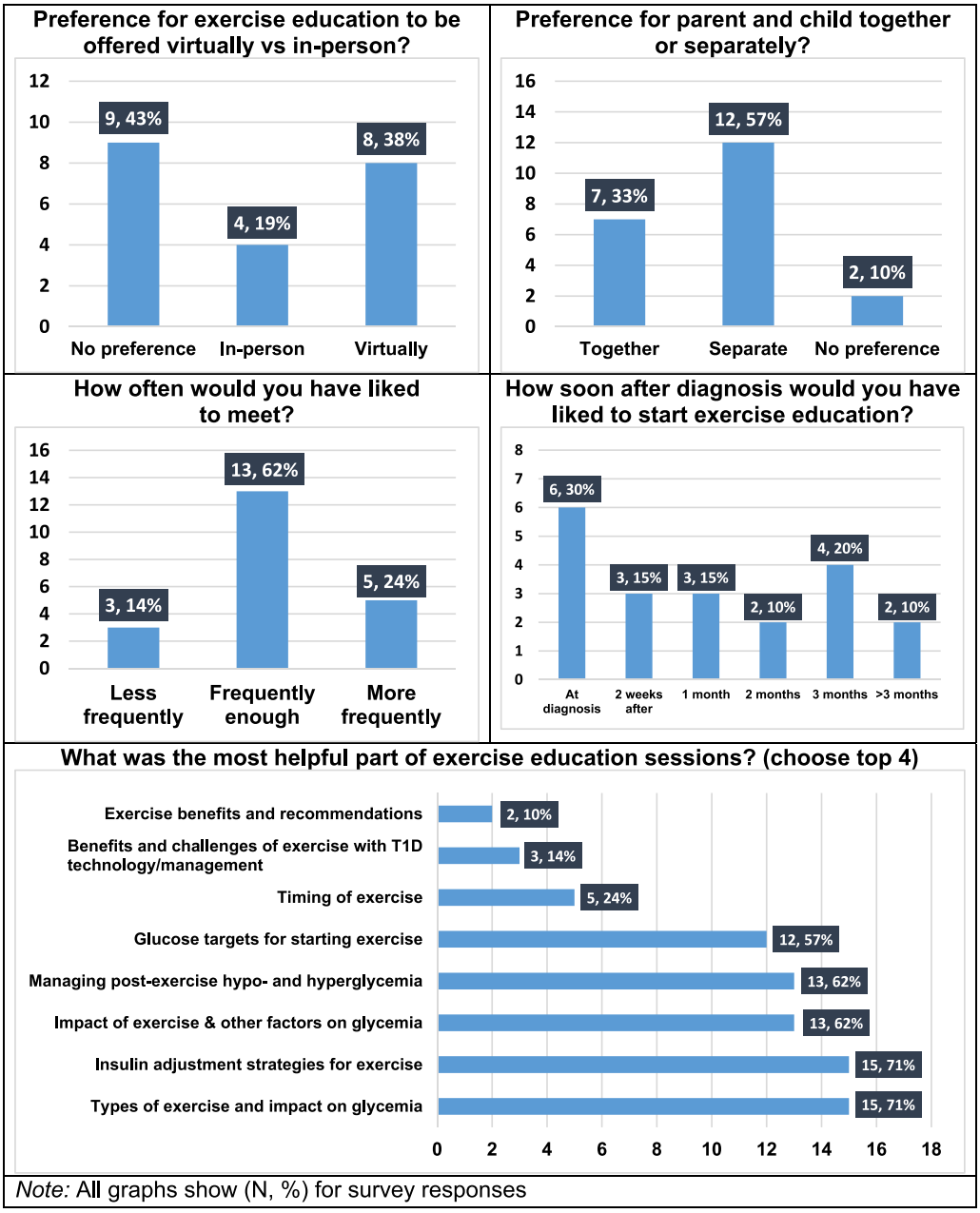

Fig. 3. Study Feedback Survey Results from Parents (n = 21) in the 4T Exercise Study.

Based on the study aim of obtaining feedback on the exercise intervention, overarching themes were: 1) impact of T1D diagnosis on PA; 2) benefits of the exercise intervention; 3) feedback on the intervention content and format; 4) experiences with CGM during PA; 5) experiences with PA tracker use; and 6) real-world challenges with integrating lessons into everyday life.

3.2.1. Impact of T1D diagnosis on PA

Prior to diagnosis, youth participants had been engaged in a wide variety of PA including formal sports (e.g., basketball, soccer, water polo, taekwondo), physical education (PE) class, and playing with friends (e.g., tag, playing outside, using a scooter). Following diagnosis, youth expressed primarily being concerned about preventing and managing hypoglycemia during PA. One participant stated, "I'm more worried about low blood sugar…just one more thing I have to worry about on top of trying to focus on playing the game" (FG14, female, aged 13). Participants who played contact sports expressed concerns about having their diabetes devices knocked off during play. Finally, some expressed not wanting to draw additional attention to themselves from teammates and coaches due to having to manage diabetes or treat lows while playing sports. One participant described being worried that "[coaches] would call me out on a lot of stuff…during the practices, and everyone would be watching me, and I wouldn't be able to participate as much 'cause of [diabetes]" (FG8, female, aged 12).

Parents described varying degrees of comfort with their child engaging in PA following diagnosis. Some wanted their child to maintain their engagement in activities and have a "normal high school experience" without the added worry about their blood glucose levels. A father of a 12-year-old stated, "I felt really driven to get her back to normal as much as possible with her lifestyle [after diagnosis]. A big part of that was physical activity and sports" (FG9). Others described feelings of anxiety about their child engaging in PA due to concerns about hypoglycemia. In these cases, they may have delayed returning to activities they had engaged in prior to diagnosis.

I haven't put him back into gymnastics yet because there's such a mixture of anaerobic exercise…I'm scared, quite honestly. I know that it's probably fine, but I just haven't done it yet.

(FG4, mother of 13-year-old son)

3.2.2. Benefits of the exercise intervention

Participants described a range of benefits from receiving the intervention and changes they made as a result of their participation. A common theme was increased confidence in managing diabetes and managing and preventing hypoglycemia. One participant stated:

My confidence boosted a lot…[The interventionist] helped me gain my confidence more than I had before of going out. I felt like a new person basically…She helped build that [confidence] back.

(FG13, female, aged 12)

Another participant described how the intervention equipped him with practical knowledge and tips that contributed to his increased comfort going into PA. He stated, "[The intervention] helped my confidence a lot, knowing a lot of tips about when to start exercise [glucose level]-wise. That helped me go into exercise confidently." (FG3, male, aged 14).

Participants also described an increased sense of safety and decreased worry when engaging in PA after receiving the exercise intervention. One participant stated, "Now I know more ways to be safer…so that your blood sugar doesn't go low or super high during exercise" (FG8, female, aged 12). Participants pointed to multiple practical strategies they learned and were able to incorporate into their daily lives. Being equipped with these strategies contributed to their confidence in their ability to manage diabetes, to prepare for engaging in PA, and to be able to make decisions about treatments. One participant shared how being given this toolbox led her to feel more able to be flexible and try out strategies in her life with less self-doubt.

Having all these things in my little tool basket that I can just pull out if I need to is really helpful…Now I know what are actual things that I can do that would be beneficial and would not harm me in any way. Before the exercise sessions, I would sometimes just eat some carbs, and I wouldn't really know, should I have done that? I would kind of be doubting it. After the sessions, I was like, 'You know what? That's okay because sometimes you just have to try things out and see if it works.'

(FG5, female, aged 16)

Parents appreciated learning practical tips, basic knowledge and strategies to prepare for PA, as well as during and after PA, because being equipped with this education helped them "get back to normal" and resume everyday activities they may have been avoiding. One parent described how initially after the diagnosis, she was asking herself, "Is life gonna be back to normal again?" Then, as a result of receiving the intervention, she stated:

My daughter] was like, okay, I have some freedom. I can go for a walk. I can play with my dog. I can go back to field hockey…I am confident because [my daughter] is confident, and her numbers look good…We just feel like life is getting back to normal.

(FG12, mother of 12-year-old daughter)

Parents described feeling better able to problem-solve with more concrete tools and steps, and better able to notice patterns and relationships between PA and glycemia. Parents also echoed the sentiment that receiving exercise education built their confidence in themselves as well as in their children to be able to manage diabetes. This confidence helped parents feel more comfortable allowing their teenage children to be more independent engaging in PA without a parent present, such as at school or during sports tournaments.

If we didn't have the [CGM] data and then didn't get this [exercise] education, I don't know that I would have had the peace of mind to let him stay [at school] in person or to let him participate on the level that he ended up participating in PE. It started out very dicey, but we pretty quickly got it under control, and then he started to thrive a little bit. ...It really made a huge difference for us.

(FG23, mother of 15-year-old son)

3.2.3. Feedback on intervention content and format

Participants were encouraged to provide constructive feedback about the intervention. Several participants mentioned appreciating that the interventionist shared slides to deliver education content. One participant stated that the "slides were…really clear and really organized" (FG5, female, aged 16). Participants found the virtual format acceptable and convenient though some stated that they might appreciate an in-person option for some of the visits rather than it being fully remote. While some participants appreciated the 60-min session length, others expressed that they would have preferred shorter (e.g., 20–30 min) sessions. Several participants wished the sessions could have occurred more frequently following diagnosis to help with reinforcing behavior change and building habits. Some parents shared this suggestion as well and would have been open to an increased number of sessions to be able to continue to build upon the education and put it into action in their own lives. One parent stated, "Four [sessions] was fine... but if it were longer, I think I probably would have benefitted from more" (FG19, mother of 17-year-old son). Finally, some participants hoped that more specific, tailored education could be included in the content. These participants expressed that they would have wanted education specific to their particular sport or type of PA. Others had questions about which specific types of carbohydrates to consume and other foods to eat prior to engaging in PA.

3.2.4. Experiences with CGM during PA

Youth participants and their parents verbalized many benefits of using CGM while engaging in PA including: less worry and more reassurance for them and their parents; more convenient (and less visible to others) than using a blood glucose meter and fingersticks; not needing to just rely on one's body to gauge glucose levels in the middle of engaging in sports; and enabling the ability to take quicker action to treat glucose levels while exercising. One participant stated:

If I was in the middle of running and my phone beeped, I knew that I was low, and I could eat something. I was relying on my own ability to feel that I was low. Every so often can go out the window when you're thinking about something else.

(FG3, male, aged 14)

Parents appreciated the peace of mind and sense of security being able to monitor their child's glycemia when they weren't together, and their child was engaging in PA.

Just having that access to that information and data in a way that's readily accessible, remotely accessible, and almost all—it's almost always available. A lot of peace of mind associated with that…From a health perspective, I can't imagine not having this.

(FG9, father of 12-year-old daughter)

One parent, whose teen engaged in an intense physically active sport, remarked that the close glucose monitoring through CGM was what enabled her son to continue participating safely in his sport. Prior to beginning CGM, he was having frequent and challenging episodes of hypoglycemia.

However, participants also described downsides of relying on CGM for exercise and PA. Some noted the data was not always accurate and could provide delayed readings, a topic addressed in the exercise education modules. Participants and their parents mentioned likelihood of sensors falling off and the need to use overlay patches; some parents

noted their dependence on the data and anxiety they felt during gaps in data. Some youth mentioned that they would lose connection if they were too far from their smartphone, which was a likely occurrence with some sports. Still, most felt the benefits outweighed these issues. As one participant described, "I think the [CGM] was really helpful because I didn't have to worry as much" during exercise (FG16, male, aged 18).

3.2.5. Experiences with PA tracker use

Participants were asked to wear a PA tracker at least 14 days each month (Garmin vívosmart 4, Garmin Ltd., Olathe, KS) throughout the study duration. Participants and parents had mixed feedback about wearing PA trackers. Some felt it was easy to learn how to use these devices and appreciated the health tracking data it provided such as heart rate, stress levels, and step count. Some participants mentioned that the PA tracker allowed them to receive text message notifications from their parents with reminders about diabetes treatment while being discreet. Finally, some mentioned that the watch was comfortable to wear.

However, many participants found aspects of the PA tracker unappealing or burdensome. A major barrier was the need to charge the watch, keep track of it and try not to lose it, and remember to put it back on after charging. Some participants found the process of having to sync the data in the Garmin Connect™ mobile app burdensome and slow. One participant and several parents mentioned wanting to be able to see CGM data on the watch, which was not possible on the study PA tracker used. Last, many participants wished they could have had a different brand of a PA tracker that would integrate with their smartphone. Some parents noted that their children were now "overloaded" with devices since their diabetes diagnosis, so a smartwatch was one additional device they needed.

> Having from one day having to not worry about anything to the next day having to wear the Dexcom and the Garmin watch and then the [personal] Apple watch and—because we're trying to keep her in a safe zone…and all those gadgets—I'm sure they can get annoying when you have to use them and not when you want to use them.
>
> (FG17, father of 13-year-old daughter)

3.2.6. Real-world challenges with integrating lessons into everyday life

Some parents mentioned that despite being empowered with knowledge and tools, they found it challenging to implement recommendations consistently into everyday life. Some described the difficulty planning for and implementing changes several hours in advance for their child's plans for PA later that day. As one parent described:

> How do I eat two hours before the game? How do I dose myself for the dinner when I have basketball practice at 8:00 at night? All those things are sort of complicated and confusing…It's hard to figure all that stuff out and keep it straight, especially for a 12-year-old, it's even harder…Not only will I struggle to figure out what we should do, I also just plain forget…I'm eating breakfast, and she's got a game at 1:00. I just forget that she should shave off some carbs and her insulin dosage.
>
> (FG9, father of 12-year-old daughter)

Another parent echoed these challenges in their own experience with implementing recommendations for exercise.

> My bigger thing is planning for exercise. I'll get home, and I'll forget that it's a Tuesday and that he has Taekwondo. I look at his numbers, and I'm like, "Crap, he's low. How am I gonna get him up to where he can go in and do exercise?
>
> (FG1, Mother of 14-year-old son)

This parent noted that part of learning to implement recommendations from exercise education has been to learn how to be flexible and adaptive – to "plan for the fact that I haven't planned" and to be equipped with strategies for entering into PA at different glycemic levels. These parents highlighted that implementing best practices for PA and diabetes involves a complex set of tasks and can be challenging to carry out in everyday life.

4. Discussion

The goal of this mixed method pilot study was to deliver structured exercise education to newly diagnosed youth with T1D and their parents to increase comfort, confidence, and knowledge of how to optimize glycemia while engaging in PA. While other exercise education interventions have been delivered to adults[34–37] and youth,[20–22,24] this is the first study to our knowledge that aimed to deliver exercise education content during the new-onset period following diabetes diagnosis.[27]

Quantitative analyses found that FoH for parents and youth from baseline to 6- and 12-months did not worsen. Similarly, PA levels tended to increase from baseline to 6- and 12-months. Although these outcomes were not significant, this could be due to several factors. First, it was a small sample size with limited power to detect changes over time. Second, baseline PA and FoH were measured soon after initial diagnosis, and repeat measurements occurred at 6- and 12-months after diagnosis, during which time youth and parents were adjusting to a significant life change and learning to manage and live with diabetes.[14,15] Thus, other factors could contribute to how FoH and engagement in PA evolve for newly diagnosed families. Finally, the IPAQ-SF is a self-report measure which limits its ability to capture objective PA.[38] PA trackers measure PA objectively and are more representative of moderate-to-vigorous PA, and these were used in the current study.[39]

Qualitative findings demonstrated positive feedback from youth and parents about their experiences receiving structured exercise education following a new diabetes diagnosis. Prior to diagnosis, many participants were already engaged in sports or other PA. While some youth and their parents described being fearful or worried about re-engaging in PA and daily activities after diagnosis (e.g., playing with a pet, going for a walk) due to FoH, participants shared how they appreciated being given specific tools and strategies that allowed them to return to regular daily activities as well as organized sports and PE with greater confidence in preventing and treating hypoglycemia. Parents expressed greater ease while their children were at school or participating in sports. In addition, parents and youth appreciated the introduction of CGM shortly following diagnosis to be able to track glycemia during PA, which led to decreased FoH. Youth had mixed feedback about the PA trackers during this study: While some appreciated the data and feedback provided, many found the additional device burdensome. Given that the purpose of using PA trackers was to document patterns and behaviors in PA during the intervention, it may not be an essential component necessary for clinical translation.

In terms of feedback on content and structure of the program, some participants would have wanted follow-up sessions to continue reinforcing content and to support sustained behavior change. Some participants requested more sport-specific tailoring in future sessions. Participants shared differing opinions of the preferred session length. Taken together, this feedback points to future potential tailoring of structured exercise education content to best meet the needs of different youth and families. A future addition to the exercise education program may include a "booster session" to reinforce and practice new skills and behaviors.

This pilot study has some limitations worth noting. For the initial pilot, only English-speaking participants were eligible which limits the generalizability of the intervention and accessibility to non-English speaking youth and parents. Since conducting the pilot study, our team has scaled the 4T Exercise intervention to include education to Spanish-speaking families facilitated by a clinical psychologist with behavioral diabetes expertise who is fluent in Spanish (D.N.). While the pilot program and structured content were initially developed by a CEP and CDCES (D.P.Z.), it was designed with the intent to be implemented

and delivered by a CDCES and/or other diabetes healthcare professionals in the future. Another limitation is the possibility of selection bias since the 4T Exercise program was offered to youth 11+ years old enrolled in the main 4T study that had the choice to opt-in for exercise education and wearing a PA tracker, but it was not mandatory for all youth and families to participate. It is unknown whether such a program would be acceptable to families if delivered to everyone following T1D diagnosis. It is also important to understand how to assess readiness for this type of education as families may be ready for exercise education at different stages in adjusting to a new diagnosis of T1D. To account for some of these potential differences, youth and families in the 4T Exercise program initiated exercise education around 1–3 months following PA tracker initiation, but there was flexibility in the timing of module delivery.

In summary, this 4T Exercise study demonstrated that, rather than presenting an additional burden during the new-onset period, exercise education was welcomed enthusiastically by youth and their parents who expressed appreciation for learning hands-on tools and strategies for managing glycemia before, during, and after PA. These exercise education tools, in conjunction with early initiation of CGM, enabled youth to reengage with their sports and other activities with a greater sense of confidence that they could manage glycemia and prevent and treat hypoglycemia. Future intervention refinement may include tailoring to specific activities and competitive sports that some youth engage in. In addition, if a larger study delivering this intervention proves effective, future considerations may include how to incorporate more exercise education into new-onset education, timed appropriately when families are ready to receive this education and put it into action to increase PA and its health benefits. Although these exercise education modules were performed as part of a larger research study, future goals include translating this unique exercise education program more broadly to diabetes clinics, starting locally with our larger CDCES team, then scaling the program nationally and globally, and to also include billing clinically.

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CRediT authorship contribution statement

Molly L. Tanenbaum: Methodology, Writing – original draft, Writing – review & editing. **Ananta Addala:** Methodology, Writing – review & editing. **Sarah Hanes:** Data curation, Formal analysis, Writing – review & editing. **Victor Ritter:** Formal analysis, Writing – review & editing. **Franziska K. Bishop:** Project administration, Writing – review & editing. **Ana L. Cortes:** Validation, Writing – review & editing. **Erica Pang:** Validation, Writing – review & editing. **Korey K. Hood:** Writing – review & editing. **David M. Maahs:** Writing – review & editing. **Dessi P. Zaharieva:** Conceptualization, Investigation, Methodology, Supervision, Writing – original draft, Writing – review & editing, Funding acquisition.

Declaration of competing interest

D.P.Z. has received honoraria for speaking engagements from Ascensia Diabetes, Insulet Canada, and Medtronic Diabetes, unrelated to this work. D.P.Z also serves as a member of the DexCom Advisory Board. D.M.M. has had research support from the NIH, JDRF, NSF and the Leona M. and Harry B. Helmsley Charitable Trust and his institution has had research support from Medtronic, Dexcom, Insulet, Bigfoot Biomedical, Tandem, and Roche; and has consulted for Abbott, Aditxt, the Leona M. and Harry B. Helmsley Charitable Trust, Lifescan, Mannkind, Sanofi, Novo Nordisk, Eli Lilly, Medtronic, Insulet, Dompe and Biospex. All other authors declare that they have no competing interests.

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