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Impact of a 4-week intensive track and field training intervention on glycaemia in adolescents with type 1 diabetes: The ChilDFiT1 study

Rebecca T. Zimmer MSc[1] | Philipp Birnbaumer PhD[2] | Christoph Sternad MD[3] | Beate E. M. Zunner[1] | Janis Schierbauer PhD[1] | Maria Fritsch MD[4] | Elke Fröhlich-Reiterer MD[4] | Peter Hofmann PhD[2] | Harald Sourij MD[3] | Felix Aberer MD[1,3] | Othmar Moser PhD[1,3]

[1]Division of Exercise Physiology and Metabolism, BaySpo–Bayreuth Center of Sport Science, University Bayreuth, Bayreuth, Germany

[2]Exercise Physiology, Training & Training Therapy Research Group, Institute of Human Movement Science, Sport and Health, University of Graz, Graz, Austria

[3]Interdisciplinary Metabolic Medicine Trials Unit, Division of Endocrinology and Diabetology, Medical University of Graz, Graz, Austria

[4]Department of Pediatrics and Adolescent Medicine, Division of General Pediatrics, Medical University Graz, Graz, Austria

Correspondence
Othmar Moser, PhD, Division of Exercise Physiology and Metabolism, BaySpo–Bayreuth Center of Sport Science, University Bayreuth, 95440 Bayreuth, Germany.
Email: othmar.moser@uni-bayreuth.de

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Abstract

Aim: To investigate the safety and efficacy of track and field training compared with intensification of insulin treatment only in adolescents with type 1 diabetes (T1D).

Materials and Methods: Eighteen adolescents (seven females) with T1D were included (age 15.1 ± 1.1 years, HbA1c 7.3% ± 1.0% [56.3 ± 10.9 mmol/mol]). After a 4-week observational control phase, participants were randomized to either stand-alone intensive glycaemic management (IT; telemedicine or on-site visits, three times/week) or additionally performed track and field exercise (EX; three 60-minute sessions/week) for 4 weeks. Glycaemia was assessed via continuous glucose monitoring during observational control and intervention phases.

Results: Time in range (70-180 mg/dL; 3.9-10.0 mmol/L) significantly improved from the observational control phase to the exercise intervention phase in EX (69% ± 13% vs. 72% ± 11%, $P = .049$), but not in IT (59% ± 22% vs. 62% ± 16%, $P = .399$). Time below range 1 (54-69 mg/dL; < 3.9 mmol/L) improved in IT (3.1% ± 1.9% vs. 2.0% ± 0.8%, $P = .017$) and remained stable in EX (2.0% ± 1.7 vs. 1.9% ± 1.1%, $P = .999$). The EX group's HbA1c ameliorated preintervention to postintervention (mean difference: ΔHbA1c −0.19% ± 0.17%, $P = .042$), which was not seen within the IT group (ΔHbA1c −0.16% ± 0.37%, $P = .40$). Glucose standard deviation was reduced significantly in EX (55 ± 11 vs. 51 ± 10 mg/dL [3.1 ± 0.6 vs. 2.8 ± 0.6 mmol/L], $P = .011$), but not in IT (70 ± 24 vs. 63 ± 18 mg/dL [3.9 ± 1.3 vs. 3.5 ± 1.0 mmol/L], $P = .186$).

Conclusion: Track and field training combined with intensive glycaemic management improved glycaemia in adolescents with T1D, which was not observed in the non-exercise group.

KEYWORDS
adolescents, exercise, time in range, type 1 diabetes

Felix Aberer and Othmar Moser are contribiuted equally last author.

1 | INTRODUCTION

With an estimated 355 900 new cases globally in 2021,[1] type 1 diabetes (T1D) is one of the most common chronic diseases among children and adolescents.[2] T1D is classified as an autoimmune disease precipitating the destruction of insulin-producing beta cells,[3] including the necessity to learn to monitor glucose levels and adjust insulin doses to the individual life situation, such as food intake or physical activity.[4,5]

Regular physical activity and exercise are recommended in children and adolescents to improve metabolic, cardiovascular and mental health, promote adequate physical development and establish an active lifestyle at an early age.[6–8] This confronts young people with T1D and their caregivers with many concerns because glucose management is substantially challenging during physical activity and exercise.[9] Even minor errors in diabetes management, which are inevitable during exercise, can lead to serious complications. Among acute exercise-induced complications, severe hypoglycaemia and ketoacidotic derailments account for potentially life-threatening situations, contributing to a sustainable burden on physiological and psychological factors.[10] Therefore, physical activity and exercise require individualized and continuous T1D treatment adjustments.[8,9]

It was recently shown that the time in range (TIR) in young people with T1D is higher on physically active days compared with days of inactivity.[11] Additionally, this study associated a higher activity level with lower mean glucose levels ($P = .02$) and a better TIR ($P < .001$), without being accompanied by more hypoglycaemic events. On the other hand, children and adolescents in particular perceive the risk of hypoglycaemia as a greater barrier to exercise the more they have previously suffered from hypoglycaemia on nights after physical activity.[12] Conclusively, despite the scientifically proven benefits of exercise in T1D, the psychological fear of hypoglycaemia and losing glycaemic control seems to be the major barrier for children, adolescents and their parents to engaging in regular exercise.[9,12]

Studies need to show that with adequate support it is possible for children and adolescents with T1D to participate in a variety of sports, without the risk of hypoglycaemia. Therefore, the aim of this two-centre, prospective, randomized controlled trial was to explore the safety via the time below glucose range 1 (TBR1: 54-69 mg/dL; 3.0-3.9 mmol/L) and efficacy via the time in range (TIR: 70-180 mg/dL; 3.9-10.0 mmol/L) of a 4-week intervention of intensive glycaemic management with or without track and field training in adolescents with T1D.

2 | MATERIALS AND METHODS

The local ethics committees of the University of Bayreuth (O 1305/1. GB; 8 December 2021; Germany) and the Medical University of Graz (34-263 ex 21/22, 1070-2022; 9 August 2022; Austria) approved the study protocol and the trial was registered at the German Clinical Trials Register (DRKS00027954). The study was conducted in conformity with the Declaration of Helsinki and Good Clinical Practice. Before any trial-related activities, potential participants and their parents were informed about the study protocol and gave their written informed consent to participate in this trial.

2.1 | Eligibility criteria

The eligibility criteria included male or female individuals aged 10-17 years with a body mass index (BMI) within the 10th (P10)-90th (P90) percentile of the respective sex and age of children in Germany.[13] Participants with a diagnosis of T1D for at least 1 year (HbA1c < 12% [< 108 mmol/mol] at screening) and with an insulin therapy established either with insulin pen therapy (multiple daily injections [MDI]) or continuous subcutaneous insulin infusion (CSII; pump therapy), were included (no hybrid closed-loop [HCL] systems). Participants reported no severe hypoglycaemia in the last 12 months and showed normal hypoglycaemia awareness (Gold score ≤ 2).[14] Abnormal ECG, heart rate or blood pressure at screening, any contraindicative medication, the presence or history of a clinically severe disease that could jeopardize the participant's safety or directly influence the study results, or clinically relevant hypoglycaemia or diabetic ketoacidosis requiring third-party help during the last 6 months, were reasons for not being included in the study.

2.2 | Study design

Following the screening visit and a 4-week observational control phase, participants were randomly assigned to one of two treatment groups[15]: the IT group, which underwent intensive glycaemic management, which was scheduled on at least 3 days per week and conducted via telemedicine or on-site consultations; or the EX group, which additionally performed track and field training on 3 days per week (Monday, Wednesday and Friday) over a 4-week period. For both groups, the ChilDFiT1 study consisted of a screening visit, a 4-week observational control phase, a follow-up visit, a 4-week intervention phase and an end-of-trial visit. The study design is presented in Figure 1.

2.3 | Laboratory visits

At the screening visit, participants and their parents were informed about all the study-related procedures. Anthropometric variables were assessed via bioelectrical impedance analysis (Inbody 720, Inbody Co., Seoul, Korea; BIACORPUS RX 4004M, MEDI CAL HealthCare GmbH, Karlsruhe, Germany) for body composition and via manual measurement for body height. For assessment of HbA1c levels, a venous blood sample was obtained from the antecubital vein. After 5 minutes in a supine position, a 12-lead ECG (CardioPart 12, Amedtec, Aue-Bad Schlema, Germany) was recorded and a cardiac assessment (blood pressure, heart rate) was performed. All participants completed the International Physical Activity Questionnaire–Short Form (IPAQ)

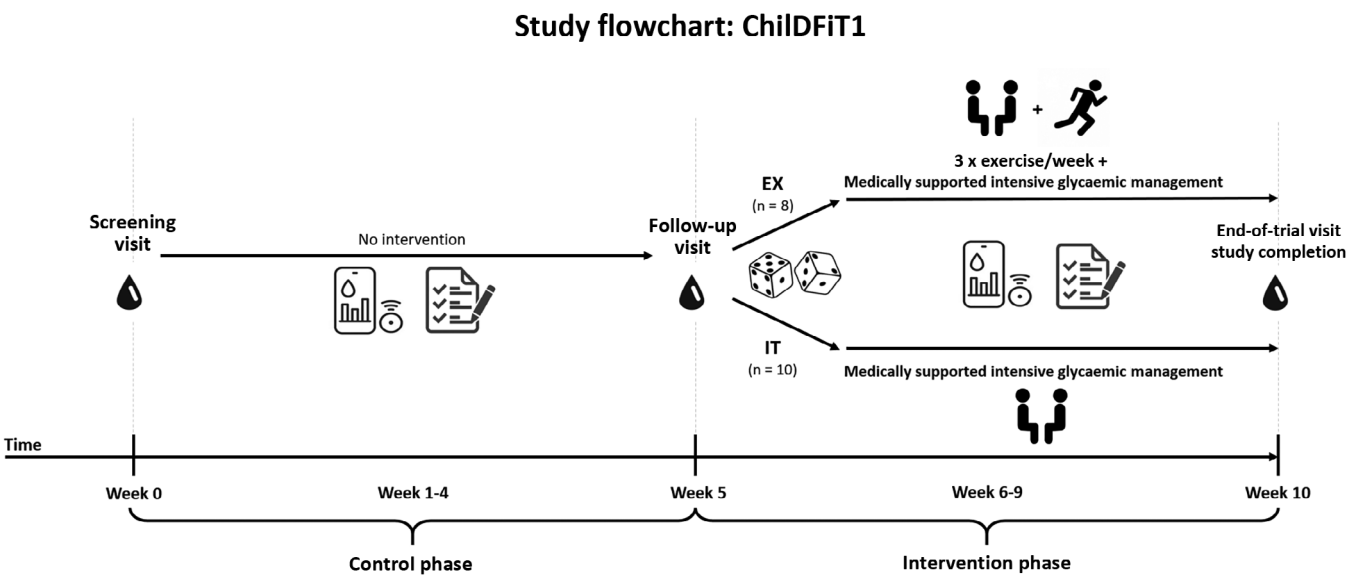

FIGURE 1 ChilDFiT1 study flowchart. = laboratory visit, = continuous glucose monitoring (CGM) use, = diaries, = randomization, = intensive glycaemic management, = exercise, IT = intensive glycaemic management only, EX = intensive glycaemic management and exercise.

regarding their daily physical activity.[16] Participants were equipped with a Dexcom G6 continuous glucose monitoring (CGM) system (Dexcom Inc., San Diego, CA) to achieve standardized conditions for CGM and data analysis. Participants were instructed about the sensor placement, the features of functionality and the interpretation of sensor values. Sensor alarms were set individually (based on the European Association for the Study of Diabetes [EASD]/International Society for Pediatric and Adolescent Diabetes [ISPAD] exercise CGM position statement[17]). No significant therapy changes were performed during the screening visit.

2.4 | Observational control phase

The 4-week observational control phase aimed to achieve non-interventional control data of glycaemia, insulin dosing and nutritional behaviour during real-life conditions. No specific recommendations for diabetes therapy were given, but participants kept a diary recording insulin doses, ingested carbohydrates (CHO), physical activity and general health status. Glycaemia was assessed by the Dexcom G6 CGM system. All CGM metrics and glycaemic ranges were determined as recommended by the international consensus statement[18]: time below range 2 (TBR2: < 54 mg/dL; < 3.0 mmol/L), time below range 1 (TBR1: 54-69 mg/dL; 3.0-3.9 mmol/L), time in range (TIR: 70-180 mg/dL; 3.9-10.0 mmol/L), time above range 1 (TAR1: 181-250 mg/dL; 10.0-13.9 mmol/L) and time above range 2 (TAR2: > 250 mg/dL; > 13.9 mmol/L). Next to the respective glucose ranges, mean glucose, glucose standard deviation (SD_{Gluc}), coefficient of variation (CV) and the glucose management indicator (GMI), an estimated HbA1c converting the mean glucose from CGM, were measured through CGM.

2.5 | Intervention phase

The 4-week intervention phase started the week after the follow-up visit, at which participants were informed about their group assignment (IT or EX). All participants wore a Dexcom G6 CGM and completed daily diaries. Both groups received intensive glycaemic management. For this, consultations with the study's diabetologist took place at least three times a week. The sessions were held online (telemedicine) or on-site and could be scheduled more frequently in case of acute demand. Apart from the counselling, the IT group continued their daily routine unchanged.

In addition to the intensive glycaemic management, the EX group performed track and field training three times per week on Monday, Wednesday and Friday afternoons (60 minutes of activity per session). Around exercise, sensor glucose was constantly recorded and, additionally, two capillary blood glucose (BG) samples were taken before and every 15 minutes during the training session from a hyperemized earlobe (Contour Next One, Ascensia Diabetes Care Deutschland GmbH, Leverkusen, Germany; BIOSENS S-Line Lab+, EKF-diagnostic GmbH, Barleben, Germany). It was anticipated that, in concordance with the EASD/ISPAD position statement for exercise management in T1D,[17] exercise start was allowed if sensor glucose was between 126 and 270 mg/dL (7.0-15.0 mmol/L). In case of lower values, an individual amount of CHO was supplemented, documented, and sensor as well as BG was rechecked.[17] If sensor glucose exceeded 126 mg/dL (7.0 mmol/L), the exercise session was initiated. In case of initial sensor glucose exceeding 270 mg/dL (15.0 mmol/L), ketones were determined via a capillary BG sample (FreeStyle Precision ß-ketone, Abbott Diabetes Care Inc., Abbott Laboratories, Chicago, IL) and insulin corrections were performed considering potential bolus insulin still on board. If ketones exceeded 1.5 mmol/L, the exercise

session was cancelled.[17] The exercise programme mirrored a children's track and field intervention and was based on the framework 'Kinderleichtathletik', developed by the DLV (German Athletics Association).[19] Participation in 75% or more of exercise visits was required not to be excluded from the study.

Based on the international consensus statement on CGM and metrics for clinical trials,[18] a percentage of sensor data availability of less than 70% during both study phases was selected as exclusion criterion.

2.6 | Statistical analyses

Data were summarized in a single trial masterfile and analysed via GraphPad Prism 8.0 (GraphPad Software, US). Data were tested for normal distribution via a Shapiro–Wilk test and are presented as mean ± standard deviation (SD). The % of time in glycaemic ranges is additionally presented as median with corresponding 95% confidence interval. For the primary outcome (TIR; TBR1 as co-primary outcome), as well as TBR2, TAR1, TAR2, mean glucose, SD_{Gluc}, CV and GMI, data were compared via a paired *t*-test for comparison of the two study phases. The control phases of each group (control: IT $n = 10$; EX $n = 8$) were compared with their corresponding intervention phase (IT $n = 10$; EX $n = 8$). TIR, TBR1, TBR2, TAR1 and TAR2 were additionally analysed as stratified day (06:00 AM-09:59 PM) and night (10:00 PM-05:59 AM) periods. For the secondary outcomes (HbA1c and anthropometric data), data were compared via analysis of variance for repeated measurements (RM-ANOVA) with a Tukey post hoc test for screening, follow-up and end-of-trial visit. Differences between the groups at baseline were compared via an unpaired *t*-test. Statistical significance was accepted at P less than .05 (two-tailed). Sample size estimation was conducted via G-power (3.1.9.7, HHU-Düsseldorf, Germany) for TIR from a comparable study by Mohammed et al.,[20] which led to a power of 0.92 for $n = 9$ per group.

3 | RESULTS

Eighteen adolescents (seven females, $n = 18$ Caucasian) with T1D were included (age 15.1 ± 1.1 years, T1D duration 5.4 ± 4.1 years, HbA1c 7.3% ± 1.0% [56.3 ± 10.9 mmol/mol], BMI 20.6 ± 2.4 kg/m^2). Ten were randomly allocated to the IT group (five females), while eight participants were allocated to the EX group (two females). One study participant from the EX group was withdrawn from the analysis because of an insufficient amount of conducted training visits. Baseline characteristics for both groups can be found in Table 1. There were no significant differences between the groups at baseline.

Six participants followed MDI therapy (EX: $n = 4$, IT: $n = 2$), while 12 participants were on CSII therapy (EX: $n = 4$, IT: $n = 8$). All participants were using CGM systems in their daily routine prior to the study. The IT group received a mean of 11.2 ± 2.1 consultations in total, whereas the EX group underwent 11.0 ± 1.8 consultation sessions ($P = .835$).

3.1 | CGM-derived glycaemia

In total, 270 187 CGM values were available (EX: 122 642 CGM values, IT: 147 545 CGM values), which corresponds to an average of 15 010 ± 896 (EX: 15 330 ± 689, IT: 14 755 ± 993) CGM values per person. Sensor usage was 95.0% ± 5.4% (EX: 97.1% ± 3.2%, IT: 93.4% ± 6.3%) of the time, with a data sufficiency of 94.3% ± 4.2% (EX: 95.3% ± 3.9%, IT: 93.5% ± 4.3%). There were no significant differences in sensor metrics when comparing the control with the intervention phases of the respective groups ($P > .05$). No major CGM sensor failures occurred and all participants obtained more than 70% of data availability over the whole study period.

For the EX group, TIR significantly improved throughout the exercise intervention phase when compared with the control phase ($P = .049$), which was not seen for the IT group ($P = .399$) (Table 2). Therefore, the recommended target of the consensus statement (> 70% TIR) was met only by the EX group during the intervention.[18] TBR1 showed a significant decrease in the IT group ($P = .017$) and remained stable in the EX group ($P = .999$). TBR2 did not vary in EX and IT (EX: $P = 1.0$; IT: $P = .50$). The consensus statement recommended target for TBR2 (< 1%) was not met by either group at any time point. The consensus target for total TBR (< 4%) was always met, except by IT in the control phase.[18] TAR1 did not change in EX during the intervention ($P = .204$), but showed a significant increase in the IT group ($P = .037$). TAR2 showed no change in EX and IT through the intervention (EX: $P = .096$; IT: $P = .305$). The consensus statement targets for TAR2 (< 5%) and total TAR (< 25%) were not met by any group in any phase.[18]

Nocturnal TBR1 increased significantly in the EX group ($P = .0075$), which was not seen in the IT group. Nocturnal TBR2, TIR, TAR1 and TAR2 did not change significantly in both groups.

3.2 | Glycaemic variables

In the EX group, HbA1c ameliorated significantly from 7.0% ± 0.5% (53.0 ± 5.5 mmol/mol) preintervention to 6.8% ± 0.4% (50.8 ± 4.4 mmol/mol) postintervention ($P = .042$), which was not seen within IT (7.4% ± 1.2% vs. 7.3% ± 1.1% [57.3 ± 13.1 vs. 56.2 ± 12.0 mmol/mol], $P = .400$) (Figure 2A). The GMI showed no significant changes in EX (6.99% ± 0.46% vs. 6.91% ± 0.33% [52.9 ± 5.0 vs. 52.0 ± 3.6 mmol/mol], $P = .222$) or IT (7.50% ± 1.06% vs. 7.34% ± 0.72% [58.6 ± 11.6 vs. 56.7 ± 7.9 mmol/mol], $P = 0.436$) (Figure 2B). No significant changes in mean glucose were found for either EX (154 ± 18 vs. 151 ± 14 mg/dL [8.5 ± 1.0 vs. 8.4 ± 0.8 mmol/L], $P = .154$) or IT (175 ± 44 vs. 168 ± 31 mg/dL [9.7 ± 2.4 vs. 9.3 ± 1.7 mmol/L], $P = .412$). Glycaemic variability assessed by SD_{Gluc} improved significantly only for EX (EX: 55 ± 11 vs. 51 ± 10 mg/dL [3.1 ± 0.6 vs. 2.8 ± 0.6 mmol/L], $P = 0.011$; IT: 70 ± 24 vs. 63 ± 18 mg/dL [3.9 ± 1.3 vs. 3.5 ± 1.0 mmol/L], $P = .186$) (Figure 2C). The CV remained stable with a tendency to decrease for both groups (EX: 34.7% ± 4.1% vs. 33.6% ± 3.8%, $P = .184$; IT: 39.2% ± 7.7% vs. 37.0% ± 4.5%, $P = .254$) (Figure 2D). In addition,

TABLE 1 Baseline mean and standard deviation as well as median with 95% CI of % time in specific glycaemic ranges according to the study group.

Baseline	IT	EX	*P* value
Age (y)	14.7 ± 1.2	15.5 ± 1.0	.138
BMI (kg/m^2)	20.3 ± 2.5	21.0 ± 2.3	.534
T1D duration (y)	5.0 ± 4.9	5.8 ± 3.8	.715
HbA1c (%) HbA1c (mmol/mol)	7.7 ± 1.2 60.6 ± 13.1	7.0 ± 0.6 53.0 ± 6.6	.149
GMI (%) GMI (mmol/mol)	7.50 ± 1.06 58.6 ± 11.6	6.99 ± 0.46 52.9 ± 5.0	.221
Mean glucose (mg/dL) Mean glucose (mmol/L)	175 ± 44 9.7 ± 2.4	154 ± 18 8.5 ± 1.0	.230
SD_{Gluc} (mg/dL) SD_{Gluc} (mmol/L)	70 ± 24 3.9 ± 1.3	55 ± 11 3.1 ± 0.6	.126
CV (%)	39.2 ± 7.7	34.7 ± 4.1	.152
TAR2 (%)	17.9 ± 19.3; 14.5 (1.0; 46.0)	6.8 ± 5.4; 6.0 (1.0; 18.0)	.135
TAR1 (%)	19.3 ± 5.6; 20.0 (15.0; 25.0)	21.6 ± 8.6; 23.5 (9.0; 31.0)	.499
TIR (%)	58.5 ± 21.8; 56.0 (32.0; 82.0)	68.9 ± 13.1; 66.5 (49.0; 88.0)	.255
TBR1 (%)	3.1 ± 1.9; 3.0 (1.0; 5.0)	2.0 ± 1.7; 1.5 (1.0; 6.0)	.212
TBR2 (%)	1.3 ± 0.7; 1.0 (1.0; 2.0)	1.0 ± 0.0; 1.0 (1.0; 1.0)	.230

Note: Baseline mean and standard deviation of HbA1c, GMI, SD_{Gluc} and CV according to the study group. The level of significance was calculated by comparing both study groups at baseline (IT vs. EX).
Abbreviations: BMI, body mass index; CI, confidence interval; CV, coefficient of variation; EX, intensive glycaemic management and exercise; GMI, glucose management indicator; IT, intensive glycaemic management only; SD_{Gluc}, glucose standard deviation; TAR1, time above range 1 (181-250 mg/dL; 10.0-13.9 mmol/L); TAR2, time above range 2 (> 250 mg/dL; > 13.9 mmol/L); TBR1, time below range 1 (54-69 mg/dL; 3.0-3.9 mmol/L); TBR2, time below range 2 (< 54 mg/dL; < 3.0 mmol/L); TIR, time in range (70-180 mg/dL; 3.9-10.0 mmol/L); T1D, type 1 diabetes.

participants' diaries showed that daily bolus insulin did not change (EX: 30.4 ± 9.1 vs. 26.7 ± 9.8 IU, $P = .083$; IT: 23.6 ± 13.8 vs. 20.7 ± 13.6 IU, $P = .070$).

3.3 | In-exercise glycaemia (EX group)

In total, 316 in-exercise, 83 pre-exercise and 47 post-exercise measurements were available. The calculated % time in respective glycaemic ranges during the active exercise period, the mean BG pre-, in- and post-exercise, as well as the mean CHO intake per exercise visit, are presented in Table 3. During the active training period, BG was significantly lower compared with pre-exercise ($P = .011$). In-exercise, no values more than 250 mg/dL (TAR2; > 13.9 mmol/L) were detected.

3.4 | Anthropometry

No significant changes in anthropometric variables occurred in the IT group. In the EX group, significant increases were recorded in fat-free mass (FFM; $P = .044$) and body cell mass (BCM; $P = .005$) from preintervention to postintervention (Table 4).

3.5 | Daily physical activity

The IPAQ showed that the daily not study-related physical activity of IT and EX (expressed as total metabolic equivalent of task [MET] minutes per week) did not change throughout the study (EX: 3134 ± 1808 vs. 3382 ± 1948 METs, $P = .184$; IT: 3308 ± 1968 vs. 3071 ± 1582 METs, $P = .630$) and was comparable for both groups ($P_{control\ phase} = .862$, $P_{intervention\ phase} = .742$).

4 | DISCUSSION

4.1 | Glycaemic management

The TIR improved significantly in the EX group, resulting in the EX group meeting the consensus statement goal (> 70% of time per day in TIR)[18] during the intervention phase. By contrast, the TIR of the IT

TABLE 2 Mean and standard deviation as well as median with 95% CI of % time in specific glycaemic ranges according to the study group.

		IT		EX	
Glycaemic ranges		**Control**	**Intervention**	**Control**	**Intervention**
Overall	TAR2 (%)	17.9 ± 19.3; 14.5 (1.0; 46.0)	12.7 ± 13.5; 6.5 (4.0; 30.0)	6.8 ± 5.4; 6.0 (1.0; 18.0)	5.3 ± 4.5 5.0 (1.0; 15.0)
	TAR1 (%)	19.3 ± 5.6; 20.0 (15.0; 25.0)	22.3 ± 4.1; 22.0 (17.0; 28.0)*	21.6 ± 8.6; 23.5 (9.0; 31.0)	19.9 ± 6.5; 20.0 (11.0; 29.0)
	TIR (%)	58.5 ± 21.8; 56.0 (32.0; 82.0)	62.0 ± 15.7 68.0 (40.0; 74.0)	68.9 ± 13.1; 66.5 (49.0; 88.0)	72.1 ± 10.6; 71.0 (54.0; 87.0)*
	TBR1 (%)	3.1 ± 1.9; 3.0 (1.0; 5.0)	2.0 ± 0.8; 2.0 (1.0; 3.0)*	2.0 ± 1.7; 1.5 (1.0; 6.0)	1.9 ± 1.1; 1.5 (1.0; 4.0)
	TBR2 (%)	1.3 ± 0.7; 1.0 (1.0; 2.0)	1.1 ± 0.3; 1.0 (1.0; 1.0)	1.0 ± 0.0; 1.0 (1.0; 1.0)	1.0 ± 0.0; 1.0 (1.0; 1.0)
Night (10:00 PM-05:59 AM)	TAR2 (%)	15.8 ± 18.5; 10.8 (0.6; 36.4)	11.5 ± 11.8; 6.6 (4.4; 29.5)	4.5 ± 3.3; 4.7 (0.0; 9.1)	3.8 ± 2.6; 4.6 (0.0; 6.9)
	TAR1 (%)	19.1 ± 7.7; 21.4 (10.6; 26.3)	22.8 ± 4.4; 23.5 (17.4; 26.8)	19.1 ± 9.5; 23.7 (3.5; 27.6)	15.0 ± 7.8; 14.1 (2.5; 25.4)
	TIR (%)	61.1 ± 24.0; 59.9 (38.5; 87.8)	62.4 ± 15.3; 66.2 (39.5; 75.8)	74.5 ± 12.9; 67.6 (61.4; 94.9)	78.3 ± 10.6; 79.2 (64.6; 95.4)
	TBR1 (%)	2.9 ± 1.3; 2.7 (1.5; 4.6)	2.1 ± 1.2; 2.4 (0.5; 3.5)	1.6 ± 0.7; 1.6 (0.4; 2.8)	2.5 ± 1.1; 2.4 (0.9; 4.0)**
	TBR2 (%)	1.1 ± 1.1; 0.7 (0.3; 2.5)	1.1 ± 1.5; 0.7 (0.0; 2.9)	0.4 ± 0.4; 0.3 (0.0; 1.3)	0.5 ± 0.3; 0.6 (0.1; 0.9)

Note: The level of significance was calculated by comparing the control and intervention phase of the respective group (IT and EX).
Abbreviations: CI, confidence interval; EX, intensive glycaemic management and exercise; IT, intensive glycaemic management only; TAR1, time above range 1 (181-250 mg/dL; 10.0-13.9 mmol/L); TAR2, time above range 2 (> 250 mg/dL; > 13.9 mmol/L); TBR1, time below range 1 (54-69 mg/dL; 3.0-3.9 mmol/L); TBR2, time below range 2 (< 54 mg/dL; < 3.0 mmol/L); TIR, time in range (70-180 mg/dL; 3.9-10.0 mmol/L).
*P < .05.**P < .01.

group did not improve significantly, which illustrates the efficiency of track and field training combined with intensive glycaemic management over 4 weeks. In terms of glycaemic safety, a significant improvement was observed in the TBR1 of the IT group, while the EX group remained stable. IT thus achieved the consensus statement TBR target of less than 4% in the intervention phase. However, the EX group already had a very low TBR1 across the whole group during the control phase, which decreased the chance of further improvements. EX's TBR remained less than 4% in both study phases, fulfilling the consensus statement goals, and, therefore, the training intervention was able to maintain glycaemic safety. Furthermore, EX's improved glycaemic management is emphasized by the significant reduction of SD_{Gluc}, which showed that regular exercise kept mean glucose levels more stable and reduced glycaemic fluctuations. The exercise-induced benefits are additionally underlined by the significant reduction in HbA1c levels, which was only observed in the EX group. Even although HbA1c represents the last ~12 weeks and the absolute value may not exactly depict the intervention, the intervention was able to significantly improve HbA1c levels in a short period of time. EX's significantly increased nocturnal hypoglycaemia (TBR1) in the intervention phase must be viewed mindfully. The risk of nocturnal hypoglycaemia after exercise is well known and a cause of fear for many children and adolescents with T1D, and should therefore be avoided. However, the international consensus statement on CGM and metrics for clinical trials recommends no more than 4% of time each day (i.e. approximately 1 hour) in TBR,[18] which was still achieved in the intervention phase of EX. Additionally, nocturnal TBR2, and therefore clinically relevant nocturnal hypoglycaemia, did not increase through the intervention.

Moreover, the results of both groups have to be evaluated considering that none of the participants used an HCL system. Children and adolescents in particular benefit from the use of HCL systems in the context of exercise, achieving higher TIR and lower TBR compared with people using non-supportive insulin pumps or MDI therapy.[21] Therefore, the positive effects of the exercise intervention must be considered even more clinically relevant.

The results of the ChilDFiT1 study partly differ from those reported by Mohammed et al.,[20] where a 12-week football programme with two 90-minute bouts per week was conducted with or without a nutritional programme. Here, only a significant improvement in HbA1c was found for the exercise and nutrition group, but not for the groups with standalone exercise or nutrition. Therefore, the differences in effect might be attributable to the combination with glycaemic management in the ChilDFiT1 study, which was not implemented by Mohammed et al., except via post-exercise basal rate reductions. They showed, however, that 12 weeks of football coupled with nutritional adjustments can indeed improve glycaemia. Besides the combination of exercise and glycaemic management, the

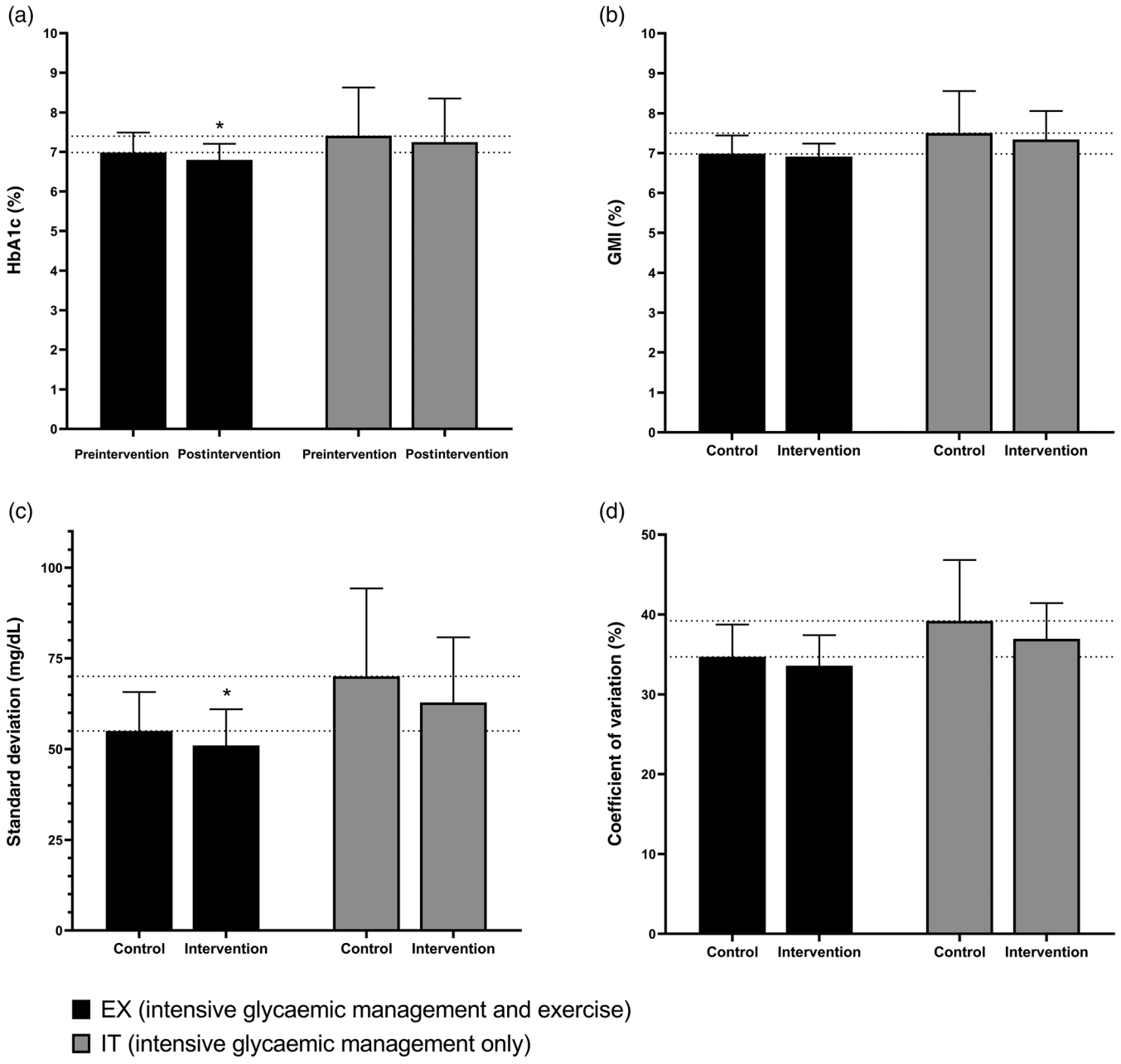

FIGURE 2 Continuous glucose monitoring-derived secondary outcome variables according to group (IT and EX), compared with the respective control and intervention phase. B, Glucose management indicator (GMI), C, Glucose standard deviation (SD_{Gluc}), and D, Coefficient of variation (CV) are presented as mean and standard deviation of control and intervention phases. A, HbA1c is presented as mean and standard deviation at the preintervention and postintervention laboratory visits. Stars indicate the level of significance; *$P < .05$.

ChilDFiT1 exercise design may have contributed to a greater effect on glycaemia compared with Mohammed et al. Dividing 180 minutes of exercise per week into 3×60 minutes (ChilDFiT1) instead of 2×90 minutes,[20] and thus exercising more regularly with a shorter exercise duration, might be more conducive to improving HbA1c and SD_{Gluc}, making exercise duration a marker that must be considered in exercise prescription.[22,23] Alternatively, the exercise type and thus the specific training stimuli could play a role. Football, as a primarily high-intensity sport,[24] could have a smaller effect on glycaemia than track and field, which combines a variety of stimuli as well as exercise types and intensities. Looking at the general body of research, the benefits of regular physical activity depend mainly on the type, intensity, duration and frequency of activity.[25–29] In children and adolescents with T1D performing aerobic and mixed aerobic-anaerobic exercise, respectively, medium-intensity exercise produced the most beneficial effects on both glycaemia and general health variables.[30–34] Aerobic exercise is recognized for its ability to improve insulin sensitivity, beneficially modify insulin resistance and decrease insulin requirements, as well as lower cardiovascular and overall mortality risk in T1D.[35] As a result, it is advisable to engage in frequent aerobic exercise to maintain a consistent improvement in physical health.[36,37] Important to note, from a physiological point of view, the

Variables around exercise		Mean ± SD	Median (95% CI)
In-exercise BG (%)	TAR2	0.0 ± 0.0	0.0 (0.0; 0.0)
	TAR1	7.0 ± 12.3	1.1 (0.0; 35.7)
	TIR	78.8 ± 15.8	82.5 (48.3; 97.1)
	TBR1	12.4 ± 11.5	8.3 (0.0; 34.5)
	TBR2	1.7 ± 2.6	0.0 (0.0; 6.9)
BG (mg/dL)	Pre-exercise	124.1 ± 19.2	129.1 (113.4; 139.7)
	In-exercise	106.7 ± 15.0*	107.5 (99.5; 113.5)
	Post-exercise	120.2 ± 20.0	115.5 (105.8; 138.1)
CHO intake (g)	Per exercise visit	21.1 ± 18.6	18.0 (12.0; 27.0)

TABLE 3 Mean ± SD as well as median with 95% CI of the respective glycaemic ranges during exercise, blood glucose pre-, in- and post-exercise, as well as CHO intake per exercise visit.

Note: * indicates the level of significance to the respective preliminary phase.
Abbreviations: BG, blood glucose; CHO, carbohydrates; CI, confidence interval; SD, standard deviation; TAR1, time above range 1 (181-250 mg/dL; 10.0-13.9 mmol/L); TAR2, time above range 2 (> 250 mg/dL; > 13.9 mmol/L); TBR1, time below range 1 (54-69 mg/dL; 3.0-3.9 mmol/L); TBR2, time below range 2 (< 54 mg/dL; < 3.0 mmol/L); TIR, time in range (70-180 mg/dL; 3.9-10.0 mmol/L).
*P < .05.

TABLE 4 Changes in anthropometric data according to the group (IT and EX), compared with the respective control and intervention phase.

Group	Time	Height (cm)	Body mass (kg)	BMI Z-Score[13]	Body fat (%)	Fat-free mass (kg)	Body cell mass (kg)
IT	Preintervention	167.0 ± 8.7	57.2 ± 8.2	0.13 ± 0.72	24.3 ± 9.9	41.9 ± 5.7	24.9 ± 3.4
	Postintervention	167.3 ± 8.9	57.2 ± 8.1	0.09 ± 0.75	24.5 ± 9.9	41.8 ± 5.7	24.4 ± 4.0
EX	Preintervention	172.3 ± 5.1	63.4 ± 8.8	0.29 ± 0.61	17.2 ± 7.0	52.2 ± 7.3	30.8 ± 7.1
	Postintervention	172.5 ± 5.2	63.4 ± 9.5	0.23 ± 0.68	16.4 ± 6.9	52.8 ± 7.5*	31.4 ± 7.2**

Note: * indicates the level of significance between preintervention and postintervention.
Abbreviations: BMI, body mass index; EX, intensive glycaemic management and exercise; IT, intensive glycaemic management only.
*P < .05.**P < .01.

improvements in insulin sensitivity are mainly based on the prolonged accumulation of glucose transporter type 4.[8] Additionally, incorporating planned short bursts of high-intensity, sprint-like exercise alongside aerobic workouts can reduce the likelihood of experiencing hypoglycaemia around exercise.[36,38] Physiologically, high exercise intensities act on the counter regulatory hormone response (catecholamines, cortisol) that enhance the rate of hepatic glycogenolysis.[38,39] Additionally, as given in the World Health Organization recommendations for physical activity and exercise, it is recommended that exercise should be diversified, containing moderate- to vigorous-intensity aerobic activity as well as muscle-strengthening activities, which is in detail reflected by our exercise intervention.[7] Consequently, track and field possess the fundamental prerequisites necessary for achieving beneficial effects on glycaemia and general health variables. Furthermore, from our point of view, track and field's variety of components (running, sprinting, jumping, throwing) immensely improved the motivation and hence adherence to participate in our trial.

A meta-analysis by Shorey et al. showed that standalone physical activity and diet-based interventions had a limited, but positively trending effect, on HbA1c in children and adolescents.[40] The generally favourable results underline the potential of exercise interventions to improve glycaemia and health-related quality of life. Consequently, a combination of exercise, medical consultations and individualized glycaemic plus nutritional training might be the gold standard.

In line with the ChilDFiT1 results, Riddell et al. showed that the TIR in adults with T1D is higher on exercise days than on sedentary days.[41,42] Likewise, Gal et al. were able to show this for children and adolescents: higher activity levels in 9-17 year-old participants with T1D were associated with better TIR (P < .001), without being linked to higher TBR.[11] Overall, the current research along with the ChilDFiT1 results show that adults as well as adolescents with properly guided assistance and the appropriate level of knowledge can participate in exercise without fear. However, especially for children and adolescents who may not have much T1D-specific experience,[43] it is important to be educated in glycaemic management around exercise.[8] Moser et al. also suggested an approach that uses personalized treatment adjustments in the EASD/ISPAD position statement.[17]

Interestingly, as given in our study, FFM and BCM significantly increased only in the EX group, which is associated with positive effects such as improved cardiovascular health, better functional ability and an increased metabolic rate,[26,27,29] and shows further potential benefits of regular training in T1D.

4.2 | Glycaemia during exercise

When evaluating the acute exercise effects, the mean TIR during exercise was 78.8%, which was even higher than seen over the

4-week intervention period. Looking at other exercise studies in children and adolescents with T1D, Elleri et al.[44] recorded TIRs between 56% and 79% during 60 minutes of continuous moderate-intensity cycling for different therapies and times of the day. Dovc et al.[45] found TIRs of 80.9% when using a closed-loop system (CL) and 68.1% in the open-loop mode (OL) for 40 minutes of moderate-intensity cycling. Additionally, they found TIRs of 75.3% (CL) and 68.4% (OL) for a 40-minute mixed protocol consisting of moderate-intensity cycling combined with high-intensity sprinting.[45] However, these studies took place in a laboratory setting in which the children and adolescents were controlled for 22[45] or 36 hours,[44] while in the present study, exercise preparations and follow-up were independently managed by the participants. The comparatively high TIR of the ChilDFiT1 study can thus show that TIR around exercise can also be ensured in everyday life, and not only in a controlled setting.

To date, there are very few comparable sport-specific studies in a non-laboratory setting that have investigated TIR involving children and adolescents. Of these, skiing studies with children and adolescents showed that the structural conditions of a sport can be a hurdle that must be taken into consideration. TIRs of 63.2% (CL) and 62.8% (CSII) for 330 minutes,[46] and of 57.8% (CL) and 55.9% (CSII) for 240 minutes,[47] for moderate-intensity skiing, were recorded. The lower TIRs could be a result of the intense, prolonged physical activity, cold temperature, altitude and psychological strain.

Despite excellent in-exercise TIR and almost no hyperglycaemic events, the acute hypoglycaemia level increased in-exercise with an average TBR1 of 12.4%, which was mainly based on the CGM lag time and inaccuracy during hypoglycaemia. McClure et al. showed in their meta-analysis that the effect of high-intensity interval exercise on BG is inconsistent, complicating the avoidance of rapidly falling glucose levels and hypoglycaemia.[48] In the context of aerobic exercise, a decline in BG levels can be anticipated and counteractive measures can accordingly be taken.[36] Conversely, anaerobic exercise, influenced by a multitude of factors, can yield variable, and often even elevated, BG responses.[36,48] Logically, track and field's multifaceted nature, characterized by the occurrence of aerobic and anaerobic stimuli in variable sequences and magnitudes, might challenge glycaemia, even although we have now shown within our ChilDFiT1 study significant improvements in TIR. To address this, providing children and adolescents with T1D with weekly training plans might improve glycaemia by allowing proactive adjustments to therapy before, during and after exercise, potentially reducing dysglycaemia. However, of utmost importance, clinically relevant hypoglycaemia (< 54 mg/dL; < 3.0 mmol/L) was very low and no exercise visit had to be discontinued because of hypoglycaemia.

4.3 | Study limitations

First, while a 3% change in TIR may not reach the commonly accepted 5% threshold for clinical significance, it is essential to acknowledge that this threshold is often based on specific, narrowly selected groups and its link to HbA1c values.[49,50] It is crucial to view our study in context, as in the field of TIR research among children and adolescents in specific sports, limited data are available. Our study paves the way for future research, emphasizing the potential for investigating interventions that could yield more substantial improvements in TIR. Consequently, particularly for the understudied group of children and adolescents with T1D, even a 1% improvement in TIR can be considered clinically meaningful from our perspective. Additionally, an improvement of HbA1c from 7.0% ± 0.5% to 6.8% ± 0.4% should be interpreted for this specific group of children and adolescents with T1D as clinically meaningful. Most importantly, our study proved the superiority of track and field sessions over controls for glycaemic control.

Second, a not significant trend towards improvement could be seen in the EX group's TAR1, TAR2, GMI, mean glucose, CV and daily bolus insulin. Therefore, a follow-up study should cover an extended period of intervention to determine long-term effects for glycaemia. However, our short-term track and field training showed that just 1 month of exercise can improve glycaemia and therefore clearly supports the importance of regular exercise, even for a short period of time (1 month). As children and adolescents often spend their summer holidays on sports camps (∼over a period of 4 weeks), our findings further support the importance of the inclusion of children and adolescents with T1D, for whom this could offer not only joy, but also improvements in glycaemia.

Furthermore, although the study setting was designed to be close to reality, it could not be implemented 100% realistically. For example, a supervising diabetologist was always present during the exercise sessions or capillary blood measurements were taken every 15 minutes, which is not feasible in everyday life. Also, the small sample size must be viewed critically. Nevertheless, we conducted a sample size estimation and fulfilled the requirement for the number of study participants for our study, which was comparatively low. However, follow-up studies should aim for a higher number of participants (which would also lead to more homogeneous groups in terms of TIR and HbA1c at baseline). In addition, the EX group was already glycaemically well adjusted during the control phase, resulting in limited possible improvements in glycaemic control. Future studies should therefore perform a stratified randomization based on the TIR and specific baseline characteristics (gender, BMI) to achieve more homogenous groups. Additionally, information on socioeconomic status and parental education would have enabled better contextualization of the results. Moreover, it is essential to delve into the psychological stress experienced by the different groups, along with assessing the practicality of sustaining the exercise routine independently, with reduced consultation frequency. In the context of this manuscript, we are unable to address this crucial psychological aspect because we did not assess this in detail.

In conclusion, track and field training in combination with intensive glycaemic management improved glycaemic efficacy in adolescents with T1D, which was not observed in the non-exercise group. At the same time, track and field training in combination with supported intensive glycaemic management resulted in stable and generally low TBR and contributed to an improvement in the anthropometric status. Therefore, we can consider track and field exercise in adolescents with T1D as feasible and safe under properly guided assistance and detailed training.

AUTHOR CONTRIBUTIONS

Conceptualization: RTZ, FA and OM. Data curation: RTZ. Formal analysis: RTZ and OM. Funding acquisition: RTZ and OM. Investigation: RTZ, FA, PB, CS, BEMZ, JS, MF, EF-R, PH, HS and OM. Methodology: RTZ, FA and OM. Project administration: RTZ, FA and OM. Resources: OM, PH and HS. Supervision: RTZ, FA and OM. Validation: RTZ, FA and OM. Visualization: RTZ. Writing (original draft): RTZ and FA. Writing (review and editing): RTZ, FA, PB, CS, BEMZ, JS, MF, EF-R, PH, HS and OM. All the authors have read and agreed to the published version of the manuscript.

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CONFLICT OF INTEREST STATEMENT

The CGM sensors were provided free of charge by Dexcom Inc.

Rebecca T. Zimmer has received a doctoral scholarship through the 'Studienstiftung des Deutschen Volkes' to perform this study.

Harald Sourij is on the advisory board and speakers bureau of by Amarin, Boehringer Ingelheim, NovoNordisk, Eli Lilly, and Daiichi Sankyo and received research funding (to the Medical University of Graz) from Eli Lilly, Boehringer Ingelheim and Sanofi. D.v.L. is on the advisory board and speakers bureau of AstraZeneca and Boehringer Ingelheim and received research funding (to the Medical University of Graz) from Boehringer Ingelheim.

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PEER REVIEW

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DATA AVAILABILITY STATEMENT

The datasets may be made available after contacting the corresponding author upon reasonable request.

ORCID

Harald Sourij https://orcid.org/0000-0003-3510-9594
Felix Aberer https://orcid.org/0000-0002-9947-1413
Othmar Moser https://orcid.org/0000-0002-1661-0685

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