Evaluation of the SPECTRUM training programme for real-time continuous glucose monitoring: A real-world multicentre prospective study in 120 adults with type 1 diabetes

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Abstract
Aims: Comprehensive knowledge, specific skills and data-analysis competences are prerequisites for the successful use of continuous glucose monitoring (CGM) systems. SPECTRUM is a structured training programme for real-time CGM (rtCGM) consisting of a web-based introduction and six group sessions of 90 min each. The ‘CGM-TRAIN study’ evaluated the efficacy and acceptance of SPECTRUM and rtCGM systems among adults with insulin therapy.

Methods: Participants (n = 120) were recruited from 10 German diabetes centres in which they were treated under usual care conditions. Outcome measures were rtCGM knowledge, practical skills, satisfaction with the training programme, satisfaction and acceptance of rtCGM system and glycaemic control. Data were collected at study entry, after training completion and at 6-month follow-up.

Results: All participants were diagnosed with type 1 diabetes (56% women, mean age 42.4 ± 13.4 years, diabetes duration 21.6 ± 11.6 years), 110 participants completed the course. After training completion, rtCGM-specific knowledge had improved by 43% (scale: 0–40 points) from 21.2 ± 7.6 to 30.4 ± 4.5 points; p < 0.001. The knowledge-level persisted until follow-up (29.4 ± 4.5). Participants were able to master nearly all the practical requirements of the technology. In addition, rtCGM was highly accepted, and participants were motivated to use their systems continuously. HbA1c improved slightly from 61 ± 14 mmol/mol (7.7 ± 1.3%) before training to 60 ± 14 mmol/mol (7.6 ± 1.3%) at follow-up (p = 0.04). The training programme itself was favourably rated by participants.

Conclusions: Under usual out-patient daily care conditions, the training programme SPECTRUM improved knowledge and skills about rtCGM in adults with type 1 diabetes. This was associated with a reduced HbA1c, high satisfaction and acceptance of rtCGM (Clinical Trials Registry no.: DRKS00014380).

KEYWORDS
devices, education, healthcare delivery, self-management
1 | INTRODUCTION

Continuous glucose monitoring (CGM) is an increasingly used diagnostic tool in diabetes management, especially among persons with an insulin therapy. Display of current glucose value, the glucose profile over the last hours, trend arrows and alarm functions enable detailed insights into glucose fluctuations over time. National diabetes associations acknowledge the benefits of CGM usage for specific groups of persons with diabetes and support CGM systems’ reimbursement.1-4 However, despite increased usage of CGM systems, translation of CGM data into adequate therapeutic action often remains suboptimal; subsequently, glycaemic control of many persons with type 1 diabetes does not improve as much as expected.5,6

Given the considerable costs associated with CGM usage by an increasing and already considerable number of persons with diabetes, this is a critical topic. For both persons with type 1 diabetes and healthcare professionals, the management of diabetes with the help of advanced technologies is challenging. It requires higher levels of health literacy and numeracy compared to former types of insulin therapy.6-8

Persons with type 1 diabetes who properly know how to interpret and react on all the information provided by CGM systems, for example, account for lag times between changes in blood and interstitial fluid glucose levels during rapid glucose changes in either compartment and who wear the systems at least 70% of the time, show the best glycaemic outcome.9,10 To achieve this, adequate handling training is essential for persons with type 1 diabetes to succeed in using a device (technical introduction). In addition, however, they must also be able to systematically analyse and interpret their CGM data to adapt their insulin therapy accordingly. CGM usage without such indispensable knowledge does usually not improve glucose control significantly.11,12 Thus, the participation of persons with type 1 diabetes in a qualified educational and technological training programme might be beneficial. Besides correct device handling, systematic data analysis, and adequate interpretation and translation in therapeutic action are required.5,13-15

Training in the optimal usage of new technology is a demanding task for persons with diabetes as well as for the members of their diabetes teams.16 At least in Germany, many healthcare professionals are more familiar with adjustment of antidiabetic therapy than with handling of the different CGM systems.5 Also, the lack of reimbursement for healthcare professionals’ time and resources hampers the implementation of CGM training in usual out-patient care. This might contribute to clinical inertia.17 Manufacturers usually offer merely product-specific training activities for their CGM system; healthcare professionals might thus become confused by the variety of CGM systems encountered in their practice while persons with type 1 diabetes have specific detailed technical questions.

In Germany, rtCGM systems may be provided at the expense of the statutory health insurance for persons with type 1 diabetes or insulin-dependent type 2 diabetes. However, the Federal Joint Committee of the German healthcare service requires specific training of patients before using an rtCGM system. Because of these issues, a comprehensive and manufacturer-independent CGM training programme was developed for real-time (rt) CGM systems. The group of authors was composed of diabetologists, certified diabetes educators and scientists. All were members of the Diabetes Technology working group (AGDT) or members of the Pediatric Diabetology working group (AGPD) of the German Diabetes Association (DDG). The structured training programme SPECTRUM (Structured Patient Education and Treatment Programme for Self-Reliant Continuous Glucose Monitoring) is available in three age-adjusted versions: for adults, parents of younger children and adolescents with type 1 diabetes. Furthermore, the CGM manufacturer-independent programme applies to all rtCGM systems and all types of insulin therapy. Specific materials and didactic tools are employed to support diabetes centres with less rtCGM experience, along with the addition of comprehensive rtCGM training with this programme. SPECTRUM consists of one introductory module followed by six training modules. Each module lasts approximately 90 min. Details of SPECTRUM were published previously.14,15,17 -‘Train-the-Trainer’ seminars with standardised sessions enable diabetes practitioners to train persons who wear CGM systems.
team members to offer the training in terms of content and didactics at a high level.17

This study evaluates the efficacy and acceptance of SPECTRUM under usual out-patient care conditions. Effects of training participation of persons with type 1 diabetes concerning rtCGM-specific knowledge and practical skills were assessed in three different groups of participants (adults, adolescents and parents of younger children). The results for adult participants are presented below.

2 | PARTICIPANTS AND METHODS

This prospective multicentre study, called CGM-TRAIN, was performed from June 2018 to April 2020 in 19 diabetes clinics or practices across Germany with three different groups of participants. The results for adult participants (from 10 diabetes clinics or practices; Appendix S1) are presented below. The first adult participant was included in the study on 21 June 2018; study completion of the last adult participant was on 26 October 2019.

The ethics committee at the Ärztekammer (medical chamber) Niedersachsen, Hannover, Germany, and the respective local ethics committees approved the clinical study protocol (internal reference number; Ärztekammer Niedersachsen, Hannover: Bo/14/2018). This trial was performed under consideration of the Declaration of Helsinki and in compliance with the Guideline for Good Clinical Practice (GCP). The study was registered at the German Clinical Trials Register (DRKS00014380).

After providing written, informed consent, participants were screened for eligibility. Inclusion criteria were as follows: type 1 diabetes, indication for rtCGM usage, being on intensive insulin therapy and >18 years of age. Participants had to be willing to use an rtCGM system for about 8 months. Participants who had already participated in rtCGM training before were excluded. Prior use of CGM system did not lead to exclusion. However, when official rtCGM usage in study was started the usage of a Flash Glucose Monitoring (FGM) was not allowed.

Demographic and diabetes-specific measures like frequency of severe hypoglycaemic events during the last 6 months (coma, seizure) and most recent HbA1c value of eligible participants were documented.

Participants attended the complete CGM training programme between the first and second study visits (Figure 1). Final measurements were completed at 6 months following the training programme (visit 3).

To assess rtCGM-specific knowledge before and after training, participants answered the knowledge test ‘rtCGM-Profi-Check’. This psychometrically evaluated 40-item multiple-choice questionnaire covers the core concepts regarding rtCGM. It was developed by rtCGM experts. Cronbach’s alpha of 0.92 reflects an excellent internal consistency, a high item-total correlation and content validity due to the expert’s selection of topics.18

After answering this knowledge test during visit 1, rtCGM usage and the first SPECTRUM module were started by certified training staff. Immediately after completion of all SPECTRUM modules (approximately 30 days after the start of training), the participants again completed the knowledge test (visit 2).

An evaluation of seven core competences like alarm setting adjustments or data download was performed by participants to assess practical skills for handling rtCGM systems. The participants’ level of performance was rated by study personal (0 = failed, 1 = completed with help or 2 = completed without help); a maximum score value of 14 could be achieved.

The satisfaction of participants with the training programme was assessed through a questionnaire based on one developed by Lange et al.19 Answers to the six questions in the evaluation were based on a grading scale from 1 (=very good) to 6 (=insufficient).

Questions regarding satisfaction with and acceptance of rtCGM were answered by participants based on the

FIGURE 1 CGM-TRAIN—Study design
Technology Acceptance Model (TAM) Questionnaire. In sum, nine questions regarding rtCGM satisfaction were answered on a scale from 1 (=low satisfaction) to 5 (=high satisfaction). The acceptance was assessed with 14 questions on a scale from 1 (=low acceptance) to 7 (=high acceptance). The knowledge and handling test, as well as the questions regarding rtCGM satisfaction and acceptance, were repeated at visit 3.

The number of severe hypoglycaemic events during the last 6 months was re-recorded at visit 3, and a blood sample for HbA1c measurement was collected (Figure 1) so that diabetes-specific measurements before and after rtCGM training could be compared.

2.1 | Sample size

As comparative data on the efficacy of an rtCGM training programme were not available, formal sample size estimation was challenging as the composition of the sample in the participating out-patient centres and the expected change of knowledge could only be roughly estimated. It has been shown that to demonstrate acceptance and efficacy of a different training programme in paediatric diabetes centres a sample size of 100 was sufficient. It was anticipated that at least 80% of visit 1 participants also participated in visit 2. Thus, a sample size up to 120 adults was planned to be recruited for CGM-TRAIN.

2.2 | Statistical analysis

Primary endpoint of this study was change in rtCGM-specific knowledge before and after training participation. Independent of the sample size, a 30% increase in rtCGM-specific knowledge from visit 1 to visit 2 was expected.

The primary analysis dataset consisted of all participants who completed the training programme (n = 110). In additional analyses, all available data were used.

Results are presented as mean ± standard deviation (SD) as well as the minimum and maximum values. Standard statistical procedures were performed for comparison of baseline data, clinical measurements, and primary and secondary endpoint measures between groups of participants (Student’s t test, Mann–Whitney U test, ANOVA, Kruskal–Wallis test where appropriate). For longitudinal analysis, Wilcoxon signed-rank tests were used. Ordinary least square regression was used for estimating effects on the dependent variable.
rtCGM knowledge at all visits. As independent variables sex, education level, age, diabetes duration, type of insulin therapy, rtCGM system and study site were included. As no assumptions were made on the hierarchy of effects, the analyses were performed by means of simultaneous estimation of effects.

Differences were regarded as statistically significant if the two-sided \( p \) value was <0.05, no allowance was made for multiplicity of statistical tests.

3 | RESULTS

In total, 120 adults (67 females and 53 males) were screened and enrolled in the study (Figure 2). Their age was 42.4 ± 13.4 years, diabetes duration was 21.6 ± 11.6 years and HbA1c was 61 ± 14 mmol/mol (7.7 ± 1.3%). Before study start, 25 participants already used a CGM system, their HbA1c level was 61 ± 13 mmol/mol (7.7 ± 1.2%) and comparable with the level of CGM-naïve participants (61 ± 15 mmol/mol [7.7 ± 1.4%]).

No significant difference based on gender was identified. Most participants (76%) were on insulin pump therapy, 24% used an insulin pen for multiple daily injections. Two participants reported severe hypoglycaemic events (\( n = 3 \)) during the last 6 months before the start of this study. A Medtronic rtCGM system was used by 58 participants (48%), a Dexcom system was used by 52 participants (43%) and 8 (7%) used a Senseonics system.

Due to an allergic skin reaction (\( n = 1 \)) and failing to attend study visits (\( n = 1 \)), two participants did not start the training programme. Another eight participants dropped out during the study due to illness (\( n = 2 \)), not attending training modules (\( n = 5 \)) and discomfort due to glucose sensor and transmitter (\( n = 1 \)). Two additional participants did not show up for visit 3 (no questionnaire was answered, unavailable due to relocation) (Figure 2). Compared to the 108 participants who completed the study, the 12 dropouts were younger (43.7 ± 13.0 years vs. 30.8 ± 12.4 years; \( p < 0.001 \)). Other measurements, like diabetes duration, HbA1c and rtCGM-specific knowledge at visit 1, were comparable between completers and dropouts.

3.1 | Primary endpoint

The rtCGM-specific knowledge (scale 0–40) increased by 43% from 21.2 ± 7.6 before the training modules to 30.4 ± 4.5 right after last module at visit 2 (\( p < 0.001 \)). This level of knowledge persisted until visit 3 (29.4 ± 4.5; 39% increase from visit 1) (Figure 3). Regression analysis indicated that neither sex, education level, age, diabetes duration, type of insulin therapy, rtCGM system, nor study site were significantly predictive of rtCGM knowledge prior to training at visit 1 (each \( p > 0.05 \)).

Participants with prior use of a CGM system showed slightly higher but not significantly different levels of rtCGM-specific knowledge at visit 1 compared to CGM-naïve participants (23.3 ± 7.3 vs. 20.5 ± 7.8; \( p = 0.114 \)).

Before training (visit 1), rtCGM-specific knowledge varied significantly (\( p < 0.001 \)) between study sites (Appendix S2). Such difference in rtCGM-specific knowledge between study sites was not apparent (\( p = 0.27 \)) after training (visit 2). In particular, questions regarding the relationship between rtCGM and blood glucose values, adequate insertion sites of the glucose sensor, interpretations of trend arrows and suitable times for calibration were answered correctly more often after participation in SPECTRUM.

After participation, age predicted the respective rtCGM knowledge at visit 2 (\( p = 0.002 \)) and at visit 3 (\( p = 0.006 \)) and in addition, educational level was a predictor at visit 3 (\( p = 0.015 \)).

3.2 | Secondary endpoints

3.2.1 | Practical skills

Most participants demonstrated all essential practical requirements for usage of rtCGM systems at visit 2 (13.2 ± 1.3; 8–14) and visit 3 (13.1 ± 1.1; 10–14) (scale: 0 = failed all tasks to 14 = completed all tasks without help). Most tasks
were performed without help from study personal during both visits. Setting time and date and recharging the receiver could be performed without help by all study participants. Nearly all participants had no problem with changing alarm settings (95% at visit 2, 97% at visit 3), turning off the vibration alarm, changing alarm sounds (94% at visit 2, 96% at visit 3), or performing calibrations (99% on both visits). However, some participants required help with data upload into an analysis tool or cloud (23% at visit 2, 16% at visit 3) and data analysis (23% at visit 2, 26% at visit 3), and a few participants failed data upload (8% at visit 2, 9% at visit 3) and data analysis (6% at visit 2, 10% at visit 3).

### 3.2.2 Satisfaction with SPECTRUM

The overall rating for satisfaction with the training itself was positive with 1.4 ± 0.5 points (1–3; n = 110) (scale: 1 = high satisfaction to 6 = low satisfaction). SPECTRUM was easy to understand (1.3 ± 0.5; 1–3), and participants felt well prepared for rtCGM use at home (1.3 ± 0.6; 1–4). They also reported that important questions were answered well (1.4 ± 0.6; 1–4), and the training motivated most of them to use rtCGM (1.4 ± 0.6; 1–4). Opportunities for improvements exist concerning the feeling of safety (1.5 ± 0.7; 1–4) and sufficient training time (1.7 ± 1.0; 1–6). A few participants documented recommendations for improvements of the training programme, such as more details regarding the effect of oral drugs on CGM results.

### 3.2.3 Satisfaction and acceptance of rtCGM

At visit 2, satisfaction with rtCGM was high with 4.2 ± 0.5 (2.0–5.0; n = 110) (scale: 1 = low satisfaction to 5 = high satisfaction). The satisfaction did not change after sustained rtCGM use at visit 3 (4.2 ± 0.5; 2.1–5.0; n = 108) (Table 1). Participants reported high satisfaction on both visits regarding...
the use of the CGM, the feeling of safety and the important information that rtCGM systems provide. However, some participants perceived the alarms as annoying or inappropriately timed (12% at visit 2, 19% at visit 3). Some items, like system application and handling, improved even at visit 3. In free-text comments, the majority of participants stated positive aspects of rtCGM like an increased overview of glucose curves and safety.

Acceptance of rtCGM was high directly after training at visit 2 with 6.3 ± 0.6 (4.1–7.0; n = 110) and remained stable until visit 3 (6.3 ± 0.7; 2.5–7.0; n = 108) (Table 1). Additionally, the time for diabetes management and the trust in the glucose measurements of rtCGM did not change after sustained rtCGM use.

### 3.2.4 | Diabetes-specific measurements

HbA1c levels decreased from 61 ± 14 mmol/mol (7.7 ± 1.3%) (ranging from 28 mmol/mol [4.7%] to 132 mmol/mol [14.2%]) at visit 0 to 60 ± 14 mmol/mol (7.6 ± 1.3%) (ranging from 32 mmol/mol [5.1%] to 146 mmol/mol [15.5%]) at visit 3 (p = 0.04). The percentage of participants with HbA1c levels >75 mmol/mol (9.0%) decreased from 12% to 9%. The percentage of participants with HbA1c levels between 58 and 75 mmol/mol (7.5% and 9.0%) increased from 36% to 40% and the glycaemic target of <58 mmol/mol (<7.5%) was reached by about half of participants on both visits (visit 0: 53%; visit 3: 51%).

The HbA1c levels between participants with previous CGM usage and CGM-naïve participants did not differ at visit 3 (60 ± 11 mmol/mol (7.6 ± 1.0%) vs. 60 ± 15 mmol/mol (7.6 ± 1.4%); p = 0.377). Two of the 120 included participants reported three severe hypoglycaemic events during the last 6 months before the start of the CGM training. The number decreased to one event after visit 3. However, a participant who initially had two hypoglycaemic events dropped out during the study. Of the 108 participants who completed the study, the number of hypoglycaemic events during the last 6 months before visit 1 and after visit 2 did not change from the initial low level.

### 4 | DISCUSSION

The benefit of diabetes training and teaching programmes on making diabetes management and therapy more effective and safe has been previously documented.\textsuperscript{11-13,21,22} The CGM-TRAIN study was the first study to evaluate the efficacy of a training programme for rtCGM under the condition of usual diabetes out-patient care.

Study results indicate that focusing on self-management and problem-solving tasks prepares persons with type 1 diabetes well for successful rtCGM usage in everyday life.

SPECTRUM was effective in increasing rtCGM-specific knowledge and skills in adult people with insulin-dependent diabetes independent from their educational level and diabetes experience. The increase in 43% in rtCGM-specific knowledge persisted at the 6-month follow-up. The level of practical skills remained constant as well. Only those tasks rarely performed by participants during rtCGM use, like data upload into analysis tools, caused difficulties, and point to the need of more and repeated practical training of data analyses.

The success of adequate training of use of rtCGM systems is reflected in the small but significant improvement in glycaemic control observed.

The reduction of HbA1c has to be evaluated in the context of other studies that evaluated the impact of CGM. Several studies showed that the use of rtCGM in persons with type 1 diabetes reduces HbA1c levels in the range 4–11 mmol/mol (0.4%–1.0%).\textsuperscript{23-27} However, participants mean baseline HbA1c was higher in these studies compared to the current study. And as described in most other studies, a higher reduction in HbA1c levels was observed in study participants with higher basal HbA1c levels.\textsuperscript{21,23,24,28} With more than 50% of study participants having HbA1c levels below 58 mmol/mol (7.5%) before entry into this study, a more pronounced reduction in HbA1c was not expected.

Another study evaluating a training programme for FGM, reported HbA1c reductions about 3 mmol/mol (−0.28%) (training group) and 1 mmol/mol (−0.11%) (control group). However, the baseline HbA1c levels of 68 ± 10 mmol/mol (8.4 ± 0.9%) were higher than in this study (60 ± 14 mmol/mol; 7.6 ± 1.3%) as well.\textsuperscript{28}

Due to the low frequency of hypoglycaemic events before starting rtCGM usage, no change in severe hypoglycaemic events was observed with rtCGM use in this study.

The positive patient-reported outcomes regarding rtCGM satisfaction and acceptance at visit 2 and visit 3 represent sustainable satisfaction with rtCGM. Additionally, the SPECTRUM training programme itself was rated positively by study participants. Thus, participants were generally satisfied with the training.

With the 6 modules and corresponding 12 school lessons in total, SPECTRUM is time- and therefore cost-intensive. However, improved diabetes management and thus cost savings due to reduced long-term complications and improved technology handling has important implications for payers.\textsuperscript{29} A health economic evaluation could help evaluate the benefit of the SPECTRUM training programme by putting the programme costs in relation to the cost savings due to improved rtCGM handling like more precise calibrations or less sensor loss.
The rapidly developing diabetes technology can only succeed if its potential is fully exploited. Therefore, persons with type 1 diabetes should have access to the technical equipment, and make sound therapy decisions with it. Thus, high levels of health literacy and numeracy are needed and assessed for therapy approaches. Through the involvement of experienced diabetes teams, SPECTRUM takes the individual knowledge and skill levels into account and enables individual education based on competencies and limits of all persons with type 1 diabetes.

Study sites did not have a significant effect on the outcome induced by the training; thus, SPECTRUM was efficient under conditions of usual out-patient care independently of circumstances of training. The level of knowledge after training was also independent of the initial rtCGM-specific knowledge, indicating that the potential to increase knowledge may be more significant in persons with type 1 diabetes who have lower health literacy before training starts.

This individually tailored training programme may reduce inequalities in health literacy and subsequently social inequality of health and glycaemic control.

In addition, the initial level of knowledge as well as the HbA1c levels of participants with prior use of a CGM-system did not differ compared to CGM-naïve participants in this study. This indicates that the use of a CGM system per se does not improve the rtCGM-specific knowledge and therapeutic action.

People using rtCGM continuously may learn every day from their personal experiences and the constant advice and feedback from their diabetes team; however, this is time-consuming and may be more expensive than getting a first comprehensive training by and experienced trainer.

One limitation of this study is the missing control group; however, evaluation of a training programme with a double-blind, randomised controlled trial design is not possible as trainers and trained participants are aware when performing for therapy approaches. From a therapeutic point of view, the use of rtCGM systems without training would not be ethically justifiable due to associated risks in therapy management. Alternative manufacturer-independent rtCGM training programmes and thus comparative data on the efficacy of other training programmes are not available. Furthermore, at the time of study conduction more than 2000 healthcare professionals were already trained with SPECTRUM. Users without training who use a rtCGM system at their own expense represent a highly selective sample; thus, it would have been difficult to define a suitable control.

As comparative data on the efficacy of an rtCGM training programme were not available, formal sample size estimation was challenging as the composition of the sample in the participating out-patient centres and the expected change of knowledge could only be roughly estimated. Thus, a clear a priori sample size calculation for this study under usual care conditions was only possible to a limited extend.

This study only had three pre-post comparisons (HbA1c, knowledge test and number of hypoglycaemic events); this may limit the interpretation of the efficacy of SPECTRUM. However, other measurements like rtCGM handling or the acceptance of rtCGM could only have been recorded when all participants had access to an rtCGM system before training. This was not the case in our study.

Clinical trials with CGM systems often consider participants’ health literacy for study inclusion. Thus, people with restrictions that prevent adequate compliance with the study device and study protocol may be excluded. An advantage of the CGM-TRAIN study is that it was conducted in multiple sites across Germany with a broad patient population representing the reality in diabetes out-patient care in a given healthcare system.

In summary, training of persons with type 1 diabetes in rtCGM usage utilising a specialised programme was shown to be effective. The respective rtCGM knowledge increased considerably and consistently; additionally, a high level of practical skills, and satisfaction with and acceptance of rtCGM, could be maintained. Besides, improvements in the efficiency of cost-intensive CGM systems have essential implications for payers.

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AUTHOR CONTRIBUTION
SS, GF, LH and KL substantially contributed to study conception and design. KL and SS developed the SPECTUM specific questionnaire rtCGM-Profi-Check and substantially contributed to data analysis and interpretation. SS was the principle investigator of the study. All authors critically reviewed and provided edits and comments on manuscript drafts. PW was project coordinator had full access to all of the data in the study. All authors take responsibility for the integrity of the data and the accuracy of the data analysis.

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**SUPPORTING INFORMATION**

Additional supporting information may be found online in the Supporting Information section.