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Original article

Impact of Sten-O Starter on Glycemic Management in Children and Adolescents with Type 1 Diabetes in the North Region of Denmark

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ABSTRACT

Objective: Educational material on type 1 diabetes (T1D) is limited. An educational application named Sten-O Starter has been implemented for children and adolescents with T1D and their parents; however, its effect on glycemic management is unknown. The objective was therefore to examine the clinical impact of the Sten-O Starter on glycemic management among children and adolescents with T1D.
Methods: The levels of glycated hemoglobin (HbA1c) at 0–12 months after diagnosis were compared between two cohorts (the intervention received Sten-O Starter and the control received usual care). A mixed model of repeated measurements adjusted for age, sex, and HbA1c at diagnosis was used. A subgroup analysis of the cohorts was performed in which the time in range, time above range, and time below range (TBR) were compared at 6 months and 12 months after diagnosis using the Wilcoxon rank sum test.
Results: 181 children and adolescents were included and all HbA1c measurements from the time of diagnosis to 12-month follow-up: No significant difference (p = 0.35) was found in HbA1c changes between the cohorts. However, the difference in median HbA1c at the 12-month follow-up between the intervention cohort and the control cohort (50 mmol/mol vs. 54 mmol/mol) was borderline significant (p = 0.059). A subgroup analysis of 30 children and adolescents revealed that TBR was significantly different (intervention: 1.2 % vs control: 2.6 %; p = 0.02) at 6 months and at 12 months (intervention: 1 % vs control; 2 %; p = 0.05).
Conclusion: The results indicate improved glycemic management among children and adolescents with T1D after use of the Sten-O Starter.

Introduction

Type 1 diabetes (T1D) is a chronic condition that requires constant attention from both the child or adolescent as well as the parents and other adults involved in the child or adolescent's life [1,2]. Such attention involves a focus on several aspects of T1D self-management, which normally includes self-monitoring of blood glucose levels, blood glucose fluctuations and causes of fluctuations; insulin administration; physical activity; and dietary behaviors, all of which seek to avoid complications caused by hypo- and/or hyperglycemia [1,3–6]. Parents are a cornerstone in supporting children's and adolescents' management of T1D. However, the diagnosis of T1D leads to thorough changes in parents, which can be stressful since they feel responsible for actions related to their child's T1D self-management [5,2,7].

There is a significant association between intensive diabetes therapy that lowers HbA1c and a reduction in the incidence of onset and progression of late diabetic complications among adolescents aged 13–18 years [8–10]. The significant association is a strong argument for implementing tools and educative procedures that improve children's and adolescents' self-management of T1D to lower HbA1c. Furthermore, a systematic review of randomized controlled trials has shown that increasing T1D management among people with T1D has the potential to positively impact quality of life [11].

A common procedure, when a child or adolescent is diagnosed with T1D, is a one-week hospitalization with one parent focusing on stabilizing blood glucose levels as well as introducing T1D self-management strategies [12,13]. According to the literature, parents feel left alone and overwhelmed by the responsibility of learning self-

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management strategies for T1D to teach their own child T1D self-management practices [13–15]. Furthermore, the existing educational materials and tools for treating T1D have limitations [13,16–19], such as being directed toward parents rather than toward children or adolescents, being outdated, not learner-centered, and not following the principles and practices of education for young people. According to Marklund et al., an educational program should be structured in a learner-centered, enjoyable, meaningful, and interesting form [18], which is in line with the newest research on how to design motivating education [12–14].

Technology-based interventions in the form of digital platforms or applications on mobile phones (mHealth) that include information, quizzes, and/or other gamification elements are a new way to increase knowledge of T1D management among children and adolescents [1,4,5,20–31]. In a systematic review, Greenwood et al. discovered how these technology-based education interventions can have a positive influence on children's and adolescents' motivation to learn about their new diagnosis [27]. However, Greenwood et al. call attention to several aspects when developing such applications. For instance, they describe how 2-way communication, feedback, and personalization of the application are key elements to include in any technology-based solution [16,27]. Several technology-based educational initiatives have been designed for children and adolescents with T1D and T2D [4,24,26,27].

In the North Region of Denmark, an educational application, the Sten-O Starter, directed toward children, adolescents and their parents has been available since 01.09.2020 [26,32]. Preliminary results indicate a positive clinical effect on HbA1c. However, it is unknown whether there was a change in glycemic management among children and adolescents after using the Sten-O Starter. The aim of this study was therefore to investigate the clinical impact of the implementation of the Sten-O Starter on glycemic management among children and adolescents with T1D.

Methods and materials

The Sten-O Starter

The Sten-O Starter is an educational application directed at children and adolescents diagnosed with T1D that seeks to educate individuals about T1D self-management. The Sten-O Starter encompasses a wide range of topics divided into nine icons (Fig. 1). When clicking on an icon, children, adolescents, and parents can access topics such as diabetes, blood glucose, insulin, nutrition, exercise, and travel. For each topic, there are illustrations, animations, quizzes, and games where it is possible to learn. Furthermore, instruction videos are available in Sten-O Starter(34). Since 1.9.2020, the Sten-O Starter has been part of the standard procedure when a child or adolescent is diagnosed and hospitalized in the pediatric ward at Aalborg University with T1D in the North Denmark Region, and it is recommended that these individuals download the educational application.

The Sten-O Starter was developed in close collaboration between clinicians, i.e., diabetes nurses from the specialized ward for children and adolescents with diabetes at Aalborg University Hospital, Denmark, and diabetes nurses from the North Region Hospital, Denmark; newly diagnosed children and adolescents with T1D hospitalized at the specialized ward for children and adolescents with diabetes; Aalborg University Hospital; and experts from the Steno Diabetes Center North in Denmark [33].

Study design

This was a retrospective cohort study conducted on data from children and adolescents diagnosed with T1D. A control cohort and an intervention cohort were compared in relation to HbA1c at 0–12 months postdiagnosis. Furthermore, a subgroup analysis of the control cohort and intervention cohort was conducted, in which CGM

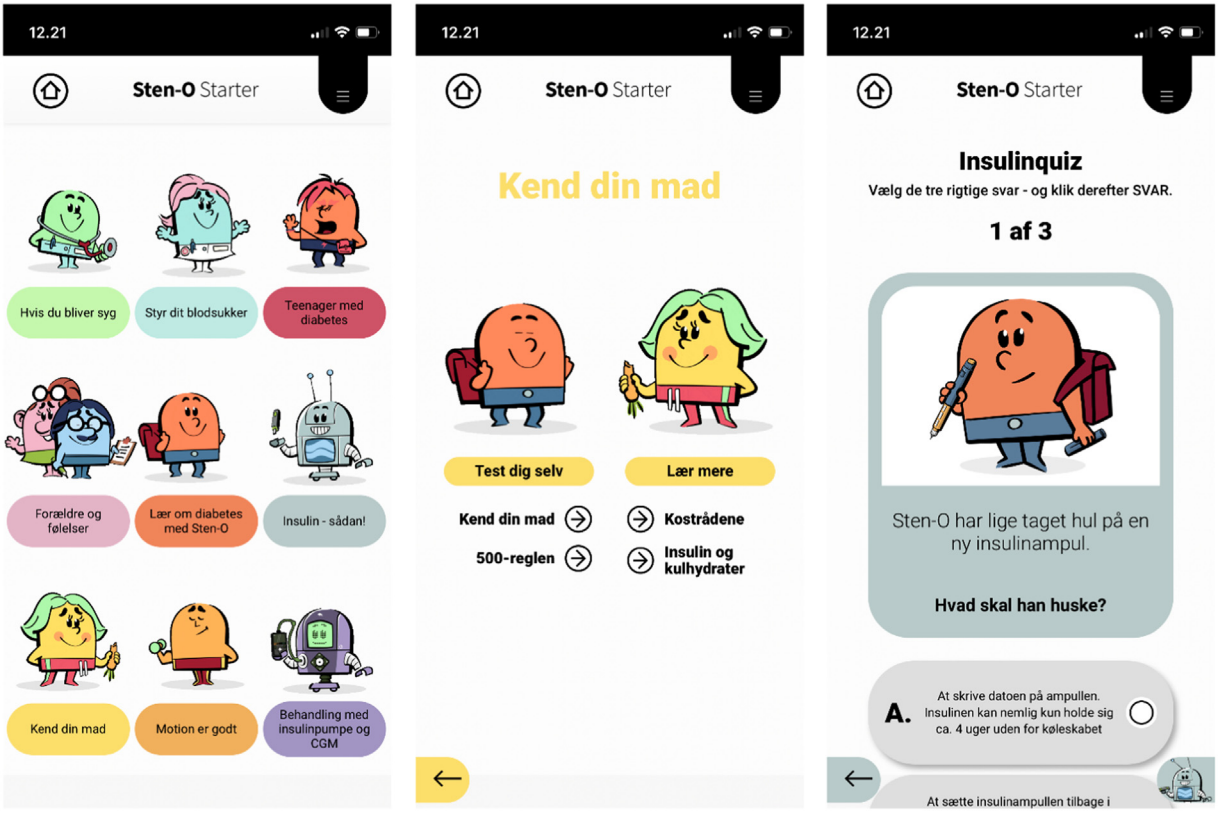

Fig. 1. displays screenshots from the Sten-O starter app, accessible on both the Apple App Store and Google Play. The application is presently offered in Danish and is published by Steno Diabetes Center Nordjylland (SDCN).

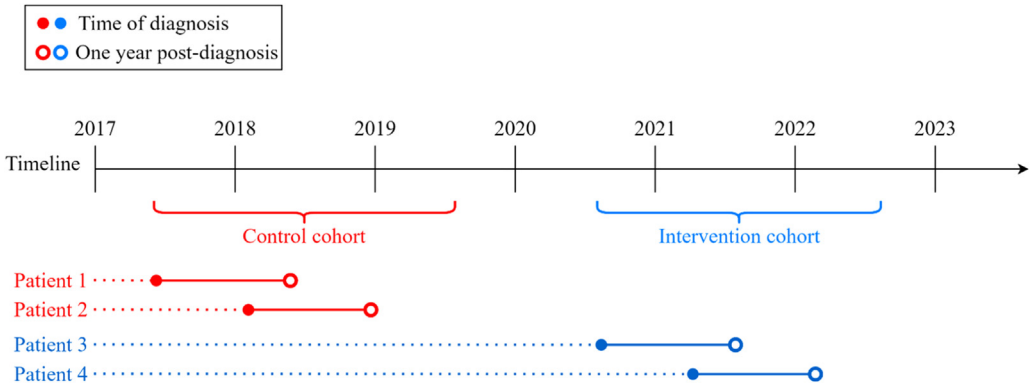

Fig. 2. An overview of the timelines for the intervention cohort and the control cohort. The brackets indicate that the time of diagnosis for each patient included in the control cohort should be between 1st of September 2017 and 31st of August 2019 or between 1st of September 2020 and 31st of August 2022 to be included in the intervention cohort.

metrics such as time in range (TIR), time above range (TAB), and time below range (TBR) were compared.

The control cohort consisted of children and adolescents diagnosed with T1D in the following period: 1st of September 2017 to 31st of August 2019. The intervention cohort consisted of children and adolescents diagnosed with T1D in the following period: 1st of September 2020 to 31 August 2022. The intervention cohort was introduced to the Sten-O Starter, whereas the control cohort received usual diabetes teaching. The study design is visualized in Fig. 2.

The included children and adolescents participated in consultations with their diabetes doctor and nurse every quarter, and the associated tests within the first year after diagnosis were included in the analysis. A one-year follow-up was subsequently conducted on each cohort. Additionally, generated CGM data were collected from children and adolescents.

Inclusion and exclusion criteria

All children and adolescents aged ≤18 at the time of T1D diagnosis were included if the diagnosis was given either between 1st of September 2017 and 31st of August 2019 (control) or 1st of September 2020 to 31st of August 2022 (intervention) at Aalborg University Hospital in Denmark and The North Region Hospital in Denmark.

A condition to be included in the analysis of the primary endpoint was that two or more HbA1c measurements were available. The first HbA1c measurement had to be from the time of diagnosis, and the second had to be within 12 months after the time of diagnosis.

Only CGM data from children and adolescents for whom both parents signed a declaration of consent were included. Furthermore, at least 6 months of CGM data had to be available in the dataset; otherwise, the participant was excluded.

End points from the retrospective cohort study

Primary end point

- Change in HbA1c after receiving treatment for one year

Secondary end points

- CGM time-spent-in-range (TIR) (3.9 mmol/L<CGM) £ 10,0 mmol/L) [34] after receiving treatment for 6 months and one year
- CGM time-spent-above-range (TAB) (10.0 mmol/L<CGM) [34] after receiving treatment for 6 months and one year
- CGM time-spent-below-range (TBR) (CGM £ 3.9 mmol/L) [34] after receiving treatment for 6 months and one year
- CGM coefficient of variance [34] after receiving treatment for 6 months and one year

Statistical analysis

The primary endpoint was analyzed with a mixed model of repeated measurements adjusted for age, sex, and HbA1c at the time of diagnosis. The secondary endpoints were related to the subgroup analysis of the CGM data, which were assessed at 6 months and 12 months postdiagnosis using the Wilcoxon rank sum test. The results and baseline characteristics are presented as either the mean ± standard deviation or median (interquartile range), depending on the distribution of the data.

Study data

In total, 181 children and adolescents were included in the analysis of the primary endpoint. The data were collected from the Region North Denmark Diabetes Dataplatform.

In total, $N = 30$ children and adolescents were included in the subanalysis of the secondary endpoints. The data were collected from three different CGM platforms: LibreView, Glooko, and Diasend. Access to CGM data in Diasend was stored in the individual children's or adolescents' personal electronic health records. Access to CGM data in Glooko and LibreView was available through each healthcare professional's personal login.

Results

Primary endpoint

For the primary endpoint analysis, a total of 181 children and adolescents (intervention group: $n = 106$, control group: $n = 75$) were included. The baseline characteristics and analysis results are presented in Table 1. Age (10.3 vs. 9.8 years), number of HbA1c measurements (5.9 vs. 6.1, n), and median HbA1c at diagnosis (92.5 vs. 94, mmol/mol) were comparable between the intervention cohort and the control cohort ($p = 0.283–0.462$). According to the mixed model, repeated measurements, including all children and adolescents and all HbA1c measurements from the time of diagnosis to the 12-month follow-up, no significant difference ($p = 0.35$) was found in the changes in HbA1c between the intervention cohort and the control cohort. Adjusting the model for age, sex, and HbA1c at diagnosis did not alter the results. However, the difference in the median HbA1c level at the 12-month follow-up between the intervention cohort and the control cohort (50 vs. 54 mmol/mol) was borderline

Table 1
Results from the primary endpoint analysis, including the characteristics of the intervention group and the control group.

	Intervention group	Control group	p value
Number of people, n	106	75	
Age (yrs), mean (SD)	10.3 (4.5)	9.8 (4.1)	0.462
Sex, % (n)			0.296
- Female	0.5 (55)	0.4 (33)	
- Male	0.5 (51)	0.6 (42)	
HbA1c measurements (n), mean (SD)	5.9 (1.7)	6.1 (1.4)	0.283
HbA1c at time of the diagnosis (mmol/mol), median (IQR)	92.5 (76;123)	94 (82;112)	0.641
HbA1c at 12 months (mmol/mol), median (IQR)[§]	50 (44;55)	54 (48;57)	0.059
Difference daily change in HbA1c (mmol/mol) Intervention group − control group	Estimate (standard error; p) −0.010 mmol/mol (0.011 mmol/mol; $p = 0.35$)[*]		

[*] Estimates are from a mixed model repeated measurement with adjustments for age, sex and HbA1c at diagnosis.
[§] HbA1c measurement closest to 12 months postdiagnosis in a window 305–365 days from diagnosis.

significant ($p = 0.059$). Fig. 3 presents the median HbA1c levels for each cohort. The figure indicates a small increase in the control cohort from 4 months postdiagnosis to 12 months postdiagnosis, which was not observed to the same extent in the intervention cohort.

Secondary endpoints

For the secondary endpoints, a subset of children and adolescents (intervention group: $n = 17$, control group: $n = 13$) was included. The results of the analysis of secondary endpoints are presented in Table 2 and Fig. 4. Only the TBR was significantly different between the groups (intervention cohort: 1.2 % vs control cohort: 2.6 %; $p = 0.02$) at 6 months and at 12 months (intervention cohort: 1 % vs control cohort; 2 %; $p = 0.05$). As shown in Table 2, a decrease in the TIR was observed in both cohorts beginning at 6 months (intervention cohort: 72.9 % vs control cohort: 68.0 %) and 12 months postdiagnosis (intervention cohort: 69.5 % vs control cohort: 62.8 %). The decline in the intervention cohort was 3.4 %, whereas the decline in the control cohort was 5.2 %.

Discussion

This retrospective cohort study aimed to investigate the impact of the implementation of the Sten-O Starter on glycemic management among children and adolescents with T1D. The results of the present study did not reveal a significant difference in the HbA1c level between the intervention cohort and the control cohort at 12 months postdiagnosis. These findings indicate a deviating trend between the intervention cohort and the control cohort. However, questions remain as to whether this trend will continue past 12 months from the time of diagnosis. The secondary analysis indicated that implementing a digital educational platform for children and adolescents decreases TBR, which could be explained by the fact that the Sten-O Starter is a motivating factor in children and adolescents' glycemic management [35].

In this study, the TBR was significantly different between the two cohorts. Moreover, at 6 months postdiagnosis and 12 months postdiagnosis, the intervention cohort spent significantly less time in the TBR than the control cohort. These findings may indicate that using the available functionalities in the Sten-O Starter mHealth application has a positive effect on glycemic management. This effect could be

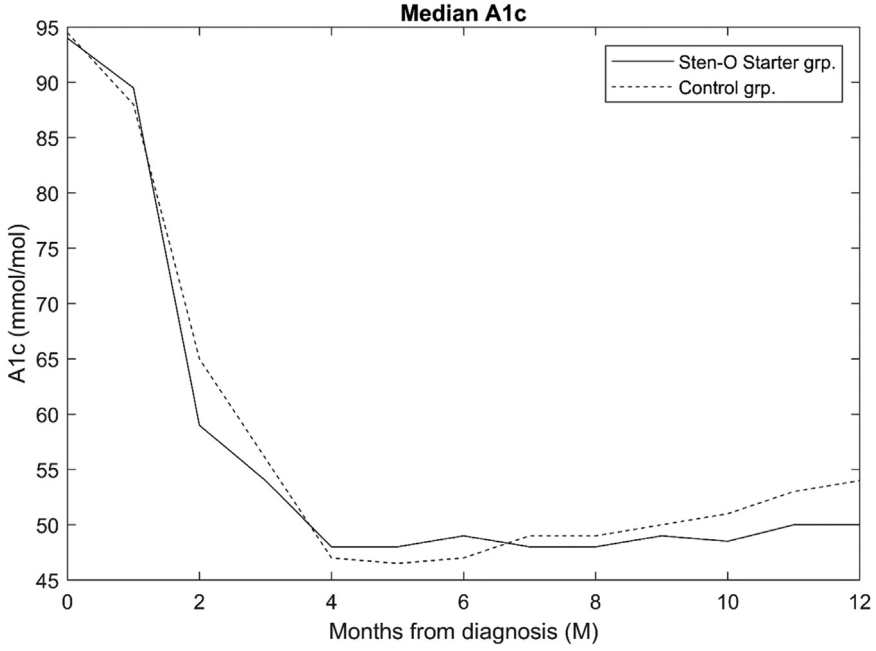

Fig. 3. Median HbA1c (A1c) from diagnosis to 12 months for the Sten-O starter group and the control group.

Table 2
CGM measurements at 6 and 12 months after the analysis of the secondary endpoints were conducted for subgrouped children and adolescents whose parents provided signed consent. The metrics are presented as the medians (interquartile ranges) for both groups (intervention group and control group).

CGM metrics	Intervention group	Control group	p value
At 6-months post diagnosis			
- n	17	13	
- TIR, % (median [IQR])	72.9 [16.7]	68 [22.9]	0.59
- TBR, % (median [IQR])	1.2 [1.8]	2.6 [2.4]	**0.02**
- TAR, % (median [IQR])	27 [16.3]	29.4 [21.4]	0.77
- Mean, mmol/L (median [IQR])	8.5 [1.4]	8.6 [1.7]	0.87
- CV, % (median [IQR])	33.7 [9.4]	37.9 [9]	0.26
At 12-months post diagnosis			
- n	16	13	
- TIR, % (median [IQR])	69.5 [14]	62.8 [14.9]	0.28
- TBR, % (median [IQR])	1 [1.4]	2 [6.4]	**0.05**
- TAR, % (median [IQR])	28.9 [12.7]	30.7 [15.4]	0.61
- Mean, mmol/L (median [IQR])	8.8 [1.1]	8.5 [1.3]	0.95
- CV, % (median [IQR])	35.7 [7.4]	38.4 [8.2]	0.18

CGM measurements at 6 and 12 months after the analysis of the secondary endpoints were conducted for subgrouped children and adolescents whose parents provided signed consent. The metrics are presented as the medians (interquartile ranges) for both groups (intervention group and control group).

caused by the increase in available knowledge concerning the dosage of insulin, technique of insulin injection, etc., tailored toward children and adolescents. The findings of the study are also in line with those of other studies focusing on glycemic management among children and adolescents [30,36]. In a cross-sectional study by Wysocki et al., they discovered that giving children with T1D and their parents access to knowledge concerning major complications of T1D increased adherence to treatment among children and decreased their HbA1c. Furthermore, in a review by Alsalman et al., the authors investigated the use of digital applications in healthcare and found that mHealth apps can be key to improving children's and adolescents' self-management of T1D [30].

The increase in glycemic management among children and adolescents may also be impacted by the increased availability of knowledge that parents and/or other members of the family have acquired through the Sten-O Starter mHealth application. The extent to which family dynamics and glycemic management are correlated is unknown, but according to several studies, the accumulated knowledge within a family has positive effects on glycemic management [1,36,37].

The significant difference in TBR may also be caused by the availability of knowledge concerning hypoglycemia and the consequences thereof tailored toward children and adolescents in the Sten-O Starter. The significant difference in TBR is also in line with the

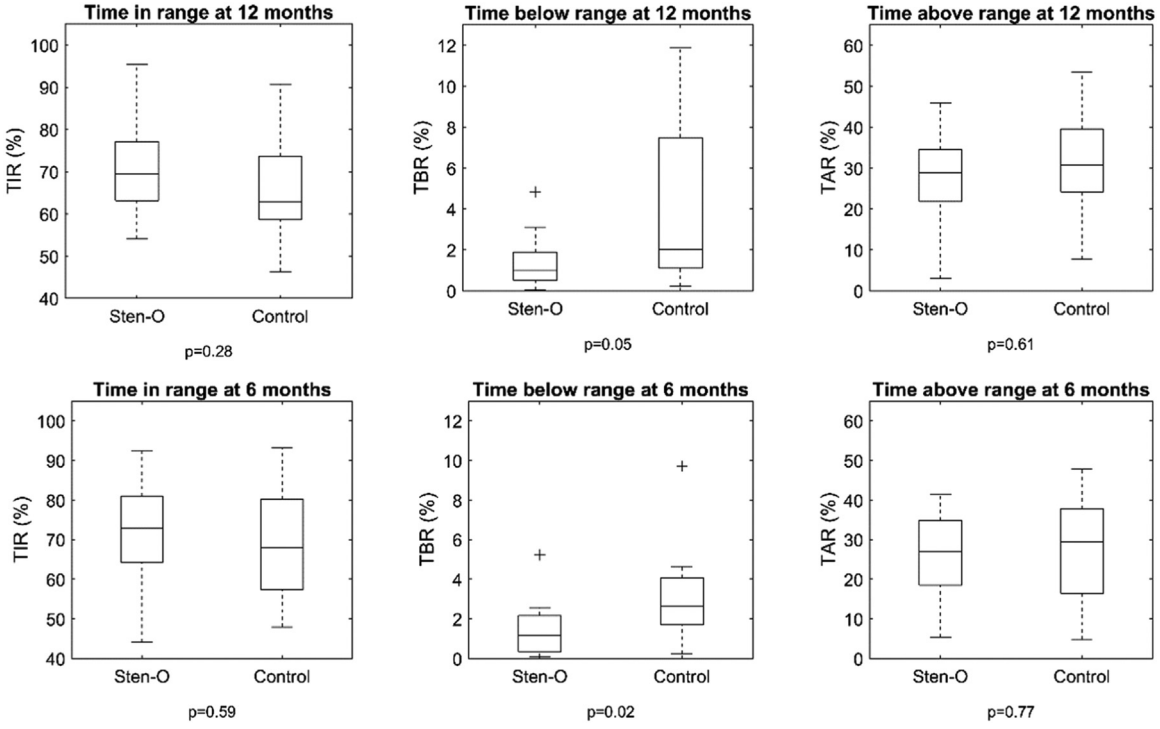

Fig. 4. Boxplot for the CGM measurements at 6 and 12 months from the secondary analysis on a subgroup of children and adolescents with a parental signed declaration of consent for analyzing the CGM patients.

findings of Wysocki et al. [36]. Furthermore, the present study showed that the decrease in the TBR in the control cohort between 6 months and 12 months postdiagnosis was greater than the decrease in the intervention cohort. These findings may indicate that the focus of the consultations with the children and adolescents in the control cohort was more focused on how to reduce the TBR and why it is important to reduce the TBR due to their higher TBR. As the intervention cohort spent less time on TBR, the focus might have been divided on other aspects of T1D self-management.

A series of studies demonstrated significant differences in clinical outcomes between patients who used gamification and those who improved T1D self-management [28–31,38], as measured by outcomes such as HbA1c. According to Land et al. and Greenwood et al., certain elements increase the positive effects afforded by gamification on clinical outcomes. These elements include feedback, patient-generated data, and two-way communication between the healthcare professional and the child or adolescent with T1D. Unfortunately, these elements are not integrated into the Sten-O Starter mHealth application. However, Land et al. specify how graphics, i.e., colourful images, real-life characters, and high definitions, are important elements in mHealth applications. In the Sten-O Starter, this element is integrated, as observed by the avatar named Sten-O, which appears in many different functionalities where he or she addresses children and adolescents.

Limitations

The process of obtaining consent from the children, adolescents, and their parents was difficult due to Danish and European legislation. Furthermore, due to the duration of the consent collection, several children and adolescents aged from one “consent group” to another, meaning that consent should be obtained from the adolescent as well as from both parents, which complicated and extended the process. Additionally, the sample size was minimized, as participants were excluded if one parent did not respond.

The sample size was further limited by the availability of CGM data, as several children and adolescents had significant data gaps in the first year postdiagnosis. These data gaps had a variety of causes, including but not limited to travel, sensor malfunction, and changes in the CGM provider. Additionally, not all children’s and adolescents’ CGM systems were synchronized to the clinic but were transferred via one-time reports. In these cases, the data were unretrievable without access to the children’s or adolescents’ login information on the platform.

During the Sten-O Starter project period in the North Region of Denmark, several projects were started or implemented concurrently. This might have had an impact on the outcome of the Sten-O Starter test among the children and adolescents. In the current study, it was not possible to adjust for these factors. Therefore, further studies are needed to investigate the impact of these factors.

Conclusions

In conclusion, a borderline significantly lower HbA1c was observed in the intervention cohort than in the control cohort at 12 months postdiagnosis. Furthermore, the TBR was significantly lower in the intervention cohort than in the control cohort at 6 months and 12 months postdiagnosis, which might indicate improved glycemic management among children and adolescents with T1D using the educational application.

Future work could include follow-ups with longer periods and larger groups of participants to investigate the differences in HbA1c.

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Declaration of competing interest

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CRediT authorship contribution statement

C. Bender: Writing – review & editing, Writing – original draft, Validation, Software, Resources, Project administration, Methodology, Formal analysis, Data curation. **M.H. Jensen:** Writing – review & editing. **S.B. Skindbjerg:** Writing – review & editing, Resources, Conceptualization. **A. Nielsen:** Writing – review & editing, Resources, Conceptualization. **C. Feldthaus:** Writing – review & editing, Resources. **S. Hangaard:** Writing – review & editing. **L.A. Hasselbalch:** Writing – review & editing, Resources, Conceptualization. **M. Madsen:** Writing – review & editing, Resources, Conceptualization. **O. Hejlesen:** Conceptualization. **S.L. Cichosz:** Writing – review & editing, Validation, Software, Resources, Project administration, Methodology, Formal analysis, Data curation, Conceptualization.

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.deman.2024.100200.

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