

ORIGINAL ARTICLE

Effect of an eHealth care programme on glycaemic control and empowerment among adolescents with type 1 diabetes mellitus: a quasi-experimental study

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Abstract

Background: Adolescents with type 1 diabetes mellitus (T1D) often face challenges in achieving optimal glycaemic control, which can lead to long-term complications. This study aimed to test the effect of an eHealth care programme on glycaemic control and empowerment among adolescents with T1D who exhibited poor glycaemic control.

Methods: This 1-year quasi-experimental study recruited 51 adolescents with T1D and suboptimal glycaemic control. Participants were allocated to an intervention group and a matched comparison group drawn from the National Diabetes Quality Register. Changes in glycaemic control metrics between the two groups as well as the empowerment scores within the intervention group were computed.

Results: The mean percent time above range (% TAR) decreased from 70.00 to 57.43% among the intervention group. A significant reduction in %TAR was observed in the intervention group compared to the comparison group ($P < 0.001$). However, no significant changes were found in other glycaemic control metrics between the two groups. The intervention group showed a significant improvement in the total Gothenburg Young Persons Empowerment Scale (GYPES) score, with the median score increasing from 60.67 [interquartile range (IQR) (59.00, 66.19)] at baseline to 63.65 [IQR (62.85, 64.12)] post-intervention ($P = 0.002$).

Conclusion: The eHealth care programme significantly reduced %TAR and improved empowerment scores among adolescents with T1D, indicating it could effectively support adolescents with poor glycaemic control. A randomised study is needed to confirm these findings and assess long-term effects.

Keywords: adolescent; glycaemic control; empowerment; eHealth; type 1 diabetes mellitus

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Diabetes mellitus (DM) is a major public health problem, and type 1 diabetes mellitus (T1D) is the most common chronic endocrine disease among children and adolescents.¹ Research indicates that glycaemic control among adolescents is suboptimal, and many adolescents with T1D exhibit poor control when compared to individuals of all age groups with T1D.² Adolescents in this critical stage of life struggle to achieve and maintain target glycaemic control due to their propensity for engaging in risky behaviours and the potential fatigue associated with intensive diabetes care.² Failure to empower such adolescents to handle their changed situation makes diabetes management more challenging and leading to diabetes-related complications.^{2,3}

eHealth is the application of information communication technology to support health and health-related

fields in providing healthcare services.⁴ eHealth has the potential to provide a better opportunity for adolescents to take responsibility for their own health. It helps DM patients in self-management activities like blood glucose monitoring, medication and early detection of DM-related complications.⁵

A continuous glucose monitoring (CGM) system is an eHealth technology that measures interstitial fluid glucose levels to deliver continuous numerical and graphical information.⁶ CGM technology enables individuals to share their blood glucose data with others, enhancing the support and complementing diabetes care.⁶ Currently, in Sweden, most adolescents with T1D use a CGM system for better health outcomes. However, the existing approach to managing DM through CGM is complex, with limited integration into the healthcare system and minimal direct

engagement from the diabetes care team. As a result, adhering to treatment and monitoring continues to present significant challenges.^{7,8}

Integrating eHealth into the clinical setting is anticipated to empower and improve adolescents' and their family's participation in glycaemic control.⁵ Studies have shown that empowering adolescents could improve their critical thinking ability and enable them to make responsible decisions, which would facilitate the achievement of glycaemic control.³ Nevertheless, the integration of eHealth into clinical practice and the provision of individualised services are still challenging.⁹ eHealth interventions that support the improvement of glycaemic outcomes and empower adolescents with T1D by granting them better self-management, and guiding clinical practice are limited and inadequate.^{7,9} The aim of this study was to test the effect of a novel eHealth care programme on glycaemic control compared with usual care, and to investigate its effect on empowerment among adolescents with T1D at a university hospital in South Sweden.

Methods

This study follows the Medical Research Council (MRC) framework for complex interventions, which involves four stages: development, feasibility/piloting, evaluation and implementation.¹⁰ This study is in the feasibility/piloting stage, and the intervention builds on a previous study comparing hospital and home-based care for children newly diagnosed with T1D, who were followed for 2 years in a randomized controlled trial (RCT).¹¹ The earlier study found that whilst most children achieved good glycaemic control, some needed extended support, particularly during the vulnerable adolescent period. This intervention was developed to address the challenges faced by this age group.

Study design

A quasi-experimental study design was used to test the effect of the eHealth care programme on glycaemic control and empowerment among adolescents with T1D. The findings of this study were reported following the Transparent Reporting of Evaluations with Nonrandomized Designs (TREND) guideline.¹²

Setting

The study was conducted for a 1-year duration at Skåne University Hospital paediatrics diabetes clinic in South Sweden. Lund and Malmö Hospital paediatrics diabetes clinics were the two diabetes clinics of Skåne University Hospital in which participants were non-randomly assigned to the intervention group receiving the eHealth care programme. The comparison group was taken from the National Diabetes Quality Register who received the usual care.

eHealth care programme

The intervention involved providing additional support to adolescents with diabetes alongside their usual CGM care.¹³ A designated diabetes nurse acted as a CGM follower, monitoring blood glucose levels and offering advice using various communication methods (e.g. text messages, phone calls or video calls). During an initial visit, the adolescent and nurse collaboratively set glycaemic control goals and determined support needs and alarm thresholds for blood glucose levels. For the first 2 weeks, the nurse monitored the adolescent's CGM data during daytime hours (8 am–5 pm) on weekdays. This support period was repeated after 3 months. At 6 months, an evaluation was conducted to assess further support needs, with an option to repeat the 2-week support period a third time if necessary.^{11,13}

Usual CGM care

The comparison group included adolescents receiving standard CGM care. This care involved an initial visit with or without parents to introduce CGM, set up alarms and provide guidance with a diabetes nurse. A follow-up meeting or phone call occurred 2–3 weeks later to adjust the system if needed. Regular follow-up visits were scheduled every 3–4 months, with or without parents, where CGM data were reviewed and discussed with a multidisciplinary diabetes team. For adolescents with unsatisfactory glycaemic control (Haemoglobin A1c (HbA1c) > 57 mmol/mol), additional meetings with a diabetes nurse were held every 2–6 weeks until adequate control was achieved.^{13,14} During the COVID-19 pandemic, some visits were conducted virtually, especially for adolescents needing closer monitoring.

Sampling and sample size

This study recruited participants by announcing the intervention during clinic visits, posting on notice boards and providing age-appropriate information to adolescents and their parents/guardians. Eligibility screening was conducted, and an informed consent was obtained. Participants were non-randomly assigned to the intervention group, whilst a matched comparison group was selected from the National Diabetes Quality Register. HbA1c was the main outcome and will be presented in another publication. This article presents CGM metrics (percent time in target range [%TIR] and percent time below target range [%TBR]) and empowerment as a secondary outcome. Based on prior research,¹¹ with a mean HbA1c difference of 10 mmol/mol, a standard deviation of 12, 85% power, and a 5% significance level, a sample size of 26 participants per group was required.¹⁵ However, 51 adolescents meeting the inclusion criteria were included: 18 in the intervention group and 33 in the comparison group.

Inclusion criteria

Adolescents of 13–16 years old with T1D under follow-up at Skåne University Hospital, who had unsatisfactory glycaemic control ($\text{HbA1c} > 57 \text{ mmol/mol}$), agreed to use the CGM system (Dexcom G6 and flash glucose monitoring system) and continue using the system during the study period and understood and spoke the Swedish language were included in this study. Adolescents with documented comorbidities were excluded from the study.

Data collection

Data collection was conducted from September 2019 to December 2020. The adolescents' background information comprising sociodemographic variables such as sex and age was collected at baseline. The adolescents' glycaemic control metrics data were collected at baseline and post-intervention from the CGM system during the 1-year follow-up period from both the intervention group and the comparison group. CGM sensor data were downloaded from the cloud platform, and data on glycaemic control were extracted from the Ambulatory Glucose Profile (AGP) CGM report, which includes %TIR (70–180 mg/dL), %TBR (<70 mg/dL), %TAR (>180 mg/dL), mean, SD and sensor usage.¹⁶ A self-administered questionnaire was used to collect information on adolescent empowerment from the intervention group only, by using the Gothenburg Young Persons Empowerment Scale (GYPES) at baseline, 6 and 12 months during the 1-year study period.¹⁷ The GYPES questionnaire was sent to the adolescents through email. They filled it out at home, and the coded GYPES dataset was documented in a secure electronic data capture tool, the REDCap (Research Electronic Data Capture) platform.¹⁸

Gothenburg Young Persons Empowerment Scale is a self-administered questionnaire used to measure the level of empowerment in young persons with DM.¹⁷ It is a 15-item instrument, answered on a 5-point Likert scale: strongly disagree, disagree, neither agree nor disagree, agree and strongly agree. The instrument covers five dimensions of youth empowerment: knowledge and understanding, personal control, identity, decision-making and enabling others. Each dimension consists of three items. The instrument allows the calculation of both a total score (empowerment level) and a subscale score for each dimension. The overall score is calculated by adding the item scores and ranges from 15 to 75 points, with a higher score indicating a greater level of empowerment. GYPES is a widely used, well-validated instrument; the psychometric property of the instrument has been tested and was found to have acceptable internal consistency reliability with a Cronbach's alpha of 0.858 for the overall scale. Factorial validity was evaluated through confirmatory factor analyses (CFAs), as reported in the STEPSTONES project, and an adequate model fit was obtained with factor loadings ranging from 0.385 to 0.941.^{17,19}

Data analysis

A statistical analysis was performed using IBM SPSS Statistics, Version 27.0. To describe the general characteristics of the participants (i.e. age, sex and DM duration), descriptive statistics were carried out using percentage, mean and \pm SD. The normality of the variables was checked using the Shapiro-Wilk test and visual examination of the histogram. Normally distributed continuous variables were analysed using a general linear model (a mixed-design analysis of variance, ANOVA). Non-normally distributed continuous variables were analysed using non-parametric tests (i.e. Friedman test) and were presented as median and interquartile range (IQR). We used %TIR, %TBR and %TAR as the main parameters of the adequacy of glycaemic control. The coefficient of variation (%CV) was chosen as a measure of glycaemic variability. Sensor usage >70% was considered to be adequate for glycaemic control data analysis. Data were interpreted according to the recommendation from the international consensus on time in range.¹⁶ The expectation maximization-imputation technique was used to impute missing values of the GYPES questionnaire. This imputation technique is a two-step process, which produces a deterministic result and is preferred to handle missed data.²⁰ *P* values of <0.05 were considered statistically significant.

Ethical consideration

Ethical approval for the study was obtained from the Swedish Ethical Review Authority (dnr 2019-00508), and ethical principles for medical research involving human subjects were followed. The study's purpose was clearly explained to participants and their parents/guardians, using age-appropriate information for adolescents. Participation was voluntary, and participants were informed that they could withdraw at any time without affecting their routine services. The risks and benefits were outlined, and confidentiality of the data was assured. A written informed consent was obtained from both participants and their parents/guardians. Data were securely stored, accessible only to the researchers, and personal identifiers were not linked to the data, reports or publications.

Results

The mean age of the study participants was 14.96 ± 1.1 SD years, and 58.8% ($n = 30$) were females. About 43% ($n = 22$) of the adolescents had 5–10 years of diabetes duration (Table 1). During the intervention period, every participant in the intervention group received both phone calls and text messages. Furthermore, 44.4% (8) of the participants also received reminders, whilst 16.7% (3) received an additional video call.

No significant differences were observed in the variables (Age, %TIR, %TBR and %CV) at baseline between the intervention group and the comparison group ($P > 0.05$). However, a significant difference was observed in the baseline %TAR between the two groups: the intervention group had higher %TAR at baseline compared with the comparison group ($P < 0.001$). The participants' demographic characteristics and baseline clinical values are presented in Table 1.

CGM sensor usage was found to be $< 70\%$ in seven (13.7%) participants at baseline and post-intervention, and the data from those participants were excluded from the glycaemic control analysis; thus, the final glycaemic control analysis dataset included data from 44 participants (intervention group ($n = 16$) and comparison group ($n = 28$)). The participants used the sensor for a mean time of 92.34% during the 1-year study period.

The mean % TAR among the intervention group decreased from 70.00 ± 13.91 SD at baseline to 57.43 ± 19.31 SD post-intervention (Table 2). The mean % TAR among the comparison group ranged from 43.17 ± 7.80 SD to 43.64 ± 10.70 SD at baseline and post-intervention, respectively. A significant reduction in %TAR was observed in the intervention group compared with the comparison group ($P < 0.001$). The %TIR among the intervention group showed improvement during the 1-year study period, increasing from 26.87 ± 12.48 SD at baseline to 29.31 ± 12.76 SD post-intervention, whilst the

%TIR among the comparison group was 29.35 ± 10.68 and 29.50 ± 11.36 at baseline and post-intervention, respectively. Nevertheless, there was no significant difference in %TIR between the intervention group and the comparison group ($P = 0.660$). In addition, no significant changes were observed in the remaining CGM metrics between the two study groups. The participants' glycaemic control metrics results are summarised in Table 2.

The median GYPES score in the intervention group ($n = 18$) was 60.67 [IQR (59.00, 66.19)], 60.22 [IQR (57.23, 63.53)] and 63.65 [IQR (62.85, 64.12)] at baseline, 6 and 12 months, respectively. The total median GYPES values showed an increment from baseline to post-intervention. A significant change was observed in the total GYPES score over time ($P = 0.002$).

Discussion

The result of this study shows that the time spent in hyperglycaemia (%TAR) was significantly reduced in the intervention group. Furthermore, the intervention group empowerment score was significantly increased over time during the 1-year intervention period. However, other glycaemic control metrics did not differ significantly between the two study groups.

The adolescents with a high %TAR at baseline were those who benefitted most from this intervention. This finding could be due to the greater collaboration that took place in our intervention between the adolescent and a

Table 1. Participants' characteristics and baseline clinical values

Characteristics	Intervention group (eHealth care programme) $n = 18$	Comparison group (Usual care programme) $n = 33$	Total $n = 51$	P
Age (year) Mean (SD)	15.28 (0.89)	14.79 (1.21)	14.9 (1.13)	0.272
Sex				
Male, n (%)	7 (38.9)	14 (42.4)	21 (41.2)	
Female, n (%)	11 (61.1)	19 (57.6)	30 (58.8)	
DM duration, n (%)				
Less than 5 years	4 (22.2)	13 (39.4)	17 (33.3)	
5–10 years	9 (50.0)	13 (39.4)	22 (43.1)	
Greater than 10 years	5 (27.8)	7 (21.2)	12 (23.5)	
Sensor usage $< 70\%$, n (%)	2 (11.1)	5 (15.15)	7 (13.7)	
Baseline HbA1C (mmol/mol) Mean (SD)	69 (8.76)	67 (9.44)		0.318
Baseline % TAR Mean (SD)	69.55 (13.24)	42.93 (7.51)		< 0.001
Baseline % TIR Mean (SD)	26.83 (11.73)	29.12 (10.52)		0.480
Baseline %TBR Median (IQR)	2.00 (1.00, 4.75)	2.00 (1.00, 4.50)		0.788
Baseline %CV Mean (SD)	39.73 (7.29)	40.06 (6.12)		0.867
Baseline % sensor usage Median (IQR)	93.50 (86.50, 98.25)	93.00 (81.00, 96.00)		0.244
Baseline total GYPES Score (median IQR)				
Male	60.67 (60.67, 60.67)			
Female	62.61 (51.85, 67.00)			0.724

%TAR, percent time above range; IQR, interquartile range; DM, Diabetes mellitus; %TBR, percent time below target range; SD, standard deviation.

Table 2. Participants' glycaemic control values before and after the intervention

Parameters	Intervention group (N = 16)		Comparison group (N = 28)		P
	Pre-intervention	Post-intervention	Pre-intervention	Post-intervention	
Time above range (%TAR) mean (SD)	70.00 (13.91)	57.43 (19.31)	43.17 (7.80)	43.64 (10.70)	< 0.001
Time in target range (%TIR) mean (SD)	26.87 (12.48)	29.31 (12.76)	29.35 (10.68)	29.50 (11.36)	0.660
Coefficient of variation (% CV) mean (SD)	38.90 (6.81)	39.87 (4.62)	39.60 (6.36)	39.19 (7.00)	0.996
Pre-intervention time below range (%TBR), median (IQR)	2.00 (1.00, 3.75)		2.00 (1.00, 3.75)		0.911
Post-intervention time below range (%TBR), median (IQR)	1.50 (1.00, 4.00)		2.00 (0.25, 3.00)		0.576
Pre-intervention sensor use (%) median (IQR)	95.00 (88.25, 98.75)		93.00 (84.50, 96.00)		0.212
Post-intervention sensor use (%) median (IQR)	96.00 (86.25, 98.75)		96.50 (91.25, 98.00)		1.000

%TAR, percent time above range; IQR, interquartile range; %TBR, percent time below target range; SD, standard deviation.

diabetes nurse to achieve the planned goal since adolescents with unsatisfactory glycaemic control required frequent follow-up and greater collaboration with a diabetes nurse.^{13,14} The higher %TAR at the time of enrolment and the use of real-time blood glucose information may also have contributed to the observed outcome. This has also been observed in other studies done in Greece and Australia, which showed a significant reduction in TAR among the intervention group having unsatisfactory glycaemic control at baseline. In both studies, participants with high TAR at baseline benefitted most from the intervention.^{21,22}

The observed lowering of TAR is clinically important, as it could reduce hyperglycaemia-associated complications and healthcare costs related to hyperglycaemia.^{23,24} This is significant because hyperglycaemia increases the development of micro and macrovascular complications, which lead to long-term diabetes complications and patient vulnerability to various infectious diseases.^{23,24} Furthermore, studies have revealed that hyperglycaemia is the most significant factor in neurodevelopmental problems among children and adolescents with T1D as well as being the main risk factor for neurocognitive complications.^{25,26} Hence, our intervention has the potential to provide support in preventing both short-term and long-term complications in adolescents who have suboptimal glycaemic control.

Our results show no significant differences in other glycaemic control metrics between the two study groups. Similar to our findings, a study conducted in Spain on the impact of telemedicine on glycaemic control showed that telemedicine intervention had no significant difference as compared with face-to-face visits.²⁷ In contrast to our findings, a study done by Alharthi et al.²⁸ among adults with T1D revealed that telemedicine visits resulted in a significant improvement in all glycaemic control metrics, as compared with usual care.

Our study incorporated an innovative eHealth intervention featuring real-time CGM (rt-CGM) data to provide support tailored to adolescents' specific needs. In this study, our findings showed the significant effect of our intervention on adolescent empowerment. This might be a result of the involvement of a diabetes nurse in our intervention, who understood the developmental changes of the adolescents, explored their emotions and boosted their motivation to address their difficulties and engage in self-management. This has been supported by a study done by James,²⁹ which showed that due to their expertise and experience, involving diabetic nurses in the care empowered patients to manage their own health.

Our intervention promotes adolescents' involvement and active participation in the care, which may have contributed to the observed improvement in empowerment scores. A study conducted by Anderson and Funnell³⁰ showed that individuals' active participation in their diabetes care enabled them to be more autonomous and make informed decisions.

Moreover, the use of technology in our study may have contributed to the observed improvement in the adolescents' empowerment scores. This could be because technology-based interventions increase the accessibility and availability of evidence-based services and support the self-management behaviours of adolescents, which has been reported in a study done by Blake et al.³¹ In contrast, other study has indicated that technology-based intervention had no significant effect on participants' empowerment. Studies carried out by Kirwan et al.²² revealed that technology-based text-message intervention had no significant effect on participants' empowerment scores. Some of the above-mentioned interventions were rooted in theoretical frameworks and were administered through text messages or online follow-up sessions. Variations in the intervention duration and the demographics of the study participants may account for the differences observed in the outcomes of these interventions.

Strength of the study

In Sweden, healthcare is accessible to all adolescents and is (almost) free; thus, the intervention was accessible to all adolescents meeting the inclusion criteria, regardless of sex or ethnicity. The intervention utilised the CGM cloud platform for real-time remote access to blood glucose values. This study included only adolescents using specific CGM systems (Dexcom G6 and flash glucose monitoring) to ensure consistency and avoid discrepancies between sensory types, following strict inclusion criteria. Individualised care was provided, tailoring the intervention to each participant's health condition. Despite these strengths, including comprehensive inclusion criteria and a long study duration, limitations were noted. These included a small sample size, potentially reducing the study's statistical power and the lack of random group assignment. The findings serve as a baseline for future eHealth interventions.

Conclusion

Our study showed that the eHealth care programme significantly reduced %TAR and improved empowerment scores among adolescents with T1D, indicating that the intervention could be useful and effective in supporting adolescents with unsatisfactory glycaemic control. A randomised study with large sample size is needed to confirm the observed and long-term effect of our intervention.

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Conflict of interests and funding

This work was funded by Lions forskningsfond Skåne. The authors declare that they have no conflicts of interest to disclose.

Availability of data and materials

The datasets used for the current study are available from the corresponding author upon request.

Authors contributions

HA performed the statistical analysis, drafted, wrote and edited the manuscript. IT developed the study, designed, coordinated the study and review the manuscript. MS designed, coordinated, assisted in the statistical analysis and reviewed the manuscript. SC assisted in drafting the manuscript. CA performed intervention implementation, data collection and assisted in drafting the manuscript.

Ethical approval and consent to participate

This study was performed in accordance with ethical principles for medical research involving human subjects and

approved by Swedish Ethical Review Authority (dnr 2019-00508). All study participants and their parents/guardians provided informed consent. This study followed the TREND guideline.

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