Original Article

Evaluating the usability of Diactive-1: mHealth for personalized exercise and education in children and adolescents with type 1 diabetes

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Background: Managing physical activity alongside glucose levels is challenging for children and adolescents with type 1 diabetes mellitus (T1DM). This study aimed to evaluate the usability of the Diactive-1 app, which was designed to support muscle-strengthening training in children and adolescents with T1DM in accordance with guidelines from the International Society for Pediatric and Adolescent Diabetes (ISPAD) and the American Diabetes Association (ADA).

Methods: Twenty-seven patients aged 8–18 years with T1DM were randomly selected. Recruitment was conducted through the Pediatric Endocrinology Unit of the University Hospital of Navarra (Spain). All participants were enrolled in a randomized controlled trial and used the Diactive-1 app during the intervention. The study lasted 24 weeks, during which the app provided personalized muscle-strengthening exercise sessions, glucose monitoring, and motivational features such as gamification. Usability of the app was assessed using the User Version of the Mobile Application Rating Scale (uMARS).

Results: The Diactive-1 app demonstrated high usability, with an overall quality mean score of 4.33 [standard deviation (SD) =0.36] out of 5.00. uMARS objective domains ratings were: functionality [4.52 (SD =0.40)], aesthetics [4.43 (SD =0.45)], engagement [4.07 (SD =0.51)], information quality [4.29 (SD =0.75)], and subjective quality score was 3.94 (SD =0.61). Usability scores showed no meaningful variation across patient demographics, including sex, age, glycated hemoglobin, engagement in muscle-strengthening activities, and fear of hypoglycemia, suggesting consistent app performance among different user groups.

Conclusions: The Diactive-1 app is a promising tool for integrating muscle-strengthening training and educating patients about safe physical exercise into the management of T1DM in children and adolescents. Its high usability and positive user feedback underscore its potential as an effective supportive strategy for managing the disease in this population. Further refinement of personalization features may enhance its effectiveness.

Keywords: Mobile health; strength training; satisfaction; pediatric endocrinology

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Introduction

Type 1 diabetes mellitus (T1DM) affects to approximately 1.2 million individuals under 20 globally, as reported by the International Diabetes Federation (IDF) (1). Poor glycemic control can lead to chronic health conditions, encompassing cognitive decline (2), cardiovascular conditions (3), neuropathy (4), retinal complications (5), chronic renal disease (6), foot lesions (7), and skin dryness (8). Despite advances in self-care technology, there remains a critical need for new, accessible, and cost-effective strategies to enhance glycemic control (9).

According to the American Diabetes Association (ADA), people under the age of 20 should participate in 60 minutes of aerobic moderate to vigorous physical activity (MVPA) per day, combined with muscle-strengthening activities at least 3 days a week (10). Regular physical activity offers numerous physical and psychological benefits for young individuals with T1DM (11), including improved cardiovascular health, effective weight management, and enhanced mental well-being (12-14). Specifically, muscle-strengthening training has been shown to moderately reduce glycated hemoglobin A1c (HbA1c) levels and daily insulin requirements in young individuals with T1DM (15,16). However, barriers such as fear of hypoglycemia and lack of awareness often discourage participation in physical activities, especially muscle-strengthening training (17). This highlights the urgent need for innovative solutions to support hypoglycemia management and encourage exercise adherence.

Recent advancements in fitness apps have shown promise in increasing physical activity levels and improving fitness outcomes (18,19). A meta-analysis by Singh *et al.* (20) demonstrated that e-Health and m-Health interventions significantly enhance physical health metrics, including a 1,329-step increase per day, a 55.1-minute increase in MVPA per week, and a reduction of 426.3 minutes per week in sedentary behavior. These digital tools also led to increased fruit and vegetable intake and a 1.89 kg reduction in body weight, highlighting their effectiveness in promoting healthier lifestyles.

In the context of T1DM, mobile apps have shown benefits in glycemic control (21), HbA1c reduction (22), and quality of life improvements (23). A previous study evaluated apps aimed at managing physical activity in adults with this disease (24), recommending enhancements such as better compatibility with Android and iOS devices, broader connectivity with diabetes management tools like continuous glucose monitors and wearables, and the use of gamification and rewards to increase adherence, particularly among younger users. They also emphasized the need for interactive clinical advice on insulin adjustments and the use of evidence-based resources, such as the International Society for Pediatric and Adolescent Diabetes (ISPAD) Clinical Practice Consensus Guidelines on exercise in children and adolescents (25). Furthermore, they called for rigorous evaluation of app usability, safety, and efficacy across diverse T1DM populations.

In light of these recommendations, our Diactive-1

Highlight box

Key findings

- The Diactive-1 app showed high usability (4.33/5), especially in functionality (4.52) and aesthetics (4.43). Usability scores showed no meaningful variation across patient demographics, suggesting consistent app performance among different user groups.

What is known and what is new?

- Managing physical activity and glucose levels is challenging for children and adolescents with type 1 diabetes. Muscle-strengthening exercises are recommended by key diabetes organizations to improve overall health and glucose control.
- This study introduces the Diactive-1 app, a novel tool designed to support type 1 diabetes management. The app is characterized by its high usability and broad applicability, addressing the specific needs of children and adolescents managing their condition.

What is the implication, and what should change now?

- The high usability and positive reception of the Diactive-1 app indicate that it could be integrated into clinical practice as a supportive tool for managing type 1 diabetes in children and adolescents. It can help improve adherence to exercise guidelines, while reducing concerns around glucose level fluctuations during and after physical activity.
- The app's personalization features need refinement to better tailor the experience to each user's unique needs. Further development and wider adoption of similar digital tools could be encouraged, integrating patient education and safe exercise practices into the daily management of type 1 diabetes.

study integrates these insights into the development of a mobile app designed for the comprehensive management of muscle-strengthening exercises in children and adolescents with T1DM (26). This app adheres to ISPAD and ADA guidelines, and we aimed to evaluate its usability within this population. Therefore, the objectives of this study were to assess the usability of the Diactive-1 app, and to examine whether there were any differences between the use of the mobile app and various metabolic and sociodemographic characteristics, including sex, age, HbA1c levels, engagement in muscle-strengthening activities, and fear of hypoglycemia in children and adolescents with T1DM.

Methods

Study design

This study is part of a larger research project that includes a randomized, controlled, single-blind, parallel-group trial with a 1:1 allocation ratio, conducted between October 2023 and September 2024 in Pamplona, Spain. The trial is registered in the Clinical Trials Registry (NCT06048757). The study's design and methodology have been thoroughly detailed in the published protocol (26).

Ethics approval

Ethical approval for this study was obtained from the University Hospital of Navarra Research Board (No. PI_2020/140). Written consent was provided by the parents or legal guardians of minor participants, and assent forms were signed by children and adolescents to confirm their voluntary participation. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013) (27).

Participant recruitment and eligibility criteria

The study initially involved 29 participants; however, only 27 were analyzed as two subjects did not complete the intervention. Boys and girls participants aged 8 to 18 years, all diagnosed with T1DM, were enrolled through the Pediatric Endocrinology Unit at the University Hospital of Navarra in Pamplona, Spain, and were randomly assigned to the intervention group. To be eligible for the study, participants had to meet the following criteria: willingness to take part in the intervention, fluency in Spanish, and a diagnosis made at least 6 months prior to the study. Exclusion criteria encompassed any comorbidity that restricted their ability to engage in physical activity or insufficient proficiency in Spanish. Furthermore, participants were not included if they lacked internet access, did not possess a smartphone or tablet, or if their parents or guardians were unable to provide one.

Intervention

The intervention group conducted a 24-week intervention using the Diactive-1 mHealth app, aimed at improving insulin dose requirements, glycemic control, adherence to muscle-strengthening training, and physical activity participation in children and adolescents with T1DM (10,28,29). Compatible with iOS and Android, the Diactive-1 app offered personalized muscle-strengthening exercise sessions based on muscular fitness levels, glucose levels, and trends, with integration available for Continuous Glucose Monitoring (CGM) Freestyle 2 devices or manual input for other CGM systems. The app provided educational glucose monitoring and guidance, advising users when exercise was inadvisable, such as when glucose levels exceeded 330 mg/dL. A gamification system encouraged participation by rewarding users with experience points for completed sessions and promoting adherence through a ranking system. Interventions could be performed in various locations and were tailored to users' fitness levels. The app included equipment-based, equipment-free, and partner-assisted training, guided by a 3D avatar and voice instructions. Sessions lasted 13–33 minutes, with a progression in exercise intensity and type based on user progress and fitness level. Aerobic exercise was substituted for muscle-strengthening training if glucose levels were unsafe for the latter (10,28,29).

Outcomes

Usability

Usability, based on the International Standards Organization's (ISO) definition of usability, refers to how well a mobile app allows specific users to achieve particular objectives effectively, efficiently, and with satisfaction within a given context (30).

To assess the usability of the Diactive-1, the Spanish adaptation of the User Version of the Mobile Application Rating Scale (uMARS) was employed (31), a tool designed to evaluate the performance and quality of mHealth apps. It includes 20 items grouped into four objective domains—

Table 1 Baseline participant characteristics from the Diactive-1 study intervention group

Variables	Value (n=27)
Age, years	13.15 (2.43)
Girls	13 (48.1)
Children <13 years old	17 (63.0)
Medtronic insulin pump	10 (37.0)
FreeStyle Libre 2	17 (63.0)
Duration of diabetes, years	8.72 (3.42)
Adherence to muscle-strengthening recommendations*	3 (11.1)
Glycated hemoglobin, %	7.59 (1.01)
Healthy glycated hemoglobin#	8 (29.7)
Fear of hypoglycemia prevents PA	6 (22.2)
Lack of diabetes information to perform PA	9 (33.3)
Mean sessions per week	3.13 (1.40)

Data are shown as mean (standard deviation) or n (%). *, at least three sessions per week of muscle-strengthening training; #, glycated hemoglobin <7%. PA, physical activity.

engagement, functionality, aesthetics, and information quality—and one subjective domain. Participants rated each item on a 5-point scale, with higher scores indicating better quality. Additionally, a "not applicable" option was provided for items that could not be evaluated.

Following the original guidelines provided by the scale's authors, two separate scores were calculated: the objective quality score, which is composed of the four objective subscales (engagement, functionality, aesthetics, and information quality), and the subjective quality score, which corresponds to the subjective subscale. Questions marked as not applicable were omitted from the final score calculation.

General overview

Information on self-reported variables was obtained using a questionnaire filled out by the parent(s) or guardian(s) of the participants. The questionnaire collected details about various aspects, including the participant's school, gender, age, place of birth, racial/ethnic background, and the primary language spoken at home.

To assess participants' engagement in resistance-training activities, they were asked the following question: "In the past 7 days, how many days did you perform exercises to enhance or tone your muscles, such as push-ups, sit-ups, or weightlifting?" Answers were recorded on a scale from 0 to 7 days.

We assessed fear of hypoglycemia as a specific barrier to physical activity using the following question: "Does fear of hypoglycemia, due to the loss of glycemic control related to physical activity, keep you from engaging in this activity?" Possible answers were "yes", "no", and "sometimes". For the purposes of this analysis, "yes" and "sometimes" were grouped together as barriers to physical activity.

Finally, to evaluate fear of hypoglycemia as a result of insufficient information on managing physical activity in diabetes, we also asked patients: "Do you feel that you need more information on how to manage your diabetes (diet and insulin) in order to engage in physical activity?" Possible answers were "yes" and "no".

Statistical analysis

An analysis using descriptive statistics was performed to summarize participant characteristics and the information derived from the uMARS evaluations. Frequencies served to describe categorical variables, while continuous variables were summarized using measures of central tendency and dispersion. A Pearson bivariate correlation analysis was conducted to evaluate potential associations between the sample characteristics' mean scores and the global app quality mean score. Additionally, a *t*-test was employed to compare the mean scores of categorical variables with the global quality mean score.

All statistical analyses of quantitative data were carried out using SPSS (version 28; IBM Corp., Armonk, NY, USA) for Windows, with the threshold for statistical significance set at $P \leq 0.05$.

Results

The study involved 27 participants [mean age 13.15 years, standard deviation (SD) =2.43], with 48.1% being girls. Most (63.0%) used the FreeStyle Libre 2 system, and the average diabetes duration was 8.72 years (SD =3.42 years). Twenty-two percent of participants reported fear of hypoglycemia, and 33.3% reported a lack of diabetes-related information as barriers to physical activity. On average, participants used the Diactive-1 app 3.13 times per week (*Table 1*).

The results from the three sections of the uMARS questionnaire are summarized in *Tables 2,3*, providing detailed insights into each subdomain. The uMARS evaluation results showed that the Diactive-1 app had an

Table 2 Results of the validated uMARS domains according to the Diactive-1 app study

Domain	Mean (SD)	Range (Min–Max)
App quality mean score	4.33 (0.36)	3.58–5.00
Engagement mean score	4.07 (0.51)	3.00–5.00
Functionality mean score	4.52 (0.40)	3.50–5.00
Aesthetics mean score	4.43 (0.45)	3.67–5.00
Information mean score	4.29 (0.75)	1.25–5.00
App subjective mean score	3.94 (0.61)	2.75–5.00
App perceived impact	4.17 (0.56)	2.67–5.00

uMARS, the User Version of the Mobile Application Rating Scale; Max, maximum; Min, minimum; SD, standard deviation.

overall quality mean score of 4.33 (SD =0.36) from a total score of 5. In terms of engagement, the mean score was 4.07 (SD =0.51). The app's functionality received the highest ratings, with an overall average of 4.52 (SD =0.40). The aesthetics domain scored on average 4.43 (SD =0.45). The information provided by the mobile app had an overall average of 4.29 (SD =0.75). The subjective quality of the mobile app received an overall average of 3.94 (SD =0.61). Finally, the perceived impact of the mobile app had an overall average of 4.17 (SD =0.56) (*Table 2*). The overall quality score of the app represents the combined average of the four main uMARS domains: engagement, functionality, aesthetics, and information quality. Each of these domains is further broken down into 16 distinct subdomains. Measured SD vary from 0.50 to 0.75, indicating moderate dispersion of the data.

Among the subdomains, customization received the lowest rating, with an overall average of 3.58 (SD =1.10), which evaluates the presence of essential settings and preferences for features such as audio options, information displays, and notification features. Conversely, the subdomain assessing source credibility received the highest score, with an overall average of 4.81 (SD =0.40), standing out among all evaluated domains. On the subjective scale, the mobile app achieved an overall average of 3.94 (SD =0.61) from a total score of 5. Results indicate that users are not particularly enthusiastic about paying for the app (mean =3.00, SD =1.27). However, the likelihood of recommending the app scored very high (mean =4.46, SD

Table 3 Results of each validated uMARS subscale domain according to the Diactive-1 app study

Domain	Mean (SD)	Range (Min–Max)
Engagement mean score		
Entertainment	3.96 (0.65)	3.00–5.00
Interest	4.23 (0.82)	2.00–5.00
Customization	3.58 (1.10)	1.00–5.00
Interactivity	3.85 (0.78)	3.00–5.00
Target group	4.77 (0.43)	4.00–5.00
Functionality mean score		
Performance	4.27 (0.79)	3.00–5.00
Ease of use	4.77 (0.43)	4.00–5.00
Navigation	4.50 (0.51)	4.00–5.00
Gestural design	4.54 (0.65)	3.00–5.00
Aesthetics mean score		
Layout	4.58 (0.64)	3.00–5.00
Graphics	4.50 (0.58)	3.00–5.00
Visual appeal	4.23 (0.64)	3.00–5.00
Information mean score		
Quality of information	4.04 (1.04)	0.00–5.00
Quantity of information	3.88 (1.07)	0.00–5.00
Visual information	4.46 (1.10)	0.00–5.00
Credibility of source	4.81 (0.40)	4.00–5.00
Subjective items score		
Would you recommend?	4.46 (0.76)	3.00–5.00
How many times?	4.35 (0.69)	3.00–5.00
Would you pay?	3.00 (1.27)	1.00–5.00
Overall (star) rating	3.96 (0.72)	3.00–5.00
App perceived impact		
Awareness	4.35 (0.75)	2.00–5.00
Knowledge	4.12 (0.77)	3.00–5.00
Attitudes	4.19 (0.85)	2.00–5.00
Intention to change	4.27 (0.67)	3.00–5.00
Help seeking	3.88 (0.91)	2.00–5.00
Behavioral change	4.27 (0.68)	3.00–5.00

uMARS, the User Version of the Mobile Application Rating Scale; Max, maximum; Min, minimum; SD, standard deviation.

=0.76). In the "How Many Times" subdomain, the average rating was 4.35 (SD =0.69), suggesting that participants expect to use the app frequently in the future. The overall rating provided by participants was 3.96 (SD =0.72), closely aligning with the quality mean score of 4.33 (SD =0.36). Lastly, the perceived impact score, including awareness and intention to change, received favorable ratings, with overall average of 4.35 (SD =0.75) and 4.27 (SD =0.67) from a total score of 5, respectively. *Table 3* provides an in-depth summary of particular subdomain findings, while *Figure 1* illustrates the performance across all objective domains using a radar chart.

Finally, the association between the mean global app quality score on the uMARS and different patient characteristics is shown in *Table 4*. Overall, the analysis did not reveal any significant relationships, as reflected in the P values provided in the table.

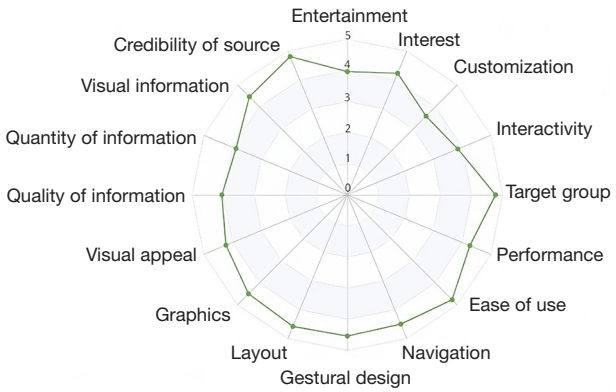

Figure 1 Radar chart illustrating the scores for each subdomain of the app's objective quality, based on uMARS. uMARS, the User Version of the Mobile Application Rating Scale.

Discussion

Principal results

The primary aim was to evaluate the usability of the Diactive-1 app, and to gather user feedback for improving the experience ahead of a larger randomized clinical trial, using the uMARS questionnaire. Overall, our findings revealed that Diactive-1 app was highly functional and well-received, with strong user satisfaction.

One of the most significant findings of this study is the absence of associations or differences among the variables and the mobile app's overall quality mean score. This suggests that the mobile app could be feasibly distributed to children and adolescents with T1DM, regardless of age, sex, glycemic control, or other demographic factors, without the need for prior customization. This is consistent with previous research that underscores the importance of integrating innovative technologies into healthcare and developing sustainable strategies that work in real-world contexts, which are crucial areas for future investigation (20,32). The Diactive-1 app, as a tool for prescribing muscle-strengthening training to children and adolescents with T1DM, shows promise regardless of the user's initial fitness level. Its high ease-of-use score of 4.77 out

Table 4 Association between the mean global app quality score on the uMARS and different patient characteristics

Variables	Test	Statistic	P
Continuous variables			
Age (years)	Pearson	0.325	0.11
Duration of diabetes (years)	Pearson	0.055	0.82
Categorical variables			
Sex (boys *vs*. girls)	*t*-value	–1.223	0.23
CGM (Medtronic insulin pump *vs*. FreeStyle Libre 2 use)	*t*-value	–0.736	0.47
Adherence to strength training recommendations (yes *vs*. no)	*t*-value	0.605	0.55
Healthy glycated hemoglobin (yes *vs*. no)	*t*-value	–0.592	0.56
Fear of hypoglycemia preventing physical activity (yes *vs*. no)	*t*-value	–1.136	0.27
Lack of diabetes information to perform physical activity (yes *vs*. no)	*t*-value	0.475	0.64

uMARS, the User Version of the Mobile Application Rating Scale; CGM, continuous glucose monitoring.

of 5.00, without requiring prior instruction, underscores its utility and accessibility. However, the app's potential could be further maximized by addressing the lower-rated aspects, particularly in the personalization subdomain. Enhancements such as enabling or disabling sounds, offering language options for English-speaking users, or adding other valuable features could make the app more adaptable to individual preferences. To our knowledge, the acT1ve app is the only other mHealth application specifically designed for T1DM that has undergone usability evaluation through the uMARS tool. In their pilot study, the acT1ve app achieved a total quality score of 4.3 (IQR, 4.2–4.6) and high functionality (4.8, IQR, 4.5–4.8), information (4.6, IQR, 4.5–4.8), and aesthetics (4.3, IQR, 4.0–4.7) scores (33). Similarly, the Diactive-1 app demonstrated a total quality mean score of 4.33, with high functionality (4.52) and esthetics (4.43). These findings highlight that Diactive-1 aligns with other high-quality mHealth solutions for T1DM, although personalization remains a common area for improvement, as indicated by the subjective quality scores of 3.94 (Diactive-1) and 4.0 (acT1ve).

Given these findings, the uMARS questionnaire was utilized to gain deeper insights into participants' opinions. This feedback is essential for implementing a co-design approach, where both researchers and users collaborate to identify and prioritize areas for improvement, similar to the methodology used in the acT1ve study (34). The acT1ve app provided personalized advice on carbohydrates and insulin, hypoglycemia treatment, pre- and post-exercise recommendations, and included an exercise advisor algorithm with 240 pathways developed by experts. This method of integrating user feedback to enhance functionality and effectiveness is mirrored in our approach (34).

Our Diactive-1 app has great potential in prescribing muscle-strengthening training for children and adolescents. Unlike other apps that have proven effective in improving HbA1c levels (22), controlling blood glucose (21), and enhancing quality of life (23), Diactive-1 stands out for its innovative approach. While many apps focus on monitoring or recording physical activity levels (35,36) or adjusting insulin dosages based on the recorded activity (37), Diactive-1 offers the unique advantage of prescribing muscle-strengthening training tailored to the user's handgrip strength level.

Moreover, this app not only focuses on the physical aspect but also educates users on the necessary guidelines to prevent hypoglycemia or hyperglycemia events. By following the clear recommendations established by the ADA and regarding physical activity for children and adolescents (10,28), Diactive-1 becomes a valuable tool that helps patients feel more confident during and after training, reducing the fear of potential complications and promoting greater empowerment in muscle-strengthening training practice. However, it is important to emphasize that this app is not a complete substitute for a physical exercise professional in T1DM and should only be used as a supportive tool.

Limitations and directions or future research

Although Diactive-1 offers many benefits, it also has some limitations. During the app's development, not all the initially planned features were included due to budget constraints. These features include the ability to activate and deactivate sounds, visual improvements, and greater avatar customization. Additionally, some features that could increase user engagement, such as integration with real-time CGM, activity trackers, and data-sharing options, were deprioritized for future modifications. Moreover, integrating with complementary technologies, such as music apps, may have enhanced its interactivity and is being explored for future updates of the mobile app.

Another significant limitation of the study was the lack of complementary interviews, which would have provided deeper insights into the users' qualitative perceptions. These interviews would have complemented the responses obtained with uMARS and helped to better understand why certain areas, such as customization, underperformed—likely due to the inability to modify these aspects in the options menu.

Finally, as uMARS scores do not directly measure the influence on behavioral adaptations or medical outcomes, further studies are required to evaluate the efficacy, safety, and clinical relevance of Diactive-1 in supporting diabetes self-care through muscle-strengthening training. The intervention has been completed, and we are now assessing its effectiveness (26).

Conclusions

Our study suggests that Diactive-1 app is a valuable tool with high overall quality and a positive perceived impact. However, improving personalization options and addressing barriers to physical activity could further enhance its effectiveness and acceptance among users.

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Footnote

Data Sharing Statement: Available at https://mhealth.amegroups.com/article/view/10.21037/mhealth-24-63/dss

Peer Review File: Available at https://mhealth.amegroups.com/article/view/10.21037/mhealth-24-63/prf

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Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://mhealth.amegroups.com/article/view/10.21037/mhealth-24-63/coif). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. Ethical approval for this study was obtained from the University Hospital of Navarra Research Board (No. PI_2020/140). Written consent was provided by the parents or legal guardians of minor participants, and assent forms were signed by children and adolescents to confirm their voluntary participation. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013).

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