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Mobile app improves treatment of functional constipation in children: a randomized single-blind study

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Abstract

Background Functional constipation is one of the most prevalent functional gastrointestinal disorders in the pediatric population, frequently resulting in quality of life impairment and elevated healthcare costs. Despite the availability of evidence-based treatment guidelines, adherence remains an essential challenge to achieving sustained therapeutic success.

Methods This randomized, single-blind per-protocol study assessed the efficacy of a mobile application compared to conventional printed educational materials in supporting the management of functional constipation in children aged 4–12 years. 100 patient–caregiver dyads were randomized into two arms: an intervention group using a mobile application and a control group receiving printed recommendations. Clinical outcomes were evaluated over a six-month follow-up using the Pediatric Quality of Life Inventory™ (PedsQL™) Gastrointestinal Symptoms Module.

Results There were 113 complete questionnaires, 65 from adults and 48 from children. Participants in the intervention cohort demonstrated significantly greater improvements in symptom control (mean difference 21.4 vs. 12.3 points; $p=0.014$), particularly in the domains of constipation, abdominal pain, and bloating.

Conclusions The mobile application's interactive features, behavioral tracking tools, and integrated reward system appeared to enhance adherence and self-efficacy among users. Overall, the results support the potential utility of mobile health interventions as adjuncts to standard care in managing pediatric functional constipation. Trial Registration: ClinicalTrials.gov NCT07025135. Registered 17/06/2025 (trial start 05/02/2023).

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Keywords Constipation, Functional disorders, Adherence, Mobile app

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Background

Functional constipation is highly prevalent among children, being one of the most common functional gastrointestinal disorders. When diagnosed using the Rome IV criteria, its global prevalence is estimated at 14.4% (95% CI: 11.2–17.6) [1, 2]. Constipation is characterized by infrequent bowel movements, passing hard and/or large stools, painful defecation, fecal incontinence, and is often accompanied by abdominal pain [3]. The clinical diagnosis is based on Rome IV criteria [4]. The condition lacks a universally accepted definition, making history-taking and physical examination crucial for diagnosis [5]. Its multifactorial pathogenesis affects individuals worldwide and contributes to significant quality of life impairment and increased healthcare costs.

Management of constipation involves a combination of approaches, including pharmacological treatment (macrogols as first-line treatment) and non-pharmacological interventions including dietary changes, increased fluid intake, and regular physical activity [6]. However, achieving consistent long-term improvement often requires sustained lifestyle modifications, which can be challenging for both children and their families to maintain.

A common problem in the treatment of constipation is poor adherence to recommendations and too short duration of their implementation [7, 8]. That is why, despite well-established treatment guidelines, this condition remains a significant issue. Many caregivers prefer immediate but temporary solutions, such as administering laxatives for a short period of time, while neglecting necessary long-term lifestyle changes. The growing incidence of childhood obesity further exacerbates constipation by impacting gut function, making it a growing public health problem [9]. This highlights the need for sustained behavioral interventions alongside clinical treatment and broader public health efforts.

Traditional methods of providing lifestyle advice typically rely on oral recommendations or printed materials, which may not be engaging or interactive enough to ensure adherence to these recommendations. Given the widespread use of smartphones and mobile technology, mobile apps have the potential to serve as a more interactive tool to support behavior change and improve treatment outcomes.

This study aims to evaluate the effectiveness of using a mobile app to support the treatment of functional constipation in children, comparing it to the standard approach of printed recommendations. By examining whether a mobile app can provide a more effective, engaging, and user-friendly way to encourage adherence to lifestyle changes, this research hopes to identify better strategies for managing pediatric functional constipation and improving patients' quality of life.

Methods

Participants

One hundred patient-caregiver dyads with newly identified or inadequately treated (i.e. not treated with macrogols as first choice; only treated by diet; with excessive amount of fiber; enemas only) functional constipation aged 4–18 years old were recruited and randomized using block randomization (five blocks of 20 dyads each) to ensure balanced allocation between study arms. Patients presenting to the hospital or outpatient clinic with constipation who required re-education and dose adjustment were considered eligible for recruitment. Randomization was performed by online random sequence generator. The patients (before allocation) and statistician were blinded through the study.

The inclusion criteria were: age 4–18, meeting Rome Criteria IV, and excluding organic causes of constipation. Prior to recruitment, each patient had been tested for most common causes of organic constipation (i.e. coeliac disease, vitamin D deficiency, hypercalcemia, hypothyroidism) [5]. The exclusion criteria involved any gastrointestinal and non-gastrointestinal (especially autism spectrum disorders) comorbidities and organic causes of constipation.

The intervention was based on the use of an interactive, children-friendly app, which ought to be used with parental advisory to achieve optimal treatment results.

The app consists of the following modules:

1. Illustrated guides for children and caregivers.
2. Bowel movement, water intake and medication trackers.
3. Reports panel.
4. Everyday games with points system.
5. Necessary information and setting panel.

Expected daily screen time using the app ranged from 5 to 30 min, depending on how regularly the guides were used. The app was intentionally designed to be simple and straightforward in order not to prolong screen time beyond what was necessary. The data which entered the system was linked to the provided email address and was kept on the university server (Medical University of Gdańsk), and the remaining data (basic personal and epidemiological information) was collected in a conventional form. The app was developed using Flutter technology and is available for both iOS and Android systems (as shown in Fig. 1).

Intervention scheme

After obtaining bioethical committee consent (NKBBN/920/2021; 14 December 2021), recruitment and randomization, half of the patients were given access to the mobile app; the other half (control group) used a

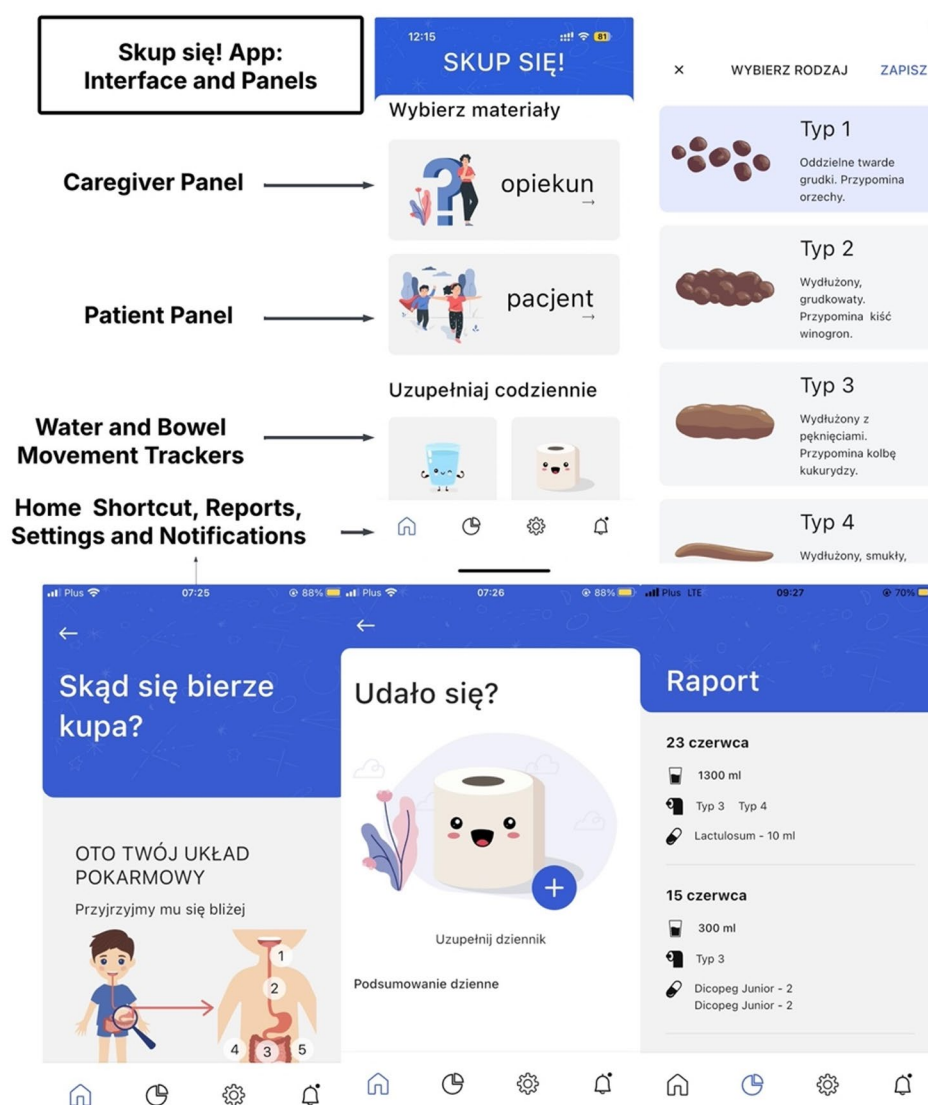


Fig. 1 Application interface

printed (booklet form) version of medical recommendations. For the control group, the content was thus the same, but the format of conveyed information varied. The guidance materials were based on ESPGHAN, NASPGHAN [5], WHO guidelines [10], created under supervision of specialists in the field: medical doctors, dietitians, and clinical psychologists. The materials contained two separate guides – one for caregivers (more concise) and one for children (written in simple language, enriched with colorful infographics). All patients and caregivers were encouraged to fill in 3 trackers (for bowel movement, water and medication intake) and to complete a daily jigsaw. They were given daily reminders and points for completing the tasks. The points could be swapped for a real-life award, after agreeing the form of the reward with the caregiver.

An important component of the application was the psychological support module, which provided guidance on coping with difficult emotions commonly associated with constipation, such as shame, embarrassment, or fear of defecation. The module included child-friendly advice on how to recognize and reframe negative thoughts, as well as exercises designed to promote self-confidence and reduce anxiety related to bowel symptoms. For caregivers, the content emphasized strategies to foster resilience in their children, including encouragement, positive reinforcement, and focusing on the child's strengths. In addition, the application incorporated practical dietary guidance, offering a simple handbook on foods recommended in constipation, explanations of the healthy eating pyramid and the 'plate model,' as well as information on the recommended amount of daily physical activity. This component included psychosocial and lifestyle

elements, focusing on the child's emotional well-being and the family's role in maintaining treatment adherence.

Children aged 5–18 completed the PedsQL™ Gastrointestinal Module [11] (child self-report). Caregivers completed the parent-proxy version for all participants aged 4–18; therefore, 4-year-olds contributed proxy reports only. Assessments were performed at qualification and at the check-up visits (30 ± 5 days)."

First visit took place onsite, in the outpatient clinic of a tertiary clinical pediatric gastroenterology ward of Medical University of Gdansk, Poland. The first visit lasted 30–60 min, depending on the patient's needs, and consisted of obtaining a written consent to participate in the study; anamnesis; physical examination; laboratory results analysis; program onboarding and installation of the app (intervention group; if possible, the app was installed on both parents and/or child's own mobile phone) or distributing the booklet materials (control group – one booklet for shared use). The patient-caregiver dyads were given a comprehensive guide regarding the treatment with a built-in reward system for patients. They were advised to track bowel movements, water, and macrogol intake. Subsequent visits were generally shorter, including advice about current problems, physical examination, and a check-up using the PedsQL Gastrointestinal Module. The intervals between visits were 30 ± 5 days and the follow-up was conducted 90 ± 5 days after the 4th visit. If required, the 3rd and 4th visits were completed online.

All patients received polyethylene glycol (macrogol) as the first-line pharmacological treatment. The initial dose was set at 1 g/kg of body weight per day, with a maximum of 40 g daily in children weighing more than 40 kg. Dosage was subsequently adjusted during follow-up visits based on stool consistency. If stool consistency was deemed unsatisfactory, the dose was modified by ± 5 g. The exact amount of macrogol ingested was not recorded, as one of the secondary aims of the program was to educate caregivers and children on appropriate dose titration without continuous medical supervision.

After the study concluded, it was registered on clinicaltrials.gov, obtaining the NCT07025135 ID number, issued 17/06/2025. The study was designed using the Consolidated Standards of Reporting Trials (CONSORT) guidelines.

Data processing

The data was analyzed following the official guidelines of the Polish version of PedsQL 3.0 questionnaire [12]. For each patient, the results from the questionnaire at the 3-months follow-up were subtracted from the scores obtained at the beginning of the study ($t = 0$). Next, the scores were converted to a scale ranging from – 100 to 100 using the following rules: 0 to 0, 1 to 25, 2 to 50, 3

to 75, and 4 to 100. Therefore, the larger the difference in the scores between the beginning and the end of the follow-up, the better the remission of symptoms (control of the condition). Converted scores in the questionnaires were treated as continuous variables.

Moreover, following the original questionnaire guidelines, questions were also grouped into 14 categories (names of categories attached in Additional Materials). For each category, a mean score was calculated. An average score for all individual questions was computed.

Statistical analysis

Categorical data was described using counts, frequencies, and proportions. Statistical significance was evaluated by arranging the data into contingency tables and applying the Chi-square test with Yates' correction. Continuous data, including patients' scores in the questionnaires, was summarized using means and 95% confidence intervals (95% CIs). The Shapiro-Wilk test was used to determine if the data was normally distributed. Appropriate parametric (Student's t-test, analysis of variance) and non-parametric (U-Mann-Whitney, Kruskal-Wallis) statistical tests were used to identify statistically significant differences. All analyses were conducted using Python 3.10, with the Pandas 2.1.3 and Scikit-learn 1.2.1 libraries. A two-sided p-value of less than 0.05 (5%) was considered statistically significant.

Results

General characteristics

The analysis was performed per protocol. In total, 100 child-parent dyads were randomized. At the end of the study, there were 113 complete questionnaires, 65 from adults and 48 from children. The adolescent group (age 13–18) was excluded from the final analysis due to insufficient data collection (high dropout rates). Only complete questionnaires were processed so that no data was missing from the study results.

The table below shows baseline characteristics of patients before and after intervention. At first, 100 children with functional constipation were included (50 in the intervention and 50 in the control group). The mean age was 6.8 years (median 6), with most patients aged 5–7 years (38%), only 4% were older than 12 years. Boys accounted for 61% of the cohort. Almost half of the children (48%) had constipation lasting more than 12 months, while 26% reported a duration of less than 6 months and 26% between 6 and 12 months. Nearly half (47%) had not received any prior treatment. Among those previously treated, macrogols were most common (40%), followed by dietary modifications (7%) and other laxatives (6%). After the third visit, data were available for 68 children (35 in the intervention and 33 in the control group). The mean age was 6.4 years (median 6); no

patients older than 12 years remained in follow-up. The sex distribution remained similar, with boys representing 62%. The duration of constipation and previous treatment patterns were also comparable (in Table 1).

Table 1 Baseline characteristics of patients pre - and postintervention

Baseline characteristics of initial population (visit 0)			
Characteristic	Intervention Group (n = 50)	Control Group (n = 50)	Total (N = 100)
Age, years			
4	16(32%)	11(22%)	27(%)
5–7	18(38%)	20(40%)	38(%)
8–12	13(24%)	18(36%)	31(%)
13–16	3(6%)	1(2%)	4(%)
Mean	6.62	7.02	6.82
Median	6	6,5	6
Sex			
Male	29(58%)	32(64%)	61(%)
Female	21(42%)	18(36%)	39(%)
Duration of constipation			
< 6 months	16	10	26
6–12 months	17	9	26
> 12 months	17	31	48
Previous treatment			
Macrogols	19	21	40
Diet	4	3	7
None	25	22	47
Other (lactulose, senes, enema)	7	5	12
Baseline characteristics of ending population(after 3rd visit)			
Characteristic	Intervention group (n = 35)	Control group (n = 33)	Total (N = 68)
Age, years			
4	12(34%)	8(24,3%)	20(29%)
5–7	13(37%)	13(39,3%)	26(38%)
8–12	10(29%)	12(36,3%)	22(32%)
13–16	0	0	0 (%)
Mean	6.06	6.81	6.42
Median	5	6	6
Sex			
Male	20(57%)	22(69%)	42(62%)
Female	15(43%)	11(31%)	26(38%)
Duration of constipation			
< 6 months	10	5	15 (22%)
6–12 months	15	6	21 (31%)
> 12 months	10	21	31 (46%)
Previous treatment			
Macrogols	12	16	28 (42%)
Diet/fiber only	3	2	5(7%)
None	19	12	31(46%)
Other (lactulose, enema)	2	5	7(10%)

Participants

Overall, participants in the intervention group reported greater score improvements (higher positive differences) from the beginning to the end of the study compared to the controls for most of the questions asked (as shown in Fig. 2). The full results are presented in additional materials.

In the intervention group, 13 and 10 reports from children aged 5–7 years and 8–12 years were collected, respectively. In the control group, there were 13 and 12 questionnaires ($p = 0.846$).

The average difference in the mean score between the beginning of the study and the end of the follow-up for the intervention group was 21.4 points (95% CI 17.5 to 25.3) and 12.3 (95% CI 6.6 to 18.1) for the control group ($p = 0.014$).

In the “Gas and bloating” category, children in the intervention group reported significantly better symptom management than those in the control group, with mean scores of 30.7 (95% CI 22.6 to 38.8) compared to 15.3 (95% CI 5.7 to 24.9; $p = 0.021$). Similar improvements were observed in the “Constipation” category, with scores of 34.1 (95% CI 25.6 to 42.6) for the intervention group versus 19.6 (95% CI 7.9 to 31.3; $p = 0.048$). The trend continued for “Stomach pain and hurt,” where the mean scores were 25.8 (95% CI 15.8 to 35.8) versus 11.7 (95% CI 3.4 to 20.0; $p = 0.037$), and for “Worry about stomach aches,” with scores of 26.1 (95% CI 13.7 to 38.5) compared to 12.0 (95% CI 3.5 to 20.5; $p = 0.049$).

Additionally, children in the intervention group showed significantly greater improvements in mean symptom management scores in comparison with the controls across several questions. Notable differences were seen in responses to “I am not able to eat what I want” (20.7 vs. 3.0, $p = 0.049$), “I have a lot of gas” (30.4 vs. 4.0, $p = 0.019$), and “My stomach feels gassy” (35.9 vs. 11.0, $p = 0.012$). Other standout improvements included “I feel like I cannot get all the poop to come out” (37.0 vs. 13.0, $p = 0.033$), “It hurts when I go poop” (47.8 vs. 19.0, $p = 0.020$), and “My bottom hurts after I go poop” (33.7 vs. 10.0, $p = 0.018$). Further differences were found for “I worry that it will hurt when I go poop” (42.4 vs. 13.0, $p = 0.021$), “I worry that my stomach will hurt at school” (26.1 vs. 11.0, $p = 0.045$), and “It is hard for me to explain my illness to my friends” (37.0 vs. 3.0, $p = 0.037$).

Caregivers

In the intervention group, reports from parents were collected for 12 children aged 0–4 years, 13 children aged 5–7 years, and 8 children aged 8–12 years. In the control group, the corresponding numbers of questionnaires collected were 8, 12, and 12, respectively ($p = 0.444$).

The mean score difference between the start of the study and the end of the follow-up was 22.3 (95% CI 18.9

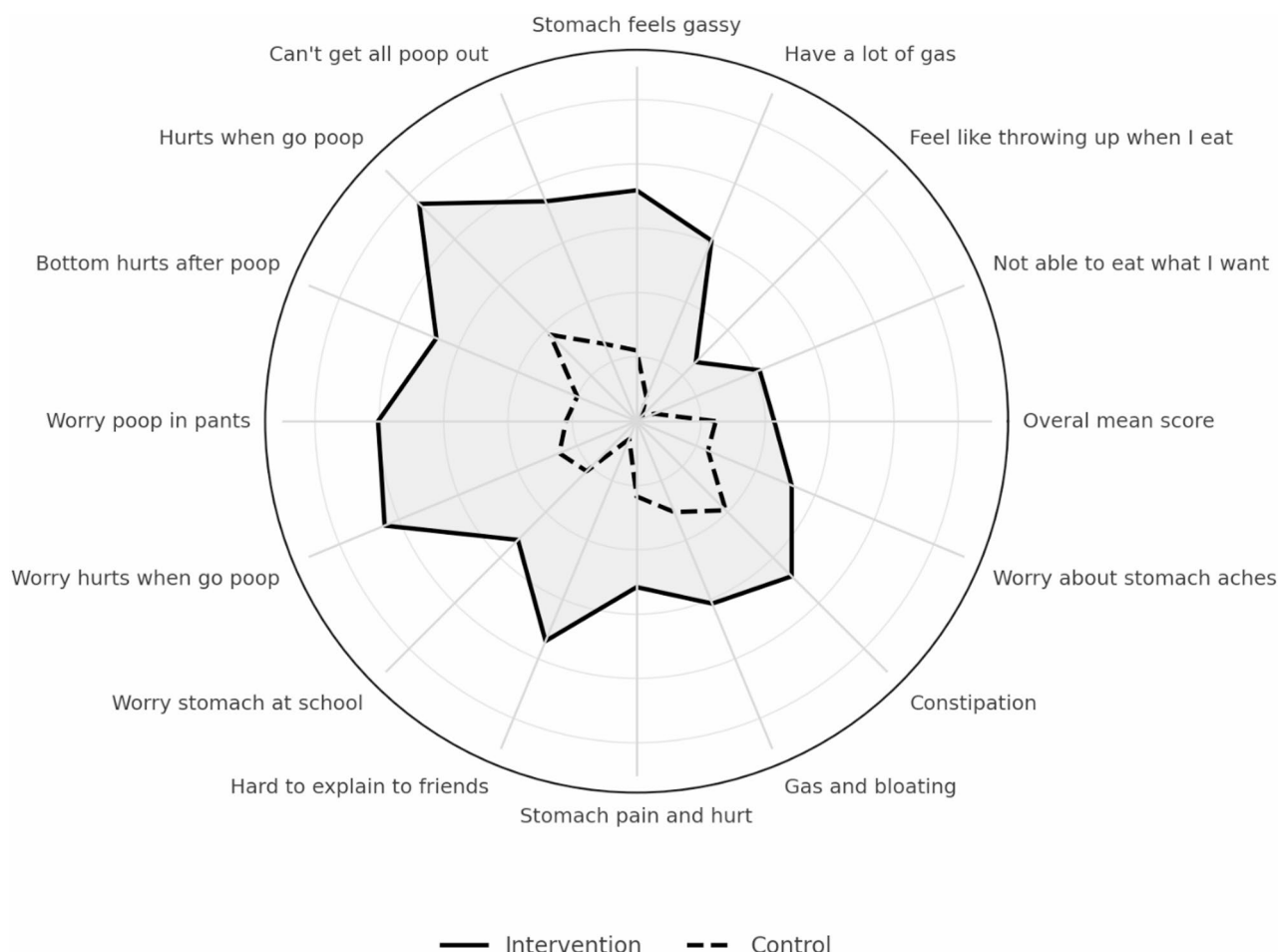


Fig. 2 Spider web graph showing significant mean score difference between the beginning and the end of the 3rd visit for questions from PedsQL 3.0 questionnaire (the higher the score, the higher the magnitude of the difference) – children group

to 25.6) for the intervention group, compared to 14.8 (95% CI 9.9 to 19.7) for the controls ($p=0.015$).

Additionally, in the “Gas and bloating” category, according to caregivers, children in the intervention group reported significantly better symptom management improvements than those in the control group, with scores of 38.0 (95% CI 30.6 to 45.4) compared to 20.0 (95% CI 9.6 to 30.3; $p=0.007$). A similar pattern was seen for “Constipation,” where the mean score differences were 44.6 (95% CI 38.6 to 50.7) for the intervention group and 31.1 (95% CI 21.3 to 40.8) for the control group ($p=0.042$), as well as for “Worry about bowel movements,” with mean scores of 33.8 (95% CI 23.7 to 43.9) for the intervention group and 15.8 (95% CI 7.0 to 24.6) for the control group ($p=0.031$).

Furthermore, parents of children in the intervention group reported significantly greater improvements in mean symptom management scores compared to the control group. The differences were notable in questions such as “Feels pain or hurt in his/her stomach” (36.4 vs. 19.5, $p=0.018$), “Gets stomach aches” (33.3

vs. 15.6, $p=0.013$), “Stomach feels full of gas” (44.7 vs. 23.4, $p=0.015$), and “Stomach feels very full” (39.4 vs. 18.0, $p=0.006$). Other significant improvements were observed in “Stomach gets big and hard” (48.5 vs. 29.7, $p=0.038$), “Stomach feels gassy” (32.6 vs. 10.9, $p=0.005$), “Takes a long time for poop to come out” (48.5 vs. 29.7, $p=0.027$), “Worries that it will hurt when he/she has a bowel movement” (47.0 vs. 19.5, $p=0.006$), and “Hard for him/her to tell the doctors and nurses how he/she feels” (31.1 vs. 17.2, $p=0.027$) (shown in Fig. 3).

Discussion

Key findings

This randomized controlled trial demonstrated that the use of a mobile application as an adjunct to standard care significantly improved symptom control and quality of life in children with functional constipation compared to conventional printed educational materials. Both caregivers and children in the intervention group reported greater improvements across multiple symptom categories, particularly in domains related to constipation,

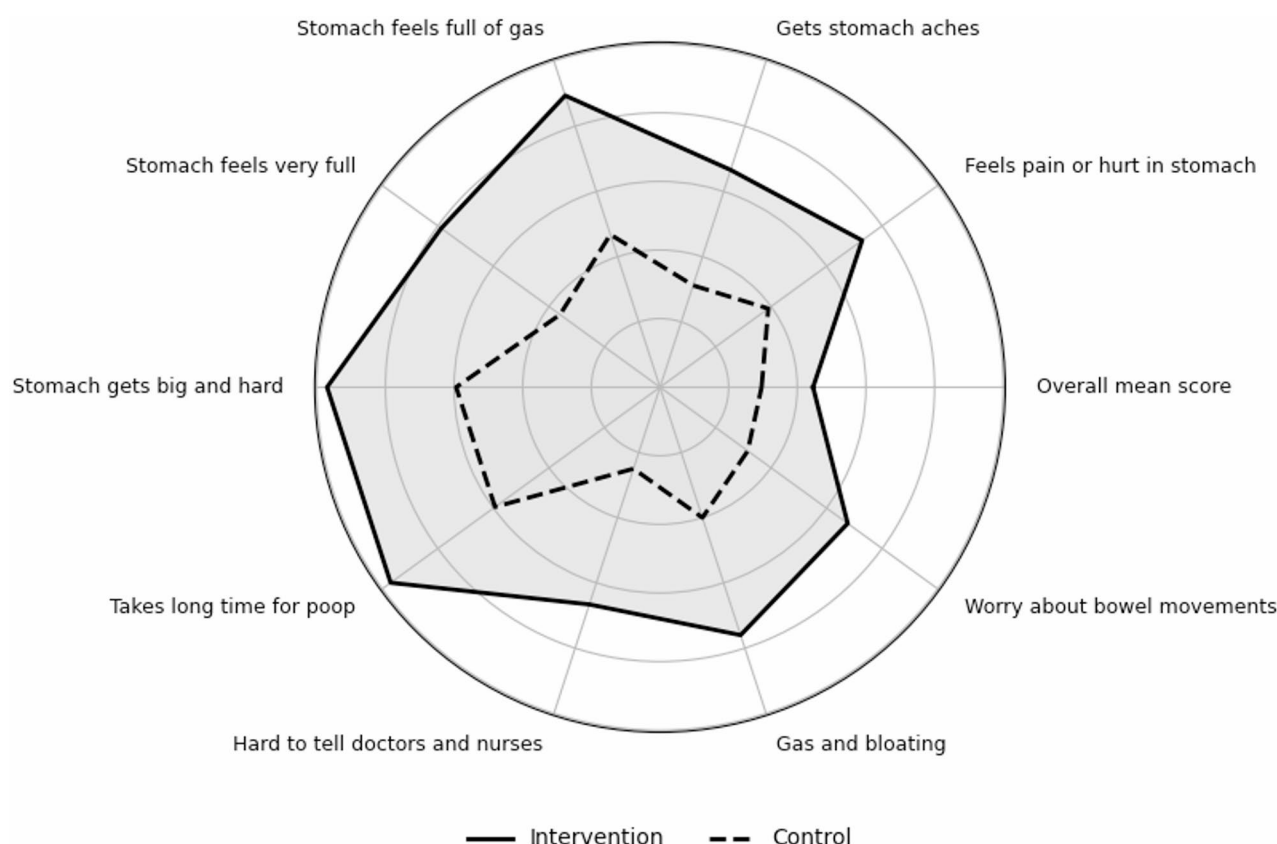


Fig. 3 Spider web graph showing significant mean score difference between the beginning and the end of the 3rd visit for questions from PedsQL 3.0 questionnaire (the higher the score, the higher the magnitude of the difference) – caregivers' group

abdominal pain, and bloating. These findings suggest that interactive digital tools may enhance adherence to therapeutic recommendations and support more effective long-term management of pediatric functional constipation.

Compliance vs. adherence

As with other chronic disorders, following the recommendations greatly impacts the effectiveness of constipation treatment. Therapeutic success is inextricably linked to two key factors: compliance and adherence. Compliance is defined as the degree to which a patient's actions align with their healthcare provider's recommendations [13]. Adherence, on the other hand, reflects a positive, proactive approach where the patient actively incorporates lifestyle changes and commits to a daily regimen [14]–[15]. Studies show that adherence rates in children with functional constipation are low [7]–[8]. Treatment inconvenience, dissatisfaction with the therapy, and the emotional toll of constipation may discourage patients' adherence to their treatment plan [7]. What is more, prolonged or recurrent therapy is frustrating and leads to a significant reduction in the quality of both children's and caregivers' lives [16]–[17], and yet, one-fourth of children with functional constipation continued to experience

symptoms in adulthood [18]. The complexity of treatment is further exacerbated by factors influencing the underlying causes of constipation. In some cases, dietary issues are predominant, while psychological factors play a more significant role in others. Thus, there is a need for an individual approach [19].

E-health perspective

There is a growing market for e-health services aimed at children and young people in disease management and improving the understanding of their condition [20]. ePRO (electronic patient-reported outcomes) are gaining more attention thanks to the digitalization of e-health and their proven feasibility, connected with patients' positive experience [21, 22]. Likewise, mobile applications are increasingly utilized in gastroenterology (and generally in medicine) for both healthcare professionals and patients. Their role is to enhance patient care, support self-management, and provide educational resources [23]. The largest professional associations offer clinical management applications such as the I-SEE app for guidance in eosinophilic esophagitis, provided by the American Gastroenterological Association (AGA) [24] or the official ESPGHAN App [25] with the latest guidelines and algorithms useful for everyday practice. Patients

and caregivers are offered apps for self-management, symptoms tracking and medication adherence monitoring. For example, Cincinnati Children's Hospital Medical Center developed SMART-IBD App [26] for children with inflammatory bowel disease, available in the United States. In Europe, My IBD Care App (developed in collaboration with the NHS) and Lyfe^{MD} are considered to be the most useful and reliable [27]. They help with tracking symptoms, appointments and offer educational resources.

Unfortunately, not every available mobile app provides high-quality support. A systematic review by Messner et al.⁽²⁶⁾ found that only few ensure secure data transfer, and none have an established evidence base. Thus, while these tools support clinical care and self-management, their quality, security, and scientific validation require careful evaluation.

Guideline gaps and digital support

Although the ESPGHAN and NASPGHAN guidelines for treatment of constipation and Rome Criteria IV [4] are essential, the research indicates that they are frequently disregarded or considered incompatible with clinical practice, often due to limited awareness of current constipation guidelines and optimal treatment recommendations [28, 29]. Awareness of guidelines on the management of constipation is poor among physicians and pharmacy personnel [30], which allows the authors to conclude that disregard of the guidelines in this area is common.

Others suggest that rather than a lack of guidelines' awareness, lack of childhood constipation knowledge (and possibly time constraints) may be responsible for inconsistent non-pharmacological health education. Some authors indicate developing the child's health literacy by involving both child and the family in all aspects of health education and decision-making as factors improving adherence [31]. The solution proposed by the authors of the app corresponds to these suggestions. The app encourages the whole family to engage in the treatment process, providing information necessary to understand the disorder. Improvements in treatment have been supported by reductions in symptoms. Significant improvement in reported symptoms concerning especially distension, bloating and constipation suggest that use of an interactive tool might improve adherence and help maintain the achieved improvement.

Psychosocial aspect

The burden of constipation is often underestimated, yet it can lead to long-term psychological distress and interfere with normal growth and development. Children with chronic constipation often experience embarrassment, frustration, shame, and anxiety, which can lower self-esteem and emotional well-being [32]. Hence, there

is a need for comprehensive management strategies to support and minimize its long-term impact. According to a Cochrane systematic review, there is some evidence that behavioral interventions plus laxative therapy, rather than laxative therapy alone, improve continence in children with functional fecal incontinence associated with constipation [33]. There are reports of implementing action plans better adjusted to patient's needs that successfully reduced health care utilization [34, 35].

The app provides clear and tailored answers and instructions, which positively encourage not only parents but also children, to implement them. Interactive quizzes and multimedia content lead to more active participation and better recall of recommendations. The part of the guide containing self-awareness advice (i.e. emotion-focused self-aid tips, support instructions for caregivers) facilitates handling challenging situations. Users of the application also report improvements in the psychological aspects of constipation, suggesting that they handle constipation-related concerns significantly better than the control group. It is reported that improving self-efficacy has been linked to better outcomes in children with functional constipation; thus, it may be beneficial to enhance self-efficacy for defecation during treatment [36].

The app used gamification to increase engagement with treatment and promote self-management. Gamification refers to the increasing integration of game-like elements into reality, enhancing skills, motivation, creativity, engagement, and overall well-being [37]. Thanks to the introduction of interactive elements in the treatment process, it is easier to get the patients (users) involved, which translates into an understanding of the condition, the importance of treatment, and has a positive effect on self-efficacy.

Limitations

Despite the promising results, certain limitations must be discussed. The largest limitation is the size of the sample that completed the whole 6-month program. Notwithstanding the initial number of enrolled participants (100 patient-caregiver dyads), only 55% of the participants were willing to report for the final follow-up. The authors did not manage to obtain data from a sufficient group of adolescents (aged 13–18). As a result, this age group was excluded from the data analysis. Although there were initially some adolescent participants, all of them dropped out before the end of the program. Perhaps the structure of the program appeared overly juvenile or simplistic to them or the constipation was a more complex problem, which resulted in a lack of motivation.

The program also required a time commitment, which certainly influenced participants' willingness to continue and contributed to a higher dropout rate. The highest dropout occurred after the 1st visit (the longest and most demanding one), likely due to the significant burden it

placed on participants, which could decrease motivation to engage. In addition to the overall time burden, completion of the PedsQL™ GI Module itself introduced further respondent load. While the PedsQL™ GI Module is a validated and appropriate measure, its length and cognitive load - especially for younger children - can be burdensome and may contribute to incomplete questionnaires. Finding a more compact questionnaire or helping with its fulfillment in the future studies would be reasonable.

Finally, not all aspects of the application were assessed parametrically. Modules such as the games were used voluntarily, and only participation in these activities was tracked. Furthermore, medication tracking data were excluded from the analysis due to inconsistent reporting and low reliability. Furthermore, the inability to enter data retrospectively in the application likely discouraged regular use of this feature.

Further studies on this topic as well as more external validation would be valuable.

One additional point should be noted. The trial was registered retrospectively due to an unintentional oversight—the authors were not aware that prospective registration was mandatory. Once informed, the authors registered it promptly and ensured transparency.

Implications for practice

The proposed solution is practical and easy to implement in both outpatient settings and hospital wards, making it suitable as an internal standard.

Future iterations of the application should be better tailored to the needs of adolescents, as their engagement in this study was very low, resulting in insufficient data from this age group. It is possible that the design appeared too juvenile for older users, reducing their willingness to engage. Moreover, since functional constipation typically begins earlier in life, adolescents may represent a group with more chronic and treatment-resistant symptoms, often requiring additional interventions such as enemas or continuous rather than one-time psychological support. For these reasons, lifestyle modification alone may have been less effective in this subgroup, which could partly explain the high dropout rate.

Adolescents may benefit from app modifications that emphasize autonomy, privacy, and age-appropriate engagement. Improvements could include a more mature design and language style, flexible customization, and gamified features that reward personal progress rather than parental supervision. Providing brief, visually appealing educational content and optional reminders tailored to school and social routines may further increase adherence. Finally, allowing adolescents to control when and how their data are shared with parents or clinicians could foster independence while maintaining clinical relevance.

Moreover, given the high prevalence of gastrointestinal complaints in children with autism spectrum disorder (ASD) - with constipation reported in up to 40% of this population and occurring significantly more often than in neurotypical peers [38] - it would be valuable to adapt and evaluate the application specifically for this group, as it was excluded from the described study. Future iterations of the intervention could incorporate features tailored to the cognitive and behavioral needs of children with ASD, as this population may particularly benefit from structured, visual, and interactive tools supporting constipation management.

Additionally, the app holds potential for use by general practitioners, further enhancing its clinical relevance. To extend the scope of its application, translation into other languages will be necessary, ensuring broader accessibility. Moreover, further research involving a larger sample size should be conducted to strengthen the evidence base and validate its effectiveness across diverse populations.

Conclusions

The authors report a significant improvement in quality of life for pediatric patients with functional constipation who utilized a mobile application as an adjunctive treatment. The mobile app provided personalized guidance on bowel habits, nutritional recommendations, and stress management techniques, leading to a statistically significant reduction in symptoms compared to traditional treatments.

These results highlight the potential value of digital technologies in managing functional constipation. Effective management requires guideline adherence, knowledge dissemination, and collaborative education among healthcare professionals. The authors propose that mobile health interventions may enhance treatment efficacy and promote more effective management strategies for functional constipation.

Abbreviations

PedsQL™	Pediatric Quality of Life Inventory™
ESPGHAN	European Society for Paediatric Gastroenterology, Hepatology and Nutrition
NASPGHAN	North American Society for Paediatric Gastroenterology, Hepatology and Nutrition
WHO	World Health Organization
CONSORT	Consolidated Standards of Reporting Trials
ASD	Autism Spectrum Disorder

Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s12887-025-06385-y>.

Supplementary Material 1.

Supplementary Material 2.

Acknowledgements

Not applicable.

Authors' contributions

J.L. and M.D.D. contributed to the study design, data collection, data interpretation, and article preparation. W.N. contributed to data analysis and interpretation. K.W.Z., A.Z.R. and P.C.A. contributed to the study design. K.P.N. contributed to receiving funding. A.S.S. supervised and reviewed the manuscript.

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Data availability

Anyone contacting the authors will be assessed and data will be given to researchers/public authorities.

Declarations

Ethics approval and consent to participate

Written informed consent was obtained from all participants' parents or legal guardians after they received verbal and written information about the study. Written consent was also obtained from children aged 13 years, in accordance with local regulations. Oral consent was obtained from underage study participants. The Bioethics Committee of the Medical University of Gdańsk approved this study. The study is in accordance with the 1964 Helsinki declaration. Bioethics Committee of the Medical University of Gdańsk approval number: NKBBN/920/2021; 14 December 2021.

Consent for publication

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Competing interests

The authors declare no competing interests.

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