Submitted: 29 September, 2025 Accepted: 02 December, 2025 Published: 03 May, 2026 DOI:10.22514/jocpd.2026.063

ORIGINAL RESEARCH

Journal of Clinical Pediatric Dentistry

Evaluation of a smartphone application in controlling oral hygiene and orthodontic urgencies in pediatric patients with rapid palatal expander: randomized clinical trial

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Abstract

Background: The present randomized clinical trial aimed to evaluate the potential effects of an orthodontic smartphone application (Ortodontika) in addition to verbal instructions for the improvement of pediatric patients' oral health and the reduction of orthodontic urgencies in the first 6 months of hyrax rapid palatal expander (RPE) treatment. **Methods**: Patients aged 6–14 years old were enrolled and modified gingival index (MGI), bleeding index (BI), and plaque index (PI) were recorded at the baseline (T0) and at follow-ups. Hyrax rapid palatal expander was cemented and patients were randomly divided into the Control group, in which instructions were given to patients for RPE activations and daily oral hygiene, and in the Trial group, in which Ortodontika application was delivered as additional aid to verbal instructions. The RPE questionnaire was delivered to all patients to evaluate their perceptions and knowledge on their orthodontic treatment. The APP questionnaire was delivered to Trial group only to assess the experience with Ortodontika application. The number of orthodontic urgencies and the number of accesses to the application for the Trial group were recorded in the time frames between follow-up appointments. **Results**: No significant between-group differences were found for MGI, BI and PI ($p > 0.05$), while significant within-group differences were found for BI and PI ($p < 0.05$). A significantly higher number of the cumulative orthodontic urgencies was found in the Control group ($p < 0.05$). The number of accesses to the application was higher in T0–T1 and T1–T2 time frames, even though with no withi-group differences ($p > 0.05$). No significant differences were found for the RPE and APP questionnaires ($p > 0.05$). **Conclusions**: Ortodontika application as an adjunct to verbal instruction could be useful for the reduction of RPE urgencies and as a reinforce for daily oral hygiene. **Clinical Trial Registration**: NCT05539469.

Keywords

Mobile application; Orthodontic appliances; Oral hygiene; Dental urgencies

1. Introduction

In recent years, orthodontics has undergone a profound digital transformation [1, 2], leading to "teleodontology", which is the application of telecommunication tools in the dentistry field [3, 4]. This approach represents a substantial advancement in terms of enhancing access to dental care, particularly for patients who are unable to reach the dental practice [5]. Digital platforms and mobile applications have become instrumental in facilitating remote clinical consultations, enabling patients to receive continuous, real-time monitoring of their treatment from the comfort of their own homes [6], together with the reduction of waiting times for check-ups. Furthermore, many of these platforms offer educational resources to help patients better understand their clinical situation, thereby encouraging greater participation in and adherence to treatment [7–9].

Mobile applications now address common issues in dentistry: bruxism [10], post-operative oral surgery [11], dental erosion [12] and daily oral hygiene [13]. However, despite the many advantages of digitisation, the role of the practitioner remains irreplaceable [14, 15], especially in orthodontics, where patients are for the most part children or adolescents [16]. In such cases, personal motivation is a critical factor in a successful treatment. The family can play a supportive role [17], but it is important that the young patient is encouraged to take the lead [18, 19].

In this context, the synergistic relationship between applications and verbal motivation provided by the practitioner

is of great importance [20, 21]. While mobile applications may offer practical tools, monitoring and reminders [9], the empathic and targeted communication led by the clinician can transform this information into a real stimulus for change [22], guiding patients to actively participate in their oral status [23–25].

Despite the many advantages of digitisation in the field of dentistry, there is still a marked lack of effective digital tools in orthodontics and the currently available applications frequently exhibit inadequate structural design, with poor reliable and truly useful contents supported by scientific evidence [26]; additionally, it seems that the orthodontic application market is underdeveloped in terms of quality and clinical functionality [27].

Considering these premises, the primary objective of the present study was to assess the effectiveness of the Ortodontika smartphone application as an adjunct to verbal instructions, in comparison with verbal instructions alone, for patients undergoing orthopaedic treatment involving the use of a hyrax rapid palatal expander (RPE). The first null hypothesis of the study was that there would be no differences in the modified gingival index (MGI), the bleeding index (BI) and the plaque index (PI) as periodontal outcomes of home oral hygiene at the end of the study. The second null hypothesis was that there would be no difference in the number of orthodontic urgencies recorded at the conclusion of the study. Ultimately, the number of accesses to the application was documented in order to ascertain whether the application was found to be both interesting and useful.

2. Materials and methods

2.1 Study design

The present study is a randomised controlled single-centre parallel-group study with a 1:1 allocation ratio conducted according to the guidelines of the Declaration of Helsinki. The study was approved by the Unit Internal Review Board (2022-0622), and its protocol was registered on clinicaltrials.gov (NCT: NCT05539469).

2.2 Participants

Pediatric patients under care at the Unit of Orthodontics and Pediatric Dentistry, Section of Dentistry, Department of Clinical, Surgical, Diagnostic and Pediatric Sciences of the University of Pavia scheduled for undergoing orthopaedic treatment with hyrax rapid palatal expander were selected for the participation in this study.

2.3 Eligibility criteria

The following inclusion criteria had to be fulfilled:

- Age 6–14 years, both sexes.
- Mixed dentition phase and fully erupted permanent first molars.
- Need for orthopaedic treatment with hyrax RPE cemented on maxillary first molars.
- Voluntary participation in the study, assent and confirmed by their parents (or legal guardians), with the signature of the informed consent and personal data processing form.
- Agreement to download and use “Ortodontika” application (system requirements: iOS $\geq$10.0 for Apple smartphones and Android $\geq$4.4 for Android smartphones). An active internet connection was required for the use of the application.

The following exclusion criteria had to be taken into consideration as well:

- Drug therapies for systemic diseases that can affect periodontal conditions and pain perception, such as antibiotics, antibacterial mouthwashes, nonsteroidal anti-inflammatory drugs, and steroids.
- Previous orthopaedic/orthodontic treatments.
- Siblings who have previously undergone orthodontic treatment with RPE.
- Need for orthodontic appliances in addition to RPE.
- Poor compliance by patients and/or parents.

2.4 Interventions

Patients and their parents who agreed to participate in the study signed the informed consent form and the personal data processing form for their child. During the initial visit (T0), a periodontal probe (UNC probe 15; Hu-Friedy, Chicago, IL, USA) was used to record bleeding index [28], the plaque index [29] and the modified gingival index [30] on the central incisors, deciduous first molars (or first premolars if already present) and permanent upper first molars. Subsequently, a professional nonsurgical periodontal debridement was performed with the aid of a piezoelectric instrument (Multipiezo, Mectron S.p.a., Carasco, Italy). After professional oral hygiene, a hyrax-type RPE with welded vestibular single tubes was bonded with bands on permanent upper first molars using a glass ionomer cement (3M Multi-Cure, 114433047, 3M Unitek, Monrovia, CA, USA). Finally, the activation of the device was performed by the parents following the instructions provided by the orthodontic operator. Patients also received an orthodontic kit containing: a toothpaste (GUM Junior 7+, Sunstar Deutschland, GmbH, Schonau, Germania), a soft-bristle toothbrush (GUM Technique PRO toothbrush), 0.6 and 0.8 diameter interdental brushes (GUM TRAV-LER) and a single-tuft toothbrush (GUM End-Tuft) for daily oral hygiene; an orthodontic wax (GUM ORTHO) for mucosal discomfort due to orthodontic tubes welded on the bands and chlorhexidine gel 1% (Curasept Periodontal gel, 1415, Curasept S.p.A, Saronno, VA, Italy) for gingival and mucosal area of inflammation.

At this point, patients were randomly assigned to one of the two groups:

- Control group: at each visit, the orthodontist provided verbal instructions to the parents regarding the correct activation of the RPE, how to clean the device, and daily practices to maintain proper oral hygiene for the patient.
- Trial Group: in addition to verbal instructions on the activation and cleaning of the RPE and on daily oral hygiene, the smartphone application “Ortodontika” was delivered to parents.

Ortodontika application was provided entirely in Italian, as patients were native Italian speakers. It consisted of three sections: Home, Hygiene and Info.

The Home section provided information on treatment dura-

tion, name of the practice, name of the clinician, the type of appliance (in this case, RPE) and the notifications set by the clinician (Fig. 1). The application was developed so that users can modify only the time of notification.

The subsection related to the RPE appliance consisted of two videos accompanied by textual information regarding the functioning of the appliance, how to perform the activations, and how to clean it (Fig. 2). The English translation of texts can be found in the **Supplementary material**.

The Hygiene section was developed with the aim of helping patients in daily oral hygiene manuveurs, also for patients without orthodontic appliances; four videos were present to properly explain how to use respectively manual brush, electric brush, interdental brush and dental floss (Fig. 3).

The Info section provided information on the project and the developers.

The Ortodontika application required user identification (name) to enable clinical communication. All information was stored on secure, password-protected servers accessible only to the research team. Before analysis, data were pseudonymized and identified by unique study codes, ensuring that no personal identifiers were included in the dataset used for research. Data handling and storage complied with the European General Data Protection Regulation (GDPR, Regulation EU 2016/679).

The clinician set the daily notifications that were sent by the application from the baseline (T0) until T1 (end of activation) to supplement the information provided by the specialist during visits. Parents were also in charge of monitoring the patient in performing daily oral hygiene practices and cleaning the RPE. To ensure that, a 2-weekly notification was sent to remind patients to see the Hygiene section with the four videos until the end of the study. Notifications could be set only by the orthodontist. In the **Supplementary material**, the complete texts regarding oral hygiene manoeuvres, the description of the RPE and the orthodontic urgencies are shown.

After the initial assessment (T0), patients underwent the recording of periodontal indices at the following stages: once completed RPE activations (T1), after 1.5 months (T2), after 3 months (T3) and after 6 months (T4). Additional visits could be present between T0 and T1 if the required maxillary expansion was not reached. During each visit, additional products for home oral hygiene were delivered, and orthodontic urgencies were recorded. To measure awareness of the goals and steps of orthodontic therapy, as well as knowledge of oral hygiene techniques, a questionnaire was administered to patients and their parents in both groups. In addition, patients and parents in the Trial Group answered a specific questionnaire on the effectiveness of the "Ortodontika" application.

2.5 Outcomes

A calibrated and blinded operator, different from the orthodontic clinician, collected the following periodontal outcomes of the study on central incisors, primary first molars/permanent first premolars and first molars of each side of the dental arch:

- Modified gingival index (MGI) [30]: a visual assessment of the inflammatory state of the gums; the score ranges from 0 (no inflammation) to 4 (severe inflammation).

- Bleeding index (BI) [28]: a clinical parameter used to assess the state of gingival health; the score ranges from 0 (no bleeding), to 2 (immediate bleeding).

- Plaque index (PI) [29]: an assessment of the amount of plaque on teeth; the score ranges from 0 (no plaque) to 4 (abundant plaque covering the tooth surface).

Orthodontic urgencies occurring during the observation period were recorded, including decementation of the RPE, patient-reported pain, requests for activation of the RPE by the specialist in the office, and parental difficulties in understanding how to perform RPE activations.

The number of accesses to the application was exported by a dedicated section of the superadmin site of the application and was recorded to evaluate the usefulness of the application.

At the baseline and during follow-up visits, both patients and their parents from both the groups were asked to complete a 12-item questionnaire based on RPE treatment. The questionnaire was divided into two sections: the first 8 items had to be filled by the parents and the other 4 by the patients. In the compilation, the participants expressed their degree of awareness of RPE treatment and oral hygiene techniques, using a rating scale from 0 to 10. The questions addressed to the parents aimed to assess how clear the treatment was for them, including aspects such as treatment duration, operation and cleaning of the appliance, and safety in case of orthodontic urgencies. Patients were also asked to answer questions regarding their understanding of braces and dental hygiene procedures, as well as the instructions received from the specialist. For the Trial group only, an additional APP questionnaire was delivered with the same structure and administered from T1 and for all the remaining time frames and was delivered to patients and parents in the Trial group to evaluate the usefulness of the application and the validity of the contents. For each item, a score was assigned from 0 (lowest negative score) to 10 (highest positive score). Both the questionnaires are shown in Table 1.

2.6 Sample size

The sample size was determined based on the modified gingival index (MGI), using data from a previous study [30], which examined the effectiveness of smartphone messages in improving orthodontic patients. To detect a clinically significant difference of 0.133 in the MGI values, we assume a mean value of 1.287 and a standard deviation of 0.14. Considering a type I error rate (α) of 0.05 and a type II error rate (β) of 85%, 20 patients are required for each group. No additional adjustment for potential dropouts was applied, as no participants were lost to follow-up.

2.7 Randomization and blinding

Patients were randomly assigned to the two parallel groups "Trial" and "Control" through a randomisation process using the online software Research Randomizer (https://www.randomizer.org), uses an algorithm to generate numbers and allows the researcher to select: the number of series to be created and how many numbers per series to generate. A block randomisation technique was applied by dividing the patients into two groups with a ratio of 1:1. Ten

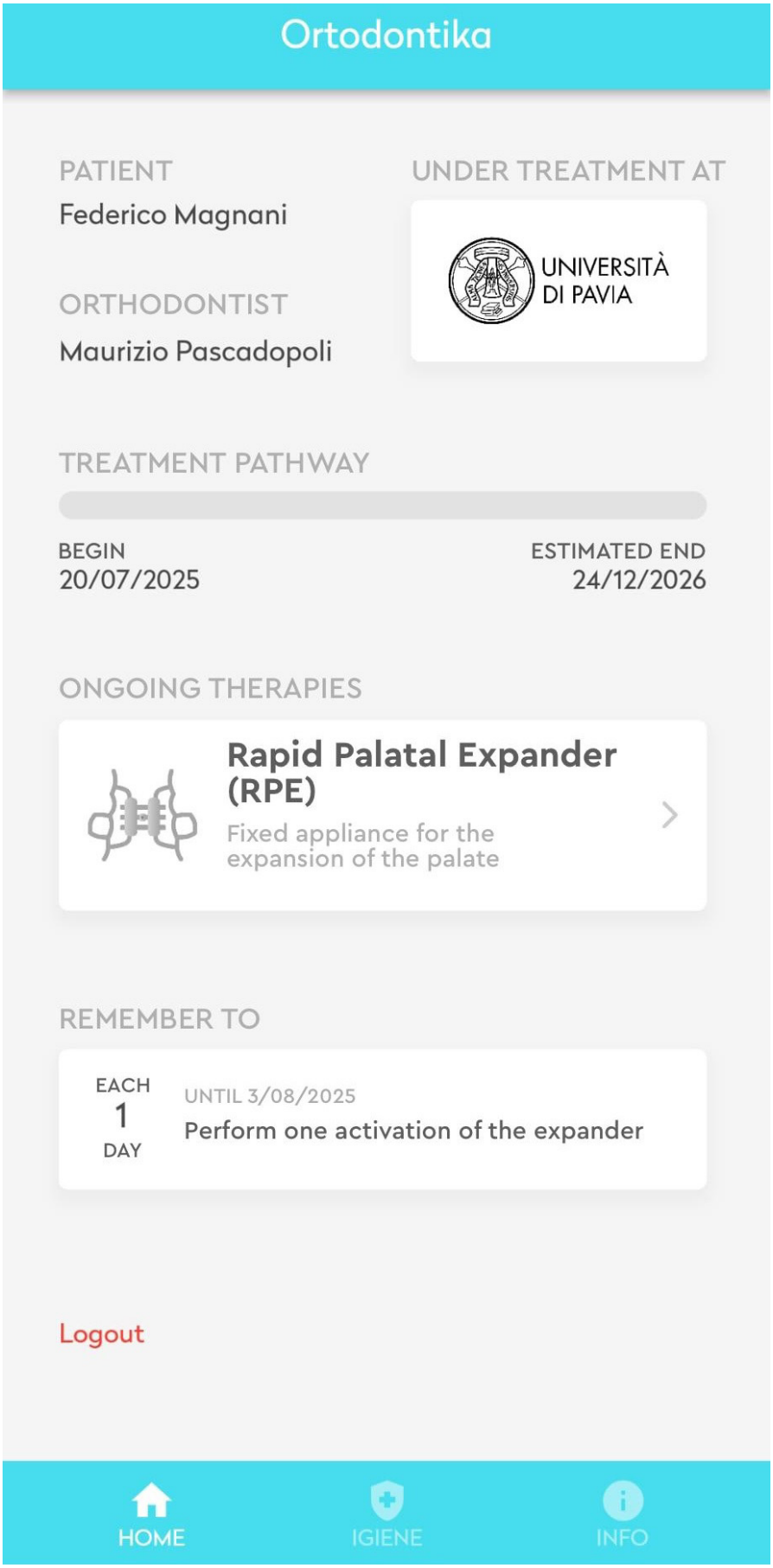

FIGURE 1. Example of initial screen of Ortodontika application showing personal data of patient, orthodontist, treatment duration, type of appliance and active notifications. The screen was translated into English.

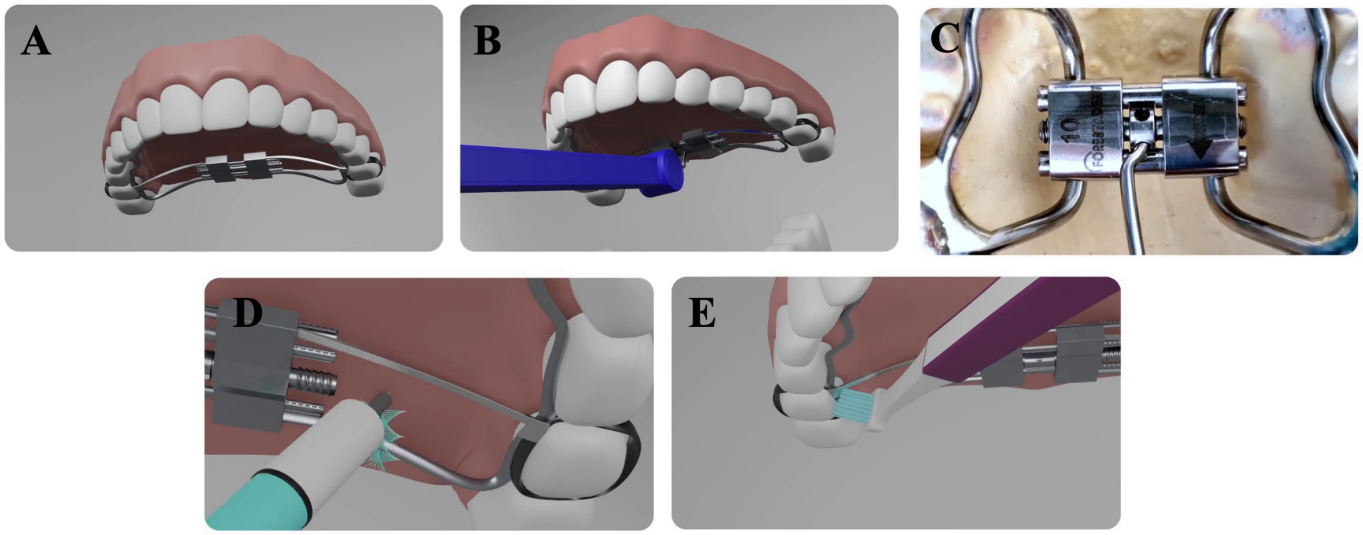

FIGURE 2. Frames from videos regarding RPE treatment. (A) RPE appliance placed, (B) activation of the RPE, (C) detail of RPE screw, (D) cleaning of the RPE with interdental brush, (E) cleaning with single-tuft brush.

FIGURE 3. Frames from videos regarding daily oral hygiene techniques. (A) electric toothbrush, (B) manual toothbrush, (C) interdental brush, and (D) dental floss.

blocks were created, each containing four patients. Patients assigned even numbers were included in the "Trial group", while those with odd numbers were placed in the "Control" group. In this investigation, the operator that collected the periodontal outcomes was blinded, as did the data analyst. However, the orthodontic treatment clinician had to be aware whether the patient belonged to the "Trial" or the "Control" group.

2.8 Statistical analysis

Data analysis was conducted with R software (R version 3.1.3, R Development Core Team, R Foundation for Statistical Computing, Wien, Austria) by calculating mean and standard deviation as descriptive statistics for each group. The normality of distributions was evaluated with the Kolmogorov-Smirnov test. As data were not normally distributed, non-parametric statistical tests were employed. The Wilcoxon signed rank test was performed to compare the cumulative urgencies between the two groups. The other outcomes were analysed as

TABLE 1. RPE and APP questionnaire items.

No.	RPE questionnaire Items for parents	APP questionnaire Items for parents
1.	How informed do you feel about your child's treatment?	How useful is the video showing how the rapid palatal expander works?
2.	How clearly do you understand how your child's appliance work?	How useful is the video explaining how to clean the rapid palatal expander?
3.	How clear is the expected duration of treatment?	How useful are the texts included in the application?
4.	How clear are the instructions for cleaning the appliance?	Did the application help you in managing urgencies?
5.	Are the dentist's instructions on how to handle and clean the appliance clear?	Did you find the application notifications useful?
6.	Was your dentist clear when explaining oral hygiene procedures to your child?	Was the application helpful in explaining oral hygiene procedures to your child?
7.	How confident are you about possible urgencies that might occur?	Is the application intuitive and easy to use?
8.	In general, how well do you think your dentist is monitoring your child's progress?	How would you rate the overall usefulness of the application?
9.	Did you understand your dentist's instructions on how to clean your appliance?	Did the videos in the application help you understand how to clean your appliance?
10.	Did you understand your dentist's instructions on how to brush your teeth?	Did the videos in the application help you understand how to brush your teeth?
11.	If something happens to your appliance, do you feel confident in following your dentist's advice?	Were the texts in the application easy to understand?
12.	In general, how do you evaluate your experience with braces?	How much do you like using the application?

follows: between-group comparisons were performed using the Kruskal-Wallis test, followed by Dunn's *post hoc* test for pairwise multiple comparisons; within-group evaluations over time were analysed with the Friedman test for repeated measures, also followed by Dunn's test for *post hoc* analysis. Concerning RPE and APP questionnaires data were submitted to adjunctive robustness check analysis excluding maximum values and subsequently using nonparametric Kruskal-Wallis and Mann-Whitney tests. This was done in order to reduce possible concealing of real differences between groups thus avoiding potential ceiling effects. Linear regression analysis was performed to assess the influence of Group on the number of urgencies and the periodontal parameters, and the influence of the number of accesses on orthodontic urgencies. For all tests, significance was set at $p < 0.05$.

3. Results

3.1 Participants flow and baseline data

In the study, all patients were enrolled and ended the study. The recruitment process started in September 2022, while the study ended in January 2025. The study sample consisted in 40 patients aged 8.92 ± 1.05; they were all enrolled and all ended the study. The complete demographic data are shown in Table 2, while Fig. 4 shows the CONsolidated Standards of Reporting Trials (CONSORT) flow chart with all the phases of the study.

TABLE 2. Demographic baseline data of the participants of the study.

Groups (n = 40)	Age, Mean ± SD (yr)
Sexes (n = 40)	
Males (n = 17)	8.80 ± 1.32
Females (n = 23)	9.13 ± 0.74
Trial (n = 20)	8.89 ± 1.15
Males (n = 7)	9.00 ± 1.41
Females (n = 13)	8.80 ± 0.92
Control (n = 20)	8.95 ± 0.97
Males (n = 10)	8.50 ± 1.22
Females (n = 10)	9.15 ± 0.80

SD, standard deviation; n, number.

3.2 Periodontal outcomes

The descriptive statistics of the periodontal outcomes are shown in Table 3 (Ref. [31]). For the three periodontal outcomes, no significant between-group differences were found ($p > 0.05$), with an overall reduction from the baseline to the end of the study. Regarding within-group comparisons, the MGI index revealed no significant differences ($p > 0.05$). The BI presented T0–T4 and T1–T4 significant comparisons in the Control group ($p < 0.05$), while in the Trial group the significant differences were found in T0–T2 and T0–T4

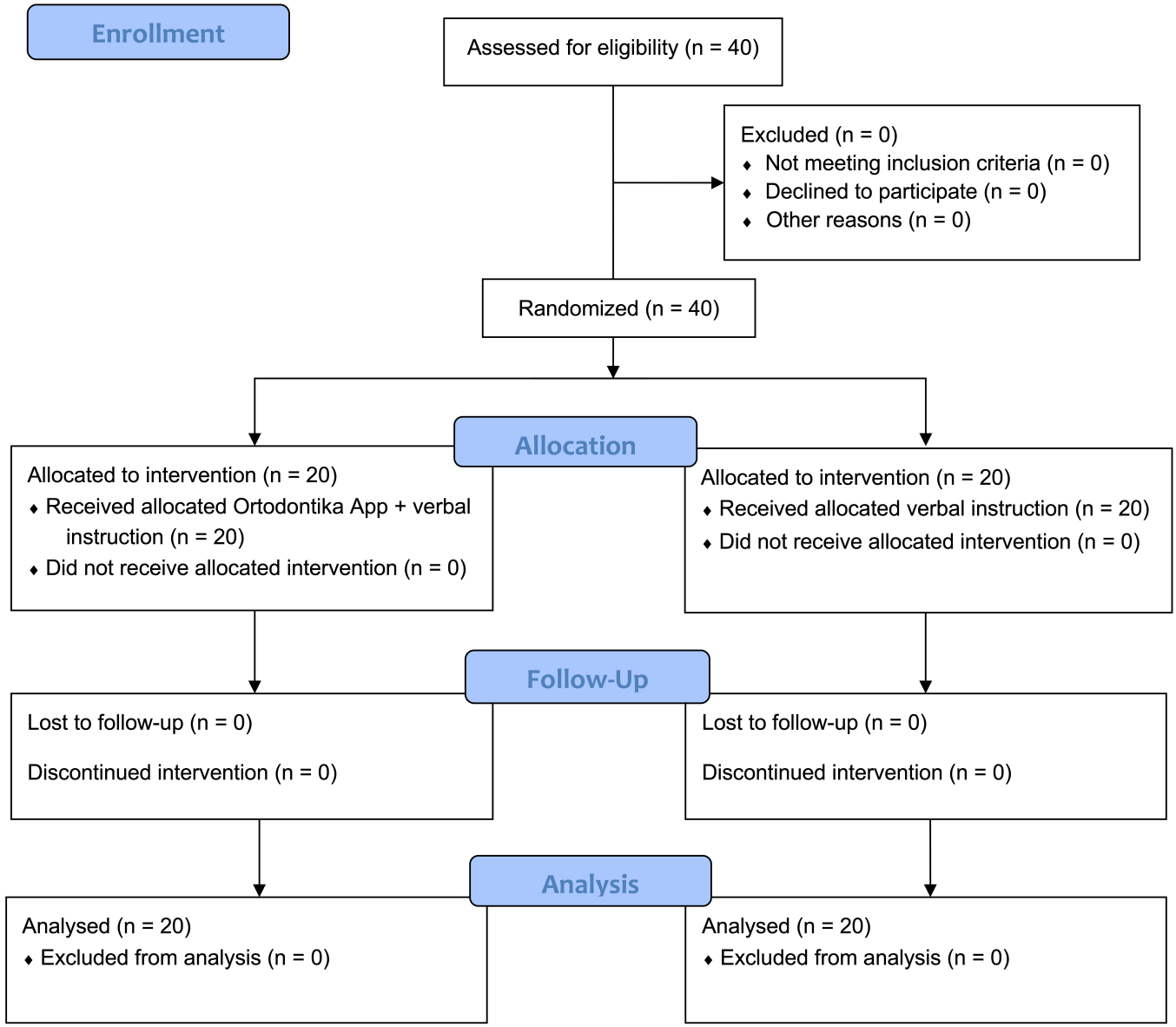

FIGURE 4. CONSORT flow chart.

TABLE 3. Descriptive (mean ± standard deviation) and inferential statistics of the periodontal outcomes of the study.

Group and time frame	MGI	BI	PI
Control T0	0.54 ± 0.65^{A}	0.28 ± 0.24^{ABD}	1.05 ± 0.69^{ABC}
Control T1	0.57 ± 0.63^{A}	0.38 ± 0.37^{ABD}	1.23 ± 0.79^{AB}
Control T2	0.59 ± 0.66^{A}	0.29 ± 0.37^{ABCDE}	0.73 ± 0.45^{ABC}
Control T3	0.49 ± 0.55^{A}	0.16 ± 0.25^{ABCDE}	0.97 ± 0.80^{ABC}
Control T4	0.31 ± 0.42^{A}	0.07 ± 0.21^{CE}	0.74 ± 0.74^{BC}
Trial T0	0.42 ± 0.64^{A}	0.24 ± 0.35^{A}	1.16 ± 0.70^{A}
Trial T1	0.35 ± 0.42^{A}	0.15 ± 0.20^{ADE}	0.68 ± 0.53^{ABC}
Trial T2	0.58 ± 0.71^{A}	0.11 ± 0.23^{CE}	0.73 ± 0.65^{ABC}
Trial T3	0.35 ± 0.36^{A}	0.22 ± 0.35^{ABDE}	0.66 ± 0.59^{ABC}
Trial T4	0.25 ± 0.26^{A}	0.12 ± 0.23^{DE}	0.54 ± 0.61^{C}

MGI, modified gingival index; BI, bleeding index; PI, plaque index. Means with the same uppercase letter/s do not present significant differences [31].

comparisons ($p < 0.05$). The PI, instead, presented only the significant T0–T4 difference in the Trial group ($p < 0.05$).

3.3 Orthodontic urgencies

Considering the number of orthodontic urgencies (Table 4, Ref. [31]), no significant within-group and between group were found in the time frame analysis ($p > 0.05$). Considering the cumulative analysis, in T0–T4 cumulative analysis the Control group showed a score of 0.42 ± 0.68 while the Trial group showed a score of 0.26 ± 0.46, with a significantly lower score for the Trial group ($p < 0.05$).

TABLE 4. Descriptive (mean ± standard deviation) and inferential statistics of the number of orthodontic urgencies among the time frames of the study.

Time frame analysis	Interval	Urgencies
Control	T0–T1	0.40 ± 0.60^{A}
Control	T1–T2	0.25 ± 0.55^{A}
Control	T2–T3	0.15 ± 0.37^{A}
Control	T3–T4	0.20 ± 0.41^{A}
Trial	T0–T1	0.30 ± 0.47^{A}
Trial	T1–T2	0.15 ± 0.37^{A}
Trial	T2–T3	0.15 ± 0.37^{A}
Trial	T3–T4	0.05 ± 0.00^{A}

Means with the same uppercase letter/s do not present significant differences [31].

3.4 Number of accesses to the application

The number of accesses to the application (Table 5, Ref. [31]) did not significantly vary among the time frames of the study ($p > 0.05$), even though in the time frames T0–T1 and T1–T2 higher mean scores were found.

TABLE 5. Descriptive (mean ± standard deviation) and inferential statistics of the number of accesses to the application from patients of the Trial group.

	Interval	Accesses
Trial	T0–T1	4.42 ± 4.82^{A}
Trial	T1–T2	4.05 ± 10.91^{A}
Trial	T2–T3	2.05 ± 4.82^{A}
Trial	T3–T4	2.11 ± 2.83^{A}

Means with the same uppercase letter/s do not present significant differences [31].

3.5 RPE questionnaire and APP questionnaire

The scores of the RPE and the APP questionnaires are shown in Tables 6 and 7, respectively. Regarding the RPE questionnaire, no significant within-group and between group differences were present ($p > 0.05$). Considering the APP questionnaire, administered only in the Trial group, no significant within-group differences were present ($p > 0.05$). Robustness check analysis confirmed the results ($p > 0.05$).

3.6 Linear regression analysis

To evaluate the effects of Group and the number of accesses to the application, the following linear regressions were performed: Group—Urgencies ($p = 0.078$), Group—BI ($p = 0.091$), Group—MGI ($p = 0.171$), Group—PI ($p = 0.061$) and Accesses—Urgencies ($p = 0.068$). The regression analysis revealed no significant associations among the present variables ($p > 0.05$).

4. Discussion

In recent years, the integration of technology in healthcare has resulted in the development of numerous mobile applications to support both diagnosis and treatment [32–34]. The utilisation of these applications in orthodontics is driven by the objective of enhancing patient compliance, thereby ensuring the optimal progression and efficacy of orthodontic interventions.

In the present study, the "Ortodontika" smartphone application was specifically designed and programmed to evaluate its effectiveness in helping patients and parents during the initial months of an orthopaedic treatment with RPE over a six-month period. The first null hypothesis of the study was accepted. Indeed, despite the Trial Group demonstrating lower scores in comparison to the Control Group, no statistically significant between-group differences were identified at any of the three time points for the three periodontal indexes evaluated. Nevertheless, it is important to acknowledge that the Trial Group demonstrated a superior enhancement in oral hygiene, as evidenced by a substantial decrease in the BI and PI scores when comparing the T0 and T4 values. The effects were not as pronounced as in previous studies, likely due to the older age of the participants and the different nature of the appliances. For instance, the "WhiteTeeth" application was previously examined in a study by Scheerman and colleagues on the management of white spot lesions in orthodontic patients [35]. The target population comprised 132 adolescents, with a mean age of 12–16 years with fixed orthodontic appliances. The application was found to be an effective means of reducing dental plaque. The present study differs from the aforementioned one in that it includes patients of a lower age. Furthermore, WhiteTeeth has been found to be more customisable than Ortodontika, with users able to set weekly goals. This has been demonstrated to encourage greater engagement and better compliance. The duration of the study was comparatively brief, with a follow-up period of only six months. Consequently, it is important to consider the possibility that patients may have been more interested in the application. Another study evaluated the mini-programme "Clean Teeth" via the WeChat platform [36], involving 44 young adults aged 17–29 years undergoing fixed orthodontic treatment. The objective of the study was to assist patients in maintaining proper oral hygiene, with the application being delivered as an adjunct to verbal instructions. In addition, the Trial group demonstrated reduced bleeding and plaque scores in this study. However, the considerations may be

TABLE 6. Mean scores and standard deviations of the RPE questionnaire.

RPE questionnaire										
	Control					Trial				
Item	T0	T1	T2	T3	T4	T0	T1	T2	T3	T4
1	8.74 ± 1.15	8.89 ± 1.10	9.10 ± 1.10	9.42 ± 0.96	9.16 ± 1.01	7.84 ± 1.86	8.11 ± 1.70	8.21 ± 1.55	8.63 ± 1.42	8.89 ± 1.25
2	8.73 ± 1.10	8.89 ± 1.10	9.10 ± 1.10	9.42 ± 0.96	9.15 ± 1.01	7.84 ± 1.86	8.10 ± 1.69	8.31 ± 1.52	8.68 ± 1.41	8.94 ± 1.22
3	8.05 ± 1.64	8.05 ± 1.98	8.63 ± 1.25	8.84 ± 1.30	8.84 ± 1.25	7.57 ± 2.19	7.63 ± 1.83	7.94 ± 1.58	8.10 ± 1.48	8.47 ± 1.17
4	7.78 ± 1.71	7.84 ± 1.97	8.42 ± 1.34	8.63 ± 1.42	8.73 ± 1.19	7.78 ± 2.12	7.78 ± 1.81	8.15 ± 1.53	8.31 ± 1.41	8.63 ± 1.21
5	8.89 ± 1.10	9.00 ± 1.10	8.94 ± 1.12	9.21 ± 1.03	9.05 ± 1.02	7.94 ± 2.36	8.47 ± 1.57	8.36 ± 1.38	8.57 ± 1.80	8.78 ± 1.35
6	8.47 ± 1.38	8.84 ± 1.21	9.05 ± 1.17	9.10 ± 1.14	9.00 ± 1.15	7.84 ± 1.95	8.05 ± 1.77	8.26 ± 1.59	8.21 ± 1.71	8.68 ± 1.37
7	7.68 ± 1.91	8.31 ± 1.45	8.36 ± 1.60	8.94 ± 1.17	8.73 ± 1.14	7.15 ± 2.31	7.42 ± 1.92	7.78 ± 2.01	7.94 ± 1.50	7.82 ± 1.87
8	8.36 ± 1.70	8.68 ± 1.63	9.15 ± 1.21	9.31 ± 1.15	9.15 ± 1.16	8.42 ± 1.67	8.73 ± 1.36	8.94 ± 1.17	9.15 ± 1.16	9.00 ± 1.27
9	8.05 ± 1.31	7.63 ± 2.11	8.47 ± 1.54	8.89 ± 1.32	9.10 ± 0.87	7.15 ± 2.31	8.05 ± 1.89	8.42 ± 1.42	8.78 ± 1.08	8.94 ± 1.24
10	8.05 ± 1.39	7.89 ± 1.79	8.57 ± 1.30	8.89 ± 1.19	8.78 ± 1.22	7.84 ± 1.92	8.05 ± 2.12	8.57 ± 1.42	9.00 ± 1.45	9.00 ± 1.36
11	8.10 ± 1.69	8.31 ± 1.52	8.47 ± 1.71	8.57 ± 1.67	8.84 ± 1.46	7.05 ± 2.59	7.57 ± 2.19	8.26 ± 1.75	8.68 ± 1.60	8.52 ± 1.66
12	7.78 ± 1.54	8.21 ± 1.71	8.31 ± 1.45	8.52 ± 1.77	8.68 ± 1.73	5.63 ± 3.09	6.63 ± 2.38	7.89 ± 1.44	7.63 ± 1.86	7.94 ± 1.43

Items here reported refer to RPE questionnaire from Table 1. No significant intergroup and intragroup differences were found ($p > 0.05$). RPE, rapid palatal expander.

TABLE 7. Mean scores and standard deviations of the APP questionnaire.

APP questionnaire				
	Trial			
Item	T1	T2	T3	T4
1	8.10 ± 1.72	8.10 ± 1.52	7.89 ± 1.59	8.26 ± 1.52
2	8.52 ± 1.57	8.15 ± 1.92	8.26 ± 1.44	8.84 ± 1.01
3	7.00 ± 2.58	7.10 ± 2.51	6.63 ± 2.45	7.05 ± 2.50
4	7.10 ± 2.86	6.84 ± 2.60	6.36 ± 2.56	7.31 ± 2.02
5	7.26 ± 3.24	7.05 ± 2.97	7.10 ± 2.96	7.15 ± 3.05
6	8.26 ± 1.62	8.00 ± 1.91	8.21 ± 1.27	8.31 ± 1.41
7	8.15 ± 1.89	7.78 ± 1.78	7.84 ± 1.67	7.84 ± 1.74
8	7.47 ± 1.98	7.63 ± 1.83	7.47 ± 1.77	8.05 ± 1.77
9	8.00 ± 1.76	8.05 ± 1.92	7.89 ± 1.91	8.21 ± 1.43
10	7.89 ± 1.88	7.68 ± 1.85	8.21 ± 1.22	8.26 ± 1.28
11	7.78 ± 1.90	7.94 ± 1.71	8.10 ± 1.69	8.10 ± 1.62
12	7.31 ± 1.76	7.52 ± 1.80	7.52 ± 1.50	7.78 ± 1.71

Items here reported refer to APP questionnaire from Table 1. No significant intergroup and intragroup differences were found ($p > 0.05$). APP, application.

analogous to those of the WhiteTeeth study with regard to the age of the participants, the type of appliance employed, and the objectives of the study. The administration of questionnaires yielded substantial results. It was observed that analogous outcomes were achieved in two additional studies [37, 38].

In view of the fact that orthodontic applications are becoming increasingly prevalent in smartphone stores, it is imperative to emphasise the necessity for the development of high-quality applications that provide evidence-based information. A recent study [27] investigated this topic and found that, in general, the information provided by the available orthodontic apps is of a poor quality, with almost 58% of applications sponsored by software developers and not by clinicians. It is evident that the predominant interest in orthodontic applications is in the domain of oral hygiene, given the challenges associated with the transmission of information regarding treatment modalities [27]. The role of social media in the dissemination of health-related information has been a subject of much debate, particularly with regard to the prevalence of low-quality content [39]. A number of studies have analysed the use of these devices as an aid in orthodontic treatments, yielding positive results [40, 41]. This is due to the fact that they provide assistance to patients in a more straightforward manner. Nevertheless, the absence of personalised notifications and/or reminders, in conjunction with the generalisability of the information, constitute limitations of this approach [40].

The second null hypothesis was partially rejected, as the cumulative orthodontic urgencies were found to be significantly lower in the Trial group than in the Control group. However, no significant differences were observed in the between-group comparisons at each time frame. It should be highlighted that the cumulative urgencies were lower in the Trial group, suggesting a possible usefulness of the application in managing this aspect of the tested orthopaedic treatment. The prevailing body of literature addresses oral hygiene [36, 37, 42], though an exploratory study has been undertaken into orthodontic concerns, albeit exclusively among dental students [43]. This underscores the necessity to consider potential bias in the selection of participants. The study on Labkhand application, for instance, furnished details on fixed orthodontic treatment and ascertained that bracket failures occurred in less than half of the patients [37]. In this particular instance, the application proved to be both beneficial and accessible to patients, serving as a valuable reinforcement of verbal instructions.

To evaluate the effective use of Ortodontika application, the number of accesses was recorded in the Trial group. The mean number of application accesses was higher during the initial treatment phases (T0–T2), when patients were adapting to the new palatal appliance. Access frequency progressively decreased over time (T2–T4), suggesting that the need for information and reassurance was greatest at the beginning of treatment. The large standard deviation observed at T1–T2 indicates heterogeneous engagement levels among patients during the adaptation period.

Regarding the questionnaires administered to both parents and children during the research, no significant intragroup and intergroup differences were found for the RPE questionnaire, and no significant intragroup differences were found in the APP questionnaire, both for the parents' and the patients' items. The reasons should be found in the fact that parents could be not so well aware of the functioning of the RPE and the estimated duration of treatment, while patients were pediatric patients with limited comprehension ability. Previous studies used questionnaires to understand the effects of oral health applications. In the study by Deleuse *et al.* [44], patient-reported outcomes were assessed through a four-item questionnaire in the intervention group. The results indicated that adolescents perceived the application as relatively easy to use and were likely to recommend it to peers. However, motivation to improve oral hygiene and the willingness to continue using the application after the trial were more moderate, suggesting that the initial enthusiasm for the application tended to decrease over time. Additionally, it should be considered that adolescents were recruited for this study. Conversely, Tayebi *et al.* [45] employed a more comprehensive seven-item questionnaire administered before and after a six-month period. Patients who used the "Labkhand" application reported a significant increase in overall satisfaction compared to controls, particularly in domains related to appointment reminders, general information on orthodontic treatment, and oral hygiene maintenance. Improvements were less pronounced in items addressing service quality and patient–orthodontist communication. In this study, no details were reported regarding the age of the patients.

The present study was subject to certain limitations. Initially, the smartphone application was downloaded and primarily utilised by parents as a support measure during the initial phase of treatment. It is therefore not possible to confirm the effective use and delivery of information as regards applications directly used by patients. Additionally, it is difficult to achieve compliance from pediatric patients as it is for older patients. Although the application was compatible with most Android and iOS devices, and freely available, the requirement of owning a smartphone with internet access may have introduced a slight selection bias toward participants with higher socioeconomic status. Further studies should consider the evaluation of other available orthodontic appliances, which affect patients' ability to perform oral hygiene manoeuvres in different ways. It is important to note the increasing use of technology in dentistry, and practitioners should be aware that tools such as smartphone applications, remote monitoring and artificial intelligence [46–48] will become increasingly part of everyday orthodontic practice, therefore future studies in this field are welcomed.

5. Conclusions

This study suggested the use of the "Ortodontika" smartphone application may reduce cumulative urgencies in patients RPE as significantly lower urgencies were found in the Trial group versus the Control group cumulatively and after 6 months of RPE treatment. The number of accesses at the application was higher in the time frame T0–T2, but with no significant differences with the other time frames, suggesting a possible usefulness of the application in the initial phase of the treatment.

ABBREVIATIONS

BI, bleeding index; MGI, modified gingival index; PI, plaque index; RPE, rapid palatal expander; GDPR, European General Data Protection Regulation; CONSORT, CONsolidated Standards of Reporting Trials; APP, application.

AVAILABILITY OF DATA AND MATERIALS

Data are available upon request to the corresponding author.

AUTHOR CONTRIBUTIONS

AS, MP and MFS—designed the research study. MP, MB and CB—performed the research. MB and MP—wrote the manuscript. FM—developed Ortodontika application. AS—analyzed the data. MP and AB—revised the manuscript. All authors read and approved the final manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

All procedures performed in this study were in accordance with the Declaration of Helsinki (1964) and its later amendments, and it was approved by the Internal Review Board of the Unit of Orthodontics and Pediatric Dentistry (2022-0622). The study was registered on clinicaltrials.gov (NCT05539469). Informed consent for the participation in the study of the minors was signed by parents/legal guardians.

ACKNOWLEDGMENT

Not applicable.

FUNDING

This research received no external funding.

CONFLICT OF INTEREST

Federico Magnani is the developer of Ortodontika application but has no financial interest. Andrea Scribante is serving as the Editor-in-Chief. Maurizio Pascadopoli is serving as Editorial Board member of this Journal. We declare that Andrea Scribante and Maurizio Pascadopoli had no involvement in the peer review of this article and have no access to information regarding its peer review. Full responsibility for the editorial process for this article was delegated to NK.

SUPPLEMENTARY MATERIAL

Supplementary material associated with this article can be found, in the online version, at https://oss.jocpd.com/files/article/2049728978124455936/attachment/Supplementary%20material.docx.

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How to cite this article: Andrea Scribante, Maurizio Pascadopoli, Andrea Butera, Federico Magnani, Camilla Bellosta, Margherita Bertola, Maria Francesca Sfondrini. Evaluation of a smartphone application in controlling oral hygiene and orthodontic urgencies in pediatric patients with rapid palatal expander: randomized clinical trial. Journal of Clinical Pediatric Dentistry. 2026; 50(3): 82-93. doi: 10.22514/jocpd.2026.063.