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Randomized Controlled Trial (RCT)

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Evaluation of the effectiveness of a tailored mobile application in increasing the duration of wear of thermoplastic retainers: a randomized controlled trial

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Summary

Background: The 'My Retainers' mobile application is a patient-informed intervention designed to enhance removable retainer wear and associated patient experiences during the retention phase.
Objectives: To evaluate the effect of receiving the 'My Retainers' application on objectively assessed thermoplastic retainer (TPR) wear time, stability, periodontal outcomes, patient experiences, and knowledge related to retainers.
Materials and methods: Eighty-four participants planned for removable retention with TPRs were assigned either to receive the 'My Retainers' application or to control not receiving electronic reminders during the 3-month period. Randomization was based on computer-generated random numbers and allocation was concealed using opaque, sealed envelopes. The primary outcome was objectively assessed retainer wear recorded using an embedded TheraMon® micro-electronic sensor. Secondary outcomes, including irregularity of the maxillary and mandibular incisors, plaque levels, bleeding on probing and probing depth, were assessed at baseline and 3-month follow-up; and analysed using a series of mixed models. Experiences and knowledge related to orthodontic retainers were recorded using questionnaires. The outcome assessor was blinded when possible.
Results: Receipt of the mobile application resulted in slightly higher median wear time (0.91 hours/day); however, this difference was not statistically significant (P = 0.56; 95% confidence interval [CI]: –2.19, 4.01). No significant differences were found between the treatment groups in terms of stability (P = 0.92; 95% CI: –0.03, 0.04), plaque levels (P = 0.44; 95% CI: –0.07, 0.03), bleeding on probing (P = 0.61; 95% CI: –0.05, 0.03) and probing depth (P = 0.79; 95% CI: –0.09, 0.07). Furthermore, similar levels of patient experiences (P = 0.94) and knowledge related to retainers (P = 0.26) were found. However, marginally better levels of knowledge were identified in the intervention group. No harms were observed.
Limitations: A relatively short follow-up period with the study confined to a single-center in a university-based hospital.

Conclusions: Provision of the bespoke 'My Retainers' application did not lead to an improvement in adherence with TPR wear over a 3-month follow-up period. Further refinement and research are required to develop and investigate means of enhancing adherence levels.
Clinical registration: NCT03224481.

Introduction

Maintenance of post-treatment orthodontic outcomes hinges on the levels of adherence to orthodontic retention. Barriers to removable retainer wear including negative impact on quality of life, forgetfulness, and a lack of appreciation of the importance of retainer wear have been identified in previous studies (1, 2). The centrality of the patient–clinician relationship in terms of sharing concerns and frequency of follow-up appointments has also been highlighted in qualitative research (1). Notwithstanding this, suboptimal adherence has been exposed in prospective studies with just one-third of participants claiming to be adherent with Essix-type retainer wear 2 years into the retention phase (3). The importance of developing and evaluating relevant interventions to enhance wear and ameliorate negative experiences associated with orthodontic retainers is therefore clear (4).

The unprecedented access to mobile phones has raised the potential for use for personalized healthcare management and delivery of health-related information (5). A total of 241 patient-centered orthodontic mobile applications were developed in 2018, representing a three-fold increase since 2014 (6). However, relatively little prospective assessment of the effectiveness of these approaches in orthodontics has been undertaken (4). In a recent randomized controlled trial, access to moderated WhatsApp groups involving photo sharing and monthly ranking was postulated to improve Hawley retainer wear, based on the superior stability outcomes in terms of inter-canine width at 1-year follow-up (7). However, neither objective nor subjective wear time was assessed (7). Nevertheless, it is conceivable that receipt of an electronic reminder can enhance adherence to removable orthodontic retainer wear. Additionally, receiving a mobile application has been shown to be effective in terms of improving oral hygiene (8, 9), reducing the occurrence of white spot lesions and caries (9), improving attendance, and reducing the duration of treatment (10).

In a recent qualitative study, participants advocated the use reminders through a mobile application to facilitate adherence to removable functional appliance wear (11). Receipt of electronic reminders is a passive process involving automatic notification when the reminder is received. Furthermore, these approaches offer the potential to motivate and educate on the importance of retainer wear. Addressing patients' needs by capturing preferences can help to make the intervention appealing and, therefore, potentially improve outcomes. The 'My Retainers' mobile application is a patient-informed intervention and was developed following a rigorous methodology involving triangulation of the findings of two qualitative methods (12).

The primary aim of this study was to analyse the effect of receiving the 'My Retainers' mobile application on adherence to thermoplastic retainer (TPR) wear. The secondary aims were to investigate the effects of receiving the mobile application on the stability of the outcome and periodontal health following removal of fixed appliances, patient experiences, and knowledge related to orthodontic retainers.

Materials and methods

Ethical approval was obtained from the East of England, Cambridge Central Research Ethics Committee (16/EE/0189). The trial protocol was registered before the commencement of the study (ClinicalTrials.gov Identifier: NCT03224481). Participants were recruited prior to planned removal of the appliances at the Institute of Dentistry, Barts and The London School of Medicine and Dentistry. The inclusion criteria were: participants aged 12–21 years; planned for removable retention with TPRs; on no medication known to have an effect on gingival health; and in the permanent dentition. The exclusion criteria were: inability to access or peruse a compatible smart phone (iPhone; Apple Inc.); cleft lip and palate or other craniofacial anomalies; and history of periodontal disease. An information sheet was provided with oral and written consent obtained from participants agreeing to take part.

Based on previous research (13) with a non-adherence rate of 31 per cent characterized by wear of the appliance for less than 2 hours daily, a minimum of 68 participants (34 in each group) was required with a power of 80 per cent to detect a minimum difference of 25 per cent in adherence rates at the 0.05 level of statistical significance. To compensate for a drop-out rate of at least 20 per cent, the final number enrolled in the trial was 84.

Randomization was based on computer-generated random numbers and was stratified in a ratio of 1:1 in relation to gender. Allocation was concealed from the treating clinician using an opaque, sealed envelope system. Participants in the intervention group received access to the 'My Retainers' mobile application via a unique identification code (12). Participants in the control group did not have access to the mobile application.

The primary outcome was objective wear time (hours per day). The following secondary outcomes were also assessed:

- Maxillary and mandibular Little's irregularity index (14)
- Periodontal outcomes including plaque scores, bleeding on probing, and probing depth
- Subjective wear time
- Patient experiences and knowledge related to retention

Standardized oral hygiene instructions were given to all participants at debond and recall appointments. Information related to oral hygiene practices were recorded at baseline (T0). Maxillary and mandibular TPRs (Essix ACE® Plastic 1 mm in thickness (DENTSPLY)) were fitted 7–10 days following debond. All participants were instructed to wear TPRs on a full-time basis (22 hours) for 6 months, followed by part-time wear (8 hours) for a further 6 months. A TheraMon® micro-electronic sensor (MC Technology GmbH, Hargelsberg, Austria) was embedded in the maxillary TPR in all participants following a standardized laboratory technique (KM'L) (Supplementary material 1). Participants in both groups had a follow-up appointment scheduled at 3 months (T1) following removal of the appliances (T0).

A reading station facilitated data transfer to an encrypted cloud database using TheraMon® Azure reader client software

(version 1.2.1.1; MC Technology GmbH, Hargelsberg, Austria). Data were transferred using radio-frequency identification technology. Appliance wear was recorded within a specific temperature range (33.5°C and 38.5°C). The TheraMon® micro-electronic sensor records temperature at 15-minute intervals; as such, data could be restored for up to 100 days. Subjective data pertaining to wear involved completion of a retainer wear chart in the control group (Figure 1), and use of a calendar tool within the mobile application in the intervention group (Figure 2).

Impressions of both dental arches were taken at T0 and T1 using hydrophilic vinyl polysiloxane (Virtual; Ivoclar Vivadent, Schaan, Lichtenstein) and study models were made from orthodontic plaster (ISO type 2; Whip Mix Corporation, Louisville, KY, USA). Periodontal assessment was undertaken at T0 and T1. Each tooth surface was divided into thirds using vertical lines based on the morphology and position of the dental papilla. The periodontal measures were scored clinically on the labial/buccal and palatal/lingual surfaces in both arches from first molar to first molar, at six sites per tooth by one researcher (DA) and included the following:

- Plaque scores: a liquid disclosing solution (Plaqsearch™, TePe®, Malmö, Sweden) was applied using a swab pressed against each papilla, followed by 10 ml water rinsing. Plaque was scored as present or absent.
- Bleeding on probing: a binary assessment of bleeding on probing was undertaken with a maximum waiting time of 15 seconds.
- Probing depth: measured to the nearest 0.5 mm from the gingival margin to the base of the gingival sulcus using a Williams probe (Hu-Friedy, Chicago, Illinois, USA).

Participants in both groups were asked to complete a questionnaire at T1 concerning their experiences and knowledge in relation to TPRs (Supplementary material 2).

Maxillary and mandibular Little's irregularity index (14) were measured by one researcher (DA) using a digital calliper (150 mm DIN 862, ABSOLUTE Digimatic calliper, model 500-191U; Mitutoyo, Andover, Hampshire, UK) with a resolution of ±0.01 mm. Mean objectively assessed hours of retainer wear was obtained from cloud software (TheraMon Azure®, version 1.2.1.11) and graphical display of the data was evaluated to detect lack of retainer wear over a period of three consecutive days or more.

Participants in both groups were aware of being monitored. Blinding of either the operator or the participants to the allocated arm during treatment was not possible for the periodontal assessment. However, the use of coded study models and data ensured that the researcher was kept blind to the treatment group when undertaking measurements and during data analysis. The statistician was also kept blind to group allocation.

In cases in which replacement of the TPR was required, reasons were recorded and the same micro-electronic sensor was used, where possible. If a participant opted to have a TPR without a micro-electronic sensor, a new TPR was fitted and the participant was retained in the study.

As the data were not normally distributed, medians and interquartile range (IQR) are presented. Imputation of missing data was undertaken to account for losses and to compensate for uncertainty surrounding missing values. Missing baseline data for periodontal (plaque levels, bleeding on probing, and probing depths) and stability outcomes were imputed using the corresponding mean for each group (15). Objective data pertaining to retainer wear were imputed

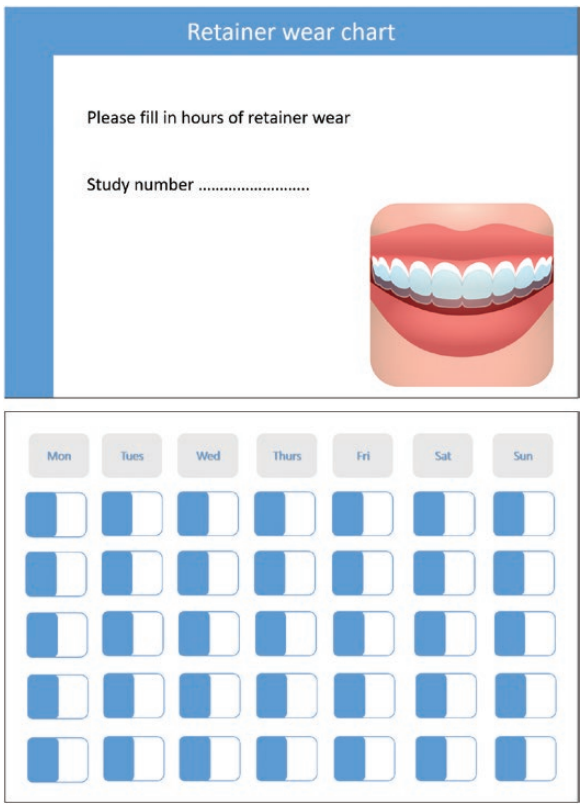

Figure 1. Retainer wear chart.

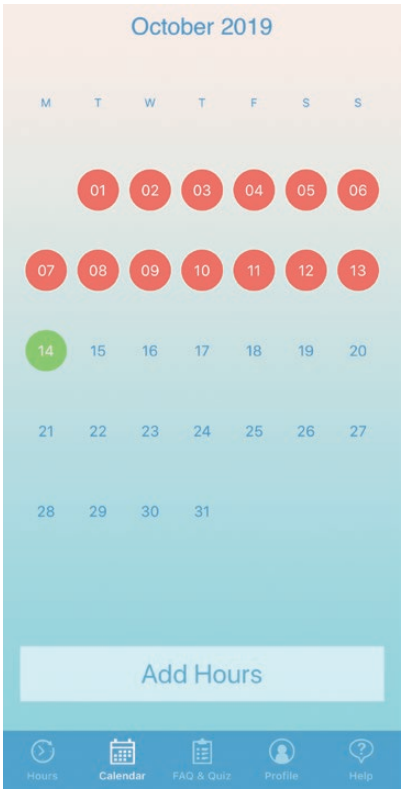

Figure 2. Screenshot of the calendar tool in the 'My Retainers' mobile application.

by creating new datasets (n = 40 iterations) with 10 values imputed by the software. For each of these datasets, estimates were calculated by fitting a corresponding separate model (16). Consequently, the estimates were combined to produce the average final estimate (17). The linear regression model accounted for treatment group, available subjective data as well as complete observation variables including age and gender. This permitted imputation of missing values using values drawn from a distribution based on observed participant values with similar baseline characteristics. A series of mixed models were then fitted in the imputed dataset accounting for correlation. The level of statistical significance was set at 0.05 with all analyses undertaken using the Stata statistical software package (version 15.1; StataCorp, College Station, TX, USA). The exact Mann–Whitney U-test was used to compare experience and knowledge outcomes between the treatment groups. The analysis was performed in R software (18).

An online course was completed (DA) to facilitate familiarization with measurement of periodontal outcomes. For stability measurements, intra-examiner reliability was performed on 10 randomly selected study models 4 weeks after the initial measurement. Intra-examiner reliability in relation to plaque scoring was assessed by repeating measurements on 10 intra-oral photographs at a 4-week interval. Probing depth measurements were repeated on 10 healthy volunteers 30 minutes apart. Differences between the repeated measurements relating to stability, mean probing depths, and mean plaque scores per tooth were assessed using intraclass correlation. Excellent agreement was observed for stability (intraclass correlation coefficient; ICC: 0.97) and periodontal outcomes including plaque score (ICC: 0.96) and probing depth (ICC: 0.93).

Results

The full trial dataset is available online (https://doi.org/10.17636/01059856). Eighty-four participants were enrolled and randomized with 42 participants per group and equal gender distribution (Table 1 and Figure 3). Overall, the groups were well matched in terms of age, duration of orthodontic treatment, and self-reported oral hygiene practices (Table 1). Slightly more participants were treated without extractions in the control group.

Stability and periodontal data were recorded for 80 participants at baseline with missing values imputed, and 64 at 3-month follow-up (Figure 3) with retainer failures recorded (Table 2). The mean duration from T0 to T1 was 100.78 (standard deviation (SD) 23.49) days.

The median duration of objectively assessed retainer wear was slightly higher in the intervention (7.25 hours/day) than control group (6.21 hours/day). After adjusting for confounders, the median wear was 0.91 hours/day higher in the intervention group (95% CI: −2.19, 4.01 hours/day); however, the between-group difference was not statistically significant (P = 0.56) (Table 3). A period of no wear for three consecutive days or more was observed in more than half of the sample in both groups (Table 3). The median percentage of days in which the retainers were worn for less than 8 hours a day and a minimum of 2 hours of continuous use was 44.3 per cent in the intervention group, and 53.3 per cent in the control group (Table 3). Objectively assessed retainer wear data were available for a mean of 87.41 (SD: 20.1) days. A median discrepancy of 4.96 hours was found between subjective and objective wear time, based on 30 participants with both measures available.

No significant difference between the treatment groups was observed in terms of incisor irregularity (P = 0.92) and periodontal outcomes including plaque scores (P = 0.44), bleeding on probing (P = 0.61), and probing depth (P = 0.79) (Table 3).

Table 1. Baseline characteristics of the sample (n = 84).

	Overall sample n = 84	Control group n = 42	Intervention group n = 42
Mean age in years ± SD	17.23 ± 1.9	17.20 ± 1.89	17.24 ± 2.00
Gender, n (%)			
Males	42 (50)	21 (50)	21 (50)
Females	42 (50)	21 (50)	21 (50)
Mean duration (years) of orthodontic treatment ± SD	2.63 ± 0.86	2.72 ± 1.04	2.55 ± 0.64
Treatment protocol, n (%)			
Extraction	51 (60.7)	29 (69) (Mx only n = 7; Mn only n = 4; both arches n = 18)	22 (52.4) (Mx only n = 2; Mn only n = 3; both arches n = 17)
Non-extraction, n (%)	33 (39.3)	13 (31)	20 (47.6)
Type of tooth-brush, n (%)			
Manual	60 (71.4)	30 (71.4)	30 (71.4)
Electric	20 (23.8)	10 (23.8)	10 (23.7)
NI	4 (4.8)	2 (4.8)	2 (4.8)
Daily tooth-brushing frequency, n (%)			
Once	11 (13.1)	6 (14.3)	5 (11.9)
Twice	67 (79.8)	32 (76.2)	35 (83.3)
Three times	2 (2.4)	2 (4.8)	0 (0)
NI	4 (4.8)	2 (4.8)	2 (4.8)
Time spent tooth-brushing, n (%)			
<1 minute	3 (3.6)	2 (4.8)	1 (2.4)
1–2 minutes	56 (66.7)	29 (69)	27 (64.3)
>2 minutes	21 (25)	9 (21.4)	12 (28.6)
NI	4 (4.8)	2 (4.8)	2 (4.8)
Use of other oral hygiene measures, n (%)			
None	45 (53.6)	20 (47.6)	25 (59.5)
Dental floss	12 (14.3)	8 (19)	4 (9.5)
Interdental brush	10 (11.9)	6 (14.3)	4 (9.5)
Toothpick	13 (15.5)	6 (14.3)	7 (16.7)
NI	4 (4.8)	2 (4.8)	2 (4.8)
Last visit to the dentist, n (%)			
≤6 months	18 (21.4)	9 (21.4)	9 (21.4)
>6 months to 1 year	15 (17.9)	8 (19)	7 (16.7)
>1 year	47 (56)	23 (54.8)	24 (57.1)
NI	4 (4.8)	2 (4.8)	2 (4.8)
Smokers, n (%)	4 (4.8)	2 (4.8)	2 (4.8)
Pregnancy, n (%)	0 (0)	0 (0)	0 (0)

Mn, mandibular; Mx, maxillary; NI, no information; SD, standard deviation.

In terms of patient experiences, the highest scores (4 and 5) were most frequently selected in both groups, indicating similar levels of satisfaction in both treatment groups (Table 4). Levels of knowledge were marginally better in the intervention group (Table 4). However, no significant difference was found between intervention and control groups for both outcomes (Table 5).

Discussion

Receipt of the mobile application did not seem to significantly improve objectively assessed adherence levels, stability, periodontal outcomes, patient experiences, and knowledge related to orthodontic retainers at 3-month follow-up. The limited benefit of interventions directed at enhancing adherence levels with orthodontic retainers has been exposed in previous research (4). This may relate to the

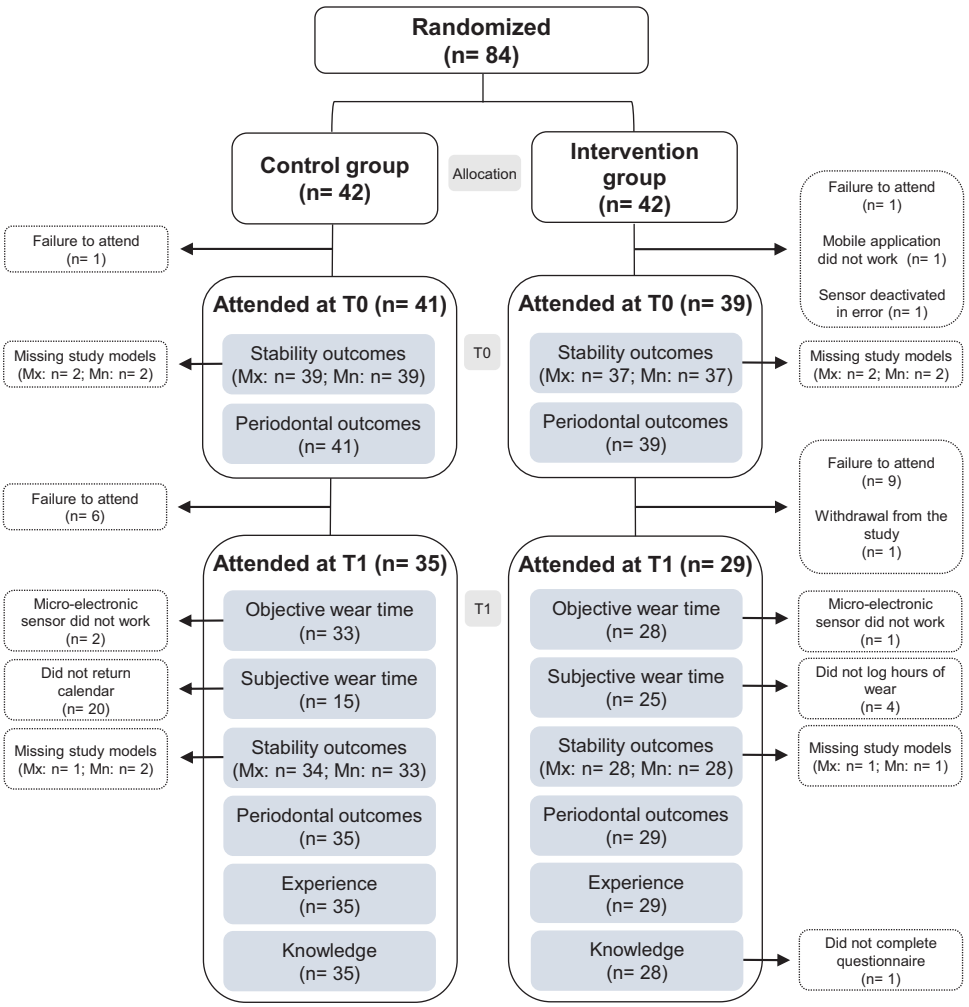

Figure 3. CONSORT diagram showing the flow of participants. Mn: mandibular; Mx: maxillary.

complex and multi-faceted nature of adherence with extraneous factors including associated negative impact on quality of life and pragmatic issues related to retainer wear also being important (1).

The multitude of functions built in the 'My Retainers' mobile application were designed to address reported barriers to retainer wear (1, 12). For example, a reminder system was included to overcome forgetfulness. An exhaustive list of frequently asked questions and the ability to contact the researcher were included to address potential concerns related to retainer wear. Furthermore, this intervention was underpinned by key behavioural change theories (12). The potential benefit of utilizing a combination of approaches to behaviour change in developing Internet-based health-related interventions was highlighted in a previous systematic review (19).

The use of supplementary methods for information provision such as written, audio, and visual information has been shown to result in improvement in recall of orthodontic information (20–22). On the corollary, participants in the mobile application group exhibited slightly higher levels of knowledge; however, retainer wear remained suboptimal. Similar findings have been reported within the medical literature with no clear association between patients' knowledge concerning diabetes and adherence behaviours (23). The limited effect of the mobile application on adherence may be explained by inadequate usage of the different features. This was evident in the median number of days in which the retainer wear was logged (n = 11; IQR: 51) and the limited interaction in terms of the number of emails sent by participants (n = 6) throughout the study. However, user engagement with the intervention, the number of times participants accessed the mobile application, consistency of use, and time spent viewing its content are unclear. Unknown barriers to the limited effectiveness of the mobile application will be addressed using an explanatory qualitative study in keeping with previous approaches (24).

Table 2. Thermoplastic retainer failures during the study.

Reasons	Maxillary TPR	Mandibular TPR
Poor fit	4	5
Retainer loss	2	2
Breakage of the retainer	7	0
Detachment of the micro-electronic sensor	2	n/a
Total	15	7

n/a, not applicable; TPR, thermoplastic retainer.

Table 3. Data pertaining to retainer wear, stability, and periodontal outcomes in both treatment groups. Data presented as median (interquartile range).

Outcomes	Control group*	Intervention group	Coefficient†	95% CI	*P* value
Adherence levels					
* Objective data (h/d)	**6.21 (7.86)**	**7.25 (6.71)**	−0.91	−4.01, 2.19	0.56
* Percentage of participants with ≥3 consecutive days of no retainer wear	57.6%	53.6%	–		
* Median percentage of days with wear as instructed (8 h/d and a minimum of 2 hours of continuous use)	46.67 (70.26)	55.70 (59.86)	–		
Stability outcomes					
Maxilla	T0: 0.12 (0.1) T1: 0.14 (0.17)	T0: 0.16 (0.18) T1: 0.19 (0.22)	0.002	−0.03, 0.04	0.92
Mandible	T0: 0.16 (0.14) T1: 0.16 (0.21)	T0: 0.11 (0.12) T1: 0.16 (0.13)			
Periodontal outcomes					
Plaque scores					
Maxilla	T0: 0.84 (0.27) T1: 0.74 (0.22)	T0: 0.84 (0.18) T1: 0.75 (0.17)	−0.02	−0.07, 0.03	0.44
Mandible	T0: 0.79 (0.25) T1: 0.76 (0.18)	T0: 0.84 (0.17) T1: 0.77 (0.17)			
Bleeding on probing					
Maxilla	T0: 0.17 (0.18) T1: 0.09 (0.1)	T0: 0.16 (0.17) T1: 0.08 (0.14)	−0.01	−0.05, 0.03	0.61
Mandible	T0: 0.17 (0.18) T1: 0.1 (0.14)	T0: 0.20 (0.14) T1: 0.11 (0.1)			
Probing depth					
Maxilla	T0: 2.0 (0.18) T1: 1.93 (0.24)	T0: 2.0 (0.25) T1: 1.92 (0.31)	−0.01	−0.09, 0.07	0.79
Mandible	T0: 1.7 (0.27) T1: 1.62 (0.22)	T0: 1.8 (0.18) T1: 1.6 (0.27)			

CI, confidence interval; h/d, hours/day.
*Reference group.
†Effect of treatment group on the outcome variables at T1.

The median wear time was slightly higher in the intervention compared to the control group; however, the difference was not statistically significant. Nevertheless, the median objectively assessed retainer wear was just 28.2 per cent and 33 per cent of 22 hours stipulated in the control and intervention groups, respectively. Moreover, participants were aware of being monitored in the current study with the latter thought to lead to artificially high wear levels. Micro-electronic sensors have been shown to under-report wear duration by the order of 4 per cent (25); this discrepancy was dwarfed by the low objective readings identified among the present group of participants. In a previous study with similar stipulated wear time, better levels of adherence (45.5–60 per cent) were found with Hawley retainers at 3-month follow-up (26). However, details of randomization and allocation concealment were not reported in the latter study. Mean wear rates varied significantly (0–19.9 hours/day) and participants over-estimated wear by an average of 5.6 hours daily (26). It is also possible that the visibility of the Hawley retainer with associated labial bow may serve as a reminder to wear this type of retainer among both patients and peers.

A number of participants in the current study relayed concerns in relation to the appearance and bulk of the retainer associated with the indwelling micro-electronic sensor. Related data were collected at 6-month follow-up; the latter will be analyzed in future. It is conceivable that this may have contributed to sub-optimal adherence levels. Furthermore, patient motivation and attitudes towards treatment have been shown to influence adherence levels in orthodontics, pointing to overlapping patterns of behaviour (27, 28).

No significant difference was found between the groups in relation to the stability outcomes. This may relate to the comparable objectively assessed adherence levels in both groups but particularly to the relatively short period of follow-up. Although objectively assessed retainer wear may provide an overall assessment of adherence levels over a particular observation period, it does not reflect patterns, consistency, and distribution of wear. Fluctuations in adherence levels were previously observed with removable and functional appliances (11, 29). Similar findings were observed in the current study, with no retainer wear over at least three consecutive days observed in more than half of the sample. Similarly, headgear (30) and removable functional appliances (31) were not worn for an average of 30 percent and 12 per cent of the duration within individual studies. This period of no wear, negatively influenced the transverse changes obtained with functional appliances (31). However, the implications of extended periods of an absence of wear may be particularly problematic with retainers, with sustained periods of non-adherence risking irreversible impairment of retainer fit and post-treatment dental changes over time.

The content of the mobile application also included general dental and oral health information (12). No significant difference was observed between both groups in terms of the periodontal measures. In previous research, superior periodontal outcomes were found at 1-month follow-up in patients receiving a mobile application including notification messages and access to an educational video focusing on oral hygiene (8), although detailed description of the intervention was not reported. Similarly, an interactive intervention involving WhatsApp group messaging resulted in better

Table 4. Responses concerning experiences and levels of knowledge related to orthodontic retainers.

Experiences

Questions	Treatment group	1. Very dissatisfied	2. Dissatisfied	3. Neither satisfied nor dissatisfied	4. Satisfied	5. Very satisfied
1. Do you feel involved in the process of wearing and taking care of your retainers?	Control (n = 35)	0 (0%)	0 (0%)	3 (8.57%)	9 (25.71%)	23 (65.71%)
	Intervention (n = 29)	0 (0%)	0 (0%)	4 (13.79%)	6 (20.69%)	19 (65.52%)
2. How well do you feel you are being looked after since your braces were removed?	Control (n = 35)	0 (0%)	0 (0%)	2 (5.71%)	14 (40%)	19 (54.29%)
	Intervention (n = 29)	1 (3.45%)	0 (0%)	2 (6.9%)	5 (17.24%)	21 (72.41%)
3. How would you rate your overall experience within the last 3 months in terms of your use of retainers and contact with the clinic?	Control (n = 35)	0 (0%)	0 (0%)	5 (14.29%)	9 (25.71%)	21 (60%)
	Intervention (n = 29)	0 (0%)	2 (6.9%)	2 (6.9%)	11 (37.93%)	14 (48.28%)

Knowledge

Questions	Treatment group	Percentage of correct responses
1. If I wear the retainers really well for the first year, I can stop wearing them after that.	Control group (n = 35)	29/35 (82.86%)
	Intervention group (n = 28)	25/28 (89.29%)
2. How many hours a day do you need to wear the retainers?	Control group (n = 35)	21/35 (60%)
	Intervention group (n = 28)	19/28 (67.86%)
3. If you stopped wearing the retainers, what is likely to happen after a few weeks?	Control group (n = 35)	35/35 (100%)
	Intervention group (n = 28)	28/28 (100%)
4. How long do you need to wear your retainers for?	Control group (n = 35)	29/35 (82.86%)
	Intervention group (n = 28)	24/28 (85.71%)
5. What would you do if your retainers no longer fit or if you had problems with wearing them?	Control group (n = 35)	31/35 (88.57%)
	Intervention group (n = 28)	26/28 (92.86%)

Table 5. Experience and knowledge outcomes in treatment groups (exact Mann–Whitney *U*-test).

Outcomes	Treatment group	Scores (median (IQR))	*P* value
Patient experiences (score out of 15)	Control group (n = 35)	14 (3)	0.94
	Intervention group (n = 29)	14 (2)	
Knowledge (score out of 5)	Control group (n = 35)	4 (1)	0.26
	Intervention group (n = 28)	5 (1)	

IQR, inter-quartile range.

periodontal outcomes at 1-year follow-up, although the difference was not significant at 3-month follow-up (9). The use of a mobile application to allow tracking of toothbrushing frequency and duration did not result in a significant difference in plaque accumulation and gingival inflammation at 3-month follow-up (32). Therefore, it seems that differences in periodontal outcomes may be observed at longer follow-up periods.

Fixed retention offers superior preservation of the alignment of mandibular anterior teeth in the long term (3). However, TPRs continue to be used due to their acceptability, simplicity, and cost-effectiveness (33). Removable retainers may be prescribed for those exhibiting suboptimal oral hygiene. This might explain the significant plaque accumulation and bleeding on probing noted at baseline in both groups. Notwithstanding this, TPRs may impede flushing of saliva from dental surfaces resulting in a significant increase in *Streptococcus mutans* and *Lactobacillus* counts (34). An initial phase of full-time wear (35, 36) is often prescribed with removable retention; however, little is known about the effect of prolonged removable retainer wear on periodontal health. Interestingly, a reduction in plaque and calculus accumulation, gingival inflammation, and bleeding on probing was noted following transition to part-time TPR wear in a previous clinical trial (37).

The type of material used to fabricate the TPR in the current study (Essix ACE® Plastic) was found to have superior wear resistance in comparison to other types of commercially available materials in an *in vitro* study (38). However, a substantial proportion of retainers required replacement (n = 22) mainly due to poor fit and breakage, despite the short period of follow-up of the current study. Lower breakage rates were observed in a previous randomized controlled trial (RCT), in which only 6.6 per cent of the participants reported breakage with vacuum-formed retainers in the first 6 months of retention (33). This could be explained by the difference in the type and thickness of the material used in the previous study (1.5 mm) (33). It is also possible that the incorporation of the micro-electronic sensor in the present study may have predisposed to fracture.

The stipulated wear time in the current study was in line with previous research (39). However, there is some evidence to suggest similar outcomes with part-time wear (40). Part-time wear is also regarded as more realistic and achievable with minimal impact on daily activities (1, 11). This is likely to explain the part-time wear of Twin Blocks despite full-time prescription with mean wear rates of 12 hours daily observed in a group advised to wear the appliance full-time and 8 hours daily in the prescribed part-time group (41). It is conceivable that the relatively disappointing wear times reported with retainers in the present study may reflect both complacency as well as a lack of understanding of the implications of poor wear in

this cohort (42). In the current study, stratified randomization was undertaken to ensure balanced gender distribution in the treatment groups. This was considered important as adherence levels to intra-oral removable appliance wear have been shown to vary significantly based on gender (43).

Limitations and generalizability

Drop-out rates in orthodontic RCTs are typically of the order of 13 per cent of those recruited (44). This was accounted for in the current trial statistically by imputation of missing data as well as by inflation of the sample size by 20 per cent in order to retain adequate power. However, the drop-out rate was 24 per cent. A greater proportion of drop-outs are typical of trials concerning retention particularly as no active treatment is being provided (3), highlighting the importance of making adequate allowance for drop-outs in future research on orthodontic retention. Furthermore, loss of objective adherence data was inevitable due to the capacity of the TheraMon® micro-electronic sensor to restore data for no more than 100 days with a measurement interval set to 15 minutes.

The study was undertaken in one university hospital in which orthodontic treatment is funded through a national healthcare system. A significant difference between university hospital and private practice in terms of adherence levels has been exposed in previous research (43). Therefore, the applicability to other settings hinges on comparability of patient characteristics. The relatively short follow-up period might limit the holistic evaluation of the intervention. Notwithstanding this, adherence to removable appliance wear also tends to reduce over time (1); it is therefore conceivable that the benefit of the mobile application may become more apparent over a more prolonged follow-up period. We therefore plan to follow up participants in the current study up to one year post-treatment.

Conclusions

Receipt of a bespoke mobile application did not result in improvement in adherence to TPR wear, stability and periodontal outcomes, and experiences with retainers in the short term. Knowledge concerning orthodontic retainers was slightly higher in the intervention group; however, the difference was not statistically significant. Evaluation of the effectiveness of the mobile application over a longer follow-up period as well as further refinement is required.

Supplementary material

Supplementary material is available at *European Journal of Orthodontics* online.

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Conflict of interest

None to declare.

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