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

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Background: The 'My Retainers' mobile application is a patient-informed intervention designed to enhance removable retainer wear and improve patient experiences during the retention phase.

Objectives: To evaluate the effect of receiving 'My Retainers' application on objectively-assessed thermoplastic retainer (TPR) wear time, stability and periodontal outcomes and participants' experiences and knowledge related to retainers.

Materials and Methods: Eighty-four participants planned for removable retention with TPRs, were assigned to either receive the 'My Retainers' application or to a control not receiving electronic reminders during the 3-month period. Randomisation 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 patients' experiences (P= 0.94) and knowledge related to retainers (P= 0.26) were found. However,

marginally better levels of knowledge was observed in the intervention group. No harms were observed.

Limitations: A relatively short follow-up period with study conducted within a single-centre 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.

Keywords: vacuum-formed retainer; Essix-type retainer; compliance; mHealth.

ClinicalTrials.gov Identifier: 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 research (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 personalised healthcare management and delivery of health-related information (5). A total of 241 patient-centred 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 randomised 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), and 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 wear and educate on the importance of retainer wear. Addressing patients' needs by capturing preferences can help 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 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, and patient experience 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 prior to study commencement (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: aged 12 to 21 years; planned for removable retention with thermoplastic retainers (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% characterised 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% to detect a minimum difference of 25% in adherence rates at the 0.05 level of

statistical significance. To compensate for a drop-out rate of at least 20%, the final number enrolled in the trial was 84.

Randomisation 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

Standardised 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 1mm 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 standardised 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 6 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 10ml water rinse. 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 0.5mm from the gingival margin to the base of the gingival sulcus using a Williams probe.

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 caliper (150mm DIN 862, ABSOLUTE Digimatic caliper, model 500-191U; Mitutoyo, Andover, Hampshire, UK) with a resolution of ± 0.01mm (19). 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 inter-quartile 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 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, Tex). The exact Mann-Whitney test was used to compare knowledge and experience outcomes between the treatment groups. The analysis was performed in R software (18).

An online course was completed (DA) to facilitate familiarisation 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

Full trial dataset is available online (*DOI:* https://doi.org/10.17636/01059856). Eighty-four participants were enrolled and randomised with 42 participants per group and equal gender distribution (Table 1, 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 (P= 0.56; 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% in the intervention group, and 53.3% 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).

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 group 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 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 utilising 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 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).

The average 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% and 33% 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 timers have been shown to under-report wear duration by the order of 4% (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%) were found with Hawley retainers at 3-month follow-up (26). However, details of randomisation 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 analysed in future. It is conceivable that this may have contributed to suboptimal 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 and 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, a period of no wear has been shown with headgear (30), and removable functional appliances (31), in 30% and 13% of the duration of the study, respectively. 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 risk irreversible impairment of retainer fit.

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); however, detailed description of the intervention was not reported. Similarly, an interactive intervention

involving WhatsApp group messaging resulted in better periodontal outcomes at 1-year follow-up; however, 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, thermoplastic retainers 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, thermoplastic retainers 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 thermoplastic retainer 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 randomised controlled trial (RCT), in which only 6.6% 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 (1.5mm) (33). It is also possible that the incorporation of the micro-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 the full-time group 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 randomisation 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 generalisability

Drop-out rates in orthodontic RCTs is typically of the order of 13% 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% in order to retain adequate power. However, the drop-out rate was 24%. 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 up to 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 thermoplastic retainer wear, stability and periodontal outcomes and experience 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 are required.

Supplementary material is available at European Journal of Orthodontics online.

Conflict of interest statement:

The authors declare that they have no competing interests.

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Figure legends:

Figure 1. Retainer wear chart.

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

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

Table captions:

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Table 2. Thermoplastic retainer failures during the study.

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

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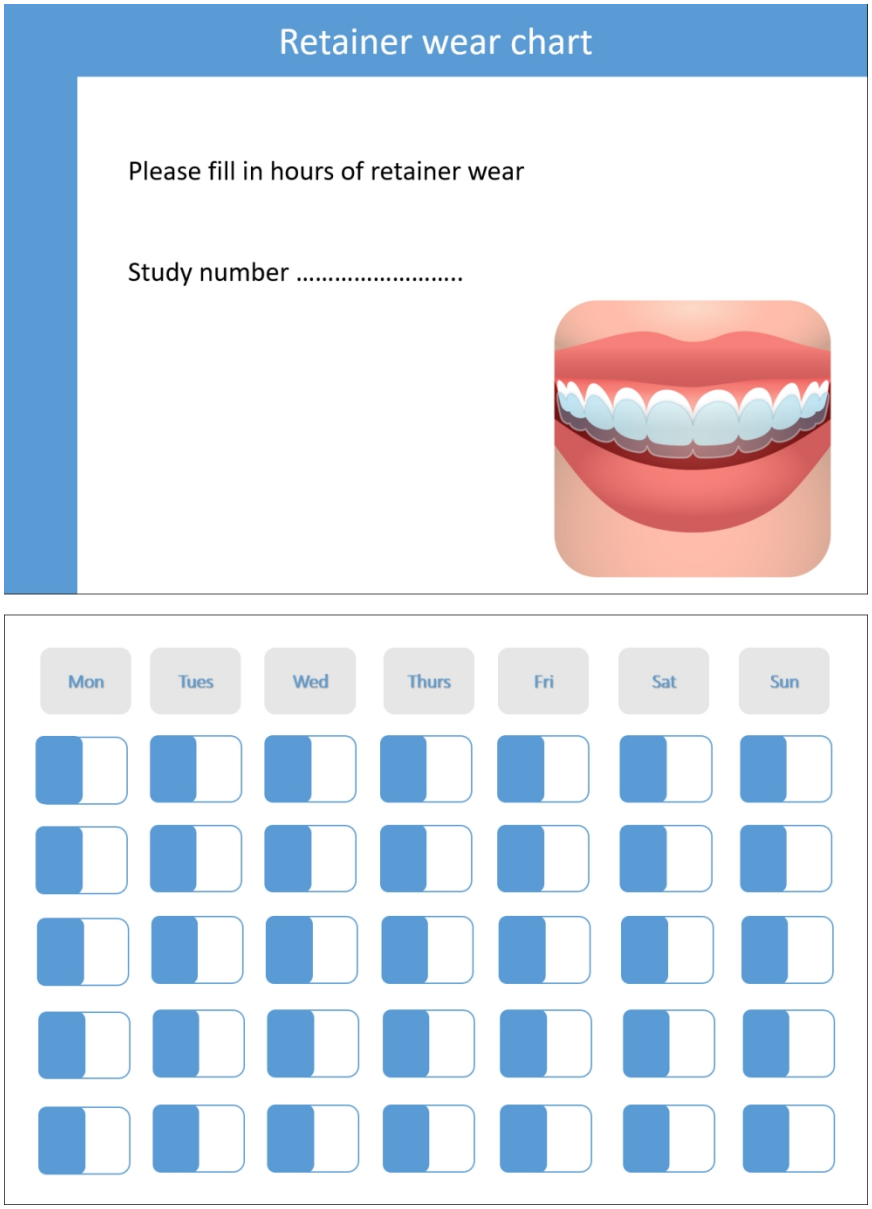


Figure 1. Retainer wear chart.

339x471mm (96 x 96 DPI)

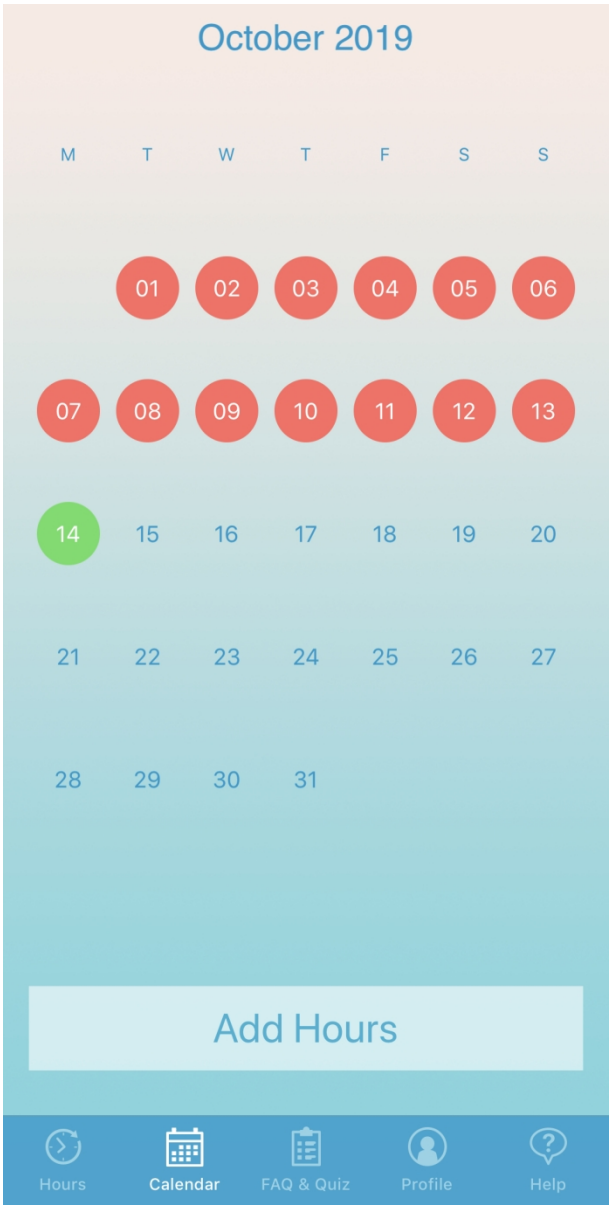


Figure 2. Screenshot of the calendar tool in the 'My Retainers' mobile application

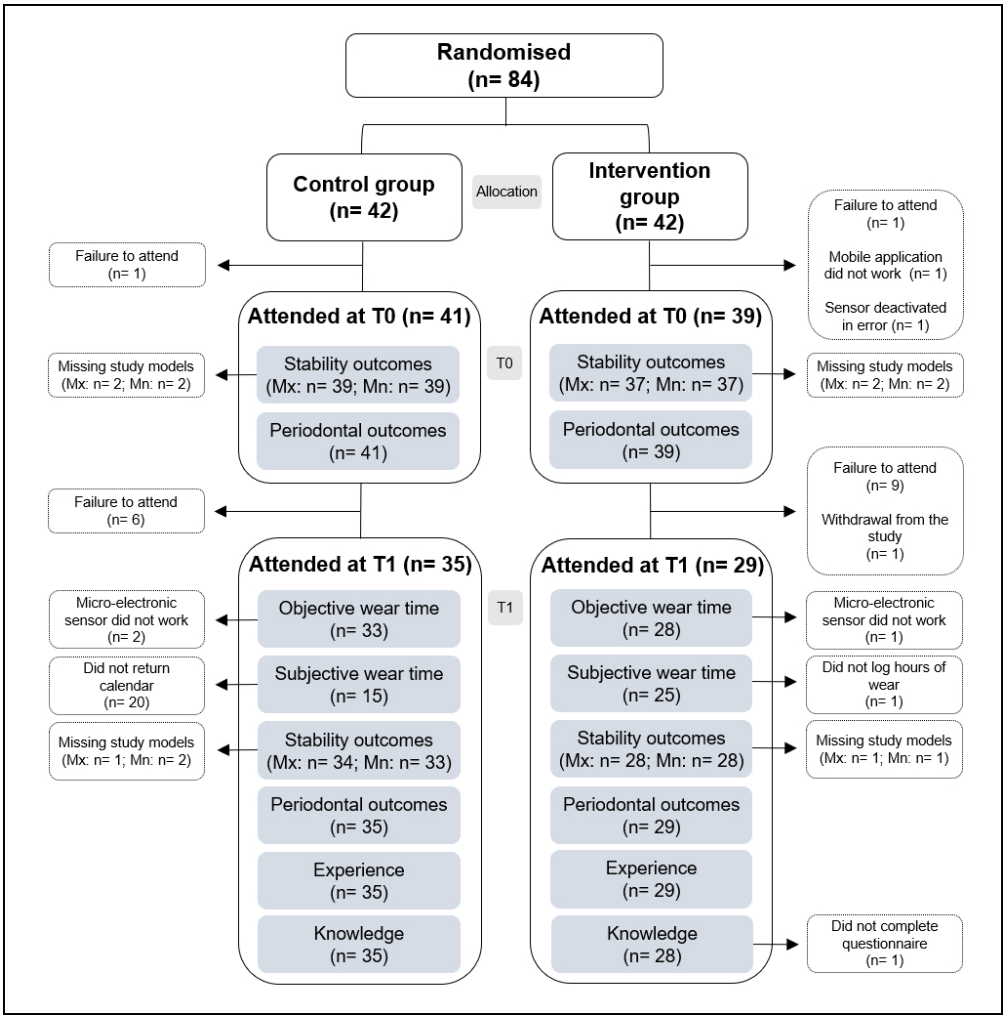


Figure 3. CONSORT diagram showing the flow of participants.Mn: mandibular; Mx: maxillary.

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

Pregnancy	n= 0 (0%)	n= 0 (0%)	n= 0 (0%)

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

Table 2. Thermoplastic retainer failures during the study.

Reasons	Maxillary TPR	Mandibular TPR
Poor fit	n= 4	n= 5
Retainer loss	n= 2	n= 2
Breakage of the retainer	n= 7	n= 0
Detachment of the micro-electronic sensor	n= 2	n/a
Total	n= 15	n= 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)	T0: 2.0 (0.25)	-0.01	-0.09, 0.07	0.79

			T1: 1.93 (0.24)	T1: 1.92 (0.31)			
		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.

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

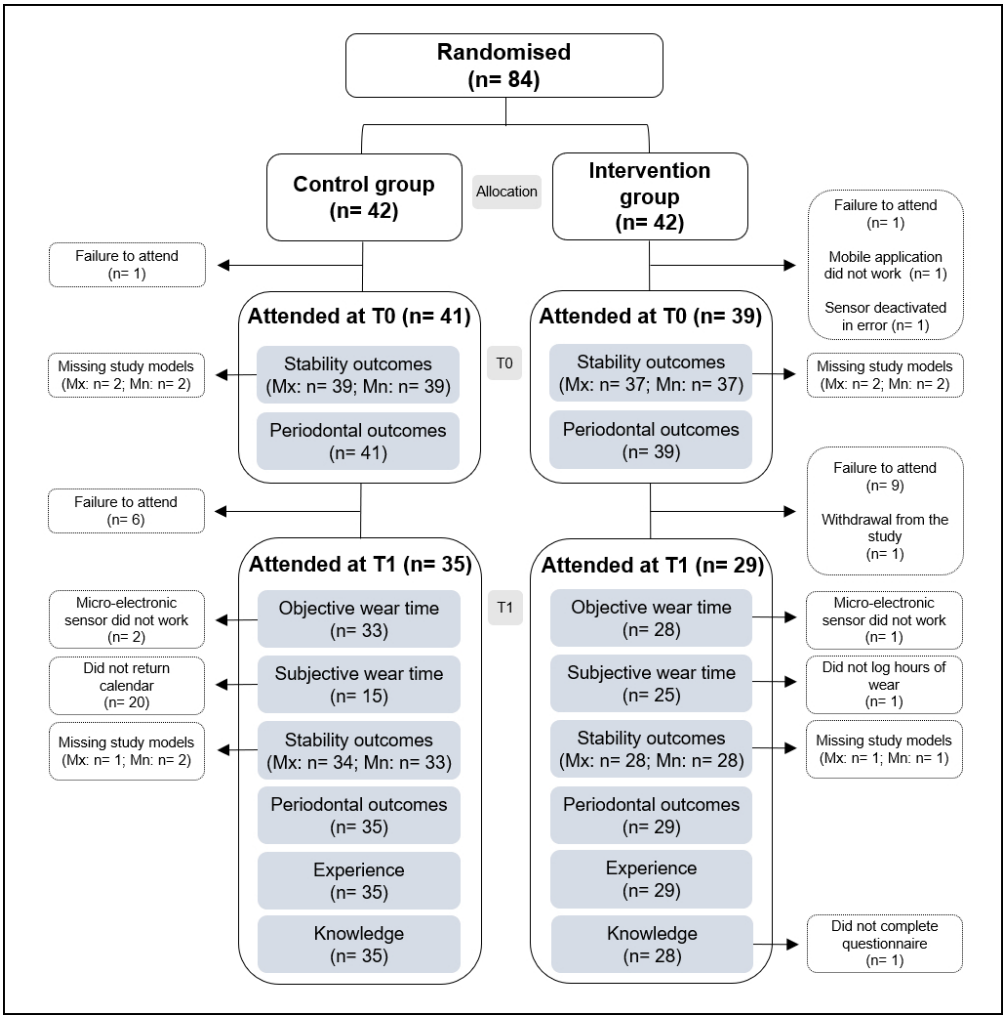
Experiences						
Questions	Treatment group	1. Very dissatisfied	2. Dissatisfied	3. Neither satisfied nor dissatisfied	4. Satisfied	5. Very satisfied
Do you feel involved in the process of wearing and taking care of your retainers?	Control (n= 35)	0 (0%)	0 (0%)	3 (8.57%)	9 (25.71%)	23 (65.71%)
	Intervention (n= 29)	0 (0%)	0 (0%)	4 (13.79%)	6 (20.69%)	19 (65.52%)
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%)
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**				
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%)				

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%)
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%)
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%)
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 test).

Outcomes	Treatment group	Scores (median (IQR))	*P*-value
Patients' 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: interquartile range.


Randomised
(n= 84)
Control group
(n= 42)
Allocation
Intervention
group
(n= 42)
Failure to attend
(n= 1)
Failure to attend
(n= 1)
Mobile application
did not work (n= 1)
Sensor deactivated
in error (n= 1)
Attended at T0 (n= 41)
Attended at T0 (n= 39)
Missing study models
(Mx: n= 2; Mn: n= 2)
Stability outcomes
(Mx: n= 39; Mn: n= 39)
T0
Stability outcomes
(Mx: n= 37; Mn: n= 37)
Missing study models
(Mx: n= 2; Mn: n= 2)
Periodontal outcomes
(n= 41)
Periodontal outcomes
(n= 39)
Failure to attend
(n= 6)
Failure to attend
(n= 9)
Withdrawal from the
study
(n= 1)
Attended at T1 (n= 35)
Attended at T1 (n= 29)
Micro-electronic
sensor did not work
(n= 2)
Objective wear time
(n= 33)
T1
Objective wear time
(n= 28)
Micro-electronic
sensor did not work
(n= 1)
Did not return
calendar
(n= 20)
Subjective wear time
(n= 15)
Subjective wear time
(n= 25)
Did not log hours of
wear
(n= 1)
Missing study models
(Mx: n= 1; Mn: n= 2)
Stability outcomes
(Mx: n= 34; Mn: n= 33)
Stability outcomes
(Mx: n= 28; Mn: n= 28)
Missing study models
(Mx: n= 1; Mn: n= 1)
Periodontal outcomes
(n= 35)
Periodontal outcomes
(n= 29)
Experience
(n= 35)
Experience
(n= 29)
Knowledge
(n= 35)
Knowledge
(n= 28)
Did not complete
questionnaire
(n= 1)

Supplementary material 1. Laboratory procedures followed to integrate the TheraMon® micro-electronic sensor within the thermoplastic retainer

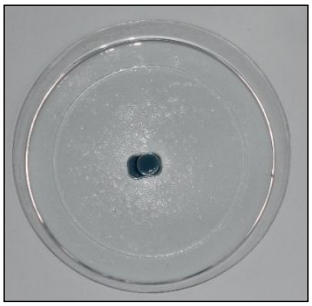
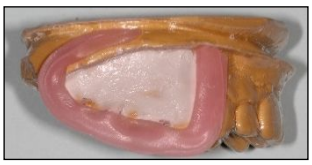
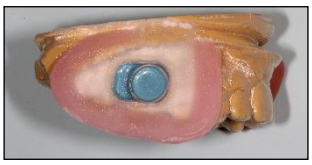
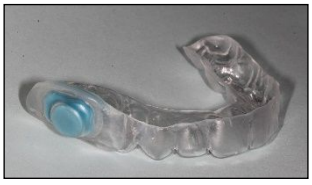
(a) Each 13 x 9 x 4.5mm micro-electronic sensor (TheraMon®) was encapsulated individually or in groups in Essix ACE® plastic 1mm in thickness (DENTSPLY) using a Biostar® pressure thermoforming machine.	
(b) The Essix ACE® Plastic was then trimmed leaving a 2-3mm margin around the TheraMon® micro-electronic sensor.	
(c) The posterior buccal aspect of the maxillary working model was covered by a thin layer of plaster to flatten the surface.	
(d) A pre-heated (180ºC, 70 seconds) sheet of Essix ACE® plastic 1mm in thickness, (DENTSPLY) was then pressure-formed on the working model at 6 bar of air pressure for 180 seconds using Biostar® pressure thermoforming machine.	
(e) The Essix ACE® Plastic was then trimmed around the base of the working model. Prior to bonding of the encapsulated micro-electronic sensor, the area was isolated using baseplate wax (Anutex® Toughened Dental Modelling Wax; Kemdent)	
(f) The micro-electronic sensor was then seated and bonded using auto-polymerising dental acrylic resin (Forestacryl®, Forestadent, Buckinghamshire, UK). The baseplate wax helped to prevent seepage of the auto-polymerising dental acrylic resin onto the TPR.	
(g) The auto-polymerising dental acrylic resin was set after placing the working model, TPR and attached micro-electronic sensor in a pressure-curing vessel. The wax was then removed.	
(h) The TPR was then removed from the working model, followed by trimming and polishing.	

Figure. Laboratory procedures followed to integrate the TheraMon® micro-electronic sensor within the thermoplastic retainer.
TPR: thermoplastic retainer.

Supplementary material 2. Questionnaire to assess knowledge and experiences related to retainer wear

Barts Health NHS
NHS Trust

Queen Mary
University of London

Evaluation of tailored electronic reminders on compliance with removable orthodontic retention: a randomised controlled trial

Chief Investigator: Dr Padhraig Fleming
Reader/Honorary Consultant in Orthodontics
Principal researcher: Dr Dalya Al Moghrabi
PhD student
Barts Health NHS Trust
Phone: 020 7882 8629

Version 4 (13/12/2018)
IRAS Id (201263)

Study number: .....

Please fill in the questionnaire below:

On a scale from 1 to 5 what would you rate the following statements?

(1: very poorly/ not at all satisfied 5: very well/ very satisfied)

Questions	1. 	2. 	3. 	4. 	5. 
1. How well do you understand the reasons for wearing the retainers?					
2. What do you think of the frequency of your follow-up appointments?					
3. Do you feel involved in the process of wearing and taking care of your retainers?					
4. Do you know where to seek advice regarding your retainers?					
5. Do you feel informed about the importance of retainers?					
6. How confident are you that your teeth won't move if you wear the retainers as advised?					
7. How satisfied are you that your questions about retainers are answered?					
8. How well do you remember to wear your retainers?					
9. How well do you feel you are being looked after since your braces were removed?					
10. How well do you remember where to store your retainers?					
11. How would you rate your overall experience within the last 3 months in terms of your use of retainers and contact with the clinic?					

Supplementary material 2. Questionnaire to assess knowledge and experiences related to retainer wear

12. If I wear the retainers really well for the first year, I can stop wearing them after that.
    - ☐ True
    - ☐ False

13. How many hours a day do you need to wear the retainers?
    - ☐ 12 hours
    - ☐ 15 hours
    - ☐ 20 hours
    - ☐ 22 hours

14. If you stopped wearing the retainers, what is likely to happen after a few weeks?
    - ☐ Nothing, my teeth are stable especially if I wore the retainers really well previously
    - ☐ Gradual changes over time

15. How long do you need to wear your retainers for?
    - ☐ 6 months
    - ☐ 1 year
    - ☐ Long-term

16. What would you do if your retainers no longer fit or if you had problems with wearing them?
    - ☐ Come for a casualty appointment
    - ☐ Wait for the next appointment
    - ☐ Stop wearing the retainers