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Influence of Multimedia Reminders on Oral Hygiene Status During Removable Orthodontic Treatment: A Randomized Controlled Trial

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Abstract

INTRODUCTION: Orthodontic appliances complicate daily oral hygiene maintenance and enhance the formation of microbial biofilm on tooth surfaces and orthodontic appliances.

OBJECTIVE: This trial was conducted to assess the effect of reminders on oral hygiene of patients during removable orthodontic treatment.

METHODS: In this 2-arm parallel randomized controlled trial, 66 orthodontic patients with removable maxillary appliance were randomly allocated with 1:1 ratio to message reminders and the control group. The patients in the messaging group received one or two message reminders and educational videos weekly during the course of treatment. A single blinded examiner measured the plaque index (PI), gingival index (GI), and dental caries index of patients in both groups at baseline (T0) and one (T1), three (T2), and six (T3) months after the first day of treatment to assess their oral hygiene status during treatment.

RESULTS: A total of 30 patients in control group and 28 in reminder group completed the study. The PI and GI scores were increased neither in control group nor in message reminder group during T0 and T1, significantly. The PI and GI scores in message reminder group were significantly lower than those in the control group at T2 (PI*: P = 0.001*, GI: *P = 0.003*) and T3 (PI: *P = 0.024*, GI: *P = 0.022*). Slight significant increasing in the PI and GI score were found during T2 and T3 in message reminder group. Caries index showed no significant difference between two groups during study.

CONCLUSION: It seems that reminders can efficiently promote oral hygiene of patients undergoing removable orthodontic treatment.

Keywords:

Oral hygiene, orthodontics treatment, reminder systems, text message

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Introduction

The maintenance of routine oral hygiene by patients is a crucial factor during orthodontic treatment. It is verified that there are challenges in patients adherence and compliance to sustained and acceptable oral hygiene during orthodontic treatments.[1] Fixed and removable orthodontic appliances complicate daily oral hygiene routine and enhance the formation and accumulation of microbial biofilm on tooth surfaces, orthodontic brackets and wires, bands, springs, elastics, and acrylic base plate.[2-5] Biofilm accumulated on orthodontic appliances and tooth surfaces leads to gingival inflammation and dental caries.[6-8] Gingival inflammation can negatively influence the periodontium and cause periodontal problems such as

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recession, pocket formation, gingival hyperplasia, and succeeding different periodontal diseases.

Moreover, poor oral hygiene negatively affects the quality of orthodontic treatment results; it can prolong the course of treatment or result in early cessation of orthodontic treatments.[9] Several methods have been proposed for prediction of the ability of oral hygiene maintenance during the course of treatment.[9-11] One of the best models for this purpose is prediction of social behavior introduced by Aizen and Fishbein in 1980, which is referred to as the theory of reasoned action.[12] This theory advocates that the behavior of individuals is influenced by their intention to present the behavior. Moreover, the intention of individuals is dependent on their attitude for that particular behavior and subjective paradigms.[12] The theory of reasoned action can be regarded when the compliance of patients in maintaining their oral hygiene in orthodontic treatments is considered. From the first session, the patients are informed, instructed, and persuaded regarding the personal and social advantages of oral hygiene. However, after oral hygiene instruction, these patients usually do not receive reminders during their treatments. Thus, there is no promise that they fully adhere to oral hygiene instructions. With the help of text messaging and social media, it is easier to maintain communication with the patients. The role of active reminders to improve attendance of patients, in-time medication intake, and behavioral change interventions has been documented in dental and medical literature.[13-17] Positive change in behavior with regard to showing up for dental appointments by postal mail reminders, automatic phone reminders, and SMS has been reported; the efficacy of these systems has been confirmed.[18,19] Moreover, it is verified that follow-up text messages sent from an orthodontic clinic after initial placement of orthodontic appliance resulted in lower self-reported pain score and decreased level of anxiety of their patients.[20] Several studies have reported the positive effect of message reminders on oral hygiene during orthodontic treatment[21-24]; however, these studies were enrolled on the patients who received fixed orthodontic treatments which are often performed after the age of 12. Studies have shown that age differences can be effective in changing their behavior.[25] To the best of authors' knowledge, the effect of message reminders on oral hygiene in younger patients using removable orthodontic appliances for treatment of dental or skeletal anomalies has not been evaluated. Young age of patients receiving removable orthodontics, insufficient attention to oral hygiene, wide palatal coverage of removable appliances, and long duration of treatment due to the possibility of need for fixed orthodontic treatment in future would entail more attention to oral hygiene in these patients. For oral hygiene evaluation, different indices have been proposed; however, plaque index (PI) and gingival index (GI) are strong indices broadly used for assessment of oral hygiene and oral and dental health worldwide.[21]

Specific objectives and hypotheses

Hence, this study aimed to assess the effect of weekly message reminders to parents or legal guardians of children received removable orthodontic treatment on their oral hygiene by assessing PI, GI, and dental caries index. The null hypothesis of the study determines no difference in the mean of PI, GI, and dental caries index in patients who received reminder compared with those not received.

Methods

Trial design and any changes after trial commencement

This study was a single-center, prospective 2-arm parallel randomized controlled trial with 1:1 allocation ratio. Ethical approval was granted from Ethics Committee of Islamic Azad University, Kazerun branch (IR.IAU.KAU.REC.1399.008) registered in the Iranian Registry of Clinical Trials (IRCT20180923041092N2). No changes to the study design were made after commencement.

Participants, eligibility criteria, and settings

A total of 66 children with age range of 8 to 12 years referred to Department of Orthodontic, School of Dentistry, Shiraz Branch, Azad University (2018-2020) for removable orthodontic treatment were requested to participate in this study if they were willing to do so and did have access to WhatsApp application by smartphone. For the purpose of standardization, children whose treatment plan included the use of a removable orthodontic appliance made of auto-polymerizing acrylic resin with a midline screw, had a minimum treatment time of 6 months, and also treated by the same orthodontist (N.N) were enrolled. The time of sending message reminder for each patient was determined with accordance to the time that parents were present at home. One of the researcher (M.M) was responsible to determine the time of sending messages based on parents' preference and access to internet and the time when parents and children are together. She checked whether the parents open the messages or not. The patients who did not have daily access to the internet by their own smartphone or their parents, and patients who suffered from specific nutritional regimens, systemic diseases, syndromic anomalies such as cleft lip or palate, and physical or mental disability were excluded from the study.

Intervention

The participants were divided randomly into two groups of message reminder and control. Both groups received

adequate oral hygiene instructions at the beginning of the study. The patients in message reminder group received message reminders in Persian and videos as oral hygiene reminder, while the control group did not receive any of these. Participants were not aware of the reason behind sending message reminders or the parameters evaluated in this study.

Experimental group

In the first phase (T1), the message reminders group received video and text messages containing information about the significance of oral hygiene twice a week for 4 weeks such as following sentences:

- *This text message is from the orthodontic clinic. We have to brush our teeth for a minimum of 3 minutes after each meal. Tooth brushing helps maintain sound beautiful teeth.*
- *Hygienic alert! How long does your tooth brush take? 1-2 minutes? Each toothbrush has around 2500 bristles. Allow all of them to do their job and clean your teeth.*
- *Your next appointment is soon. If you have forgotten to regularly brush your teeth, start now!*
- *Did you know that after eyes, teeth have the greatest impact on facial beauty? Pay more attention to the health and appearance of your teeth!*
- *Just wanted to remind tooth brushing after each meal! Do it and see the extraordinary result. See you soon!*
- You are approaching your next appointment fast! Keep up the good work! See you *soon!*

The message reminders were sent when both parents and patients were at home. The time interval between lunch and dinner was often chosen for most patients. For the rest of the patients, a convenient time was arranged following discussion with the parents. In the second phase (T2), patients received text message and educational videos for oral hygiene once a week for 2 months. In the third phase (T3), message reminders were sent to the message reminder group once a week for 3 months. Thereafter, PI, GI, and dental caries index were recorded at baseline (T0) and one (T1), three (T2), and six (T3) months after the first day of treatment by the same blinded examiner who did not have any information about participant's division in the two groups.

Control group

The control group did not receive any text message or video during this period. The indices were measured at T0 (onset of study) and at the end of each phase (T1, T2, and T3) similar to message reminder group by the same blinded examiner.

Outcomes (primary and secondary) and any changes after trial commencement

The PI was measured using the Silness-Loe PI.[26] For this purpose, presence of dental plaque was evaluated at four areas namely mesiobuccal, buccal, distobuccal, and lingual of teeth #44, 24, 32, 12, 36, and 16, and each surface was given a score of 0 to 3. The GI was determined by assessing the degree of gingival inflammation around teeth #44, 24, 32, 12, 36, and 16; Each surface was allocated a score of 0 to 3. This index is used for assessment of the severity of gingival inflammation and its quantification. Bleeding on probing is an important criterion in this index.[27] All teeth were examined for caries and were allocated a score of 0 to 6. Presence of caries was determined by clinical examination.[28]

On the day of delivery of removable orthodontic appliance (T0), patients received a hygienic package including an Oral-B fluoridated toothpaste (with 1100 ppm fluoride) and a soft Trisa toothbrush (6+ years). Both groups received instructions on tooth brushing during the course of orthodontic treatment and recommendations regarding maintenance of orthodontic appliance. The modified Bass tooth brushing technique was taught to all patients. They were requested to brush each of the upper and lower dental arches for 2 to 3 min, three times a day. Also, patients received comprehensive information regarding dental plaque, dental calculus, and their effects on oral health.

Sample size selection

Randomization

Participants were randomized according to the minimization method proposed by Pandis.[29] Randomization ensured patients' allocation to both groups with 1:1 ratio. The first participant was allocated to one of the group at random. For each subsequent participant, we determined that allocation to which group would lead to better balance between the groups in the variables of interest. Allocation concealment and implementation were performed before randomization process by a researcher who was not involved in the study.

Sample size calculation

A total of 40 participants were required to achieve 85% power (instituted by G power, version 3.0.1; Franz Faul university, Kiel, Germany) and detect significant differences considering the effect size of 0.47 ($P < 0.05$). Considering the possible dropouts, the sample size was increased to 66.

Blinding

Examiner clinician, the person performing the data entry, and the statistician were blinded to the intervention. It was not possible to blind the participants because the patients knew whether they had received the message reminder.

Statistical analysis

Data were analyzed using SPSS version 24. After descriptive analysis of the data, their normal distribution was evaluated using the Shapiro-Wilk test and Levene's test. The effects of sociodemographic such as gender, father's education level (primary school graduate or below, secondary school, post-secondary, or above), mother's education level (same grades as father's), father's job (self-employed, employee, unemployed), and mother's job (same levels as father's) on the patients behavior modification in plaque controls were analyzed using bivariate analysis. For comparison between two groups, we employed the Mann-Whitney U test and for others we used the Kruskal–Wallis H test.

Friedman test was used for intra-group comparisons of the mean PI and GI in each group of the message reminder g and control groups among T0, T1, T2, and T3. The Wilcoxon Mann–Whitney test was used to compare the mean PI and GI between the message reminder and control groups at each phase (T0, T1, T2, and T3).

The McNemar and Cochrane's tests were used for intra-group comparison of dental caries. The Pearson chi square test was applied to compare the two groups in terms of dental caries at each time point. Level of significance was set at 0.05. The intraclass correlation coefficient (ICC) for measurement of PI, GI, and caries index was determined by assessing 10 randomly chosen participants within 1 h at T0.

Results

Participant flow

A total of 58 patients successfully completed the study. A CONSORT diagram showing the flow of participants through the study is given in Figure 1.

Baseline data

The baseline characteristics for sex, age, and recruitment site in both groups were similar and are illustrated in Table 1. The results of bivariate analysis between sociodemographic and patient's behavior modification in plaque controls are presented in Table 2.

The PI and GI scores in message reminder group were significantly lower than those in the control group at T2 (PI*: P = 0.001*, GI: *P = 0.003*) and T3 (PI: *P = 0.024*, GI: *P = 0.022*).

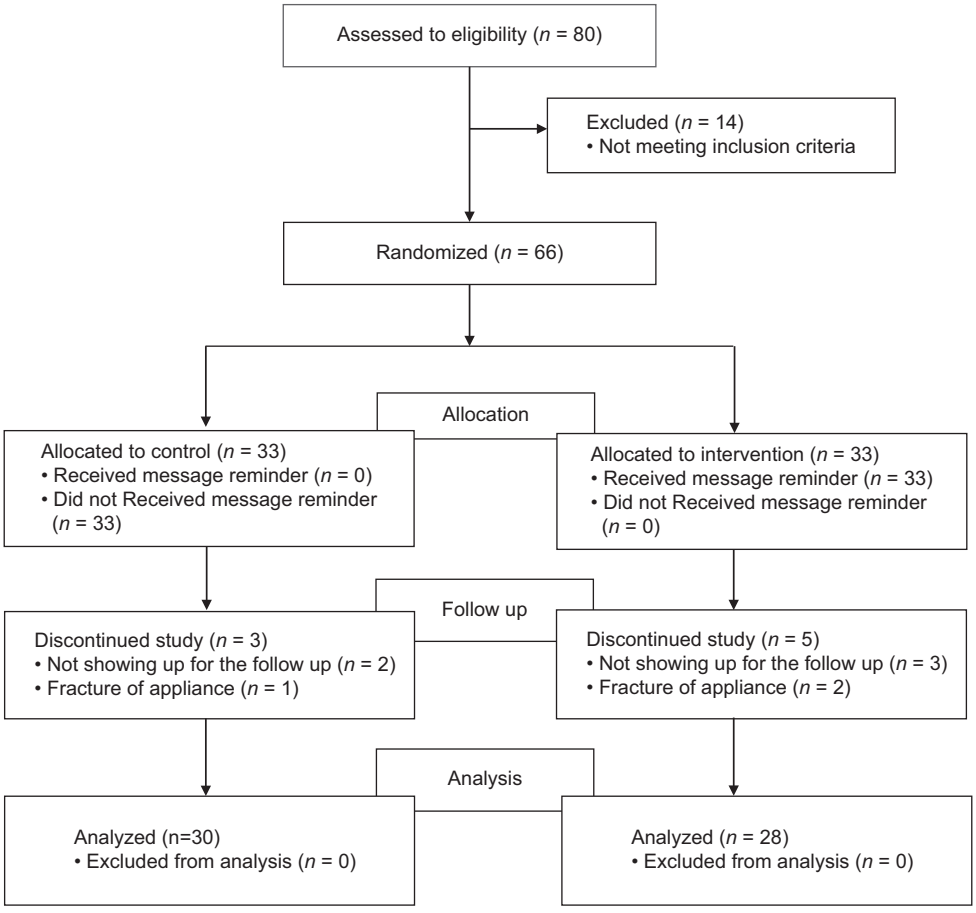

Figure 1: CONSORT diagram showing the flow of participants through the study

Table 1: Baseline characteristics for patients in each group

	Control group (*n*=30)	Message reminder group (*n*=28)
Mean age	10.58±1.28	10.11±1.20
Age category		
8-10	15 (50%)	13 (46.3%)
10-12	15 (50%)	15 (53.7%)
Sex		
Boy	14 (46.67%)	14 (50%)
Girl	16 (53.33%)	14 (50%)

Numbers analyzed for each outcome, estimation and precision, subgroup analysis

Plaque index

Comparison of message reminder and control groups revealed a significant difference in the mean PI at T2 (*P = 0.001*) and T3 (*P = 0.024*). The control group did not show significant increasing in PI score during the study period. However, PI score in the message reminder group significantly decreased over time from T0 to T2 (*P = 0.013*) and T0 to T3 (*P = 0.032*) and significantly increased from T2 to T3 (*P = 0.016*) [Table 3].

Gingival index

Significant differences in GI score between message reminder and control groups was found at T2 (*P = 0.001*) and T3 (*P = 0.022*). GI score in the message reminder group significantly decreased from T0 to T2 (*P = 0.012*), T0 to T3 (*P = 0.043*), and T1 to T2 (*P* = 0.026); however, significant increase in GI was observed during T2 to T3 (*P = 0.011*). In the control group, no significant change in PI was noted during the study period; except significant increase from T0 to T2 (*P = 0.046*) [Table 4].

Dental caries index

No significant change was found in caries index during the study period in the message reminder and control groups (*P* > 0.05). The ICC was found to be 0.83 to 0.86, which indicated complete agreement in measurements.

Discussion

To the best of authors' knowledge, this study is the first randomized controlled trial to assess the effect of message reminders on oral hygiene status of children and adolescents between 8 and 12 years using removable orthodontic appliances. In this study, minimization method was used for participant randomization; minimization is a method of randomization used to ensure the balance of important prognostic factors among the groups and does not have the disadvantages of other randomization methods. List of randomization is not prepared in this method before the onset of study; instead, it is prepared in the process of selection of participants. It is a dynamic method of randomization.[29]

The gender of participants presented no effect on the behavior modification in plaque controls in this study; similarly, it has been reported that oral hygiene of patients in fixed orthodontic appliances was not different regarding sex differences.[21,22] Mother's and father's job status and their educational level had no siginificantimpact on behavior modification. Sun *et al*.[30] reported that among some family factors such father's and mother's education level and household income, only household income presented the most influence on subjects' Oral Health related Quality of Life (OHRQoL). Concerning some cultural impacts, the exact report of household income may not be possible in some population and it may hold some errors and under-report results. Therefore, we ignored this part to be studied.

The effect of message reminders on oral hygiene was evaluated by measuring the PI, GI, and caries index. The results showed that the message reminder group had significantly lower PI and GI at T2 (3 months after the onset of treatment) and T3 (6 months after the onset of treatment). However, no significant difference was found between the message reminder and control groups in PI or GI at T1 (one month after the onset of treatment). According to psychosocial studies, the mean time required for change of behavior to a habit is approximately 66 days.[31] Thus, absence of a significant difference between the two groups at T1 may be due to inadequate time for formation of a new habit.[32] Moreover, it has been shown that at the beginning of treatment, the conditions are very challenging for patients since they ought to get used to the new appliance and learn how to practice oral hygiene and clean the appliance. This explains the reason why at T1, challenges encountered by patients to get used to the appliance can result in insignificant effect of message reminders on PI and GI compared with T2 in the two groups.

Previous studies revealed that orthodontic appliances complicate daily oral hygiene practice in patients, which may lead to accumulation of dental plaque and microbial biofilm on tooth surfaces and orthodontic appliances.[2-5] Nonetheless, the current results showed significant increase in GI in the control group between T0 and T3 and no significant increase in PI during the course of the study. This trend of change can be due to the fact that patients knew that they were participating in a study and this positively affected the behavior of patients in the control group with regard to oral hygiene. Oral hygiene instructions provided for both groups at the beginning of the study may have influenced the results accordingly.

Thus, significantly lower PI and GI in the message reminder group at T2 and T3 are strong evidence supporting the positive effect of message reminder on

Table 2: Bivariate analysis between sociodemographic and patient's behavior modification in plaque controls

	Reminder Group								
	N	T1		T2		T3		T4	
		Mean (SD)	*P*	Mean (SD)	*P*	Mean (SD)	*P*	Mean (SD)	*P*
Sex									
Boy	14	1.18 (024)	0.088	1.65 (0.24)	0.161	1.22 (0.32)	0.229	1.21 (0.58)	0.121
Girl	14	1.26 (0.31)		1.54 (0.36)		0.88 (0.51)		1.26 (0.25)	
Fathers' education									
Primary school graduated or below	4	1.27 (0.67)	0.223	1.45 (0.23)	0.116	0.94 (0.67)	0.213	1.17 (0.15)	0.131
Secondary school gradated or below	6	1.35 (0.22)		1.61 (0.32)		1.09 (0.81)		1.42 (0.29)	
College graduated or above	18	1.45 (0.22)		1.51 (0.25)		0.89 (0.17)		1.11 (0.56)	
Mothers' education									
Primary school graduated or below	0	---------	0.320	--------	0.254	--------	0.107	---------	0.214
Secondary schoolgraduated or below	8	1.59 (0.19)		1.65 (0.81)		1.06 (0.45)		1.21 (0.36)	
College graduated or above	20	1.34 (0.24)		1.65 (0.22)		1.01 (0.76)		1.41 (0.34)	
Father's job									
Self-employed	20	1.85 (0.71)	0.065	1.70 (0.62)	0.171	1.20 (086)	0.360	1.28 (0.17)	0.238
Employee	8	1.54 (0.48)		1.64 (0.12)		0.88 (0.19)		1.21 (0.42)	
Unemployed	0	--------		--------		---------		----------	
Mother's job									
Self-employed	18	1.36 (0.29)	0.67	1.64 (0.54)	0.342	1.46 (0.52)	0.154	1.29 (0.51)	0.117
Employee	10	1.49 (0.21)		1.67 (.91)		1.01 (0.42)		1.13 (0.17)	
Unemployed	0	----------		--------		--------		----------	
	Control Group								
	N	T1		T2		T3		T4	
		Mean (SD)	*P*	Mean (SD)	*P*	Mean (SD)	*P*	Mean (SD)	*P*
Sex									
Boy	14	1.51 (0.15)	0.323	1.21 (0.26)	0.175	1.9 (0.56)	0.331	1.95 (0.34)	0.151
Girl	16	1.44 (0.36)		1.30 (0.44)		1.71 (0.44)		1.69 (0.56)	
Fathers' education									
Primary school graduated or below	4	1.47 (0.37)	0.144	1.61 (0.22)	0.320	2.05 (0.26)	0.345	1.30 (0.34)	0.058
Secondary school graduated or below	9	1.26 (0.14)		1.83 (0.62)		1.91 (0.61)		1.95 (0.74)	
College graduated or above	17	1.43 (0.24)		1.59 (0.35)		1.81 (0.58)		1.71 (0.28)	
Mothers' education									
Primary school graduated or below	0	----------	0.011*	----------	0.243	----------	0.171	----------	0.192
Secondary school graduated or below	14	1.77 (0.45)		1.71 (0.17)		1.91 (0.71)		1.27 (0.26)	
College graduated or above	16	1.55 (0.33)		1.47 (0.25)		1.79 (0.21)		1.70 (0.51)	
Father's job									
Self-employed	19	1.51 (0.24)	0.351	1.69 (0.56)	0.146	1.68 (0.46)	0.243	1.21 (0.45)	0.105
Employee	11	1.33 (0.14)		1.45 (0.56)		1.95 (0.34)		1.37 (0.19)	
Unemployed	0	---------		--------		---------		----------	
Mother's job									
Self-employed	12	1.26 (0.53)	0.072	1.51 (0.74)	0.042	1.75 (0.12)	0.234	1.75 (0.61)	0.061
Employee	8	1.49 (0.31)		1.22 (0.23)		1.28 (0.41)		1.81 (0.67)	
Unemployed	2	1.34 (0.13)		1.81 (0.45)		1.19 (0.43)		1.85 (.27)	

oral hygiene status. The current results were in agreement with those of studies that reported the positive efficacy of message reminders for oral hygiene promotion of patients during fixed orthodontic treatment.[21-24]

Evidence shows that dental caries following orthodontic treatment can negatively affect the patients' perception of orthodontic treatment, which would negatively impact the future attendance of patients.[21] Although initial enamel lesions may develop within 2 to 3 weeks following microbial plaque accumulation on tooth surfaces,[32] this study did not show any significant change in caries index in the two groups during the 6-month course of treatment and the two groups were the same in this respect. Eppright *et al*.[21] suggested that studies on initial enamel lesions should follow-up patients for more than 6 months.

Several studies have evaluated the positive efficacy of Short Message Serivice (SMS) and email reminders for acceptance of orthodontic treatment by patients.[21-24] In our study, the message reminder group showed

Table 3: Comparison of plaque index at T0, T1, T2, and T3 between the control and message reminder group

	Control Group Mean (SD)	Reminder Group Mean (SD)		*P*		
T_0	1.61 (0.70)	1.68 (0.44)		0.921		
T_1	1.73 (0.77)	1.66 (0.63)		0.225		
T_2	1.89 (1.00)	1.04 (0.60)		0.001**		
T_3	1.82 (0.78)	1.25 (0.76)		0.024*		
		Control Group				
T_0 Vs T_1	T_0 Vs T_2	T_0 Vs T_3	T_1 Vs T_2	T_1 Vs T_3	T_2 Vs T_3	
0.821	0.076	0.065	0.722	0.521	0.618	
		Message reminder Group				
T_0 Vs T_1	T_0 Vs T_2	T_0 Vs T_3	T_1 Vs T_2	T_1 Vs T_3	T_2 Vs T_3	
0.067	0.013**	0.032*	0.046	0.515	0.016*	

T_0 to indicate baseline; T_1, after 1 month; T_2, after 3 months; T_3, after 6 months *P=0.05; **P=0.01; ***P=0.001; ****P=0.0001

Table 4.Comparison of gingival index at T0, T1, T2, and T3 between the control and message reminder groups

	Control Group Mean (SD)	Reminder Group Mean (SD)		*P*		
T_0	0.71 (0.50)	0.73 (0.49)		0.254		
T_1	0.84 (0.51)	0.68 (0.42)		0.090		
T_2	0.79 (0.52)	0.38 (0.37)		0.001***		
T_3	0.95 (0.61)	0.62 (0.41)		0.022*		
		Control group				
T_0 Vs T_1	T_0 Vs T_2	T_0 Vs T_3	T_1 Vs T_2	T_1 Vs T_3	T_2 Vs T_3	
0.428	0.090	0.046*	0.223	0.427	0.412	
		Message reminder Group				
T_0 Vs T_1	T_0 Vs T_2	T_0 Vs T_3	T_1 Vs T_2	T_1 Vs T_3	T_2 Vs T_3	
0.075	0.002**	0.012*	0.026*	0.516	0.011*	

T_0 to indicate baseline; T_1, after 1 month; T_2, after 3 months; T_3, after 6 months *P=0.05; **P=0.01; ***P=0.001; ****P=0.0001

a significant reduction in oral hygiene indices over time compared with the control group; although the trend of this reduction was not the same throughout the study. During T2-T3, a significant increase in PI and GI was noted in the message reminder group. Significant increase in PI and GI in T3 can be due to the decreased impact of the "novelty effect"; the novelty effect is defined as initial improvement in performance in response to increased interest in new technology.[19] Thus, after a while, the new technology, that is, the SMS or email reminders would no longer have its initial novelty and attractiveness and gradually loses its efficacy. Although this study was performed over a longer period of time (6 months) compared with previous studies,[21-24] it appears that assessment of the long-term effects of reminders requires further studies.

Sending weekly text or multimedia messages to parents to remind their children to adhere to their oral hygiene protocol does not seem to be a difficult task for a private office. At present, several communication companies provide services with regard to automatic sending of message reminders and many of such services are available free of charge on the web. Moreover, particular applications in smartphones can be used as reminders. Providing such services would strengthen the communication between orthodontists and patients and indicate that the orthodontists are concerned about each one of their patients. Such behaviors can positively affect the patient satisfaction as well.

The generalizability of these results might be limited to 8- to 12-year-old children with removable orthodontic appliance. This study was a single-center study; a multi-centric study would increase the sample in a shorter period and would increase validation of results. In this study, we used just clinical indices to determine oral hygiene status, further studies with microbial evaluation of acrylic base plate can be useful.

Conclusion

Sending message reminders and educational videos to parents emphasizing the significance of oral hygiene maintenance is an efficient method to promote oral hygiene status of orthodontic patients. Moreover, orthodontists can use an active reminder system to increase patient cooperation during orthodontic treatment.

Ethics approval and consent to participate

Ethical approval to conduct the study was granted by the Medical Ethics Committee, Shiraz branch, Islamic Azad university, Iran (IR.IAU.KAU.REC.1399.008) and registered in the Iranian Registry of Clinical Trials (IRCT20180923041092N2). Written informed consents were obtained from parents or guardians for participants under 16 years of age.

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Conflicts of interest

There are no conflicts of interest.

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