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**THE EFFECT OF MOBILE TEXT MESSAGES AND A NOVEL FLOSS HOLDER ON
GINGIVAL HEALTH: A RANDOMIZED CONTROL TRIAL**

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Abstract

Purpose: The purpose of this study was to evaluate the effects of using mobile text messages and a novel floss holder as compared to finger flossing or the novel floss holder alone, on the psychological, behavioral, and clinical parameters of patients with gingivitis.

Methods: A total 165 adults were assessed for eligibility and 144 met the criteria for randomization into three groups: Finger Floss (FF, n=43), Novel Floss Holder (NFH, n= 40), and Novel Floss Holder plus Text Messages (NFH+TM, n= 61) following a dental hygiene consultation appointment. Gingival bleeding points were measured on probing (BOMP) at baseline and four months later by a calibrated dental hygienist, blinded to the experimental groups. Participants also self-reported their oral hygiene behaviors, and indicated psychological determinants of behavior change prior to the dental hygiene consultation and at four months. Descriptive statistics and repeated measures analysis of variance (ANOVA) were used to compare groups over time.

Results: Two subjects dropped out of the study making the total number of participants 142. At the four month follow-up, the NFH group and the NFH+TM groups demonstrated significantly higher levels of self-reported flossing, action self-efficacy, intention, action planning, and action control. The NFH+TM group showed lower levels of bleeding and higher levels of oral hygiene and recovery self-efficacy than the other groups, in addition to higher levels of maintenance self-efficacy as compared to the FF group.

Conclusions: The use of a novel floss holder, NFH, was shown to improve the behavioral and psychological determinants of periodontal health four months after introduction of the device. However the clinical measures of BOMP only improved significantly when used in conjunction with text messages (NFH+TM). The use of a consciousness awareness technique, TMs, in combination with a novel device, may help patients to reach therapeutic objectives and contribute to the management of periodontal pathologies such as gingivitis.

Keywords: flossing, interdental cleaning, gingivitis, patient motivation, oral self-care, oral hygiene, mobile text messages

Introduction

Mechanical control of biofilm is the primary therapeutic strategy for preventing gingival diseases^{1,2}. Toothbrushing plays an important role to that end and is the most used mean of controlling plaque² but is not sufficient for efficiently reaching into interdental surfaces³. Recent literature reviews have found interdental brushes (IDB) as the most effective interdental cleaning devices^{3,4}. However, some limitations have been noted for IDB, as several shapes and sizes are required and most of the interdental spaces in the anterior teeth are not sized for their use³. Additionally, some authors have drawn attention to the scarcity of well-designed studies showing the relative clinical value of flossing, arguing that it may be premature to set floss aside⁵. A more recent systematic review mentions that both floss and interdental brushes may contribute to reduce gingivitis⁴. With this in mind, many researchers advocate that it is advisable for dental professionals to change their mindset from 'flossing' to 'interdental cleaning', choosing the best interdental cleaning methods according the dimensions of the embrasure space and patients' skill levels and motivation – not only according to the comparative results of efficacy³⁻⁵.

Individuals often fail to exert control over their behavior despite being motivated to do so⁶, and control can be even more challenging when routine behaviors are involved, such as those concerning dental hygiene. Therefore, some models of health behavior change, such as the Health Action Process Approach (HAPA)⁷, take volitional^a or self-regulatory aspects of behavior into consideration. According to the HAPA, a change in health behavior is the result of a motivational phase where individuals form an intention to act, but it also involves a volitional, post-intentional phase where the individuals plan how they will put their intentions into practice and maintain their behavioral changes⁶⁻⁹ (Fig. 1). When compared to other social cognitive models, the HAPA proved to be a good predictor of oral hygiene behaviors^{8,9}.

It is also known that people thrive on novelty and challenge, seeking new experiences and stimulating activities^{10,11}. Under most theories of motivation, both curiosity and a personal sense of control influence readiness and motivation to initiate behavior and expend effort¹², which is particularly important when approaching novel situations, such as using a new floss holder or receiving text messages about oral health issues. Floss holders have long been used, with studies showing benefits for patients lacking the dexterity to use finger flossing and in helping patients establishing a long-term flossing habit in comparison to finger flossing^{13,14}. New floss holders (NFH) may be a way to increase curiosity, control, and flossing frequency, thereby fostering dental hygiene efficacy.

One way of disrupting undesired habits, such as failing to control interdental spaces, is by bringing habitual behavior and its context to conscious awareness⁹. Consciousness-raising for health behavior may be facilitated by mobile digital technologies, which provide the opportunity to display habit-disrupting cues¹⁵. Mobile text messages

^a Volition or will is the cognitive process by which an individual decides on and commits to a particular course of action.

(TM) may offer an opportunity to disrupt habitual behavior by keeping a goal salient or by bringing the goal back to working memory at an appropriate time. Moreover, according to a recent systematic review with a meta analysis¹⁶, the use of mobile health interventions has been shown to positively influence communication between patients and providers, facilitating relationship-centered healthcare. In the same vein, TM have been shown to foster social support mechanisms¹⁷.

The aims for this randomized controlled trial were (1) to investigate whether the effect of using a new floss holder would improve adherence and help to develop positive health behaviors in order to promote gingival health, and (2) to investigate the possibility of boosting the sustainability and clinical efficacy of those behaviors by using mobile text messages between appointments. For the primary outcomes of this study, we sought to test whether the use of a NFH plus TM – compared to the NFH alone and to the usual finger flossing (FF) – would have a positive effect on gingival health as indexed by gingival bleeding, through an increase of self-reported flossing. For secondary outcomes we examined the effects of the intervention on relevant psychological determinants as outlined by the HAPA. We hypothesized that:

1 – In comparison to finger flossing, the NFH would increase individuals' levels of motivation to use dental floss, owing to its novelty and ease of use. We therefore expected higher levels of motivational determinants (e.g., outcome expectancies, action self-efficacy), and consequently greater intention to floss among patients who used the NFH.

2 – TM would serve as “cues to action” and would bring the behavioral objectives for dental hygiene to consciousness, reinforcing subjects' self-regulatory mechanisms (planning, self-efficacy, and action control) in contrast to the other two groups.

3 – The NFH would contribute to increased frequency of flossing compared to FF, and the use of the NFH plus TM would contribute more than the use of the NFH alone.

4 – Bleeding would be lower in the NFH group when compared to the FF group, and the use of NFH plus TM would contribute to even lower BOMP (Bleeding on Marginal Probing Index) levels than those obtained with the NFH.

Methods

Participants

A total of 165 patients were initially enrolled in the study, but twenty-one patients failed to meet the inclusion criteria (Fig. 2). Two others dropped out, resulting in a final longitudinal sample of 142 participants (Table I).

Procedure

Participants were recruited among the local urban community, through newspaper ads and advertisements in local shops. A dental hygiene consultation was delivered to participants with gingivitis by an experienced dental hygienist in two private dental clinics and a randomized controlled trial was conducted over a span of four months with two assessment points.

First, participants filled in an online informed consent and a questionnaire (T1) with measures on psychological determinants and oral health behaviors. Two weeks later, the gingival condition (BOMP - Bleeding on Marginal Probing)¹⁸ was evaluated in the appointment. After the bleeding index values were collected, each participant was allocated by a research assistant through a computer-generated random sequence into one of three groups: Finger Floss (FF), New Floss Holder (NFH), or New Floss Holder plus Text Messages (NFH+TM). Next, a dental hygiene consultation (DHC) was performed by an experienced dental hygienist who was blind to the patients' assigned groups. In order to treat the gingival inflammation, the DHC included a Professional Mechanical Plaque Removal session and individualized oral hygiene instructions. At the end of the consultation, patients were asked to answer to another questionnaire (T2). The same measures were collected again four months later (T3) (see Fig. 2).

A new floss holder, GumChucks®, was offered at the DHC to all the patients from the NFH and NFH+TM groups, who additionally rated their satisfaction with its use after 4 months. This new flossing system resembles miniature nunchucks, featuring disposable tips connected by a piece of dental floss. The two-handle system apparently increases dexterity and control, enabling the recommended "C" shape with the floss. The FF group used a waxed non flavoured floss (GUM® ButlerWeave®).

Those assigned to the TM group were informed about how the messaging system would operate and asked to provide their mobile phone number in order to receive the TM, at the rate of one per week, over the next four months. Messages had approximately 140 characters; their content concerned oral hygiene and gingival inflammation and was designed to include characteristics described as important for improving their effectiveness, such as humour, assertiveness, comprehensibility, originality, size, and individualization¹⁹. TM were pretested with an independent sample of 40 adults in order to evaluate their perceptions of the messages on these attributes. An example of one of the TM was: *"It is impossible to sneeze with your eyes open, BUT it is possible to take care of the gum between your teeth, even if it has been some time without doing so. You'll see! If you can, your gums will be healthy again. (Hygienist's name)"^b.*

The dental hygiene consultations (professional mechanical plaque removal session and individualized oral hygiene instructions), which lasted for approximately 60 minutes, were free of charge and was the same for all the groups and included specific behavior change techniques²⁰. The individualized oral hygiene instructions required by

^b Messages can be made available to all interested researchers upon request.

the patients were delivered through verbal and practical demonstration (tell, show, and do) and with the help of a hand mirror, if needed. Data confidentiality and anonymity were assured and the ethics committees of the institutions involved approved the clinical trial (Ethics Committee Doc. No. 6/14). The study was registered at the ClinicalTrials.gov database (NCT03120559). A detailed description of the consultation is given in Fig. 2.

Measures

Gingival condition was assessed using the BOMP index, as described by Van der Weijden et al.¹⁸. In this index, bleeding is scored during 30 seconds of probing using a 3-point scale, from 0 to 2 (0 = no bleeding, 1 = pinprick bleeding and 2 = excessive bleeding). Moderate gingivitis was defined as at least 40% of the test sites showing bleeding on probing at screening¹⁸. The BOMP healthy score was considered to be equal to or less than 0.5 — fewer than 25% of sites bleeding on marginal probing²¹. Four months later, the same measure and procedure was used. At baseline and four months one-fifth of the patients were re-evaluated during the BOMP level assessment by another dental health professional – also blind to the assigned groups – in order to calculate the inter-rater agreement, a procedure that is common whenever evaluations may be subject to a certain degree of variability. High agreement was found between the two judges who evaluated bleeding level, $\kappa = .718$ (95% CI, .50; .94), $p < .001$.

In order to assess dental hygiene, two questions were answered on brushing and flossing habits, using a 5-point scale (1 - not using, 2 - barely, 3 - once a day, 4 - twice a day, 5 - more than twice a day). Scores for brushing and flossing were calculated and a composite (mean) score for dental hygiene was also computed. Satisfaction with the NFH was assessed by: “How do you rate the use of the GumChucks®?”: (1) “They are easy to use and I like them”; (2) “ I like them, but they are difficult to use”; (3) “I don’t like them”; (4) “They are a waste of time”.

Measures adapted to oral health from previous studies with the HAPA model were used²², with a seven-point Likert-type scale ranging from “totally disagree” (1) to “totally agree” (7). The total number of items, item examples, and Cronbach’s alphas are displayed in Table II.

Evaluation of the TM, according to the overall interest (comprehensibility, interest, and relevance) and usefulness, was measured by adapting a 10-item scale²² using a five-point Likert scale. A four-point scale ranging from “Less than one message per week” (1) to “More than three messages per week” (4) was also used to determine the frequency at which participants were willing to receive more messages. To ask what participants usually did when they received the TM, a five-point scale was used, ranging from “Ignored it” (1) to “Read it immediately” (5).

The fidelity of the intervention checked by two other oral health professionals over 20% of the consultations (selected at random), in order to verify whether the consultation script was similar for all the patients and to ensure that the effects on gingival health did not depend on the consultation, using a four-item checklist (introduction and diagnosis, explanations, hygiene goals, and clinical procedures). In 80% of the checked appointments, the fidelity obtained was 100%. For the remaining 20%, the fidelity was above 90%.

Data analysis

A dropout analysis and a randomization check were performed through multivariate analysis of variance (MANOVA) for the psychological determinants, behavior, and clinical gingival outcome, while ANOVA and Chi-square tests were used to compare continuous and categorical variables, respectively. Distribution normality (Shapiro-Wilk) and variance homogeneity (Levene's test) were verified for all outcome variables. To compare the three groups at the four-month follow-up, mixed between/within-subject repeated measures ANOVA with intervention group (FF, NFH, NFH+TM) x assessment time (baseline vs. four months) were computed. Whenever differences of interest were found at baseline in outcome variables, the same analysis was repeated introducing baseline scores as a covariate.

Results

Dropout analysis and randomization check

No significant differences between the longitudinal sample ($n = 142$) and those who dropped out ($n = 2$) were found in any baseline sociodemographic variables. However, a difference was found in intention, which was lower among those who dropped out ($M = 4.00$, $SD = 4.24$) in comparison to those who remained in the study ($M = 6.00$, $SD = .86$), $p = .003$.

No differences across the three groups were found at baseline in relation to sociodemographics, frequency of flossing, tooth brushing, or BOMP, nor on most of the psychological determinants ($p > .10$). Exceptions were found for intention, maintenance self-efficacy, and coping planning. At baseline, intention was significantly higher in the FF group than in the NFH+TM group; maintenance self-efficacy was significantly higher in the FF and NFH groups than the NFH+TM group; and coping planning was higher in the NFH+TM than the NFH group (all $p < .05$).

Descriptive statistics

Demographic descriptive data for the sample are presented in Table I. Participants' daily frequency of flossing was low at baseline; the majority never or barely used dental floss. Reference to other interdental devices to control dental plaque was low, with only 2.8% of individuals using interdental brushes. However, the majority of the sample brushed their teeth twice a day (Table III). The initial level of BOMP for the entire sample was relatively high, an average of 60% of points bleeding (Table III).

The majority of the sample considered the messages useful for the treatment and rated the TM very positively overall in terms of comprehensibility, interest, and relevance (Table III). Concerning the new floss holder, 69% liked it after four months of usage, although around a third of participants reported some difficulties in using it.

Intervention effects on clinical and behavioral outcomes

Values for interaction between group and time, and for the main effects of group and time at baseline and at the four-month follow-up are presented in Table II^c. Significant interactions between intervention group and time were obtained for BOMP ($F[1,139]=262.95, p<.001$) (Fig. 3a), for flossing ($F[1,139]=134.74, p<.001$) (Fig. 3b), and for dental hygiene ($F[1,139]=103.07, p<.001$) (Fig. 3c). While at baseline no differences between the groups were found for any of these three outcomes, at the four-month follow-up the NFH+TM group presented a significantly lower BOMP value (i.e., 0.6; $SD=.32$) and a significantly higher level of dental hygiene than the other two groups.

The average BOMP score in the NFH+TM group lowered from 1.2 ($SD=.35$) at baseline, to 0.6 ($SD=.32$) at 4 months, which corresponds to a change from 60% to 30% of sites bleeding from baseline to 4 months. Thus, the bleeding in the NFH plus TM group was lower than in the other two groups, as expected, but the NFH group results were not significantly lower than the FF group.

The NFH+TM group reported higher frequency of flossing at the four-month follow-up (67% of the individuals started using floss once a day) than the NFH group (50% started to use it once a day), which itself showed higher flossing frequency than the FF group (37% started to use it once a day).

Intervention effects on psychological determinants of dental hygiene

Interaction effects between intervention group x assessment time were obtained for nearly all the assessed psychological determinants. The two exceptions were for outcome expectancies, which were not affected by either time or the intervention, and for coping planning, which was significantly affected by time only, with all groups showing an increase in the planning of coping responses from baseline to four months, despite this increase only being significant in the NFH group ($M_{diff\ 4month - baseline} = 0.56, SE = 0.24, p = .02$).

While no significant differences existed between the groups at baseline in relation to action self-efficacy (Fig. 3d), action planning (Fig. 3e), or action control (Fig. 3i), the levels for these determinants at the four-month follow-up were significantly higher in both the NFH and NFH+TM groups when compared to the FF group.

Despite the FF group showing a slightly-but-significantly higher level of intention at baseline (Fig. 3f) the level of intention among participants in this group was significantly lower than those in the other two groups at the four-month follow-up; those in the NFH+TM group further showed a significantly higher level of intention than the NFH group. Participants in the NFH+TM group at the follow-up showed significantly higher levels of maintenance self-efficacy compared to FF (Fig. 3g), as well as showing significantly higher levels of recovery self-efficacy than both FF and NFH groups (Fig. 3h).

^c Given that baseline differences across the three groups were found for intention, maintenance self-efficacy, and coping planning, the repeated measures analyses described below were repeated using the baseline scores as covariates. However, the results were equivalent.

In summary, for the psychological determinants, the NFH+TM and the NFH groups showed a positive and significant change in action self-efficacy, action planning, and action control when compared to the FF group. Intention and recovery self-efficacy increased in the NFH+TM compared to the other two groups, and maintenance self-efficacy became higher in NFH+TM compared to FF.

Discussion

This study was designed to evaluate the effects of using a new floss holder and text messages between appointments to improve gingival health. To that end, we assessed changes in adherence to interdental hygiene behaviors, clinical outcomes, and underlying psychological determinants among patients with gingivitis. Patients that received TM in addition to the NFH showed a higher frequency of flossing four months after the first appointment – on average attaining the recommended frequency of dental floss use (i.e., once a day) and, consequently, a lower level of gum bleeding – than individuals who used finger floss or only the NFH.

In the present study, the average BOMP score in the NFH+TM group fell significantly from baseline to the four-month follow-up, with only 30% of sites bleeding at this follow-up. This is a good score when compared with that described by Barendregt, Timmerman, Velden and Weijden (2002)²¹. According to these authors, a score of 0.5 or less in BOMP (i.e., fewer than 25% of sites bleeding on marginal probing), can be considered to correspond to gingival health. However, it should be acknowledged that the values for percentage of bleeding have since been updated by Chapple et al²³, now defining periodontal stability as corresponding to fewer than 10% of sites with bleeding on probing.

As expected, the use of floss was also more frequent in the NFH group at 4 months than in the finger floss group, although this difference in behavior was not translated into a significant difference in the level-of-bleeding score⁴. As such, our fourth hypothesis was only partially confirmed, as it was expected that the NFH without TM would also present a significantly lower level of BOMP than the FF group, which was not the case. The same effect was found in other studies where the efficacy of floss holders was compared with finger floss^{13,14}.

It was also expected that TM would work as reminders or “cues to action”, thereby increasing proximity with the patient and frequency of flossing, and ultimately contributing toward effective use. In this regard, significant results were obtained for frequency of use. The combined use of TM with the NFH contributed to better results than those found in systematic reviews which show that dental floss has a weaker effect on plaque or bleeding indices when used alone³, due to patients’ difficulty in accepting it and using it correctly as well as their low levels of motivation and of dexterity^{2,3,4}.

In comparison to traditional finger floss, the use of NFH can only be considered a different way to get the string between the teeth. However, the satisfaction with its use reported in other studies of floss holders was lower than was

found in the present study (i.e., around 70%¹⁶ vs. 90.1%)^{13,14}. This could have contributed to an increase in patients' motivation at follow-up, inferred by increases in action self-efficacy and intention, thereby confirming hypothesis one.

Levels of recovery self-efficacy were higher in the NFH+TM group, as expected, but the other self-regulation variables were shown to be as high as in the NFH group. Hence, the second hypothesis was only confirmed for recovery self-efficacy. One explanation for this may be that, as the messages functioned as reminders for oral hygiene behaviors, they reinforced the subjects' beliefs that it is possible to return to and reach the objective even after a lapse (i.e., recovery self-efficacy). However, the fact that the NFH+TM group showed improved results at the behavioral level, without any significant differences in self-regulation variables (except in recovery self-efficacy), may mean that part of the effect TM had on behavior operated via non-deliberated, automatic processes – not mediated by these deliberate self-regulatory cognitive processes²⁴.

The primary and secondary outcomes therefore point to an increase in motivation resulting from the use of a new device to facilitate flossing, but only when accompanied by the use of TM does this new floss holder ultimately help to reduce levels of gingival bleeding. Similarly to what is described in the literature, we found that the use of floss improved with increasing levels of intention, but that intention alone did not suffice to attain the desired outcome, and that other self-regulatory processes or cues to action must also be deployed²⁵. The TM seem to have worked as a cue to action in the NFH+TM group, causing an effect on flossing that could not be fully explained through an increase in self-regulation. Moreover, and as in some previous studies, it was not the changes in planning but rather changes in self-efficacy that helped to explain the behavioral and clinical modifications obtained²⁵.

In light of patients' positive reactions to the TM, and considering the formality that traditionally characterizes the relationship between the oral health professional and the patient²⁰, the use of a strategy such as sending TM may also have contributed to forming a closer relationship between the professional and the patient, facilitating relationship-centered healthcare¹⁶. It may also have contributed to behavior changes as it consisted of persuasive messages coming from a credible source and a source of social support, fostering patients' self-efficacy and belief in being able to handle the challenge^{16,20}.

Several study limitations should be considered in the interpretation of our findings. Although all patients used floss less frequently than recommended, they were generally motivated for oral hygiene behaviors, as can be inferred by high levels of intention at baseline. This is not surprising, considering that all patients had gingivitis and had been invited to treat it at no cost. Hence, these results can only be generalized to similarly motivated individuals with low levels of floss usage. In order to better understand the motivational contribution provided by the new floss holder, a group combining the use of finger floss with TM will be important to include in future studies. Future studies should also consider the comparison of floss holder devices vs another interdental cleaning aid such as interdental brushes, water flossers, and wood sticks.

In spite of the aforementioned limitations, this study had several strengths. The first was having included not only self-reported measures, but also objective clinical measures. Secondly, the consultation was designed to include important behavior change techniques in both groups, which represents an important addition to the usual care employed in dental consultations. Thirdly, having included a follow-up at four months; although this interval should be lengthened in future studies, it is greater than many of the follow-ups normally used^{4, 20}.

The findings presented also have important implications for practice, especially considering that TM are inexpensive, easy to apply, and may be easily introduced into the routines of oral health professionals and integrated within a broader stepped-care approach¹⁶. The option of articulating different interventions (NFH+TM) is also innovative, seeking to create a multi-action strategy to optimize the oral health behaviors addressed in the consultation. Simply telling our patients to brush and floss is just not working²⁶. However, flossing can work if people become motivated do it frequently and correctly^{4,5}.

Finding positive results not only in motivation, but especially in self-regulation processes underlying behavioral change, is an unusually good result. Even when interventions are effective in fostering motivation for change, the translation of this intention into self-regulation for behavior change is more difficult to achieve^{22, 27}. The coaction of the NFH and the TM contributed to behavioral changes four months after the first consultation, with resulting clinical improvements²⁸. This research stresses the utility of text messaging used in conjunction with a floss holder to improve oral health behavior.

Conclusion

Flossing with a new floss holder contributed to improving behavioral and psychological determinants of gingival health, but clinical parameters only reached significant improvements when used in conjunction with text messages. By fostering patients' motivation and by serving as an alternative way to create cues to action and form alternative routines and strategies, mobile text messages and alternative flossing devices can help to reach therapeutic objectives and make the management of pathologies such as gingivitis more effective.

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