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GENGIVITE E QUALIDADE DE VIDA RELACIONADA À SAÚDE BUCAL: USO ADJUNTO DO FIO DENTAL E AUTOPERCEPÇÃO APÓS TREINAMENTO DE HIGIENE ORAL

Santa Maria, RS
2022

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Tese apresentada ao Curso de Doutorado do Programa de Pós-Graduação em Ciências Odontológicas, da Universidade Federal de Santa Maria (UFSM, RS), como requisito parcial para obtenção do título de **Doutor em Ciências Odontológicas.**

Orientador: Prof. Dr. Carlos Heitor Cunha Moreira

Santa Maria, RS
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Rodrigo da Cunha Rossignollo Tavares

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Aprovado em 18 de agosto 2022:

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Santa Maria, RS
2022

DEDICATÓRIA

À Deus, minha família e meu amor Ana Carolina

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RESUMO

GENGIVITE E QUALIDADE DE VIDA RELACIONADA À SAÚDE BUCAL: USO ADJUNTO DO FIO DENTAL E AUTOPERCEPÇÃO APÓS TREINAMENTO DE HIGIENE ORAL

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A gengivite induzida por biofilmes dentais é considerada a doença oral mais comum e o tipo mais frequente de doença periodontal. Além das repercussões locais, a gengivite está associada com a redução da qualidade de vida. A escovação manual é o método mais utilizado para o autocontrole mecânico de placa e, consequentemente, prevenção e tratamento da gengivite. A eficácia da escovação, porém, é questionável em áreas interdentais. Dessa forma, a limpeza interdental é reconhecida como parte essencial na manutenção de saúde gengival e o fio dental é o dispositivo interdental mais recomendado para espaços sem perda de inserção. Entretanto, a despeito da importância desta questão, há uma limitada evidência científica disponível sobre o impacto do uso do fio dental na qualidade de vida relacionada à saúde bucal (QVRSB). Além disso, não se sabe qual o impacto da autopercepção de melhora na qualidade de vida dos indivíduos após treinamento de higiene oral. Para responder estas questões foi utilizado a amostra de um ensaio clínico randomizado, o qual avaliou a eficácia do fio dental adjunto a escovação dental, comparado com a escovação sozinha, no tratamento da gengivite em adultos. Sessenta e cinco indivíduos foram randomizados em dois grupos experimentais: Grupo escovação dental manual sem o uso de fio dental (escova); Grupo escovação dental manual e uso de fio dental (escova+fio), os indivíduos receberam orientações semanais de higiene oral durante 60 dias. Para avaliar a autopercepção de melhora na QVRSB, a diferença mínima clinicamente importante (MID) foi estimada utilizando uma combinação de medidas âncoras e de distribuição para triangular em direção a um valor MID que foi estimado em 6,4 pontos nos escores de Oral Health Impact Profile (OHIP-14), classificando os indivíduos naqueles que alcançaram (≥MID) ou não (<MID) esse valor. Foram utilizados OHIP-14 e Índice Gengival (IG) para avaliar os desfechos desta tese que foram QVRSB e sangramento gengival ao longo do tempo. A análise de regressão Multinível de Poisson para medidas repetidas foi realizada para comparar os escores do OHIP-14 entre os grupos. As diferenças nas porcentagens médias de IG ao longo do tempo foram analisadas através de modelos lineares mistos. Após 60 dias, os regimes de higiene oral contribuíram para uma melhor percepção da QVRSB independente do uso do fio dental. Durante o acompanhamento, os indivíduos no grupo ≥MID mantiveram menores níveis de sangramento gengival até dois meses após as intervenções, entretanto após seis meses não houve diferença entre os grupos. Portanto, pode ser concluído que regimes de higiene oral contribuem para melhorar a QVRSB, além disso, indivíduos que percebem melhora na QVRSB após treinamento em higiene oral apresentam menores índices de sangramento gengival ao longo do tempo.

Palavras-chave: Diferença mínima clinicamente importante. Fio dental. Gengivite. Higiene Bucal. Qualidade de vida.

ABSTRACT

GINGIVITIS AND ORAL HEALTH-RELATED QUALITY OF LIFE: ADJUNTIVE FLOSSING AND SELF-PERCEPTION AFTER ORAL HYGIENE TRAINING

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Gingivitis caused by dental biofilms is considered the most common oral disease and the most frequent type of periodontal disease. In addition to oral repercussions, gingivitis is associated with reduced quality of life. Manual toothbrushing is the principal method for mechanical biofilm self-control and, consequently, prevention and treatment of gingivitis. The efficacy of brushing, however, is questionable in interdental areas. Thus, interdental cleaning is recognized as an essential part of maintaining gingival health and dental floss is the most recommended interdental device for spaces without attachment loss. However, despite the importance of this issue, there is limited scientific evidence available on the impact of flossing on oral health-related quality of life (OHRQoL). In addition, the impact of self-perception on improved quality of life after oral hygiene training is not known. To answer these questions, we used a sample from a randomized clinical trial, which evaluated the effectiveness of flossing in addition to toothbrushing, compared with brushing alone, in the treatment of gingivitis in adults. Sixty-five subjects were randomized into two experimental groups: Manual toothbrushing without flossing (brush) group, Manual toothbrushing and flossing (brush + floss) group, the individuals received weekly oral hygiene instructions for 60 days. To assess self-perception of improvement in OHRQoL, the difference clinically important minimum (MID) was estimated using a combination of anchor and distribution measures to triangulate towards a MID value that was estimated to be 6.4 points on the Oral Health Impact Profile (OHIP-14), classifying subjects into those who achieved (≥MID) or not (<MID) that value. OHIP-14 and Gingival Index (GI) were used to evaluate the outcomes of this thesis were gingival bleeding and OHRQoL over time. Poisson multilevel regression analysis for repeated measures was performed to compare OHIP-14 scores between groups. Differences in mean percentages of GI over time were analyzed using mixed linear models. After 60 days, oral hygiene regimens contributed to a better perception of OHRQoL regardless of flossing. During follow-up, individuals in the ≥MID group maintained lower levels of gingival bleeding up to two months after the interventions, however, after six months there was no difference between the groups. Therefore, it can be concluded that oral hygiene regimens contribute to improving OHRQoL, in addition, individuals who perceive improvement in OHRQoL after oral hygiene training present lower rates of gingival bleeding over time.

Keywords: Dental floss. Gingivitis. Minimal Clinically Important Difference. Oral Hygiene. Quality of life.

SUMÁRIO

1 INTRODUÇÃO

A gengivite induzida pela placa é uma inflamação na margem gengival causada pelo acúmulo de biofilme nos dentes que leva a uma disbiose na composição do biofilme e a resposta imuno-inflamatória do hospedeiro (MURAKAMI et al., 2018). Löe e colaboradores (1965) demonstraram que o acúmulo de placa sobre a gengiva saudável induziu gengivite entre 10 a 21 dias, e o restabelecimento dos procedimentos de higiene bucal por 7 a 10 dias reestabeleceu saúde gengival. Dados epidemiológicos apontam alta prevalência de gengivite em adultos, podendo afetar 95% da população (LI et al., 2010), além de ser o tipo mais frequente de doença periodontal (WHITE et al., 2012).

Os principais sinais clínicos da gengivite são edema, eritema e sangramento à sondagem. Dor, halitose e redução da qualidade de vida relacionada a saúde bucal (QVRSB) também podem ser relatados pelo paciente (CHAPPLE et al., 2018). Os sinais clínicos são restritos à gengiva e são reversíveis com a remoção do fator etiológico sem qualquer prejuízo ao periodonto de suporte (MARIOTTI, 1999).

A gengivite é considerada um fator de risco no curso clínico da periodontite, Lang et al. (2009) observaram que os dentes associados com gengiva inflamada tiveram um risco significativamente maior de perda dentária do que dentes com gengiva saudável ou levemente inflamada. Hugoson et al. (2008) mostraram que melhorias no controle de placa reduziram a prevalência de gengivite e periodontite moderada em quatro estudos transversais realizados ao longo de 30 anos na Suécia. Dessa forma, prevenção e tratamento da gengivite podem reduzir indiretamente a perda de inserção periodontal.

Além das repercussões locais, a condição gengival produz impacto na qualidade de vida (NEEDLEMAN et al., 2004). De acordo com a *International Dental Federation* (FDI), a saúde bucal é multifacetada e continuamente influenciada pelos valores e atitudes das pessoas e comunidades e reflete os atributos fisiológicos, sociais e psicológicos essenciais para a qualidade de vida (GLICK et al., 2016). Assim, a qualidade de vida tem sido considerada um parâmetro válido na avaliação do paciente em todas as áreas da saúde (GLICK et al., 2016; HARALDSTAD et al., 2019). A qualidade de vida relacionada à saúde bucal é um construto multidimensional, que pode medir subjetivamente o impacto da saúde bucal nas experiências sociocomportamentais do indivíduo, na saúde psicológica e nas funções diárias (SISCHO; BRODER, 2011). A avaliação subjetiva de QVRSB reflete o conforto do indivíduo para comer, dormir e se envolver em interações sociais, sua autoestima e satisfação com sua saúde bucal

(SISCHO; BRODER, 2011). Muitas doenças, incluindo a doença periodontal podem afetar negativamente a QVRSB (Yactayo-Alburquerque et al., 2021). Estudos indicam que a autopercepção de gengivas inchadas e dor gengival estão relacionadas a redução na QVRSB (NEEDLEMAN et al., 2004). Segundo Oliveira et al., (2020), indivíduos com ≥ 20% dos sítios com sangramento à sondagem apresentaram uma QVRSB 37% pior. Esse impacto também é observado em crianças, onde pelo menos 15% do sangramento gengival está relacionado a 15% pior QVRSB (TOMAZONI et al., 2014). Além disso, foi demonstrado que os pacientes percebem uma melhora em sua QVRSB durante a terapia periodontal, especialmente após o tratamento supragengival (MENDEZ et al., 2017).

O controle mecânico da placa supragengival é o principal mecanismo de prevenção e tratamento da gengivite (PINTO et al., 2013; WORTHINGTON et al., 2019). Os benefícios de um adequado controle de placa incluem manutenção de uma dentição funcional, otimização de valores estéticos, como aparência e bom hálito, redução do risco de perda de inserção periodontal e da necessidade de tratamento periodontal complexo, desconfortável e de alto custo (CLAYDON, 2008). Além disso, a melhora nos indicadores clínicos periodontais está correlacionada com aumento na qualidade de vida relacionada à saúde bucal em adultos (SHANBHAG; DAHIYA; CROUCHER, 2013).

A escovação manual é o método mais utilizado para controle de placa (VAN DER WEIJDEIN; SLOT, 2015). A eficácia desse procedimento depende da habilidade individual na remoção de placa e da frequência em que esta remoção é executada (JEPSEN, 1998). Entretanto, a eficiência da escovação é questionável em áreas interproximais. A razão para isso é que a gengiva interdental preenche o espaço apical ao ponto de contato entre dois dentes adjacentes, portanto há dificuldade de acesso das escovas dentais, o que pode possibilitar o estabelecimento e a maturação da placa bacteriana (SALZER et al., 2015). Dessa forma, a remoção de placa interdental é reconhecida como parte essencial na manutenção de saúde gengival (AMERICAN DENTAL ASSOCIATION, 2021; CHAPPLE et al., 2015).

O uso diário de fio dental é o procedimento recomendado para a remoção de placa interdental de áreas com papila preenchendo todo espaço interdental (AMERICAN DENTAL ASSOCIATION, 2021). Contudo, ensaios clínicos randomizados (ROSEMA et al., 2008; SCHIFF et al., 2006; SHARMA et al., 2002) mostraram que a escovação manual sem o auxílio de dispositivos de remoção de placa interdental reduz os níveis de placa e gengivite e mantém a saúde gengival. Graziani e colaboradores (2017) concluíram que o uso de fio dental adjunto a escovação não adicionou benefício na redução de placa e inflamação gengival. Em revisões

sistemáticas que avaliaram o efeito do fio dental combinado a escovação (BERCHIER et al., 2008; WORTHINGTON et al., 2019) os achados não são congruentes. Berchier e colaboradores (2008) mostraram que em pacientes com saúde gengival, o uso de fio dental não tem efeito adicional a escovação nos índices de placa e sangramento gengival.

Além disso, o uso regular de fio dental entre os adultos é baixo (ASADOORIAN; LOCKER, 2006; RIMONDINI et al., 2001; SCHUZ et al., 2006) devido à falta de habilidade individual e motivação (ASADOORIAN; LOCKER, 2006; TEDESCO, KEFFER; FLECK-KANDATH, 1991). Dessa forma, a razão para a sua falta de eficácia pode ser devido: (a) à complexidade manual da técnica, ou seja, os indivíduos não conseguem usar adequadamente o fio; (b) a falta de adesão dos pacientes em relação ao uso adequado e diário do fio dental (SALZER et al., 2015).

Em contrapartida, Worthington e colaboradores (2019) observaram que o uso de fio dental adjunto a escovação pode reduzir placa e gengivite, porém ressaltaram que essa evidência é de baixa certeza. Um recente ensaio clínico randomizado avaliou pacientes com gengivite generalizada sem perda de inserção proximal e concluiu que a escovação quando bem executada desorganiza placa bacteriana no espaço proximal promovendo saúde gengival. Além disso, o uso adjunto do fio dental significativamente diminuiu sangramento gengival proximal (LONDERO et al., 2022).

De forma geral, a odontologia normalmente se concentra em avaliações de saúde bucal relevantes para o profissional de atendimento odontológico utilizando desfechos substitutos, tais como: sangramento à sondagem, escores de placa, profundidade de sondagem e nível de inserção clínica (GRAZIANI et al., 2019). Entretanto, esses desfechos não são perceptíveis pelos pacientes, além disso, a autopercepção dos pacientes sobre sua condição bucal não é avaliada na maioria dos estudos. A autopercepção dos pacientes sobre sua saúde periodontal é importante porque suas preocupações podem diferir dos desfechos clínicos tradicionais (NG; LEUNG, 2006) usados por profissionais de saúde bucal e pela literatura científica. Porém, não se sabe se esses desfechos são importantes em relação à QVRSB, pois com certeza não são fáceis de traduzir em benefícios diretos percebidos pelos pacientes.

As medidas de desfecho relatadas pelo paciente (PROMs), como a qualidade de vida, devem complementar os indicadores clínicos do estado periodontal, proporcionando uma melhor compreensão das percepções do paciente sobre a doença e o tratamento (GRAZIANI et al., 2019). A maneira mais importante de descrever e interpretar essa significância das mudanças na QVRSB é por meio do estabelecimento da diferença mínima importante (MID),

que é a menor diferença em uma pontuação considerada clinicamente significativa (MASOOD et al., 2014). Pacientes com pontuação igual ou superior ao MID podem ser considerados pacientes que percebem um claro benefício do efeito da intervenção (MASOOD et al., 2014). Os pacientes percebem isso como benéfico, o que levaria uma mudança nos cuidados de saúde do paciente (COLE et al., 2009; JAESCHKE et al., 1989; NICHOL; EPSTEIN, 2008).

Portanto, considerando os pressupostos acima mencionados, esta tese tem como objetivo responder questões de pesquisa a respeito da relação entre uso adjunto do fio dental e QVRSB, além de verificar o efeito da autopercepção de melhora na QVRSB nos níveis de sangramento gengival ao longo do tempo. Dessa forma, a presente tese está apresentada na forma de dois artigos científicos:

ARTIGO 1 – "The impact of adjunctive flossing on oral health-related quality of life: A secondary analysis of a randomized clinical trial". Com o objetivo de verificar o impacto do uso adjunto do fio dental na QVRSB de indivíduos com gengivite e sem histórico de periodontite.

ARTIGO 2 – "Impact of self-perception of improvement on oral health-related quality of life after oral hygiene training on gingival bleeding: A secondary analysis". Que objetivou verificar o impacto da percepção de melhora QVRSB no sangramento gengival em até 6 meses após treinamento de higiene oral.

2. ARTIGO 1 - THE IMPACT OF ADJUNCTIVE FLOSSING ON ORAL HEALTH-RELATED QUALITY OF LIFE: A SECONDARY ANALYSIS OF A RANDOMIZED CLINICAL TRIAL

Este artigo será submetido ao periódico Clinical Oral Investigations, ISSN: 1436-3771, Fator de impacto: 3.606, Qualis A1. As normas para publicação estão descritas no Anexo C.

The impact of adjunctive flossing on oral health-related quality of life: A secondary analysis of a randomized clinical trial

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Abstract

Objectives: To evaluate the impact of adjunctive flossing on oral health-related quality of life (OHRQoL) in individuals with gingivitis and without a history of periodontitis.

Methods: This study is a secondary analysis of a randomized clinical trial. Sixty-five participants presenting at least 15% of proximal bleeding were randomized into two groups: adjunctive use of dental floss to toothbrushing (TB+DF) or Toothbrushing alone (TB). All receiving oral hygiene instructions and professional plaque removal once a week, during 8 weeks. OHRQoL (Oral Health Impact Profile [OHIP-14]), Gingival index (GI) and Plaque Index (PlI) were evaluated at baseline and after 60 days. Multilevel Regression analysis for repeated measures was performed to compare the OHIP-14 scores between the groups, evaluation time and gingivitis status were analyzed as prediction variables. The Incidence Rate Ratio (IRR) and 95% confidence interval (95% CI) were calculated.

Results: After 60 days the total OHIP-14 scores significantly decreased in both groups. There were no significant differences in overall OHIP-14 scores between groups (IRR 1.50; 95%CI 0.95-2.37). Both time and gingivitis status were identified as significant predict variables ($p<0.01$)

Conclusions: OHRQoL improved over time irrespective of flossing, most probably whereby oral hygiene instructions and gingivitis reduction levels.

Clinical Relevance: Although oral hygiene regimens improve OHRQoL over time, the impact of flossing is not noticeable to individuals

Keywords: Dental floss, Gingivitis, Oral Health Quality of Life, Secondary Analysis, Toothbrushing.

Introduction

Plaque-induced gingivitis is an inflammation of the gingival margin caused by the accumulation of biofilm dental that leads to a dysbiosis between the biofilm and the host's immune-inflammatory response [1]. Epidemiological data indicate a high prevalence of gingivitis in adults, which may affect 95% of the population [2], and is the most frequent type of periodontal disease [3]. The main clinical signs of gingivitis are edema, erythema, and bleeding on probing [4], which are restricted to the gingiva and are reversible with the removal of the etiological factor without any damage to the supporting periodontium [5].

In addition to local repercussions, the gingival status may cause a negative impact on oral health-related quality of life (OHRQoL) [6, 7]. The subjective OHRQoL assessment reflects individuals' comfort for eating, sleeping, and engaging in social interactions, their self-esteem, and satisfaction with their oral health [8]. Thus, the OHRQoL can be reduced through the self-perception of swollen gums and gum pain [9]. Despite that, it has been shown that patients perceive an improvement in their OHRQoL during periodontal therapy, especially after supragingival treatment [10, 11]. Patient Report Outcome Measures (PROMs), such as quality of life, should complement clinical indicators of periodontal status, providing a better understanding of the patient’s perceptions of the disease and treatment [12].

Mechanical plaque control is the main mechanism for preventing and treating gingivitis [13, 14], and manual brushing is the most used method [15]. Likewise, flossing is also often recommended, since, interdental cleaners are an important oral hygiene practice and an essential part of taking care of teeth and gums [16]. Despite that, previous studies point to doubts on the effectiveness of dental floss by not conclusively discerning the additional benefits of its use as a supplement to toothbrushing to reach gingival health [17–19], possibly due to lack of individual skill and motivation for their right use [20, 21]. Nevertheless, recent studies indicate that flossing can lead to a decrease in gingival bleeding [14, 22].

Therefore, has been recognized that periodontal treatment may lead to OHRQoL improvement [10, 23], however, to the best of our knowledge, there is no evidence about the impact of oral hygiene regimens on OHRQoL of individuals without a history of periodontitis. Thus, this secondary analysis aims to verify the impact of adjunctive flossing on OHRQoL in individuals without a history of periodontitis. The conceptual hypothesis is that oral hygiene regimens improve OHRQoL over time, with no additional benefits in the flossing group.

Materials and Methods

Study design

This study represents a secondary analysis of a randomized clinical trial (RCT) that aimed to evaluate the efficacy of dental floss plus toothbrushing (TB+DF) compared to toothbrushing alone (TB) in individuals with gingivitis at baseline. The original RCT was performed from June 2017 through February 2020 [22] at the Federal University of Santa Maria (UFSM), Post-Graduate Program in Dental Science, Dental School, located in Santa Maria, Southern Brazil. Entire details on the methodology used in the RCT are available in Londero et al.2022 [22]. This study is reported following the Standardized Reporting Of Secondary data Analyses (STROSA) [24, 25]. Originally published in German language and translated by van der Sluijs et. (2018) [26]. For details, see online appendix S1.

Ethical considerations

The eligible individuals provided informed consent, including for secondary analysis. This study was conducted following the Guidelines and Norms Regulating Research involving humans. The research protocol was submitted and approved by the Research Ethics Committee of the Federal University of Santa Maria, RS, Brazil (CAAE: 53831715.5.0000.5346) and ClinicalTrials.gov (NCT04909840).

Sample

The original sample of the study was composed of 75 individuals with a minimum age of 18 years. The individuals included could not have a history of periodontitis, which was considered loss of clinical interdental attachment, with papilla filling the interdental space and with at least 24 teeth. In addition, these individuals must have ≥ 15% of the proximal sites with the presence of score 2 of the Gingival Index (GI) [27]. Individuals with xerostomia, pregnant women, diabetics, smokers, patients with orthodontic appliances and/or restraint, individuals who needed antimicrobial prophylaxis for oral exams, as well used any systemic drug capable of changing gingival conditions in the last three months and who have psychomotor disorders were not included. 65 individuals were taken into account as these fulfill OHIP-14 questionnaire and all clinical measurements at baseline and after 60 days, this implies a retention rate of 86.7% (Figure 1).

For this secondary analysis, no sample size calculation was performed and was analyzed based on the data of a previous clinical trial [22], which revealed that at least 29 participants per group were needed, considering these parameters: Mean gingival bleeding in the group performing toothbrushing only 0.59 (standard deviation: 0.31), mean gingival bleeding in the group using toothbrushing and dental floss 0.40 (standard deviation: 0.19) and 1:1 ratio in the sample size between the groups, 95% confidence interval, 80% test power [28]. For this study, the post hoc power was calculated.

Variables of interest

The short version of the Oral Health Impact Profile instrument (OHIP-14) [29], validated for Brazil [30], assessed the impact of oral conditions on aspects of participant's daily life. This instrument consists of 14 questions divided into seven domains: functional limitation (questions 1 and 2), physical pain (questions 3 and 4), psychological discomfort (questions 5 and 6), physical disability (questions 7 and 8), psychological disability (questions 9 and 10), social disability (questions 11 and 12) and handicaps (questions 13 and 14). The questions were answered on a Likert scale from 0 to 4 for each item: never = 0; almost never = 1; sometimes = 2; often = 3; very often = 4. The overall individual score was calculated by adding the scores of all items [29]. The total scores ranged from 0 to 56 and, the higher the OHIP-14 score, the greater the negative impact on OHRQoL. For the data analysis, was considered the overall OHIP-14 scores. The questionnaire was self-reported and performed at baseline and 60 days. The clinical variables were assessed before the OHIP questionnaire.

At the baseline, data on sociodemographic characteristics such as sex, age and socioeconomic status were collected using structured questionnaires.

Two blinded examiners performed the clinical examinations for the experimental groups. The exams were performed using a periodontal probe (CP 15 UNC, Neumar, Brazil) and the clinical variables evaluated were: PlI, GI, PD (measured as the distance from the gingival margin to the most apical bottom of the sulcus/pocket), CAL (considered the distance from the cementoenamel junction to the most apical bottom of the sulcus/pocket) and BoP (recorded up to 15 seconds and classified into scores: 0 (absence) and 1 (presence)). The interproximal measurements were performed as close as possible to the contact point. All clinical measurements were recorded at six sites per tooth at the baseline and after 60 days. The third molars were not taken into account for this study.

Training and calibration of examiners

Both examiners (A.P.R and R.C.R.T) received training from an experienced examiner (C.H.M). Training consisted of a theoretical evaluation of the periodontal parameters followed by a clinical examination of subjects not included in the study. The examiner R.C.R.T performed the exams of the Gingival Index (GI) [27], Probing Depth (PD), Clinical Attachment Loss (CAL) and bleeding on probing (BoP), while the examiner A.P.R performed the Plaque Index (PlI) [31]. Discussion about each score or category and possible disagreements were performed. The training was concluded as a reasonable level of agreement and understanding of the parameters was achieved. The examiner R.C.R.T was calibrated before the start of the study for PD (Intraclass Correlation Coefficient = 0.78) and CAL (Intraclass Correlation Coefficient = 1) evaluations. Intra-examiner reproducibility was assessed in 7 subjects not included in the study through duplicate tests with an interval of one hour.

Randomization and intervention

Before randomization on the original RCT, supragingival scaling, restorations adjustment, and cavity sealing were performed according to the individual needs of the participants.

Using a computer program (Random Allocation Software, version 2.0), the randomization sequence was generated (blocks of 10) in two experimental groups according to the devices used for their oral hygiene: Adjunctive use of dental floss to toothbrushing (TB+DF) and toothbrushing alone (TB). The randomization confidentiality was maintained using serially numbered opaque envelopes, which matched the sequence from the first to the last subject to be randomized. A researcher (M.L.R) not involved with the outcome performed the randomization process.

At the baseline, all individuals received coronary polishing with a rubber cup (Microdont®, São Paulo, SP, Brazil) and pumice (SS White, New Jersey, NJ, USA). After, two blinded examiners (A.P.R and R.C.R.T) performed a full mouth clinical examination and a clinical staff member (A.B.L) was responsible for revealing the experimental group to which the subject belongs and applying the intervention.

The intervention consisted of professional personalized oral hygiene instruction and professional toothbrush exercises performed once a week for 60 days. First, the researcher (A.B.L) realized an explanation and demonstration in front of a mirror of how oral hygiene should be performed, emphasizing areas with the presence of plaque and gingival bleeding.

Then, the individuals were asked to perform oral hygiene according to the group and if necessary inadequacies were corrected.

Regarding the frequency of oral hygiene, the individuals of both groups (TB+DF and TB) were instructed to brush their teeth twice a day [32] using a soft toothbrush (Colgate® Twister® Compact Head, New York, NY, USA) and applying the fluoride dentifrice (Colgate® Triple Action®, 90 grams, New York, NY, USA) across the width of the brush bristles at one point to standardize the amount used (± 0.5 g). In addition, the individuals of the TB+DF group were instructed to use 20 centimeters (18 inches) of floss (Colgate®, New York, NY, USA) once a day following the targeted technique [32]. All hygiene materials were provided at no cost to the participants.

Statistical analysis

Data were analyzed using Stata 14.1 (StataCorp. 2014. Stata Statistical Software: Release 14.1. College Station, TX: StataCorp LP). A descriptive analysis of the sample according to the groups was performed according to demographic, socioeconomic, and clinical characteristics. The comparison among the characteristics of the groups (TB+DF and TB) at the baseline was analyzed using chi-square (categorical variables) and the t-test (continuous variables).

Changes in overall OHIP-14 scores and specific domains were evaluated by subtracting the 60 days mean score from the baseline mean score. A negative change indicates the improvement in OHRQoL. The effect size (ES) was also calculated [mean difference / standard deviation of the change score (SD)]. A commonly used interpretation is to measure the magnitude of the effect sizes as: small (ES = 0.2), medium (ES = 0.5), and large (ES = 0.8) (Cohen, 1988; Lakens, 2013). The difference in overall OHIP-14 scores and each domain between baseline and 60 days in each group was assessed using the paired t-test.

Multilevel Poisson Regression analysis for repeated measures was performed to compare the OHIP-14 scores between the groups of the RCT, evaluation time and gingivitis status. For gingivitis status, the patients were classified according to the current classification of gingivitis (Chapple et al., 2018) with gingivitis (≥10% bleeding sites) or without gingivitis (<10% bleeding sites). In the structure of the analysis, repeated OHIP-14 measurements (level 1) were nested in the individuals (level 2). The data are presented as Incidence Rate Ratio (IRR) and 95% confidence interval (95% CI). $P < 0.05$ was considered significant.

Results

The 65 individuals included were followed up to evaluate the OHRQoL, 28 were in the TB+DF group and 37 were in the TB group, for details on patient distribution and study flowchart see Figure 1. At the baseline, the mean age of the sample was 21.57 (SD 7.68) and 24.08 (SD 5.52) for TB+DF and TB groups, respectively. Most individuals presented an income of more or equal to 2 BMW and education at least 12 years. In both groups individuals had generalized gingivitis, at the baseline IG≥2 TB+DF 35.77% (15.50), TB 38.67% (15.53). Comparing the individuals allocated to the TB+DF and TB groups, there was no difference in demographic, socioeconomic, and clinical characteristics ($p > 0.05$) (Table 1).

Table 2 presented the overall and also domain-specific OHIP-14 scores at baseline and 60 days according to the group. The overall OHIP-14 scores at baseline in the general sample was 23.75 (SD 17.78). After the intervention, there were a relative average reduction of 55.71% (ES 1.86) and 55.52% (ES 1.06) in the levels of gingival bleeding of the TB+DF and TB, respectively. In general, overall and specific OHIP-14 scores decreased in both groups in the follow-up period, indicating improvement in OHRQoL after oral hygiene regimens. The changes in overall OHIP-14 scores from baseline to 60 days were 10.96 (SD 17.18; ES 0.63) and 6.89 (SD 11.64; ES 0.59) for the TB+DF and TB groups, respectively ($p<0.05$). Regarding specific domains, the psychological discomfort presented the greater scores in both evaluations.

The multilevel model to evaluate the association of predictors variables in overall OHIP-14 scores over time is shown in table 3. The OHIP-14 scores decreased 37% at 60 days of intervention in the general sample (IRR 0.63; 95%CI 0.56-0.70), indicating improvement in OHRQoL. There were no significant differences in overall OHIP-14 scores between the TB+DF and TB groups (IRR 1.50; 95%CI 0.95-2.37). Patients that remained with gingivitis (≥ 10% bleeding sites) at 60 days presented a poorer OHRQoL than the gingival health patients (< 10% bleeding sites) (IRR 1.45; 95%CI 1.20-1.76).

For evaluating the sample size, a post hoc test was performed to verify the power of the study sample. The calculation considered an alpha error probability of 0.05, and mean scores of OHIP-14 (standard deviation [SD]) of 23.75 (SD 17.78), and 15.1 (SD 15.05) between baseline and 60 days, resulting in a sample power of 85%.

Discussion

This study aimed to evaluate the impact of two oral hygiene regimens on the OHRQoL. Our findings demonstrated that both oral hygiene regimens improved the OHRQoL, in agreement

with the conceptual hypothesis. In addition, there was no difference between flossing and non-flossing groups in OHIP-14 scores over time. Individuals who achieved <10% of gingival bleeding after the intervention had more improvement on their OHRQoL than contra parts. Previous studies have shown that periodontal treatment may lead to OHRQoL improvement [10, 11, 23], however, the impact of gingivitis treatment on OHRQoL of individuals without a history of periodontitis has not been explored yet.

Considering the general sample, the OHIP-14 scores decreased significantly after the intervention, indicating improvement in OHRQoL. A possible explanation for these findings is that gingivitis causes several oral and psychological symptoms that can be perceived by the individuals. Previous studies have demonstrated that individuals with gingivitis or gingival bleeding are more likely to experience gingival bleeding when brushing, bad breath, difficulties in their social relationships and are more likely to suffer episodes of dental bullying [6, 7, 33]. Thus, the oral hygiene regimens impact the reduction of oral and emotional symptoms arising from this condition, which directly impacts the patient's OHRQoL. Similarly, previous studies have shown improvements in OHRQoL after periodontitis treatment and dental treatment in general [10, 11, 23, 34].

Regarding specific domains, the psychological discomfort presented the greater scores in both evaluations. Previous studies have shown that aesthetic characteristics caused by gingival bleeding, such as edema and redness, may cause sadness and dental shame [35]. Thus, individuals who present a poorer aesthetic appearance of the smile and gum tend to be less confident, present low self-esteem [33], and consequently more psychological discomfort, which can explain our findings. In addition, most domains improved after intervention, in agreement with a previous study [36]. The weekly appointments and the frequency of visits could have provided patients the feeling of being cared for, which may also have corroborated the significant improvement of these domains.

Our results also showed that there were no significant differences in overall OHIP-14 scores between the TB+DF and TB groups. A previous study evaluating this same sample observed a significant effect of dental floss decreasing interdental gingival bleeding [22]. Even the TB+DF group showed a significant reduction in interdental bleeding, this difference was not perceived by the individuals, since there was no difference on the OHRQoL scores between the groups. Probably by the fact that dental floss promotes a restricted effect on the interdental bleeding, which may be less noticeable to the patient than the general decrease in gingival bleeding. This may be one of the reasons for the low adherence to flossing [37, 38], which

technique is difficult to perform [19] and, as we can see from the results of this study, its benefit may not be entirely perceived by the patient, which can lead to loss of individual motivation [20, 21]. Notwithstanding, the overall OHIP-14 score decreased by 10.96 points in the TB+DF group and 6.89 points in the TB group. According to Locker et al. (2004) [39], a five-point reduction in the OHIP-14 scale can be considered as the minimal important difference needed to observe clinical changes after treatment. Moreover, the oral hygiene regimens resulted in moderate effect sizes on OHRQoL in both groups [40, 41].

Patients that remained with gingivitis at 60 days presented a poorer OHRQoL than the gingival health patients. Despite that, these individuals presented an improvement on their OHRQoL after the intervention. This can be explained by the fact that receiving the treatment led individuals to a perception of improvement on their quality of life, and gingival inflammation was reduced even those who remained with gingivitis, however, individuals who reached levels considered as gingival health obtained significant additional improvement on the OHRQoL.

The current study represents a secondary analysis of an RCT study [22], which was designed to verify the efficacy of flossing for the treatment of proximal gingivitis in adults, which may represent a study limitation. However, PROMs represent an important analysis that should be implemented in the dentistry field then, through the present data, this study analyzed the patient's quality of life through a sample with sufficient power. Furthermore, this is the first study evaluating the relationship between oral hygiene regimens and improvements on OHRQoL in non-periodontal individuals. The patient's perception of its disease and the benefit associated with treatment is considered a real study outcome [42, 43]. Nevertheless, most studies evaluating periodontal treatment use substitute outcomes such as mean changes in BoP, plaque scores, PD, or CAL, however, these measures may not be tangible to the patient [12, 42, 44, 45]. In this sense, the patient's perception may be neglected during dental treatment but it is an important aspect for evaluating therapies [46].

Our findings showed that both oral hygiene regimens improve OHRQoL over time, however, the impact of flossing is not noticeable for individuals without a history of periodontitis. In addition, subjects who achieved gingival health after treatment had a better OHRQoL than those who remained with gingivitis status.

Declarations

Ethical approval: This study was conducted following the Guidelines and Norms Regulating Research involving humans. The research protocol was submitted and approved by the Research Ethics Committee of the Federal University of Santa Maria, RS, Brazil (CAAE: 53831715.5.0000.5346) and ClinicalTrials.gov (NCT04909840).

Consent to participate: The eligible individuals provided informed consent, including for secondary analysis.

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Conflict of Interest: All authors declare they have no conflict of interest related to this study.

Authors' contribution statements:

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Figure legends

Figure 1. Flowchart of study procedures and patient distribution

Figure 1.

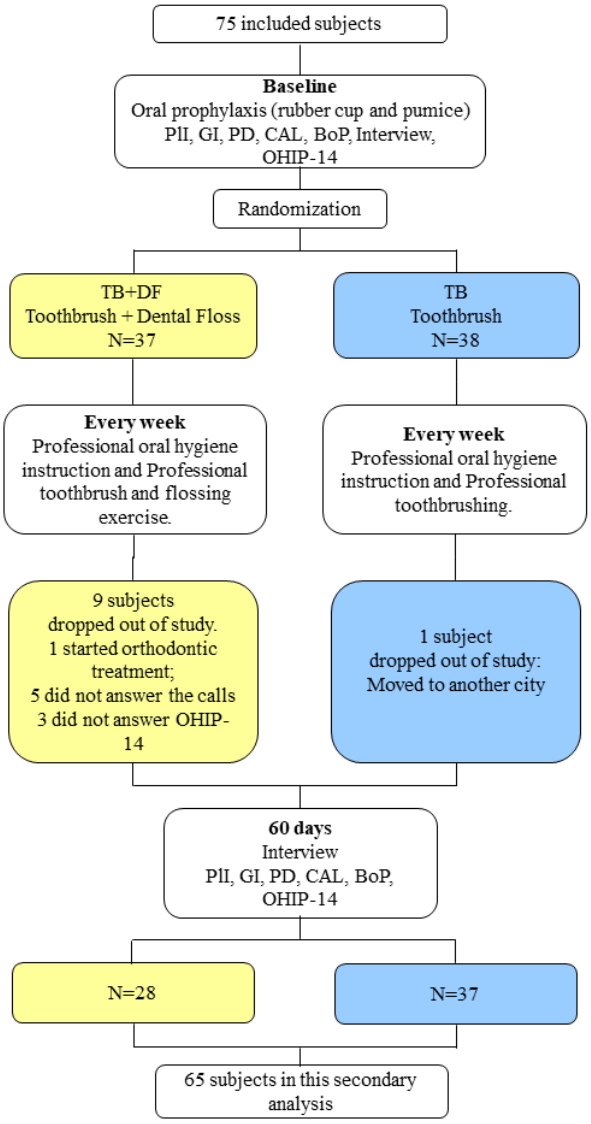

Table 1. Sociodemographic and clinical characteristics at baseline of individuals who fulfill all clinical measurements and OHIP-14 questionnaire (n = 65).

Variables	**Toothbrush**	**Toothbrush+ Dental floss**	**p-value**
Sociodemographic variables	(n= 37)	(n= 28)	
Sex [n (%)]			0.16*
Female	16 (43.2)	17 (60.7)	
Male	21 (56.8)	11 (39.3)	
Age in years [mean (SD)]	24.08 (5.52)	21.57 (7.68)	0.13**
Household income [n (%)]			0.87*
≥ 2 BMW	28 (82.3)	21 (80.8)	
≤ 1 BMW	6 (177)	5 (19.2)	
Years of study [n (%)]			0.77*
> 12 years	35 (94.6)	26 (92.8)	
≤ 12 years	2 (5.4)	2 (7.2)	
Clinical characteristics [mean (SD)]			
PlI≥2 (%)	43.56 (24.28)	46.61 (22.92)	0.60**
GI≥2 (%)	38.67 (15.53)	35.77 (15.50)	0.45**
PD (mm)	1.73 (0.23)	1.64 (0.31)	0.09**
BoP (%)	22.88 (11.06)	23.09 (14.52)	0.09**
CAL (mm)	0.05 (0.09)	0.04 (0.07)	0.91**

BMW, Brazilian minimum wages; SD, standard deviation; PlI, Plaque Index; GI, Gingival Index; PD, probing depth; BoP, bleeding on probing; CAL, clinical attachment loss *Chi-square test; **T-test.

Table 2. Overall and domain-specific OHIP-14 scores at baseline and at 60 days according the groups, with change scores and effect sizes (n=65).

OHIP-14	**Baseline Mean (SD)**	**60 days Mean (SD)**	**Change mean (SD)**	**Effect size**	**p-value***
Toothbrush n=37					
Functional limitation	0.62 (0.89)	0.43 (0.76)	0.18 (0.65)	0.27	0.08
Physical pain	2.72 (1.05)	1.86 (1.60)	0.86 (1.88)	0.45	**<0.05**
Psychological discomfort	3.02 (2.61)	2.29 (2.34)	0.72 (1.92)	0.37	**<0.05**
Physical disability	1.08 (1.62)	0.54 (1.16)	0.48 (1.34)	0.35	**<0.05**
Psychological disability	2.02 (2.33)	1.40 (1.78)	0.62 (1.49)	0.41	**<0.05**
Social disability	1.24 (1.58)	0.86 (1.33)	0.37 (1.13)	0.32	0.05
Handicaps	0.67 (1.14)	0.33 (0.73)	0.33 (0.87)	0.37	**<0.01**
Overall scores	**22.10 (19.54)**	**15.21 (14.99)**	**6.89 (11.64)**	**0.59**	**<0.01**
Toothbrush+ Dental floss n=28					
Functional limitation	0.78 (1.10)	0.46 (0.79)	0.32 (0.98)	0.32	0.09
Physical pain	3.17 (1.63)	2.39 (1.61)	0.78 (1.79)	0.43	**<0.05**
Psychological discomfort	3.43 (2.28)	2.07 (2.22)	1.39 (2.34)	0.58	**<0.05**
Physical disability	1.53 (1.62)	0.71 (1.43)	0.82 (2.01)	0.40	**<0.05**
Psychological disability	1.96 (1.66)	1.14 (1.71)	0.82 (1.98)	0.41	**<0.05**
Social disability	1.67 (2.00)	0.50 (1.03)	1.17 (1.96)	0.59	**<0.01**
Handicaps	0.64 (1.15)	0.29 (0.70)	0.35 (0.67)	0.52	**<0.01**
Overall scores	**25.92 (15.22)**	**14.96 (15.39)**	**10.96 (17.18)**	**0.63**	**<0.01**
Overall difference score between groups	**Diff (p-value)****				
	3.82 (0.39)	3.79 (0.94)			

SD, standard deviation. Diff, difference. *Paired t-test. **T-test

Table 3. Association of predictors variables in overall OHIP-14 scores over time, determined using multilevel Poisson regression analysis for repeated measures (n=65).

Variables	**OHIP-14 overall scores**	
	IRR (95% CI)	**p-value**
Group		
Toothbrush	1.00 (reference)	
Toothbrush + Dental floss	1.50 (0.95-2.37)	0.075
Time		
Baseline	1.00 (reference)	**<0.01**
60 days	0.63 (0.56-0.70)	
Gingival bleeding (GI ≥2) at 60 days		
< 10% sites	1.00 (reference)	**<0.01**
≥ 10% sites	1.45 (1.20-1.76)	

IRR, incidence rate ratio; CI, confidence interval.

Online Supplemental Information S1:

The impact of adjunctive flossing on oral health-related quality of life: A secondary analysis of a randomized clinical trial

Rodrigo da Cunha Rossignollo Tavares[1], Jessica Klöckner Knorst[1], Gabriela Barbieri Ortigara[1], Ana Paula Pereira Reiniger[1], Karen Finger Tatsch[1], Dagmar Else Slot[2], Carlos Heitor Cunha Moreira[1]

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Standardized Reporting Of Secondary data Analyses (STROSA) statement regarding methodological quality (Swart & Schmitt 2014, Swart et al. 2016) originally published in German language and translated by van der Sluijs et. (2018)

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24	Conclusion	**10**
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3. ARTIGO 2 - IMPACT OF SELF-PERCEPTION OF IMPROVEMENT ON ORAL HEALTH-RELATED QUALITY OF LIFE AFTER ORAL HYGIENE TRAINING ON GINGIVAL BLEEDING: A SECONDARY ANALYSIS

Este artigo será submetido ao periódico Clinical Oral Investigations, ISSN: 1436-3771, Fator de impacto: 3.606. As normas para publicação estão descritas no Anexo C.

Impact of self-perception of improvement on oral health-related quality of life after oral hygiene training on gingival bleeding: A secondary analysis

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Abstract

Aim: To evaluate the impact of perceived improvement in oral health-related quality of life (OHRQoL) within 6 months after oral hygiene training (OHT) on gingival bleeding.

Methods: Sixty-five participants presenting at least 15% of proximal gingival bleeding were included in this secondary analysis. They received weekly oral hygiene instructions, professional control plaque according the group: Adjunctive use of dental floss to toothbrushing (TB+DF) or Toothbrushing alone (TB) for 60 days, followed by a period which any more oral hygiene instructions was done (6 months). Gingival index (GI) were evaluated at baseline and after 60, 120 and 240 days, OHRQoL (Oral Health Impact Profile [OHIP-14]) was evaluated at baseline and after 60 days. The Minimal Clinically Important Difference (MID) was estimated using a combination of anchor and distribution measures to triangulate toward a single value, classifying the individuals in those who achieved (≥MID) or not (<MID) this value. Mixed linear models were used for the analysis and comparison between groups and follow-up.

Results: The MID was determined as 6.4 points of OHIP. <MID group presented significantly higher gingival bleeding levels (20.7 (SE 2.05) versus 14.6 (SE 2.2) $p<0.05$) after 120 days of the instructions. There were no differences at 60 and 240 days. Individuals in TB+DF group who perceived improvement in OHRQoL presented less gingival bleeding over time.

Conclusion: Individuals who perceive an improvement in their OHRQoL after oral hygiene training presented lower rates of gingival bleeding.

Clinical Relevance: A return for periodic maintenance is necessary for the individuals to remain motivated and to maintain low gingivitis levels, even in individuals who notice an improvement in their OHRQoL after initial oral hygiene training period.

Keywords: Gingivitis, Minimal Clinically Important Difference, Quality of Life, Oral Health, Oral Hygiene.

Introduction

According to the International Dental Federation (FDI), oral health is multifaceted and continuously influenced by the values and attitudes of people and communities and reflects the physiological, social, and psychological attributes essential to the quality of life [1]. Thus, quality of life has been considered a valid parameter in patient assessment in all areas of health care [1, 2]. The oral health-related quality of life (OHRQoL) is a multidimensional construct, that can subjectively measure the impact of oral health on the individual's social-behavioral experiences and psychological health and daily functions [3].

It is suggested that many diseases and conditions, including periodontal disease, affect negatively the OHRQoL [4]. Plaque-induced gingivitis is the most frequent type of periodontal disease [5]. This inflammation of the gingival margin is caused by the accumulation of biofilm in the teeth that leads to a dysbiosis between the biofilm and the host's immune-inflammatory response [6]. The main clinical signs of gingivitis are edema, erythema and bleeding on probing. Pain, halitosis and reduced OHRQoL can be reported by the patient [7], and the periodontal treatment may improve the OHRQoL during the therapy [8, 9].

Patient-reported outcomes (PROs), such as OHRQoL, can strengthen the knowledge of the self-perception of patients and its impact on behaviour change, so important in gingivitis control and many others outcomes in dental practice. It also provides evidence to clinical dental researchers that improving the quality of life and individual's well-being goes beyond simply treating oral diseases [3]. Most studies report the impact of treatments on OHRQoL based on differences among interventions [10]. Minimal important difference (MID) is the smallest difference in a score considered to be clinically meaningful. Patients perceive it as beneficial and which would mandate, in the absence of side effects and excessive cost, a change in the patient’s health care [11–13]. Patients with a score equal or greater to the MID might be considered to have a clear percept effect benefit from the intervention [10].

Gingivitis can negatively impact OHRQoL (Oliveira et al., 2020; Tomazoni et al., 2014), as a consequence, its treatment may improve it. Lower levels of gingival bleeding are important for maintaining gingival health and preventing diseases such as periodontitis [16]. After oral hygiene training (OHT), it is not known to which extent the perceived improvement on OHRQoL is related to gingival bleeding. This study aims to verify the impact of perceived improvement in oral health-related quality of life (OHRQoL) within 6 months after OHT on gingival bleeding. The hypothesis is that individuals who perceived improvement in OHRQoL have less probability to experience gingival bleeding over time.

Materials and Methods

Protocol and ethics

This study represents a secondary analysis of a follow-up of a randomized clinical trial (RCT), evaluating dental floss efficacy as a supplement to toothbrushing, performed from June 2017 through February 2020 at the Federal University of Santa Maria (UFSM), Post-Graduate Program in Oral-Science, Dental School, RS, Brazil [17].

The participants provided informed consent, including data used in this secondary analysis. This study was conducted following the Guidelines and Norms Regulating Research involving humans. The research protocol was submitted and approved by the Research Ethics Committee of the Federal University of Santa Maria, RS, Brazil (CAAE: 53831715.5.0000.5346) and ClinicalTrials.gov (NCT04909840).

This study is reported following the Standardized Reporting Of Secondary data Analyses (STROSA) (Swart et al., 2016; Swart & Schmitt, 2014). Originally published in German language and translated by van der Sluijs et al. (2018) [20]. For details, see online Appendix S1.

Sample contents

For details regarding the sample, training and calibration of examiners, original design, pre-experimental period, oral hygiene training period and detailed variables description, see online Appendix S2.1-5.

Study design and follow-up

The present analysis was proposed to evaluate the impact of perceived improvement on the quality of life-related to gingival indexes in individuals without a history of periodontitis. This study was divided into two parts, during the first one; all participants received weekly some type of oral hygiene instruction and professional plaque control according the randomized groups adjunctive use of dental floss to toothbrushing (TB+DF) or toothbrushing alone (TB), for 60 days. In the second part, the participants were followed and evaluated for 6 months, without receiving additional oral hygiene instructions.

Follow-up period

After the oral hygiene training period (60 days), no further interventions were carried out. Subjects were instructed to perform oral hygiene according their group (TB+DF or TB) following the technique and frequency recommended. Clinical examinations were performed at baseline, at the end of the training period (60 days), and after 120 and 240 days. Adhesion measures to oral hygiene procedures performed at home were evaluated by a questionnaire applied at 60 and 240 days, with questions about daily frequency of toothbrushing and flossing. For flowchart of the study, see Figure 1.

Variables measured

At baseline, data on sociodemographic characteristics such as sex, age and socioeconomic status were collected using structured questionnaires.

Two blinded examiners performed the clinical examinations for the experimental groups. The exams were performed using a periodontal probe (CP 15 UNC, Neumar, Brazil). The clinical parameters evaluated were: Plaque Index (PlI) [21], Gingival Index (GI) [22], at baseline, 60, 120 and 240 days.

The short version of the OHIP instrument (OHIP-14) [23], validated for Brazil (De Oliveira & Nadanovsky, 2005), assessed the impact of oral conditions in aspects of participant's daily life. It consists of 14 questions in seven domains: functional limitation (questions 1 and 2), physical pain (questions 3 and 4), psychological discomfort (questions 5 and 6), physical disability (questions 7 and 8), psychological disability (questions 9 and 10), social disability (questions 11 and 12) and handicaps (questions 13 and 14). The questions were answered on a Likert scale from 0 to 4 for each item: never = 0; almost never = 1; sometimes = 2; often = 3; very often = 4. The overall individual score was calculated by adding the scores of all items [23]. The total scores can vary from 0 to 56 and, the higher the OHIP-14 score, the greater the negative impact on OHRQoL. The questionnaire was self-reported and performed at baseline and 60-day.

The global health transition scale, self-perceived oral health was obtained after the OHT following question to the individual: Since the end of dental treatment, your quality of life: (0) It has worsened a lot; (1) Aggravated a little; (2) Remained the same; (3) Improved a little; (4) Much better [25, 26].

Minimal important difference (MID)

The minimal important difference for the individual to perceive an improvement on their quality of life was calculated. To carry out the statistical analysis, the individuals were divided into two groups, those who perceived an improvement on their OHRQoL (≥ MID) and those who did not (< MID). According to the proposal of Massod et al., (2014) [10]. The MID was determined based on the distribution-based approaches and the anchor-based approach.

The distribution methods included: 1) effect size (ES); calculated as the mean change as a ratio of the standard deviation (SD) of the OHIP-14; 2) the standard error of measurement (SEM); the SEM incorporates both the SD at baseline and the reliability of the OHIP-14 to represent how the observed change may be affected by random measurement error; 3) one-half of the SD of the OHIP-14 at baseline; 4) t-test comparisons - consider the change in the overall OHIP-14 scores divided by the standard error (SE) of the difference. The MID value distribution-based approach is the result value of the calculation according to (Masood et al., 2014).

For the MID anchor method, the global health transition scale was used to verify the individuals who perceived changes in their OHRQoL. Subsequently, the mean of the OHIP-14 scores of those who reported perceived few changes (scores 1 and 3) was subtracted from those who did not perceive any change (score 2), obtaining the MID value (Masood et al., 2014).

The final MID was estimated using a combination of anchor and distribution measures to triangulate toward a single value. This was calculated through the average of the 5 MID values, 4 from the distribution approach and 1 from the anchor method [10, 27]. For the present study, MID was 6.4 as an indication of OHRQoL improvement.

Statistical analysis

Data were analysed using the Statistical Package for Social Science (SPSS for Windows, version 25.0, SPSS Inc., Chicago, IL, USA). A descriptive analysis of the sample according to demographic, socioeconomic, and clinical characteristics was performed.

The participants were dichotomized according to MID (≥ MID or <MID) for OHRQoL according to changes in OHIP at baseline and 60 days. Mixed linear models was performed to compare the Gingival Index mean among the individuals according to the MID in 60, 120 and 240 days. The interaction between the groups from original RCT and the MID overtime was analysed. The level of significance was set at 5%. For this secondary analysis, no sample size calculation was performed and, was analyzed based on the data of a previous clinical trial [17], which revealed that at least 29 participants per group were needed, considering these

parameters: Mean gingival bleeding in the group performing toothbrushing only 0.59 (standard deviation: 0.31), mean gingival bleeding in the group using toothbrushing and dental floss 0.40 (standard deviation: 0.19) and 1:1 ratio in the sample size between the groups, 95% confidence interval, 80% test power [28].

Results

Table 1 presents the baseline data of socio-demographic and clinical variables. A total of 65 individuals of the 75 allocated to RCT could be included, which data on the baseline and 60 days were collected. The mean age was 23.16 (6.65). 57% of the individuals presented at least 12 years of study and 77% presented an income of more or equal to 2 BMW.

Table 2 shows mean percentage sites with gingival bleeding at 60, 120 and 240 days between MID classifications. At 120 days, individuals who perceived a minimal improvement in their OHRQoL had less gingival bleeding than the group who did not perceive. At 60 and 240 days there were no significant differences between MID groups.

Table 3 displays mean percentage sites with gingival bleeding over time for the toothbrush + dental floss (TB+DF) and the toothbrush alone (TB) groups according MID. Individuals who used dental floss adjunctive to toothbrushing and perceived a significant change in their OHRQoL, presented significantly less gingival bleeding over time. There were no significant differences in TB group.

Discussion

This study aimed to evaluate the impact of self-perceiving improvement on OHRQoL in gingival bleeding presence over time. We consider that individuals who reached the MID in this case a decrease of at least 6.4 points of OHIP-14 after the OHT, perceived improvement in their OHRQoL. The results support our hypotheses that individuals who perceived improvement on OHRQoL presented lower rates of gingival bleeding during follow-up. Although previous studies have shown positive effects of dental treatment on patient-reported outcomes [8, 29], the impact of using MID as perceived by the patient in gingival bleeding levels over time has not yet been explored.

Dentistry has typically focused on assessments of oral health relevant to the dental care professional rather than the patients' experience of their periodontal diseases. Most studies evaluate periodontal treatment by use of substitute outcomes such as mean changes in BoP, plaque scores, PD, or CAL [30]. It is unknown whether these outcome measurements are of

importance regarding the OHRQoL, for sure these measurements are not easy to translate into direct benefits perceived by patients. Patients' perception is important because their concerns may differ from the traditional clinical endpoints [31] used by dental care professionals and by scientific literature.

According our results, there were no differences between MID groups after oral hygiene training period. However, during the follow-up of 120 days, the individuals that did not reach the MID presented more gingival bleeding than their counterparts. A possible explanation for this finding is that despite the initial clinical results, which a substantial improvement was observed in both groups [17], those who perceived an improvement in their OHRQoL remain motivated in performing good oral hygiene and change behaviours related to plaque control, even after the end of the weekly OHT. Previous studies have demonstrated that the initial treatment adherence is influenced by patients' perception of periodontal disease treatment [32]. Thus, those who did not perceive a change in their OHRQoL at the end of the weekly consultations did not become motivated for oral hygiene practices and consequently had increased dental plaque and gingival bleeding throughout the other evaluations.

Individuals who used flossing and perceived the improvement in OHRQoL presented fewer rates of gingival bleeding than individuals in this group who did not notice an improvement in OHRQoL, however in the TB group there were no differences between individuals ≥MID and <MID. According to a previous study [17], individuals who use flossing present less gingival bleeding compared with the individuals of TB group. In addition to this information, our study presents how important it is for the individual to perceive an improvement in its OHRQoL for gingival treatment. In this sense, we can add information in the literature that individuals who use dental floss and perceive an improvement in their OHRQoL decreased gingival bleeding. Individuals in TB+ DF group, perceived that there was an improvement in their OHRQoL and become more engaged improving their oral hygiene practices, which results in fewer levels of gingival bleeding. Considering the entire follow-up, 6 months after the end of the OHT (240 days), there was no difference between the MID groups. This may be clarified by the fact that during this period the participants did not receive supportive oral hygiene instructions. Based on studies with minimal 6 months of duration, it was shown in a systematic review that a single oral hygiene instruction, describing the use of a mechanical toothbrush, in addition to a single professional 'oral prophylaxis' provided at baseline, had a significant, albeit small, positive effect on the reduction of gingivitis [33]. The effect of individual-specific motivational/informational interventions has not yet been clearly

demonstrated neither for the prevention of caries nor for periodontal diseases [34]. Taken all together, it would be important that the patients receive some oral hygiene instruction reinforcement to maintain their motivation in oral hygiene self-care. This may indicate that a recall period between 2 and 6 months is important for individuals to remain motivated and keep low gingivitis levels [35, 36]. Strategies of treatments need to be patient-based, as it is important for individuals to perceive the importance of their own adherence in oral hygiene self-care to maintain good gingival health [36]. Besides that, long-term adherence to optimal self-care requires that the patient have the knowledge, skills, and the ability to self-assess and respond to changes in their condition [37].

The current study represents a secondary analysis of an RCT study [17], which can be considered a limitation. On the other hand, it evaluated a new aspect of the same data. Moreover, the number of dropouts (N=21, usually due to Covid-19 Pandemic) can have influenced the results of the follow-up in the 240 days, as motivation can be a reason for dropout the case. Then, these dropouts can be responsible by overestimation. The strength of the present study is that it shows the importance of the patient's perception during the maintenance of gingival bleeding levels over time. In addition, in daily practice the focus of gingival treatment should not be only on bleeding reduction, also patient-reported outcomes are of importance. Individuals who reduced gingival bleeding without enhancing their OHRQoL may lose the clinical results over time. Therefore, motivational and educational strategies should be performed into account when treating the patient.

Conclusion

Individuals who notice a minimal clinically important difference in their OHRQoL after oral hygiene training presented lower rates of gingival bleeding later. Thus, the patient-reported outcomes are important factors to be considered for the maintenance of the gingival bleeding over time.

Declarations

Ethical approval: This study was conducted following the Guidelines and Norms Regulating Research involving humans. The research protocol was submitted and approved by the Research Ethics Committee of the Federal University of Santa Maria, RS, Brazil (CAAE: 53831715.5.0000.5346) and ClinicalTrials.gov (NCT04909840).

Consent to participate: The eligible individuals provided informed consent, including for secondary analysis.

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Conflict of Interest: All authors declare they have no conflict of interest related to this study.

Authors' contribution statements:

Rodrigo da Cunha Rossignollo Tavares – data collect, data analysis drafting and revising manuscript

Jessica Klöckner Knorst - data analysis, drafting and revising manuscript

Ananda Barrachini Londero - data collect and revising manuscript

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Ana Paula Pereira Reiniger - data collect and revising manuscript

Dagmar Else Slot – drafting and revising manuscript

Carlos Heitor Cunha Moreira - study design, data analysis, coordination, drafting and revising manuscript

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Figure legends

Figure 1. Flowchart of study procedures and patient distribution.

Figure 1.

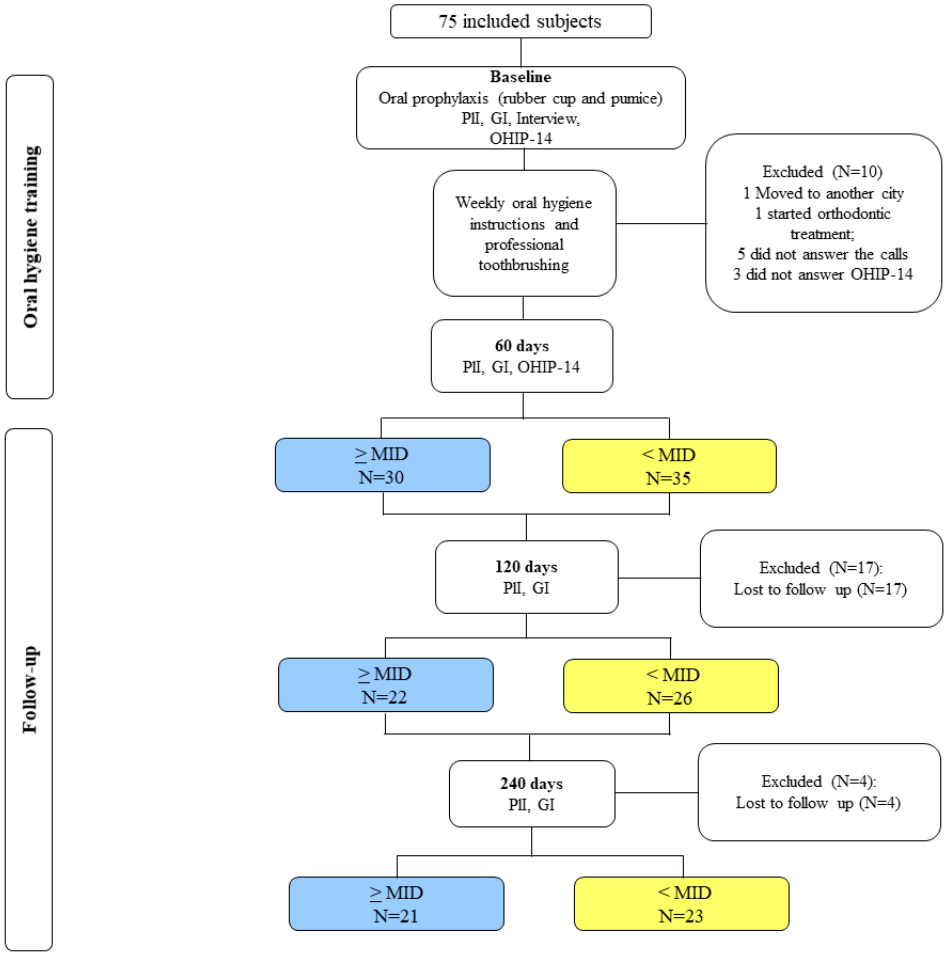

Table 1. Sociodemographic and clinical characteristics of the individuals included in the study (n = 65).

Variables	**Total**
Sociodemographic variables	
Sex [n (%)]	
Female	33 (50.8)
Male	32 (49.2)
Age in years [mean (SD)]	23.0 (6.60)
Household income [n (%)]	
≥ 2 BMW	48 (81.4)
≤ 1 BMW	11 (18.6)
Years of study [n (%)]	
> 12 years	59 (93.6)
≤ 12 years	4 (6.4)
Oral health-related quality of life	
OHIP-14 baseline [mean (SD)]	23.7 (17.7)
OHIP-14 60 days [mean (SD)]	15.1 (15.0)
Gingival bleeding	
GI ≥ 2 (%) baseline [mean (SD)]	37.4 (15.4)
GI ≥ 2 (%) 60 days[mean (SD)]	18.8 (13.3)
GI ≥ 2 (%) 120 days[mean (SD)]	17.1 (10.8)
GI ≥ 2 (%) 240 days[mean (SD)]	15.3 (11.5)
Dental plaque	
PlI ≥ 2 (%) baseline [mean (SD)]	44.8 (23.5)
PlI ≥ 2 (%) 60 days [mean (SD)]	33.3 (22.3)
PlI ≥ 2 (%) 120 days [mean (SD)]	10.0 (11.2)
PlI ≥ 2 (%) 240 days [mean (SD)]	13.5 (15.2)

BMW, Brazilian minimum wages; SD, standard deviation; PlI, Plaque Index; GI, Gingival Index.

Table 2. Mean percentage sites with gingival bleeding (standard error) at 60, 120 and 240 days between MID classifications

Time	MID	Gingival bleeding Mean (SE)
60 days (n=65)	≥ MID	18.8 (2.3)
	< MID	18.5 (2.2)
120 days (n=48)	≥ MID	14.6 (2.2)
	< MID	20.7 (2.05)*
240 days (n=44)	≥ MID	17.2 (2.5)
	< MID	17.8 (2.3)

MID, minimal important difference (calculated as 6.4 OHIP points for this sample), SE, standard error.
Mixed linear models' analysis
Asterisks demonstrate intergroup differences regarding gingival bleeding (P<0.05)

Table 3. Comparison between groups (TB vs TB+DF) on gingival bleeding (x=/- SE) according MID in entire time.

RCT Group	MID	Gingival bleeding Mean (SE)
TB+DF	≥ MID	10.3 (2.8)
	< MID	19.9 (3.0)*
TB	≥ MID	23.4 (2.8)
	< MID	18.2 (2.2)

TB+DF, Adjunctive use of dental floss to toothbrushing, TB, Toothbrushing alone, MID, minimal important difference (calculated as 6.4 OHIP points for this sample), SE, standard error.
Mixed linear models' analysis
Asterisks demonstrate intergroup differences regarding gingival bleeding (P<0.05)

Online Supplemental Information S1:

Impact of self-perception of improvement on oral health-related quality of life after oral hygiene training on gingival bleeding: A secondary analysis

Rodrigo da Cunha Rossignollo Tavares[1], Jessica Klöckner Knorst[1], Ananda Barrachini Londero[1], Gabriela Barbieri Ortigara[1], Ana Paula Pereira Reiniger[1], Dagmar Else Slot[2], Carlos Heitor Cunha Moreira[1]

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Standardized Reporting Of Secondary data Analyses (STROSA) statement regarding methodological quality (Swart & Schmitt 2014, Swart et al. 2016) originally published in German language and translated by van der Sluijs et. (2018)

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Online Supplemental Information S2:

Impact of self-perception of improvement on oral health-related quality of life after oral hygiene training on gingival bleeding: A secondary analysis

Rodrigo da Cunha Rossignollo Tavares[1], Jessica Klöckner Knorst[1], Ananda Barrachini Londero[1], Gabriela Barbieri Ortigara[1], Ana Paula Pereira Reiniger[1], Dagmar Else Slot[2], Carlos Heitor Cunha Moreira[1]

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S2.1 Sample

The sample of this study is composed of 65 individuals with a minimum age of 18 years, with the absence of interdental clinical attachment loss, and with at least 24 teeth with papilla filling the interdental space. In addition, the individuals had to present more than 15% of interproximal sites with gingival bleeding after probing, according to the Gingival Index score 2 (Löe, 1967).

Individuals with orthodontic appliances and/or restraint, psychomotor disorders, diabetics, smokers, pregnant women, patients with xerostomia, who needed antimicrobial prophylaxis for oral exams, as well used antibiotic/anti-inflammatory drugs in the last three months were not included in the sample.

S2.2 Training and calibration of examiners

Training consisted of a theoretical evaluation of the periodontal parameters followed by clinical examination in subjects not included in the study. The examiner R.C.R.T performed the exams of GI, PD and CAL, while the examiner A.P.R performed the PlI exam. Both examiners (A.P.R and R.C.R.T) received training from an experienced examiner (C.H.M). Discussion about each score or category and possible disagreements were performed. The training was concluded as a reasonable level of agreement and understanding of the parameters was achieved.

The examiner R.C.R.T was calibrated before the start of the study for PD (Intraclass Correlation Coefficient = 0.78) and CAL (Intraclass Correlation Coefficient = 1) evaluations. Intra-examiner reproducibility was assessed in 7 subjects not included in the study through duplicate tests with an interval of one hour.

S2.3 Pre-experimental period and original design

According to the individual needs, the participants received supragingival scaling, restorations adjustment and cavity sealing in a maximum period of 10 days, after that the individuals were included in the study.

The randomization sequence for toothbrushing or toothbrushing plus dental floss was generated using a computer program (Random Allocation Software, version 2.0) with blocks of 10 in two experimental groups according to the devices used for their oral hygiene: only toothbrush and toothbrush plus dental floss. The randomization process was conducted by a researcher not involved with the outcome (M.L.R). Serially numbered opaque envelopes (from 1 to 76) matching the sequence from the first to the last subject to be randomized were used to maintain the randomization confidentiality.

S2.4 Oral hygiene training period

This period consisted of a standardized hygiene guideline performed weekly for 60 days. To do so, the researcher (A.B.L) first demonstrated in the subject's mouth how brushing should be performed, emphasizing areas with the presence of plaque and gingival bleeding based. Only one group also received an orientation of flossing on all proximal surfaces. All the demonstrations were performed in front of a mirror. Second, the individuals were asked to perform tooth brushing and flossing according to the group. When necessary, inadequacies were corrected in front of the mirror.

The individuals were instructed to brush their teeth twice a day (Chapple et al., 2015). To standardize the amount of dentifrice used, the individuals were instructed to apply the dentifrice across the width of the brush bristles at one point (± 0.5 g). Besides that, the individuals of the dental floss group were instructed to use 20 centimetres (18 inches) of floss once a day following the targeted technique (Chapple et al., 2015). The hygiene materials consisted of a soft toothbrush (Colgate® Twister® Compact Head, New York, USA), fluoride dentifrice (Colgate® Triple Action®, 90 grams, New York, USA) and a 50-meter waxed dental floss box (Colgate®, tarpaulin, New York, USA). This hygiene materials were delivery to the

individuals during all study without costs. Dental floss was replaced at 60 days, toothbrush was replaced at 120 days, and fluoride dentifrice was replaced every 80 days.

S2.5 Subgingival variables

Probing depth (PD) was measured as the distance from the gingival margin to the most apical bottom of the sulcus/pocket), clinical attachment level (CAL) was considered the distance from the cementoenamel junction to the most apical bottom of the sulcus/pocket) and bleeding on probing (BoP) was recorded up to 15 seconds and classified into scores: 0 (absence) and 1 (presence). PD and CAL were measured in millimetres and rounded to the nearest whole millimetre. The interproximal measurements were performed as close as possible to the contact point. All clinical parameters were recorded at six sites per tooth. The third molars were not taken into account for this study.

Table S3. Subgingival variables at baseline of the individuals included in the study (n=65).

PD (mm) [mean (SD)]	1.1 (0.2)
BoP (%) [mean (SD)]	22.5 (12.3)
CAL (mm) [mean (SD)]	0.04 (0.08)

PD, probing depth; BoP, bleeding on probing; CAL, clinical attachment loss.

4 CONSIDERAÇÕES FINAIS

A presente tese se propôs, por meio de dois artigos científicos, responder questões relacionadas a percepção da qualidade de vida relacionada a saúde bucal, avaliando a associação da condição gengival com a mesma. O artigo 1 teve objetivo de verificar o impacto do uso adjunto do fio dental na QVRSB de indivíduos sem histórico de periodontite, além disso também avaliou se regimes de higiene oral contribuem para melhorar a qualidade de vida desses indivíduos. A partir dos resultados encontrados podemos concluir que regimes de higiene oral contribuem para uma melhor percepção da QVRSB, além disso indivíduos que alcançam níveis de sangramento gengival <10% apresentam melhor QVRSB, apesar disso o uso adjunto do fio dental não impactou na QVRSB.

O fio dental é eficaz como mecanismo de controle de placa em áreas proximais em indivíduos sem perda de inserção proximal, porém não apresenta impacto significante na QVRSB.. Uma possível explicação é o fato da técnica ser difícil de ser executada de forma apropriada, além disso, o fato da ação do fio dental ser restrita a áreas proximais diminuindo sangramento gengival apenas nessas áreas, pode tornar seu impacto menos perceptível para o indivíduo, e por isso pode ter um impacto limitado na qualidade de vida.

O artigo 2 verificou o impacto da percepção de melhora na qualidade de vida relacionada a saúde bucal (QVRSB) no sangramento gengival em até 6 meses após treinamento de higiene oral. De acordo com os resultados, indivíduos que percebem melhora em sua qualidade de vida apresentam menor sangramento gengival em até dois meses após treinamento de higiene oral, mas esses resultados foram reduzidos na avaliação de 6 meses, possivelmente pela falta de reforço nas orientações durante o acompanhamento. A percepção do paciente após o tratamento pode ser importante para a manutenção dos resultados ao longo do tempo, dessa forma, indivíduos que percebem melhora na qualidade de vida tendem a ter maior adesão ao tratamento enquanto aqueles que não percebem podem retornar aos hábitos iniciais.

Portanto a partir destes achados podemos concluir que o fio dental apesar de ser eficaz para o tratamento da gengivite proximal em indivíduos que não apresentam perda de inserção proximal, não impacta significativamente na qualidade de vida desses indivíduos. Em contrapartida, indivíduos que percebem melhora em sua qualidade de vida após treinamento de higiene oral mantem menores níveis de sangramento gengival ao longo do tempo.

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APÊNDICE A – ENTREVISTA

Entrevista

1) Nome:_____

2) Telefone(s):_____

3) Endereço:_____

4) Sexo: ( )M ( )F

5) Data de nascimento:_____ **Idade:**_____ anos.

6) Raça: ( ) branca; ( ) preta; ( ) parda; ( ) indígena; ( ) amarela;

Dados odontológicos:

7) Qual a frequência com que você realiza escovação dos dentes?

( ) não escova; ( ) menos de uma vez ao dia (escova somente alguns dias); ( )1 vez por dia; ( ) 2 vezes por dia; ( ) três vezes ou mais que três vezes por dia.

8) Que tipo de escova você usa? ( ) macia; ( ) média; ( ) dura

9) Qual frequência com que você utiliza dispositivo de limpeza interdental?

( ) não utiliza; ( ) menos de uma vez ao dia (utiliza somente alguns dias); ( )1 vez por dia

10) Qual tipo de dispositivo de limpeza interdental você usa?

( ) fio; ( ) escova interdental; ( ) escova unitufo; ( ) outro_____

11) Você usa pasta de dentes? ( ) sim ( ) não

12) Você usa alguma solução para bochecho? ( ) sim ( ) não

13) Você observa que suas gengivas sangram? ( ) sim ( ) não

14) Você sente sensibilidade nos dentes? ( ) sim ( ) não

15) Você sente mau hálito na boca? ( ) sim ( ) não

16) Alguém já comentou a respeito do seu hálito? ( ) sim ( ) não

17) Você procurou o dentista nos últimos 6 meses? ( ) sim ( ) não

18) Quando foi a última visita ao dentista? ( ) até 3 meses; ( ) 3 a 6 meses; ( ) 6 meses a 1 ano; ( ) mais que 1 ano; ( ) nunca visitou

19) Motivo da última consulta: ( ) dor de dente; ( ) dor na boca; ( ) batidas e quedas; ( ) exames de rotina. **Outros:**_____

20) Tipo de serviço que você procurou na última consulta: ( ) dentista particular; ( ) dentista público (posto de saúde, faculdade, escola)

Dados médicos:

21) Você está fazendo tratamento médico atualmente?

( ) sim ( ) não. **Qual?** _____

22) Você esteve em tratamento médico nos últimos 3 meses?

( ) sim ( ) não. **Qual?** _____

23) Você tem alguma doença sistêmica?

( ) sim ( ) não. **Qual?** _____

24) Você está tomando alguma medicação?

( ) sim ( ) não. **Qual?** _____

Nível socioeconômico e escolaridade

25) No mês passado, quanto receberam em Reais, juntas, todas as pessoas que moram na sua casa? (Incluindo valores de salários, bolsa família, pensão, aposentadoria e outros rendimentos) _____ reais.

26) Você trabalha? ( ) sim ( ) não

27) Você estudou até: ( )não estudou; ( )1º grau incompleto; ( )1º grau completo; ( )2º grau incompleto; ( )2º grau completo; ( )3º grau incompleto; ( )3º grau completo

28) Quantos anos de estudo você tem? _____anos

APÊNDICE B – FICHA CLÍNICA

Nome:_____ **Data:**_____

Avaliação: ( ) *baseline* ( ) 30 ( ) 60 ( ) 120 dias ( ) 240 dias

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Nome:_____

Data:_____ **Avaliação: ( ) *baseline;* ( ) 60; ( ) 240 dias**

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APÊNDICE C – QUESTIONÁRIO SOBRE EFEITOS ADVERSOS

Questionário efeitos adversos

Avaliação: ( ) 30; ( ) 60; ( ) 120; ( ) 240 dias

1) Você percebeu alguma alteração sobre as superfícies de seus dentes a partir da última avaliação que fizemos?

_____

_____

2) Você apresentou alguma alteração de sua gengiva durante a higiene bucal?

_____

_____

3) Você tem sentido gosto ruim na boca?

_____

_____

4) Você percebe outras alterações além das expostas acima?

_____

_____

_____

APÊNDICE D – ADESÃO AO TRATAMENTO

Pergunta sobre adesão ao tratamento

1) Quantas vezes por dia você utilizou a escova e o fio dental desde a última visita ao dentista?

Avaliação 30:

( ) escova; ( ) fio

Avaliação 60:

( ) escova; ( ) fio

Avaliação 120:

( ) escova; ( ) fio

Avaliação 240:

( ) escova; ( ) fio

ANEXO A – QUESTIONÁRIO PERFIL DO IMPACTO NA SAÚDE ORAL (OHIP – 14)

Questionário Perfil do Impacto na Saúde Oral (OHIP – 14)

Avaliação: ( ) *baseline*; ( ) 60; ( ) 240 dias

Nos últimos seis meses, por causa de problemas com seus dentes ou sua boca:

1 – Você teve problemas para falar alguma palavra?

nunca ( ) raramente ( ) às vezes ( ) repetidamente ( ) sempre ( )

2 – Você sentiu que o sabor dos alimentos tem piorado?

nunca ( ) raramente ( ) às vezes ( ) repetidamente ( ) sempre ( )

3 – Você sentiu dores em sua boca ou nos seus dentes?

nunca ( ) raramente ( ) às vezes ( ) repetidamente ( ) sempre ( )

4 – Você se sentiu incomodada ao comer algum alimento?

nunca ( ) raramente ( ) às vezes ( ) repetidamente ( ) sempre ( )

5 – Você ficou preocupada?

nunca ( ) raramente ( ) às vezes ( ) repetidamente ( ) sempre ( )

6 – Você se sentiu estressada?

nunca ( ) raramente ( ) às vezes ( ) repetidamente ( ) sempre ( )

7 – Sua alimentação ficou prejudicada?

nunca ( ) raramente ( ) às vezes ( ) repetidamente ( ) sempre ( )

8 – Você teve que parar suas refeições?

nunca ( ) raramente ( ) às vezes ( ) repetidamente ( ) sempre ( )

9 – Você encontrou dificuldade para relaxar?

nunca ( ) raramente ( ) às vezes ( ) repetidamente ( ) sempre ( )

10 – Você se sentiu envergonhada?

nunca ( ) raramente ( ) às vezes ( ) repetidamente ( ) sempre ( )

11 – Você ficou irritada com outras pessoas?

nunca ( ) raramente ( ) às vezes ( ) repetidamente ( ) sempre ( )

12 – Você teve dificuldade para realizar suas atividades diárias?

nunca ( ) raramente ( ) às vezes ( ) repetidamente ( ) sempre ( )

13 – Você sentiu que a vida, em geral, ficou pior?

nunca ( ) raramente ( ) às vezes ( ) repetidamente ( ) sempre ( )

14 – Você ficou totalmente incapaz de fazer suas atividades diárias?

nunca ( ) raramente ( ) às vezes ( ) repetidamente ( ) sempre ( )

ANEXO B – JULGAMENTO GLOBAL DE SAÚDE BUCAL

Julgamento Global de Saúde Bucal

ANTES DA TRATAMENTO – Data: _____

1) Você diria que a saúde dos seus dentes, lábios, maxilares e boca é:

( ) Excelente; ( ) Boa; ( ) Regular; ( ) Ruim; ( ) Péssima

2) Até que ponto a condição dos seus dentes, lábios, maxilares e boca afetam a sua vida em geral?

( ) De jeito nenhum; ( ) Um pouco; ( ) Moderadamente; ( ) Bastante; ( ) Muitíssimo

DEPOIS DO TRATAMENTO - Data: _____

1) Você diria que a saúde dos seus dentes, lábios, maxilares e boca é:

( ) Excelente; ( ) Boa; ( ) Regular; ( ) Ruim; ( ) Péssima

2) Até que ponto a condição dos seus dentes, lábios, maxilares e boca afetam a sua vida em geral?

( ) De jeito nenhum; ( ) Um pouco; ( ) Moderadamente; ( ) Bastante; ( ) Muitíssimo

Julgamento de transição global

1) Desde o término do tratamento dentário, a sua qualidade de vida geral...

( ) Agravou muito; ( ) Agravou um pouco; ( ) Permaneceu a mesma; ( ) Melhorou um pouco; ( ) Melhorou muito

ANEXO C – NORMAS PARA PUBLICAÇÃO NO PERIÓDICO CLINICAL ORAL INVESTIGATIONS

Instructions for Authors

Types of papers

Papers may be submitted for the following sections:

- Research Article
- Invited review
- Brief Report – with up to 2000 words and up to two figures and/or tables
- Correspondence (Discussion paper)
- Debate (Letter to the Editor)

It is the general policy of this journal not to accept case reports and pilot studies.

Editorial Procedure

If you have any questions please contact:

Professor Dr. M. Hannig

University Hospital of Saarland

Department of Parodontology and Conservative Dentistry

Building 73

66421 Homburg/Saar

Germany

Email: eic.hannig@uks.eu

Manuscript Submission

Manuscript Submission

Submission of a manuscript implies: that the work described has not been published before; that it is not under consideration for publication anywhere else; that its publication has been approved by all co-authors, if any, as well as by the responsible authorities – tacitly or explicitly – at the institute where the work has been carried out. The publisher will not be held legally responsible should there be any claims for compensation.

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The Springer Author Academy is a set of comprehensive online training pages mainly geared towards first-time authors. At this point, more than 50 pages offer advice to authors on how to write and publish a journal article.

Springer Author Academy

Title Page

The title page should include:

- The name(s) of the author(s)
- A concise and informative title
- The affiliation(s) and address(es) of the author(s)
- The e-mail address, telephone and fax numbers of the corresponding author

Abstract

Please provide a structured abstract of 150 to 250 words which should be divided into the following sections:

- Objectives (stating the main purposes and research question)
- Materials and Methods
- Results
- Conclusions
- Clinical Relevance

These headings must appear in the abstract.

Keywords

Please provide 4 to 6 keywords which can be used for indexing purposes.

Text

Text Formatting

Manuscripts should be submitted in Word.

- Use a normal, plain font (e.g., 10-point Times Roman) for text.
- Use italics for emphasis.
- Use the automatic page numbering function to number the pages.
- Do not use field functions.
- Use tab stops or other commands for indents, not the space bar.
- Use the table function, not spreadsheets, to make tables.
- Use the equation editor or MathType for equations.

- Save your file in docx format (Word 2007 or higher) or doc format (older Word versions).

Manuscripts with mathematical content can also be submitted in LaTeX. We recommend using Springer Nature's LaTeX template.

Headings

Please use no more than three levels of displayed headings.

Abbreviations

Abbreviations should be defined at first mention and used consistently thereafter.

Footnotes

Footnotes can be used to give additional information, which may include the citation of a reference included in the reference list. They should not consist solely of a reference citation, and they should never include the bibliographic details of a reference. They should also not contain any figures or tables.

Footnotes to the text are numbered consecutively; those to tables should be indicated by superscript lower-case letters (or asterisks for significance values and other statistical data). Footnotes to the title or the authors of the article are not given reference symbols.

Always use footnotes instead of endnotes.

Acknowledgments

Acknowledgments of people, grants, funds, etc. should be placed in a separate section on the title page. The names of funding organizations should be written in full.

References

Citation

Reference citations in the text should be identified by numbers in square brackets. Some examples:

1. Negotiation research spans many disciplines [3].

2. This result was later contradicted by Becker and Seligman [5].

3. This effect has been widely studied [1-3, 7].

Reference list

The list of references should only include works that are cited in the text and that have been published or accepted for publication. Personal communications and unpublished works should only be mentioned in the text.

The entries in the list should be numbered consecutively.

If available, please always include DOIs as full DOI links in your reference list (e.g. "https://doi.org/abc").

- Journal article

Gamelin FX, Baquet G, Berthoin S, Thevenet D, Nourry C, Nottin S, Bosquet L (2009) Effect of high intensity intermittent training on heart rate variability in prepubescent children. Eur J Appl Physiol 105:731-738. https://doi.org/10.1007/s00421-008-0955-8

Ideally, the names of all authors should be provided, but the usage of "et al" in long author lists will also be accepted:

Smith J, Jones M Jr, Houghton L et al (1999) Future of health insurance. N Engl J Med 965:325–329

- Article by DOI

Slifka MK, Whitton JL (2000) Clinical implications of dysregulated cytokine production. J Mol Med. https://doi.org/10.1007/s001090000086

- Book

South J, Blass B (2001) The future of modern genomics. Blackwell, London

- Book chapter

Brown B, Aaron M (2001) The politics of nature. In: Smith J (ed) The rise of modern genomics, 3rd edn. Wiley, New York, pp 230-257

- Online document

Cartwright J (2007) Big stars have weather too. IOP Publishing PhysicsWeb. http://physicsweb.org/articles/news/11/6/16/1. Accessed 26 June 2007

- Dissertation

Trent JW (1975) Experimental acute renal failure. Dissertation, University of California

Always use the standard abbreviation of a journal's name according to the ISSN List of Title Word Abbreviations, see

ISSN.org LTWA

If you are unsure, please use the full journal title.

Authors preparing their manuscript in LaTeX can use the bibliography style file sn-basic.bst which is included in the Springer Nature Article Template.

Back to top

Tables

- All tables are to be numbered using Arabic numerals.
- Tables should always be cited in text in consecutive numerical order.
- For each table, please supply a table caption (title) explaining the components of the table.
- Identify any previously published material by giving the original source in the form of a reference at the end of the table caption.
- Footnotes to tables should be indicated by superscript lower-case letters (or asterisks for significance values and other statistical data) and included beneath the table body.

Artwork and Illustrations Guidelines

Electronic Figure Submission

- Supply all figures electronically.
- Indicate what graphics program was used to create the artwork.
- For vector graphics, the preferred format is EPS; for halftones, please use TIFF format. MSOffice files are also acceptable.
- Vector graphics containing fonts must have the fonts embedded in the files.
- Name your figure files with "Fig" and the figure number, e.g., Fig1.eps.

Line Art

- Definition: Black and white graphic with no shading.

- Do not use faint lines and/or lettering and check that all lines and lettering within the figures are legible at final size.
- All lines should be at least 0.1 mm (0.3 pt) wide.
- Scanned line drawings and line drawings in bitmap format should have a minimum resolution of 1200 dpi.
- Vector graphics containing fonts must have the fonts embedded in the files.

Halftone Art

- Definition: Photographs, drawings, or paintings with fine shading, etc.
- If any magnification is used in the photographs, indicate this by using scale bars within the figures themselves.
- Halftones should have a minimum resolution of 300 dpi.

Combination Art

- Definition: a combination of halftone and line art, e.g., halftones containing line drawing, extensive lettering, color diagrams, etc.
- Combination artwork should have a minimum resolution of 600 dpi.

Color Art

- Color art is free of charge for online publication.
- If black and white will be shown in the print version, make sure that the main information will still be visible. Many colors are not distinguishable from one another when converted to black and white. A simple way to check this is to make a xerographic copy to see if the necessary distinctions between the different colors are still apparent.
- If the figures will be printed in black and white, do not refer to color in the captions.
- Color illustrations should be submitted as RGB (8 bits per channel).

Figure Lettering

- To add lettering, it is best to use Helvetica or Arial (sans serif fonts).
- Keep lettering consistently sized throughout your final-sized artwork, usually about 2–3 mm (8–12 pt).
- Variance of type size within an illustration should be minimal, e.g., do not use 8-pt type on an axis and 20-pt type for the axis label.
- Avoid effects such as shading, outline letters, etc.
- Do not include titles or captions within your illustrations.

Figure Numbering

- All figures are to be numbered using Arabic numerals.
- Figures should always be cited in text in consecutive numerical order.
- Figure parts should be denoted by lowercase letters (a, b, c, etc.).
- If an appendix appears in your article and it contains one or more figures, continue the consecutive numbering of the main text. Do not number the appendix figures,"A1, A2, A3, etc." Figures in online appendices [Supplementary Information (SI)] should, however, be numbered separately.

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- Each figure should have a concise caption describing accurately what the figure depicts. Include the captions in the text file of the manuscript, not in the figure file.
- Figure captions begin with the term Fig. in bold type, followed by the figure number, also in bold type.
- No punctuation is to be included after the number, nor is any punctuation to be placed at the end of the caption.
- Identify all elements found in the figure in the figure caption; and use boxes, circles, etc., as coordinate points in graphs.
- Identify previously published material by giving the original source in the form of a reference citation at the end of the figure caption.

Figure Placement and Size

- Figures should be submitted within the body of the text. Only if the file size of the manuscript causes problems in uploading it, the large figures should be submitted separately from the text.
- When preparing your figures, size figures to fit in the column width.
- For large-sized journals the figures should be 84 mm (for double-column text areas), or 174 mm (for single-column text areas) wide and not higher than 234 mm.
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- Patterns are used instead of or in addition to colors for conveying information (colorblind users would then be able to distinguish the visual elements)
- Any figure lettering has a contrast ratio of at least 4.5:1

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- Aspect ratio: 16:9 or 4:3
- Maximum file size: 25 GB for high resolution files; 5 GB for low resolution files
- Minimum video duration: 1 sec
- Supported file formats: avi, wmv, mp4, mov, m2p, mp2, mpg, mpeg, flv, mxf, mts, m4v, 3gp

Text and Presentations

- Submit your material in PDF format; .doc or .ppt files are not suitable for long-term viability.
- A collection of figures may also be combined in a PDF file.

Spreadsheets

- Spreadsheets should be submitted as .csv or .xlsx files (MS Excel).

Specialized Formats

- Specialized format such as .pdb (chemical), .wrl (VRML), .nb (Mathematica notebook), and .tex can also be supplied.

Collecting Multiple Files

- It is possible to collect multiple files in a .zip or .gz file.

Numbering

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Transparency in authors' contributions and responsibilities to promote integrity in scientific publication, McNutt at all, PNAS February 27, 2018

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All authors are requested to include information regarding sources of funding, financial or non-financial interests, study-specific approval by the appropriate ethics committee for research involving humans and/or animals, informed consent if the research involved human participants, and a statement on welfare of animals if the research involved animals (as appropriate).

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All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by [full name], [full name] and [full name]. The first draft of the manuscript was written by [full name] and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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A Graduate Student's Guide to Determining Authorship Credit and Authorship Order, APA Science Student Council 2006

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• This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the Ethics Committee of University B (Date.../No. ...).

• Approval was obtained from the ethics committee of University C. The procedures used in this study adhere to the tenets of the Declaration of Helsinki.

• The questionnaire and methodology for this study was approved by the Human Research Ethics committee of the University of D (Ethics approval number: ...).

Examples of statements to be used for a retrospective study:

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Summary of requirements

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Please see the various examples of wording below and revise/customize the sample statements according to your own needs.

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The authors affirm that human research participants provided informed consent for publication of the images in Figure(s) 1a, 1b and 1c.

The participant has consented to the submission of the case report to the journal.

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