

Assessment of oral health-related quality of life as a function of non-invasive treatment with high-fluoride toothpastes for root caries lesions in community-dwelling elderly

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Purpose: Non-invasive treatment of root caries lesions (RCLs) may impact oral health-related quality of life (OHRQoL), but no evidence is available. The purpose of the study was to assess changes in OHRQoL among patients exposed to non-invasive treatment of RCLs with conventional or high-fluoride dentifrices. **Methods:** To be eligible, subjects had to be ≥ 60 years of age, independently living, with at least five teeth and one RCL. The 14-item Oral Health Impact Profile for adults in Spanish (OHIP-14Sp), oral examination and sociodemographic data were documented at the beginning of the study (T0). The presence and activity of RCLs were detected and diagnosed. Subjects were randomly assigned to either the control (1,450 ppm fluoride) or the experimental (5,000 ppm fluoride) treatment group. A new set of measurements was obtained at 12 months (T1). Mean comparisons were carried out using the Student's *t*-test for total OHIP-14Sp scores. To determine whether T1 OHRQoL scores were different regarding sex, age, educational level and socio-economic status, mean OHIP-14Sp scores were obtained and compared with those variables at 12 months. **Results:** An overall improvement in OHRQoL after the non-invasive treatment of RCLs was verified when T1 was compared with T0 ($P < 0.0001$). Regarding treatment type, no significant differences were detected between groups ($P = 0.114$). Subjects with higher income and more years of formal education had better OHRQoL than those with a lower salary ($P < 0.0001$) and with fewer years of education ($P = 0.0006$). **Conclusions:** Non-invasive treatment for RCLs in community-dwelling elders appears to cause a positive impact on OHRQoL. Better OHRQoL was associated with higher socio-economic status and educational level. No significant differences were detected regarding the fluoride concentration in the dentifrices.

Key words: Quality of life, oral health-related quality of life, oral health, OHIP, root caries lesions, dental caries, fluoridated toothpaste, high-fluoride dentifrices, non-invasive treatment, elderly

INTRODUCTION

The world is facing an unprecedented demographic transition. In addition to living longer, people are retaining more teeth^{1,2}. Having more teeth retained into older age has resulted in increased prevalence of the most frequent oral diseases: periodontal diseases and dental caries. Regarding dental caries, older adults are usually affected by root caries lesions (RCLs), with a worldwide prevalence of approximately 30–60%³.

RCLs usually affect older adults with predisposing risk factors, including high root-caries experience, advanced age, smoking and medication use with resulting xerostomia, among many others that have been identified⁴. In this scenario, understanding the disease and its consequences is important. Restoration of RCLs is challenging, as restorative procedures are associated with difficulties in moisture control, the nature of the tissues for adhesion and the lack of retention in deeper root cavities. Furthermore, a growing

number of patients with RCLs experience limited mobility, which means restrictions to traditional and appropriate restorative treatment⁵. On the other hand, dental anxiety or dental fear is reported for about 36% of the population, including 12% describing extreme dental fear⁶. Dental anxiety can have serious implications for a subject's oral health, by acting as a barrier to dental care⁷. High dental anxiety has been associated with low oral health-related quality of life (OHRQoL)^{8,9}. Conversely, when people attend routine dental visits a protective effect on OHRQoL¹⁰ has been found.

Considering the drawbacks of conventional therapy for RCLs, non-invasive treatment of these lesions is highly desirable for patients and clinicians and may impact OHRQoL. Several approaches to prevent initiation of, or to inactivate, RCLs have been proposed. A recent systematic review of the literature identified different types of applications and agents to reduce the initiation of, or to inactivate, RCLs¹¹. Daily use of dentifrice containing 5,000 ppm fluoride showed greater efficacy in reducing active RCLs than dentifrices containing 1,100–1,450 ppm fluoride. We carried out a comprehensive search for the potential association between non-invasive therapies for RCLs and OHRQoL in older people, but no evidence seems to be available. The purpose of the present study, therefore, was to assess changes in self-reported OHRQoL among older patients exposed to non-invasive treatment of RCLs using high-fluoride toothpastes over a period of 1 year. This study is part of a randomised controlled clinical trial designed to evaluate arrest of RCL using non-invasive therapies with fluoridated dentifrices.

METHODS

Subjects

This longitudinal study was conducted among Chilean community-dwelling older adults who participated in a randomised controlled clinical trial of self-administered non-invasive therapy with high-fluoride dentifrices on preventing and arresting RCLs. The study protocol for this trial was registered at ClinicalTrials.gov NCT02647203. Data were collected from July 4, 2014 to December 18, 2015 in the School of Dentistry of the University of Talca. To be enrolled in the primary study, participants had to meet the following inclusion criteria: to be 60 years of age or older; independently living according to the Functional Evaluation of Older Adults (EFAM; its abbreviation in Spanish) criteria¹²; have at least five teeth and at least one RCL; and be able to answer the 14-item Oral Health Impact Profile for adults in Spanish (OHIP-14Sp) questionnaire¹³. Participants were excluded from the study if they

showed signs of cognitive impairment or alcoholism, which were corroborated by the principal investigator. If there was no clarity on the exclusion criteria, the Short Mini-Mental State Examination (MMSE-SF)¹⁴ and the Alcohol Use Disorders Identification Test (AUDIT-C Test)¹⁵ were applied.

Sample size was calculated using the software GRANMO, for the comparison of two means (presence of carious lesions) in independent populations, considering a previous study¹⁶. Accepting an alpha risk of 0.05 and a beta risk of 0.2 in a two-sided test, a total of 342 participants was required ($n = 171$ per group). A difference of ≥ 4 units was needed to consider the differences as statistically significant. The common standard deviation was assumed to be 11.79. When designing the study, an anticipated drop-out rate of 20% was established to calculate the sample size. Hence, a sample of 274 older adults was necessary. The study and the informed consent form were approved by the Bioethics Committee of the University of Talca (number: 2013-047). All participants signed an informed consent form and received oral explanation about the nature of the study.

Questionnaire

The instrument for the present investigation (OHIP-14Sp) was the Chilean validation¹³ of the OHIP-14 questionnaire developed by Slade and Spencer¹⁷. Items were grouped into seven domains and respondents were invited to answer the OHIP-14Sp questions on frequency of the problems. The responses were recorded using a 5-point Likert scale (0, never; 1, hardly ever; 2, occasionally; 3, fairly often; and 4, very often) using the original tool proposed by Slade and Spencer, based on the assumptions made by Locker *et al.*^{18–20} Questions were read out loud, one by one, by two trained dentists, making sure that the subjects clearly understood each question. A printed chart with a Likert-type scale, with clear and large characters, was used to show each oral question graphically, so the participants would have a visual reference to facilitate the answers. This ordinal scale is considered as a valid response scale for this type of survey²¹. Once all the questions were answered, the researchers filled in the questionnaire. This strategy was devised because of the high prevalence of elderly Chileans with low educational levels and high rate of visual problems. Scores were calculated using the additive method, considering values ranging between 0 and 56, which has demonstrated a high discriminatory ability^{22–24}. The final score was calculated by the sum of fairly often/very often responses, and occasionally/fairly often/very often responses. Thus, the total score ranged from 0 to 14, with higher scores indicating poorer OHRQoL^{13,25}.

Data collection

The OHIP-14Sp questionnaire was completed before starting the self-administered non-invasive therapy with fluoridated dentifrices at baseline (T0). Subsequently, all participants received one session of supragingival prophylaxis every 6 months. Oral examination and sociodemographic data of the participants were documented at the start of the study. RCLs were detected and diagnosed according to the International Caries Detection and Assessment System (ICDAS) II criteria for presence²⁶ and according to Nyvad's criteria for caries activity^{27,28}. Baseline and follow-up clinical examinations were performed by one calibrated examiner (intra-examiner Kappa = 0.81). Subjects were interviewed to fill out a sociodemographic survey that included sex, age, socio-economic status and educational level. Once the evaluations were complete, each patient was provided with an oral hygiene kit, consisting of a toothbrush and toothpaste (either of high or low fluoride concentration, depending on the study arm to which the patient was randomly assigned for the clinical trial). The same protocol was applied again 12 months after starting treatment (T1). The protocol for the clinical trial of self-administered non-invasive therapies with fluoridated dentifrices included instructions for brushing twice a day, after breakfast and just before bedtime²⁹, with the toothpaste containing 5,000 ppm fluoride as NaF (Duraphat® 5,000 Plus; Colgate-Palmolive, Therwill, Switzerland) or the toothpaste containing 1,450 ppm fluoride as NaF (Colgate Total®; Colgate-Palmolive, San José Iturbide, Mexico), without post-brushing water rinsing³⁰ and only spitting out the excess toothpaste. A pea-sized amount of toothpaste (about 0.25 g) had to be used at each brushing. The correct dose of toothpaste was demonstrated to each participant. The toothpaste tubes were blinded with tape and both the patients and the study's principal investigator were blinded to the type of treatment each participant received for the entire duration of the study. Subjects were instructed to replace, every 3 months, the toothbrushes (soft bristles) provided with a new toothbrush (Super 7 Soft, PHB®; Dentaïd®, Cerdanyola, Spain), which was also provided by the researchers. At each toothbrush change, the protocol was reinforced to the participants to maximise compliance. Patients received the same material every 3 months (toothbrushes and fluoridated dentifrices).

Ethical considerations

The study was approved by the Bioethics Committee of the University of Talca (number: 2013-047). Procedures performed on human subjects followed the ethical standards of the Institutional and National Research Committee and the Helsinki Declaration of

1964 and its later amendments. Informed consent was signed by all participants in the study.

Data analysis

Mean comparisons were calculated using the Student's *t*-test for total OHIP-14Sp scores at T0 and T1. To determine whether the T1 OHRQoL scores of subjects undergoing non-invasive therapies for RCLs were different regarding sex, age, educational level and socio-economic status, mean OHIP-14Sp scores obtained at the 12-month time-point were analysed for each of those sociodemographic variables. The Student's *t*-test and ANOVA for educational level were used to estimate the differences, with a significance level of 0.05. Statistical analyses were performed using the statistical software R v3.2.2 (The R Foundation for Statistical Computing, Vienna, Austria).

RESULTS

The OHIP-14Sp test was applied to 345 older adults at baseline (T0), before the start of the self-administered non-invasive therapy with fluoridated dentifrices. The second questionnaire (T1) was completed by 306 subjects. Of these 306 subjects, 75% were female and 25% were male, with mean age \pm standard deviation (SD) of 69.63 ± 6.25 years. After 1 year, 39 individuals were lost to follow-up for different reasons (*Figure 1*). Sociodemographic variables are presented in *Table 1*. OHRQoL assessed at T0 showed that 51% of the subjects had a score lower than 14, which was considered as good OHRQoL. At T1 there was an overall increase, to 65.7%, in subjects with an OHRQoL score of lower than 14. Moreover, a reduction, from 49% at T0 to 34.3% at T1, was observed for subjects who self-reported poor OHRQoL (*Figure 2*). Mean comparison between OHIP-14Sp scores obtained at T0 and T1, regardless of the type of intervention received, showed significant differences between both scores (Student's *t*-test, $P < 0.0001$), with an overall improvement in OHRQoL after non-invasive treatment for RCLs (*Table 2*). When the variation in OHRQoL was analysed, according to the type of fluoridated dentifrice used, at T1, no significant differences were detected (Student's *t*-test, $P = 0.114$).

When exploring the influence of sociodemographic variables on OHRQoL at T1, significant differences were found between subjects with higher and lower socio-economic status (Student's *t*-test, $P < 0.0001$). Subjects with higher socio-economic status had lower OHIP-14Sp scores, indicating better OHRQoL than those with lower socio-economic status. Significant differences between OHIP-14Sp scores were detected for educational level (ANOVA, $P = 0.0006$).

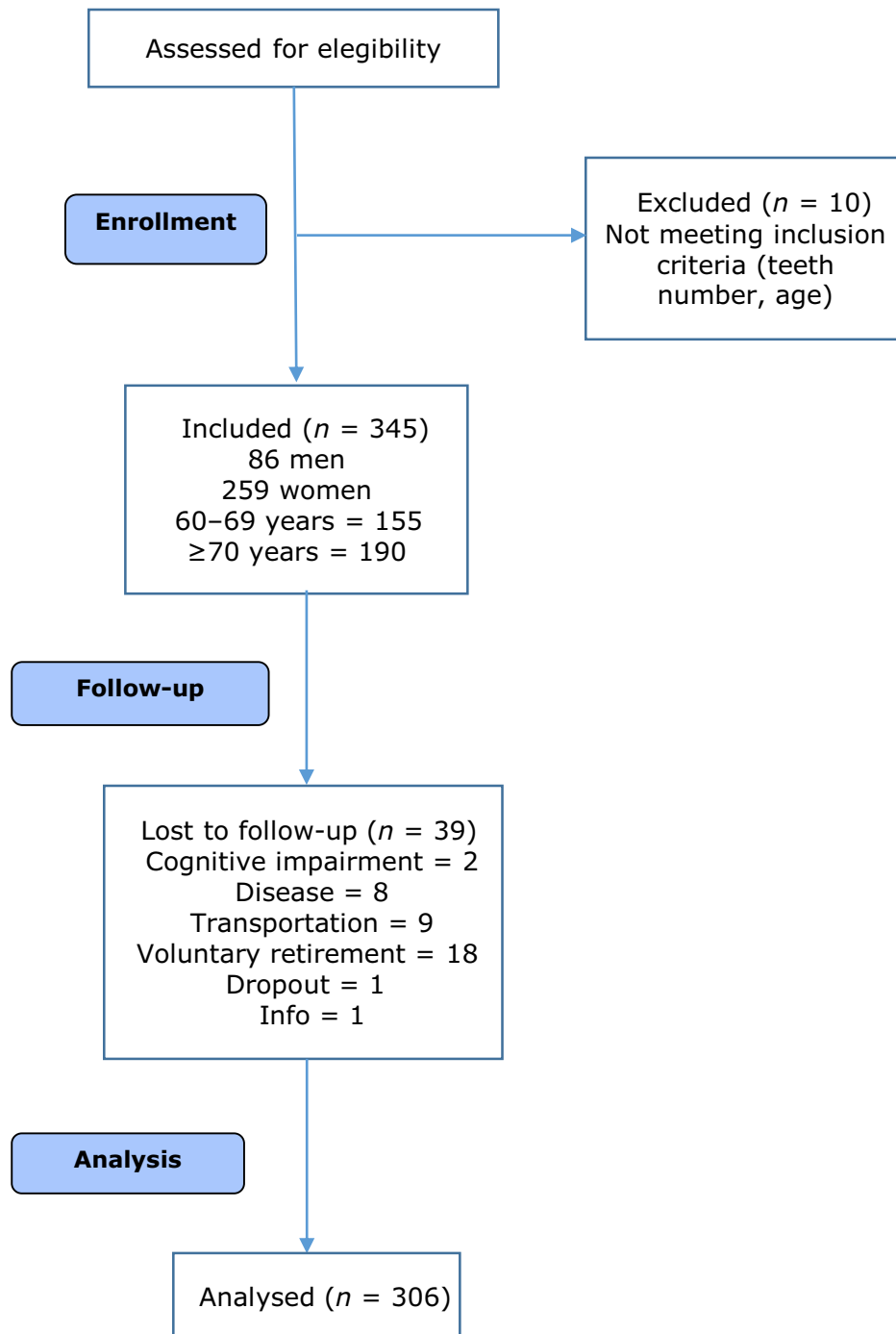


Figure 1. Flow diagram.

Participants with a low educational level, represented as ≤ 8 years of formal education, had higher OHIP-14Sp scores, indicating poor OHRQoL. No significant differences were observed for sex or age (Table 3).

DISCUSSION

Despite the improvement in OHRQoL after 1 year of non-invasive therapy with fluoridated dentifrices for

RCLs, the results might be explained by multiple factors involved in the same intervention besides the use of the dentifrice. Indeed, no differences were detected between the experimental arms of the randomised controlled trial for RCLs. The original hypothesis was that higher concentrations of fluoride would decrease dentin hypersensitivity and the progression of RCLs, resulting in better OHRQoL. The results, however, failed to show differences between treatments, but did

Table 1 Sociodemographic characteristics of the study population of older adults

Variable	n	%
Sex		
Women	231	75.5
Men	75	24.5
Age (years)		
60–69	162	52.9
≥70	144	47.1
Educational level (years)		
>12	118	38.6
9–12	109	35.6
≤8	79	25.8
Socio-economic status		
Upper	201	65.7
Middle or lower	105	34.3

show an overall improvement in OHRQoL, regardless of the type of treatment. Hence, the search for an explanation of the results in OHRQoL must focus on other intervening factors. The prophylaxis performed on all the participants every 6 months could result in lower self-perceived halitosis, as such procedures have been shown to reduce the amounts of volatile sulphur compounds in patients with periodontitis³¹. Periodontal diseases may compromise OHRQoL. In fact, most studies have shown a negative impact of periodontitis on OHRQoL³². Furthermore, halitosis is part of one of the OHIP-14Sp dimensions, so its reduction may impact the overall questionnaire score and be interpreted as good OHRQoL. Similarly, supragingival prophylaxis every 6 months could have improved the periodontal condition, affecting oral health perception. Although several clinical studies have been conducted to assess the impact of periodontitis on OHRQoL, comparing and synthesising those findings is difficult as a result of the lack of clarity on an operational definition of the periodontal status and OHRQoL^{13,33–38} and the high heterogeneity of

Table 2 Means comparison for the total 14-item Oral Health Impact Profile for adults in Spain (OHIP-14Sp) score at baseline (T0) and after 12 months of treatment (T1) of the study population of older adults

OHRQoL (OHIP-14Sp)	Mean	SD	P
T0	15.85	9.9	<0.0001 (T)
T1	12.22	9.3	

OHRQoL, oral health-related quality of life; SD, standard deviation; T, Student's *t*-test.

Table 3 Means comparison for the total 14-item Oral Health Impact Profile for adults in Spain (OHIP-14Sp) score for sociodemographic variables at the 12-month study time point (T1) of the non-invasive treatment for root caries lesions (RCLs)

Sociodemographic variables	Mean	SD	P
Sex			
Woman (n = 231)	12.77	9.76	0.068 (T)
Man (n = 75)	10.51	7.66	
Age (years)			
60–69 (n = 162)	12.66	9.65	0.378 (T)
≥70 (n = 164)	11.72	9.83	
Socio-economic status			
Upper (n = 201)	10.44	8.28	<0.0001 (T)*
Middle or lower (n = 105)	15.61	10.29	
Educational level (years)			
>12 (n = 118)	10.20	8.0001	0.0006 (A)*
9–12 (n = 109)	12.12	8.89	
≤8 (n = 79)	15.35	10.92	

A, ANOVA/Tukey; SD, standard deviation; T, Student's *t*-test. *P < 0.05.

methods and reporting in the studies. It is therefore important to adjust for confounding factors, particularly any of the multiple clinical conditions that may impact people's lives, consequently avoiding data misinterpretation or spurious associations³². Thus, preventive dental care received periodically during the

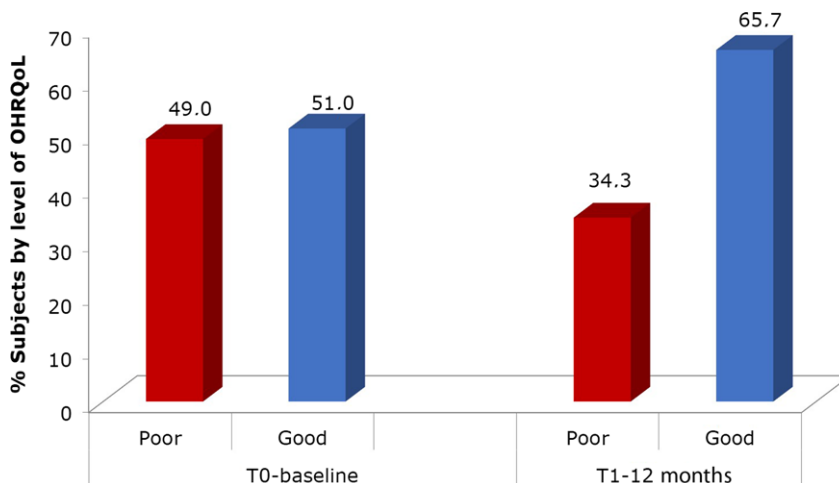


Figure 2. Changes in oral health-related quality of life (OHRQoL) after the 12-month follow-up (i.e. T1). Bars represent percentage of participants with poor (red) or good (blue) OHRQoL, according to a predetermined cut-off point.

intervention may lead to better OHRQoL. As a matter of fact, it has been shown that positive health-related behaviour and regular dental check-ups have a protective effect on OHRQoL and are associated with better dental status^{10,39}. Furthermore, older adults who reported brushing once a day or less and who had fewer natural teeth also reported lower OHRQoL⁴⁰ compared with those who brushed at least twice per day.

On the other hand, the Hawthorne effect could be another explanation for our results. This effect is recognised as a reaction of subjects to the realisation that they are in a study under observation⁴¹. The Hawthorne effect corresponds to any unexplained result in an experiment carried out on human subjects, on the assumption that the results occurred because of the mere presence of the subjects in the experiment. Thus, volunteers in a study have experiences or signs that otherwise would not have appeared had they not participated in the research⁴². The Hawthorne effect has been described to alter subject behaviours, which may account for the improvement in some of the outcome variables^{43–46}. The Hawthorne effect, however, could be experienced by a limited amount of time, usually not exceeding 6 months⁴⁵. Thus, based on the latter, we believe that this artifact can be ruled out in our study and the impact of the non-invasive therapy could be explained by a direct effect of the treatment, including a positive dental experience, as discussed below. Additionally, the non-invasive intervention applied here could have impacted dentin hypersensitivity, which is also one of the dimensions of the OHIP-14Sp. Fluoridated toothpastes containing 5,000 ppm fluoride may help to reduce, to some degree, the symptoms of dentin hypersensitivity associated with non-carious lesions and active RCLs⁴⁷.

Another variable associated with a self-administered treatment is dental fear, which is likely to induce treatment delays, leading to more severe dental issues and/or symptomatic dental attendances. People with dental fear are usually afraid of visiting a dentist, and it has been reported that they have more missing teeth than people with lower or no dental fear⁴⁸. A study from our group showed that older adults who self-reported dental fear were less likely to have visited a dentist than those who did not self-report dental fear⁴⁹. As participants in our study experienced a relaxing clinical environment, without the use of a high-speed drill or any other invasive procedure, results in terms of perceived OHRQoL could also have been influenced by the absence of dental fear and high compliance.

The effect, on OHRQoL, of the interpersonal relationship between dentist and patient is an underexplored research area. Although few OHRQoL studies

have examined into patient–provider dynamics⁵⁰, studies from other fields have reported positive experiences in terms of patient communication, trust, empathy and respect, influencing health outcomes and therefore quality of life⁵¹. Unmet physical health-needs negatively affect quality of life⁵². This is likely to be similar in dental health. In our study, participants were periodically examined and listened to, so their positive OHRQoL may have derived from a better rapport. Trust in dental service providers could also have been particularly important for elders, typically less prone to engage in shared decisions with professionals, unlike younger adults. It has been shown that older people's increased trust in physicians leads to a more compliant and deferential role⁵³. Therefore, trust and confidence in dental professionals may ease stress and reduce hesitation during dental treatment. If lack of trust in a dentist is added to the unmet dental needs, dental anxiety, a factor known to be associated with poor OHRQoL, may be greatly increased⁵⁴.

When analysing sociodemographic variables, significant differences were found between subjects with a high income compared with those with a low income, in that the former had a better OHRQoL. In our study, we intentionally chose to work with participants from clubs. People of higher socioeconomic status tend to participate more in clubs, as they do not have to work after retirement. A further benefit is that working with organised groups facilitates compliance and follow-up⁵⁵. Furthermore, people of higher socioeconomic status usually retain more teeth. The same situation was observed regarding educational level. Subjects with ≤ 8 years of education had higher OHIP-14Sp scores, denoting worse OHRQoL, than subjects with > 8 years of education. Demographic and socio-economic characteristics added to oral health status may have an impact on OHRQoL in older adults^{56,57}. It has been reported that there is a gradient between social position and OHRQoL in elderly adults^{56–58}. Moreover, sociodemographic variables, including race, transport constraints, education and income, have been associated with OHRQoL^{59,60}. It has been shown that poverty directly predicts poorer dental health, which leads to worse OHRQoL. Therefore, socio-economic inequalities are an important determinant of OHRQoL⁶¹. General oral disease in people from lower socio-economic status over a lifetime may explain the OHRQoL results. Our results agree with previous studies showing the relationship between socio-economic indicators and poor oral health in older people^{57,58,62,63}. Regarding sex and age, there were no statistically significant differences in the perceived OHRQoL. The study had a greater proportion of women, like many other international studies^{64,65}. Subjects were recruited from community clubs for older adults, which have a predominantly

female participation, like other social organisations in Chile⁶⁶. Yet, no statistically significant differences were found in OHRQoL between male and female older adults.

Subjectivity of the OHRQoL construct encourages the deepening of these findings through a qualitative approach. As discussed above, many variables may have intervened in explaining changes in OHRQoL. Thus, a deeper analysis of each is suggested. Although we decided to conduct the randomised controlled trial with both arms using non-invasive therapies for RCLs, it would be of interest to compare the effect, on OHRQoL, of a non-invasive treatment with a conventional treatment. Given the results of this study, non-invasive therapies for RCLs in community-dwelling older people seem an attractive option for many reasons.

CONCLUSIONS

Non-invasive treatment for RCLs in community-dwelling elders appears to impact positively on OHRQoL. Better oral health perception was associated with higher socio-economic status and educational level. No significant differences were detected regarding the fluoride concentration in the dentifrices. A deeper understanding of the reasons why this type of therapeutic approach may affect quality of life is strongly suggested and deserves further research.

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Conflict of interest

The authors declare that they have no conflict of interest.

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