Does a sage-based mouthwash improve OHRQoL and Xerostomia in elders?

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Objectives

The aim of this randomized controlled trial (RCT) was to test whether a sage-based mouthwash improves Oral Health-Related Quality of Life (OHRQoL) and xerostomia-related symptoms compared to a placebo.

Methods

This study was ethics approved (Basec-Nr.: 2016-01383) and registered (clinicaltrials.gov: NCT0283080). Potential subjects (inclusion: ≥65 years, dentate) from private practice and long-term-care facilities were included in this randomized, double-blind, placebo-controlled, parallel, clinical trial. Participants were randomly allocated into either group A (active agent, Dr. Hauschka Med Mundspülung Salbei, WALA Heilmittel GmbH, Bad Boll/Eckwälden, Germany; Fig. 1) or group B (taste and color matched custom-fabricated water/alcohol-based placebo).

The mouthwash was used once a day for 30 seconds in addition to performing the usual oral hygiene measures, for an intervention period of six weeks. The primary endpoints were the evaluation of OHRQoL and the xerostomia-related impairments using the 14-item German versions of the Oral Health Impact Profile (OHIP-14) and Xerostomia Inventory (XI, 14 items). Linear regression models were applied for the statistical analysis (alpha = 0.05).

Results

Forty-eight subjects were included in the study (mean age = 77.5±7.3 years). Forty-two participants completed the trial and were included for the data analysis (excluded: n = 6, group A = 3, group B = 3; reason for exclusion: incomplete data).

Results of linear regression analysis of intervention effect on OHIP-14 and XI summary scores at follow-up, statistically controlled for baseline scores revealed no effect of the intervention (p = 0.521 and p = 0.379, respectively; Tabs. 1 + 2). The XI summary score was highly correlated to the OHIP-14 summary score at baseline and at follow-up (Pearson product moment correlation coefficients: 0.55 and 0.60).

Figure 1: *Evaluated sage-based mouthwash (active agent; Group A)*

	Baseline	Follow-up	Diff		
	Mean (SD)		Mean (CI)	p-value	Effect size
Intervention	0.7 (2.2)	0.5 (1.4)	0.2 (–0.3; 0.7)	.463	0.10
Control	1.4 (2.1)	1.0 (1.7)	0.4 (–0.8; 1.6)	.462	0.22

Table 1: *OHIP-14 summary scores at baseline and follow-up for both groups with corresponding differences*

	Baseline	Follow-up	Diff		
	Mean (SD)		Mean (CI)	p-value	Effect size
Intervention	8.9 (11.4)	10.7(10.0)	1.8 (–0.5; 4.1)	.115	0.17
Control	7.7 (6.2)	8.2 (10.4)	0.5 (–1.7; 2.6)	.652	0.06

Table 2: *XI summary scores at baseline and follow-up for both groups with corresponding differences*

Conclusions

The findings of this study do not indicate that the sage-based mouthwash was better than the placebo in improving the OHRQoL and the xerostomia-related impairments. The results indicate a sufficient convergent validity of the XI to assess a person's OHRQoL impairments due to xerostomia.

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