Supplementary Material

Effectiveness of a dental intervention to improve oral health among home care recipients: a randomized controlled trial

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Part A: Primary Outcome assessed at t_1 (results from the subgroup analysis)

Individuals receiving only informal care

The total Oral Health Assessment Tool (OHAT) mean score in the treatment group (TG) was significantly lower compared to the control group (CG) (2.66 [standard deviation (SD) 2.66] vs. 3.36 [SD 2.42], p=.0108).

The percentage distribution of the total OHAT scores also differed significantly between the groups: 24.4% vs. 9.8% (total score 0), 34.9% vs. 32.4% (total score 1-2), and 40.7% vs. 57.8% (total score 3+) (p=.0118).

With regard to the individual OHAT categories, scores for "gums and tissues" and "oral cleanliness" were lower among TG participants than among CG participants (**Table S1**).

Table S1. Oral Health Assessment Tool (OHAT) scores for participants of the treatment group and participants of the control group (individuals receiving informal care only).

Category	Treatment group (n=86)			Control group (n=102)			p-value
	0=healthy	1=changes	2=unhealthy	0=healthy	1=changes	2=unhealthy	
	%	%	%	%	%	%	
Lips	89.5	8.1	2.3	88.1	11.9	0.0	.2381
Tongue	80.0	16.5	3.5	73.5	23.5	2.9	.4941
Gums and tissues	62.4	28.2	9.4	43.1	41.2	15.7	**.0314**
Saliva	68.6	24.4	7.0	75.5	21.6	2.9	.3657
Natural teeth[a]	50.0	38.6	11.4	45.6	40.0	14.4	.7957
Dentures[b]	64.9	28.1	7.0	58.6	31.0	10.3	.7277
Oral cleanliness	54.7	31.4	14.0	34.3	42.2	23.5	**.0173**
Dental pain	91.9	8.1	0.0	87.1	9.9	3.0	.3424

Notes: Boldface indicates significant differences (p<.05).

Missings (n=1 (lips), n=1 (tongue), n=1 (gums and tissues), n=2 (natural teeth), n=2 (dentures), and n=1 (dental pain)) were not considered.

[a] n=72 (treatment group); n=90 (control group).

[b] n=58 (treatment group); n=59 (control group).

In the linear regression, controlled for sex, age group, LTC grade, and time in days between randomization and t_1, the total OHAT score was not significantly lower in the TG compared to the CG (-0.69 [95% confidence interval (CI) -1.49 to 0.08]; p=.0781).

Individuals also receiving formal care

The total OHAT mean score did not differ significantly between the TG and CG (3.39 [SD 2.32] vs. 3.17 [SD 2.77], p=.5075).

The percentage distribution of the total OHAT scores in the TG and CG also did not differ significantly between the groups: 15.4% vs. 14.3% (total score 0), 19.2% vs. 37.1% (total score 1-2), and 65.4% vs. 48.6% (total score 3+) (p=.3250).

With regard to the individual OHAT categories, do differences were found (**Table S2**).

Table S2. Oral Health Assessment Tool (OHAT) scores for participants of the treatment group and participants of the control group (individuals also receiving formal care).

Category	Treatment group (n=26)			Control group (n=35)			p-value
	0=healthy	1=changes	2=unhealthy	0=healthy	1=changes	2=unhealthy	
	%	%	%	%	%	%	
Lips	92.3	7.7	0.0	71.4	22.9	5.7	.1433
Tongue	76.0	24.0	0.0	82.9	14.3	2.9	.6028
Gums and tissues	42.3	50.0	7.7	52.9	29.4	17.6	.2584
Saliva	65.4	15.4	19.2	77.1	20.0	2.9	.1278
Natural teeth[a]	45.5	45.5	9.1	59.3	18.5	22.2	.1110
Dentures[b]	45.0	40.0	15.0	66.7	16.7	16.7	.2429
Oral cleanliness	38.5	46.2	15.4	48.6	22.9	28.6	.1392
Dental pain	96.2	3.8	0.0	91.4	5.7	2.9	.9999

Notes: Missings (n=1 (tongue), n=1 (gums and tissues), and n=1 (dentures)) were not considered.

[a] n=22 (treatment group); n=27 (control group).

[b] n=20 (treatment group); n=25 (control group).

In the linear regression, controlled for sex, age group, LTC grade, and time in days between randomization and t_1, the total OHAT score was also not significantly lower in the TG compared to the CG (0.56 [95% confidence interval (CI) -0.85 to 1.97]; p=.4259).

Part B: Secondary Outcomes assessed at t_1 (results from the subgroup analysis)

Individuals receiving only informal care

The total Oral Health Impact Profile (OHIP) mean score did not differ significantly between the TG and CG (9.09 [SD 10.39] vs. 8.35 [SD 11.22], p=.3602).

The percentage distribution of the total OHIP scores in the TG and CG also did not differ significantly between the groups: 30.6% vs. 34.3% (total score 0-1), 21.2% vs. 28.4% (total score 2-5), and 48.2% vs. 37.3% (total score 6+) (p=.2877).

With regard to the individual OHIP items, do differences were found (**Table S3**).

Table S3. Oral Health Impact Profile (OHIP) scores for participants of the treatment group and participants of the control group (individuals receiving informal care only).

Dimension and item	Treatment group (n=85)					Control group (n=102)					p-value
	0=never	1=hardly ever	2=occa-sionally	3=fairly often	4=very often	0=never	1=hardly ever	2=occa-sionally	3=fairly often	4=very often	
	%	%	%	%	%	%	%	%	%	%	
Functional limitation											
Trouble pronouncing words	70.6	12.9	8.2	0.0	8.2	75.5	8.8	7.8	2.9	4.9	.3798
Taste worse	76.8	9.8	3.7	4.9	4.9	75.5	5.9	10.8	1.0	6.9	.1571
Physical pain											
Painful aching	71.8	10.6	8.2	7.1	2.4	63.7	10.8	13.7	3.9	7.8	.2715
Uncomfortable to eat	57.6	9.4	16.5	10.6	5.9	64.7	9.8	5.9	7.8	11.8	.1166
Psychological discomfort											
Self-conscious	69.4	5.9	14.1	8.2	2.4	67.6	9.8	6.9	6.9	8.8	.1536
Tense	69.0	8.3	11.9	6.0	4.8	69.6	9.8	7.8	9.8	2.9	.7083
Physical disability											
Diet unsatisfactory	76.2	9.5	4.8	4.8	4.8	84.3	4.9	2.0	5.9	2.9	.4898
Interrupt meals	78.8	8.2	8.2	2.4	2.4	78.2	10.9	3.0	5.0	3.0	.4766
Psychological disability											
Difficult to relax	64.7	9.4	11.8	8.2	5.9	71.3	10.9	4.0	9.9	4.0	.3287
Been embarrassed	70.2	11.9	10.7	3.6	3.6	70.6	7.8	11.8	5.9	3.9	.8603
Social disability											
Irritable with others	76.2	8.3	10.7	4.8	0.0	81.2	8.9	5.0	3.0	2.0	.4128
Difficulty doing jobs	67.9	11.9	4.8	6.0	9.5	82.4	4.9	2.9	5.9	3.9	.1476
Handicap											
Life unsatisfying	63.9	7.2	7.2	16.9	4.8	66.7	7.8	10.8	7.8	6.9	.3844
Unable to function	74.1	7.1	5.9	5.9	7.1	84.3	3.9	5.9	3.9	2.0	.3242

Notes: Missings (n=3 (taste worse), n=1 (tense), n=1 (diet unsatisfactory), n=1 (interrupt meals), n=1 (difficult to relax), n=1 (been embarrassed), n=2 (irritable with others), n=1 (difficulty doing jobs), and n=2 (life unsatisfying)) were not considered.

In the linear regression, controlled for sex, age group, LTC grade, and time in days between randomization and t_1, the total OHIP score was also not significantly lower in the TG compared to the CG (-0.52 [95% confidence interval (CI) -3.78 to 2.73]; p=.7514).

Regarding the periodontal situation, the prevalence of any periodontal problems in the TG was significantly lower than in the CG (77.0% vs. 95.4%, p=.0006). The prevalence of periodontitis did not differ between TG and CG participants (32.4% vs. 45.4%, p=.0955).

In the logistic regressions, controlled for sex, age group, LTC grade, and time in days between randomization and t_1, the odds ratio for periodontal problems for TG vs. CG participants was 0.13 (95% CI 0.04 to 0.49; p=.0022), whereas the odds ratio for periodontitis was 0.96 (95% CI 0.46 to 2.03; p=.9194).

Individuals also receiving formal care

The total Oral Health Impact Profile (OHIP) mean score did not differ significantly between the TG and CG (8.37 [SD 8.13] vs. 6.91 [SD 8.35], p=.3253).

The percentage distribution of the total OHIP scores in the TG and CG also did not differ significantly between the groups: 22.2% vs. 34.3% (total score 0-1), 25.9% vs. 20.0% (total score 2-5), and 51.9% vs. 45.7% (total score 6+) (p=.5713).

With regard to the individual OHIP items, scores for difficulty doing jobs" and "unable to function" were higher among TG participants than among CG participants (**Table S4**).

Table S4 Oral Health Impact Profile (OHIP) scores for participants of the treatment group and participants of the control group (individuals also receiving formal care).

Dimension and item	Treatment group (n=27)					Control group (n=35)					p-value
	0=never	1=hardly ever	2=occa-sionally	3=fairly often	4=very often	0=never	1=hardly ever	2=occa-sionally	3=fairly often	4=very often	
	%	%	%	%	%	%	%	%	%	%	
Functional limitation											
Trouble pronouncing words	84.6	11.5	3.8	0.0	0.0	74.3	11.4	8.6	0.0	5.7	.6903
Taste worse	70.4	11.1	3.7	11.1	3.7	74.3	5.7	11.4	2.9	5.7	.5439
Physical pain											
Painful aching	63.0	11.1	11.1	11.1	3.7	54.3	5.7	20.0	14.3	5.7	.8136
Uncomfortable to eat	51.9	14.8	14.8	11.1	7.4	71.4	0.0	11.4	5.7	11.4	.1344
Psychological discomfort											
Self-conscious	59.3	18.5	7.4	7.4	7.4	80.0	5.7	11.4	0.0	2.9	.1416
Tense	69.2	23.1	3.8	3.8	0.0	71.4	8.6	11.4	2.9	5.7	.3440
Physical disability											
Diet unsatisfactory	77.8	14.8	3.7	3.7	0.0	82.9	11.4	0.0	0.0	5.7	.7619
Interrupt meals	74.1	14.8	3.7	3.7	3.7	91.4	8.6	0.0	0.0	0.0	.2188
Psychological disability											
Difficult to relax	73.1	7.7	19.2	0.0	0.0	68.6	11.4	8.6	2.9	8.6	.3927
Been embarrassed	70.4	22.2	3.7	3.7	0.0	85.7	2.9	5.7	2.9	2.9	.0794
Social disability											
Irritable with others	81.5	11.1	3.7	3.7	0.0	94.3	0.0	5.7	0.0	0.0	.1362
Difficulty doing jobs	61.5	7.7	15.4	11.5	3.8	88.6	2.9	2.9	0.0	5.7	**.0320**
Handicap											
Life unsatisfying	51.9	22.2	7.4	18.5	0.0	68.6	11.4	8.6	2.9	8.6	.0960
Unable to function	61.5	23.1	7.7	7.7	0.0	91.4	5.7	0.0	0.0	2.9	**.0085**

Notes: Boldface indicates significant differences (p<.05).
Missings (n=1 (trouble pronouncing words), n=1 (tense), n=1 (difficult to relax), n=1 (difficulty doing jobs), and n=1 (unable to function)) were not considered.

In the linear regression, controlled for sex, age group, LTC grade, and time in days between randomization and t_1, the total OHIP score was also not significantly lower in the TG compared to the CG (0.42 [95% confidence interval (CI) -3.95 to 4.79]; p=.8477).

Regarding the periodontal situation, the prevalence of any periodontal problems (77.3% vs. 80.8%, p=.9999) and the prevalence of periodontitis (45.5% vs. 42.3%, p=.8267) did not differ between TG and CG participants.

In the logistic regressions, controlled for sex, age group, LTC grade, and time in days between randomization and t_1, the odds ratio for periodontal problems for TG vs. CG participants could not be estimated because of the low number of individuals without periodontal problems, whereas the odds ratio for periodontitis was 1.36 (95% CI 0.33 to 5.60; p=.6685).

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	1-2
	2b	Specific objectives or hypotheses	2
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	2
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	not applicable
Participants	4a	Eligibility criteria for participants	2
	4b	Settings and locations where the data were collected	2-3
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	2-3
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	3-4
	6b	Any changes to trial outcomes after the trial commenced, with reasons	not applicable
Sample size	7a	How sample size was determined	4
	7b	When applicable, explanation of any interim analyses and stopping guidelines	not applicable
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	2
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	2
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	2
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	2
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	3

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	not applicable
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	4-5
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	4-5
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	5-6, Figure 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	6, Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	2-3
	14b	Why the trial ended or was stopped	not applicable
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	6-8
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	6-8
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	not applicable
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	7-8
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	not applicable
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	10-11
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	11
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	9-10
Other information			
Registration	23	Registration number and name of trial registry	2
Protocol	24	Where the full trial protocol can be accessed, if available	not applicable
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	11-12

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.