Effectiveness of scaling-and-root-planing with and without adjunct probiotic-therapy in the treatment of chronic periodontitis among *shamma*-users and non-users: A randomized controlled trial

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ABSTRACT

Background: Effectiveness of scaling-and root-planing (SRP) with/without adjunct probiotic (*Lactobacillus reuteri*) treatment towards the reduction in periodontal inflammatory parameters (clinical attachment loss [AL], marginal bone loss [MBL], plaque index [PI], and

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bleeding on probing in *shamma*-users and non-users (controls) with chronic periodontitis (CP) remains uninvestigated. The aim of the present randomized controlled trial was to compare the efficacy of SRP with and without adjunct probiotic therapy (PT) in the treatment of CP among *shamma*-users and controls (individuals not using tobacco in any form).

Methods: The study was conducted in accordance with the Consolidated Standards of Reporting Trials guidelines. Patient demographics were recorded using a questionnaire. Therapeutically, patients were allotted into 4 groups as follows: (a) Group-1:Shamma-chewers that underwent SRP alone; (b) Group-2:Shamma-chewers that underwent SRP+PT; (c) Group-3:Non-chewers that underwent SRP alone; and (d) Group-4:Non-chewers that underwent SRP+PT. Periodontal parameters (PI, BOP, PD, clinical AL and mesial and distal MBL) were measured on all teeth except third molars at baseline and at 3- and 6-months' follow-up. Level of significance was set at $P<0.05$.

Results: In total, 31, 32, 31 and 33 individuals were included in groups 1, 2, 3 and 4, respectively. Among *shamma*-users, there was no significant difference in the scores of PI, BOP, PD, clinical AL and MBL when SRP was performed with/without adjunct PT. Amongst control-individuals, SRP with adjunct PT was more effective in reducing PI ($P<0.05$), BOP ($P<0.05$) and PD ($P<0.05$) at 3-months follow-up. There was no significant difference in periodontal parameters at 3- and 6-months follow-in patients that underwent SRP with and without adjunct PT.

Conclusion: Habitual *shamma*-use compromises the outcome of SRP in patients with CP. Among patients that do not use any form of ST product, SRP is an effective treatment modality for the treatment of CP; and this relationship is independent of use of adjunct PT.

Keywords (MeSH): Alveolar bone loss; Gingival bleeding; Periodontal disease; Questionnaire; Smokeless tobacco.

<PE-FRONTEND>

INTRODUCTION

Scaling-and-root-planing (SRP) is the gold-standard for the treatment of periodontal diseases including chronic-periodontitis (CP).[1] However, adjunct therapies such as low-level laser irradiation and probiotic-therapy (PT) help reduce periodontal inflammation than merely SRP.[2, 3] In a split-mouth double-blinded randomized controlled clinical trial (RCT), Vivekananda et al.[3] assessed the effects of SRP with and without adjunct probiotic (*Lactobacilli reuteri* [*L. reuteri*]) therapy in the treatment of CP. The 6-weeks' follow-up results showed a marked decline in clinical attachment loss (AL), probing-depth (PD), plaque-index (PI) and bleeding on probing (BOP) at sites that underwent SRP+PT compared with individuals that underwent SRP alone.[3] The study concluded that SRP+PT is more effective in the treatment of CP than SRP alone.[3] Moreover, it has also been reported in-vitro that probiotics exert an antibacterial effect against periodonto-pathogenic micro-organisms including *Tannerella forsythia*, *Prevotella intermedia*, *Aggregatibacter Actimomycetemcomitans* and *Porphyromonas gingivalis*.[4] Furthermore, Ikram et al.[5] reported that SRP with adjunct PT using *L. reuteri* is a reliable therapeutic approach for the management of CP than SRP alone. However, it is well-known that the outcomes of SRP are compromised in tobacco-product users (such as cigarette-smokers) than individuals that do not consume tobacco.[6-8] One reasoning in this context is that nicotine (a major and addictive constituent in tobacco) reduces the proliferation of fibroblasts, red blood cells, macrophages and increases platelet aggregation;[9] which in turn compromises tissue perfusion and healing due to formation of micro-clot in vessels.[9, 10]

It has well-documented that intake of smokeless tobacco (ST) products increases the risk of oral-inflammatory disorders such as CP.[11-13] *Shamma* is a form of ST that is composed of ground-tobacco, flavoring oils (such as mint or menthol), ash, carbonate of lime, black pepper, and metals including chromium, copper and lead-oxide.[14-16] It is sold in pouches and is frequently consumed in Middle-Eastern countries including Yemen and Saudi Arabia.[14, 17-19] *Shamma* is generally placed as a quid in the buccal cavity; however, some users may place it in the lower labial vestibule.[14] There is no data regarding the prevalence of *shamma* chewing among males and females; however, based upon the currently available evidence, the habit seems to be dominant among males than females.[14-16, 20, 21] To the authors' knowledge, previous studies[20, 21] have primarily compared the oral and periodontal health status among ST users with individuals not using tobacco in any form. According to Al-Askar et al.[19], parameters of periodontal disease (PI, BOP, clinical AL and MBL) are worse in *shamma*-users compared with controls; and cytology-based results by Brima EI[21] showed that oral mucosal changes such as inflammation, keratinization, atypia and infection were more often manifested in the oral mucosal samples collected from *shamma*-users than controls. A vigilant review of pertinent indexed literature showed that there is there are no studies that have assessed the outcome of SRP with/without adjunct PT in the treatment of CP among *shamma*-users and controls.

It is hypothesized that in CP patients, the efficacy of SRP+PT is compromised in *shamma*-users than controls. The aim was to compare the efficacy of SRP with and without adjunct PT in the treatment of CP among *shamma*-users and controls.

MATERIALS AND METHODS

Ethical guidelines

Guidelines recognized by Helsinki-Declaration for experimentation involving humans were followed. All participants were obligated to read and sign a consent form. Ethical approval was obtained from ethics research committee of Centre for specialist dental practice and clinical research (UDCRC/142-71) at Specialist Practice and Research Centre, Riyadh, Saudi-Arabia. The study was conducted in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines (CTRI/2018/04/0125).[22] All participants reserved the right to withdraw at any phase without penalty.

Inclusion-and-exclusion criteria

The inclusion criteria were as follows: (a) shamma-users (individuals who reported to have been consuming *shamma* at least once daily since at least 12 months)[20]; (b) self-reported controls[20]; and (c) patients diagnosed with CP according to the new classification of periodontitis.[23, 24] The exclusion criteria were: (a) self-reported tobacco-smoking; (b) immunocompromised health status (such as individuals with acquired-immune-deficiency-syndrome, cardiovascular disorders, diabetes mellitus (DM), hepatic disorders and/or renal diseases); (c) use of antibiotics, bisphosphonates, steroids and/or non-steroidal anti-inflammatory drugs within the past 3-months; (d) periodontal therapy (such as mechanical plaque and calculus debridement) within the past 90 days; (e) pregnancy and/or lactation; (f) carious teeth with remaining root remnants; (g) supernumerary and/or impacted teeth and (h) refusal to sign the consent form.

Trial design

This parallel design RCT was conducted between December 2018 and July 2019 at the College of Dentistry, King Saud University, Riyadh, Saudi Arabia; and comprised of shamma-users and controls with CP. Initially, 141 male individuals with CP visiting the outpatient division of the College of Dentistry, King Saud University, Riyadh, Saudi Arabia

were invited. Six patients did not meet the inclusion criteria and 8 refused to participate in the present study. In total, 127 patients (63 shamma users and 64 controls) volunteered to participate in the present study and signed the informed consent form.

Study groups

The participants were randomly allotted into 4 groups by picking a paper from an opaque bag. Grouping was done based on *shamma* usage and mode of treatment adopted for the treatment of CP. The patients were divided into the following groups (a) Group-1: *Shamma*-chewers that underwent SRP alone; (b) Group-2: *Shamma*-chewers that underwent SRP with adjunct PT; Group-3: Non-users that underwent SRP alone; and (d) Group-4: Non-users that underwent SRP with adjunct PT. Supplementary Figure 1 (see Supplementary Figure 1 in online Journal of Periodontology), shows a CONSORT flow diagram of progress through the phases of the present RCT.

Questionnaire

A qualified and experienced co-author (SAS) used a standardized questionnaire to collect information regarding the daily frequency of *shamma*-use, gender, age, duration of habit in years and period of placement of *shamma* in the mouth (in minutes). Individuals were also inquired about the number of times they brushed their teeth daily. Dental records of all participants were assessed to determine the duration since diagnosis of CP.

Scaling and root planing

All patients underwent full-mouth SRP using sterile Graceys curettes[‖]; and an ultrasonic scaler[¶] with water irrigation and power set at medium mode. The SRP was performed by an experienced and standardized investigator (IAB; *Kappa* 0.88) blinded to the study groups. Oral hygiene instructions regarding toothbrushing and flossing were given to all individuals. An oral rinse (0.12% chlorhexidine gluconate) was prescribed to all

individuals with the following directions of use: rinse for 1 minute with 15 ml twice a day for 2 weeks.[25]

Probiotic therapy

The PT was initiated at the onset of SRP. Lozenges of probiotics[#] that contained active units of 2 *L. reuteri* strains (1×10^8 CFU of ATCC-PTA 5289, and 1×10^8 CFU of DSM 17938) were administered as described elsewhere.[26, 27] Participants that were randomly nominated to undergo SRP with adjunct PT were advised to use one lozenge every 12 hours, twice daily for 21-days, after tooth brushing.[28]

Clinical and radiographic periodontal examination (primary outcome measures)

The clinical examination was done by one trained and calibrated examiner (FV) (*Kappa* 0.90) who was blinded to the individuals in each study group. Full-mouth PI[29], BOP[29], PD[29], and clinical AL[29] were measured at six sites (mesio-lingual/palatal, mesio-buccal, mid-buccal, mid-lingual/palatal, disto-buccal and disto-lingual/palatal,) on all teeth. Number of missing teeth were also recorded. The PD was measured with a conventional periodontal-probe[**]. Full mouth intraoral digital radiographs (4 bite wings of posterior teeth, 5 periapical radiographs in upper anterior teeth and 3 periapical radiographs in the mandibular anterior teeth) were taken using an x-ray machine[††] and viewed on a standardized computer screen[‡‡]. The MBL was calculated using a software[§§]; and was defined as the perpendicular distance 2 mm below the cemento-enamel junction (CEJ) to the most apical part of the jaw bone.[30] Teeth surfaces at which, the crestal bone and/or the CEJ were not clearly visible (for technical reasons such as interdental caries, dental restorations and/or poor radiographic quality) were excluded. Clinical periodontal examination was performed at baseline and at 3- and 6-months' follow-up. Radiographic evaluation was done by one trained and calibrated examiner (FV) (*Kappa* 0.92). The severity of periodontal conditions in the

participants was based upon the classification scheme for periodontal diseases by Caton et al.[31, 32]

Statistical analysis

Statistical investigations were performed using a software[‖]. Comparisons of periodontal inflammatory parameters among the study groups was performed using the Wilcoxon rank-sum and Bonferroni *Post-hoc* adjustment tests. The sample-size were estimated using a computer-based software[¶¶]. Sample-size estimation was based on detecting changes in primary outcome of periodontal disease measurements, PD and clinical AL in millimeters (mm). Results of an initial pilot investigation showed that inclusion of 31 patients per group will give a 95% power to the study with a two-sided significance level of 0.05. $P<0.05$ reflected statistical significance.

RESULTS

Questionnaire

Out of the 141 male individuals that were invited, 127 CP patients volunteered to participate in the present study. In total, 31, 32, 31 and 33 individuals were included in groups 1, 2, 3 and 4, respectively. The mean age of individuals in groups 1, 2, 3 and 4 were 53.2±4.6, 50.7±1.8, 51.5±3.4 and 52.8±1.6 years, respectively. In all groups, the participants had been diagnosed with CP within the past 2 months. The mean duration of *shamma*-chewing habit among individuals in groups 1 and 2 was 17.5±2.6 and 15.8±0.4 years, respectively. A family history of tobacco use was more often reported by individuals in groups 1 and 2 (58.1% and 56.2%, respectively) as compared to participants in groups 3 and 4 (9.7% and 6.1%, respectively). Participants in groups 1 and 2 were consuming *shamma* 5.2±0.3 and 5.4±0.5 times daily. *Shamma*-users in groups 1 and 2 were carrying the ST-

product in the right-sided vestibule (for 26.6±3.5 and 24.5±2.8 minutes, respectively. In all groups, most of the participants reported to brush teeth once daily and none reported to have every used a dental floss (Table 1).

Clinical and radiographic parameters

Participants in all groups had Stage-III CP with a Grade-C rate. At baseline, there was no statistically significant difference in PI, BOP, PD, clinical AL and MBL were comparable in *shamma*-users and controls (Table 2).

- *SRP with adjunct PT in shamma-users (Group-1)*

The PI ($P<0.05$), BOP ($P<0.05$) and PD ($P<0.05$) were significantly lower at 3-months follow-up compared with baseline. There was no significant difference in clinical AL and MBL at all time intervals. There was no difference in the periodontal parameters at 3- and 6-months follow-up. At 6-months follow-up, all periodontal parameters were comparable with their respective baseline values (Table 3).

- *SRP alone in shamma-users (Group-2)*

The PI ($P<0.05$), BOP ($P<0.05$) and PD ($P<0.05$) were significantly lower at 3-months follow-up compared with baseline. There was no significant difference in clinical AL and MBL at all time intervals. There was no difference the periodontal parameters at 3- and 6-months follow-up. At 6-months follow-up, all periodontal parameters were comparable with their respective baseline values (Table 3).

- *SRP+PT versus SRP alone in shamma-users (Group-1 versus Group-2)*

There was no difference in PD, MBL, PI, clinical AL, and BOP at 3- and 6-months' follow-up (Table 3).

- *SRP with and without PT in non-users (Groups 3 and 4, respectively)*

The PD, PI, and BOP were significantly lower at 3- ($P<0.05$) and 6-months' ($P<0.05$) follow-up in patients that underwent SRP with and without adjunct PT compared with baseline. There was no difference in clinical AL and MBL at all time intervals. There was no difference in periodontal parameters at 3- and 6-months follow-in patients that underwent SRP with and without adjunct PT (Table 4).

- *Comparison of periodontal parameters in shamma-users and non-users*

At 3-months follow-up, PI ($P<0.05$) and BOP ($P<0.05$) were significantly higher among *shamma*-users than controls that had undergone SRP with and without adjunct PT (Figure 1). There was no significant difference in clinical AL, PD and MBL in all groups at 3- and 6-months' follow-up (Figure 2). At 6-months follow-up, there was no significant difference in all clinical and radiographic inflammatory parameters among *shamma*-users and controls that had undergone SRP with and without PT (Figures 1 and 2).

DISCUSSION

We hypothesize that the effectiveness of SRP with and without adjunct PT is compromised in *shamma*-users than individuals not using any form of tobacco product (non-users). The results of the present study are in accordance with this hypothesis as there was no statistically significant difference in the scores of PI, BOP, PD, clinical AL and MBL among *shamma*-users that underwent SRP with and without PT. Although studies[3, 33] have shown that PT is effective in the treatment of CP; the results of the present study suggest that habitual use of ST-products compromises the effectiveness of SRP regardless of the use of PT as an adjunct therapeutic measure. A clarification for this can be derived from the *in-vitro* study by Lallier et al.[34] in which, the effect of smokeless tobacco extract (STE) on cell

survival and motility of periodontal-ligament (PDL) and gingival-fibroblasts was assessed. In this study, gingival fibroblasts and PDL cells were exposed to STE. The results showed that STE cause a direct inhibition of normal PDL and gingival fibroblast function.[34] In our study, *shamma*-users were consuming the ST for nearly 2 decades. Moreover, results by Payne et al.[35] showed that use of ST-products decreases the volume and density of macrophages and erythema, ulceration, or white striations in oral tissues. Furthermore, slaked lime (a major constituent in *shamma*) augments oral mucosal irritation and hyperplasia by creating an alkaline environment in the oral cavity;[36] and nicotine induces hyperemia in gingival blood vessels.[37] This seems to explain the significantly higher BOP, PI, clinical AL and PD observed in shamma-users than controls. It is hypothesized that the prolonged exposure to ST damaged the periodontal and gingival fibers in *shamma*-users to an extent, which compromised repair using SRP with and without adjunct PT. Further studies are needed in this regard. However, amongst non-users, SRP with or without adjunct PT resulted in a statistically significant decrease in PI, BOP and PD. This could be attributed to a statistically significant reduction in periodontopathogenic microbes in the OB and reduced production of proinflammatory cytokines in the GCF of controls following SRP. In this regard, the contribution of adjunct PT seems insignificant. Nevertheless, it is worth mentioning that to date, there is no absolute dosage and frequency of PT that should be administered in terms of achieving the optimal results in terms of reduction in periodontal inflammation. In the present study, PT was prescribed for 21 days as recommended in the studies by Hallström et al[38] and Tekce et al.[28] However, there seems to be a lack of consensus regarding the actual duration of PT for the treatment of CP. For instance, in the study by Shah et al.[39] probiotics were prescribed to CP patients for 2-months; whereas in the study by Pelekos et al.[40], PT was performed for 28 days. In this regard, the precise yet effective duration of PT remains to be determined. It is however speculated that if PT was performed for 60 days in the present

study, then a significant difference in periodontal inflammatory parameters would have been observed at least among CP patients that were not using any form of tobacco product. Further studies are needed to test this hypothesis.

Studies[13, 20, 41, 42] have shown that periodontal inflammatory parameters (MBL, PI, BOP, clinical AL and PD) are poorer in ST-product users compared with controls. This is in contradiction to the results of the present investigation as there was no statistically significant difference in these parameters among *shamma*-users and controls at baseline. One explanation for this is associated with the eligibility criteria adopted in the current investigation. In the present study, one of the criterions used for inclusion of participants was diagnosis of CP. This was primarily done to justify the treatment (SRP) performed in all patients. One explanation for this is that although daily tooth brushing habits were comparable among *shamma*-users and controls, the trend of toothbrushing once daily was higher among the controls. Moreover, poor oral hygiene status (OHS) and maintenance (as seen in patients with CP) is associated with a higher count of periodontopathogenic microbes in the oral biofilm;[43] and an increased production and expression of destructive inflammatory cytokines in the saliva and gingival crevicular fluid.[44, 45] These factors contribute towards aggravating periodontal inflammation in susceptible patient groups. These results suggest that a compromised OHS predisposes non-smokers to periodontal inflammatory conditions like those observed in tobacco-product users. This warrants the need of anti-tobacco and patient education programs to educate the community about the detrimental effects of tobacco on health and significance of routine oral hygiene maintenance towards a better quality of life.

One limitation of the present study is that all participants were male and were relatively young (approximately 50 years old). It has been reported that severity of periodontal inflammation increases with aging.[30] It is therefore hypothesized that periodontal

inflammation is worse in elderly (for example 70 years old and above) ST chewers as compared to relatively younger ST chewers. Moreover, the results were based on a single session of SRP with and without adjunct PT. However, it seems exigent to provide an ethical justification for exposing patients to multiple sessions of SRP (with/without PT) in the short-term. The questionnaire was administered to the patients only at baseline. It is speculated that if the questionnaire was administered at the follow-up visits, the authors could have identified any changes in the patients' oral hygiene-related parameters (toothbrushing and flossing). Furthermore, it is well-known that periodontal inflammation is significantly higher in patients with systemic diseases such as DM;[30, 46, 47] it is hypothesized that inflammation is significantly higher in *shamma*-users with poorly-controlled DM than systemically healthy *shamma-users*. This warrants additional research studies.

CONCLUSION

Habitual *shamma*-use compromises the outcome of SRP in patients with CP. Among patients that do not use any form of ST product, SRP is an effective treatment modality for the treatment of CP; and this relationship is independent of use of adjunct PT.

FOOT NOTES

[ǀ] Hu-Friedy Mfg., EverEdge® 2.0 scalers, Chicago, IL.

[¶] D5 DTE Guilin zhuomuniao Medical Instrument Co., Ltd, Guilin, China.

[#] Gum PerioBalance®-Sunstar Etoy, Berne, Switzerland.

[**] Hu-Friedy, Chicago, IL.

[††] Owandy Altis DC Interoral Radiology Periapical X-Ray, Wichita Falls, TX.

[‡‡]Samsung SyncMaster digital TV monitor, Suwon City, Gyeonggi-do, Korea.

[§§]Image Tool 3.0, Department of Dental Diagnostic Science, University of Texas Health Science Center, San Antonio, TX.

[‖]SPSS v.18, IBM, Chicago, IL.

[¶¶]nQuery Advisor-6, StatisticalSolutions, Saugas, MA.

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CONFLICT OF INTEREST STATEMENT

The authors declare that they have no conflict of interest.

AUTHORS' CONTRIBUTIONS

FV designed the study and wrote the results. IAB performed the scaling and root planing. SAS administered the questionnaire to all participants. RA wrote the introduction. MN performed the statistical analysis and wrote the results. FV, SAS, RA and MH wrote the discussion and introduction. FV performed the statistical analysis.

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Table 1 General characteristics of the study groups

Parameters	***Shamma*-chewers**		**Controls**	
Study groups	SRP + PT (Group-1)	SRP alone (Group-2)	SRP + PT (Group-3)	SRP alone (Group-4)
Number of participants	31	32	31	33
Gender (Male)	31	32	31	33
Mean age in years (mean±SD)	53.2±4.6 years	50.7±1.8 years	51.5±3.4 years	52.8±1.6 years
Duration since diagnosis of CP in months (mean±SD)	1.8±0.07months	2±0.06 months	1.6±0.04 months	1.6±0.05 months
Duration of chewing habit in years (mean±SD)	17.5±2.6 years	15.8±0.4 years	NA	NA
Family history of tobacco use (%)	58.1%	56.2%	9.7%	6.1%
Daily frequency of shamma-use (no. of times/day)	5.2±0.3 times/day	5.4±0.5 times/day	NA	NA
Duration of placement of ST in the mouth in minutes (mean±SD)	26.6±3.5 minutes	24.5±2.8 minutes	NA	NA
Daily tooth brushing				
Once (%)	77.4%	78.1%	93.5%	90.9%
Twice (%)	22.6%	21.9%	6.4%	9.1%
Flossing	None	None	None	None

NA: Not applicable

Table 2 Mean ± standard deviations of periodontal soft tissue inflammatory parameters and crestal bone levels at baseline in all groups

Parameters	***Shamma*-chewers**		**Controls**	
Study groups	SRP + PT (Group-1)	SRP alone (Group-2)	SRP + PT (Group-3)	SRP alone (Group-4)
PI (%)	61.3±10.2%	64.5±5.1%	58.3±4.5%	52.7±5.1%
BOP (%)	66.4±11.3%	71.2±9.3%	65.4±8.4%	69.3±6.6%
PD in mm (mean±SD)	6.2±1.6 mm	6.5±0.5 mm	6±0.4 mm	5.8±0.6 mm
Clinical AL (in mm)	4.6±0.4 mm	4.1±0.3 mm	4.5±0.5 mm	4.3±0.4 mm
MBL (in mm)	4.1±0.08 mm	4.2±0.04 mm	3.9±0.05 mm	4±0.07 mm

Table 3 Mean ± standard deviation of periodontal soft tissue inflammatory parameters and crestal bone levels at baseline and at 3- and 6-months follow-up in *Shamma*-users

Periodontal parameters	SRP + PT			SRP alone		
	Baseline	3-months follow-up	6-months follow-up	Baseline	3-months follow-up	6-months follow-up
PI (%)	61.3±10.2% *†	36.3±4.2 %‡	52.4±6.7	64.5±5.1% §‖	42.2±6.5%¶	53.4±7.6 %
BOP (%)	66.4±11.3% *†	40.1±6.1 %‡	60.5±9.1 %	71.2±9.3% §‖	50.5±10.2 %¶	58.4±8.2 %
PD in mm	6.2±1.6 mm*†	4.5±0.3 mm‡	5.6±0.5 mm	6.5±0.5 mm§‖	5±0.6 mm¶	5.6±0.4 mm
Clinical AL	4.6±0.4 mm*†	4.4±0.2 mm‡	4.5±0.08 mm	4.1±0.3 mm§‖	4.2±0.08 mm¶	4.2±0.05 mm
MBL in mm	4.1±0.08 mm*†	4.1±0.06 mm‡	4.2±0.02 mm	4.2±0.04 mm§‖	4.2±0.06 mm¶	4.3±0.1 mm

*Compared with 3-months follow-up in the SRP+PT group (P<0.05) †Compared with 6-months follow-up in the SRP+PT group (P>0.05; No difference) ‡Compared with 6-months

follow-up in the SRP+PT group (P>0.05; No difference) [§]Compared with 3-months follow-up in the SRP alone group (P<0.05) [‖]Compared with 6-months follow-up in the SRP alone group (P>0.05; No difference) [¶]Compared with 6-months' follow-up in SRP alone group (P>0.05; No difference)

NA: Not applicable PD: Probing depth PI: Plaque index SD: Standard deviation

Table 4 Mean± standard deviation of periodontal soft tissue inflammatory parameters and crestal bone levels at baseline and at 3- and 6-months follow-up in non-users

Periodontal parameters	SRP + PT			SRP alone		
	Baseline	3-months follow-up	6-months follow-up	Baseline	3-months follow-up	6-months follow-up
PI (%)	58.3±4.5%[*†]	20.5±2.9%[‖]	32.4±3.5 %	52.7±5.1%[‡§]	26.2±5.1%[¶]	29.6±4.7 %
BOP (%)	65.4±8.4%[*†]	22.8±3.9%[‖]	30.3±4.1 %	69.3±6.6%[‡§]	30.3±2.4%[¶]	31.1±3.4 %
PD in mm	6±0.4 mm[*†]	2.4±0.6 mm[‖]	3.6±0.5 mm	5.8±0.6 mm[‡§]	3.1±0.3 mm[¶]	3.05±0.5 mm
Clinical AL in mm	4.5±0.5 mm[*†]	4.2±0.08 mm[‖]	4.3±0.05 mm	4.3±0.4 mm[‡§]	4.2±0.05 mm[¶]	4.1±0.06 mm
MBL in mm	3.9±0.05 mm[*†]	3.9±0.1 mm[‖]	3.8±0.07 mm	4±0.07 mm[‡§]	4±0.06 mm[¶]	4.1±0.08 mm

[*]Compared with 3-months follow-up (P<0.05)

[†]Compared with 6-months follow-up (P<0.05)

[‡] Compared with 3-months follow-up (P<0.05)

[§] Compared with 6-months follow-up (P<0.05)

[‖]Compared with 6-months' follow-up in patients that underwent SRP+PT (P>0.05; No difference)

¶Compared with 6-months' follow-up in patients that underwent SRP alone (P>0.05; No difference)

Figure 1 Three- and 6-months follow-up results for plaque index (dark grey bars) and bleeding on probing (light grey bars) after scaling and root planing with and without adjunct probiotic therapy among shamma-users and controls. *Compared with SRP+PT in controls (P<0.05) †Compared with SRP+PT in controls (P<0.05) ‡Compared with SRP alone in controls (P<0.05) §Compared with SRP alone in controls (P<0.05)

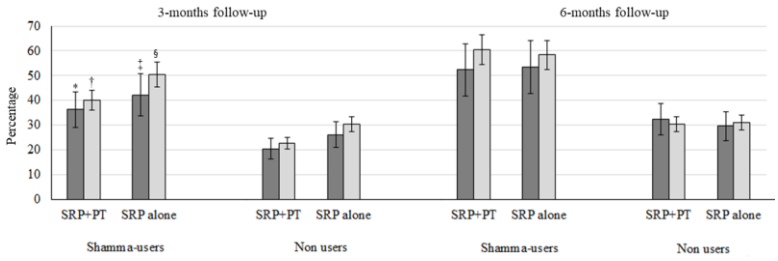

Figure 2 Three- and 6-months follow-up results for probing depth (dark grey bars), clinical attachment loss (light grey bars) and marginal bone loss (colorless bars) after scaling and root planing with and without adjunct probiotic therapy among shamma-users and controls.