To the Editor,

Letter to the editor regarding "Impact of cigarette smoking and vaping on the outcome of full-mouth ultrasonic scaling among patients with gingival inflammation: a prospective study".

We read this paper, which presents the findings of a study on a topical and important research area, with interest [1]. However, we have a number of concerns about the quality of the research and its reporting that we consider important to highlight.

The study design is unclear. In Figure 1 (flow diagram), it is reported that participants were randomized to one of three groups: cigarette-smokers, vaping individuals and never-smokers ('dividing' into groups is also described in the abstract). We presume this is an error, as clearly, randomizing patients to such groups would be unethical. We suspect this study did not randomly allocate participants to groups, but rather the researchers followed over time self-selected smokers, vapers and never-smokers (i.e. it was an observational prospective cohort study).

Assuming this is the case, we consider that it would be highly unlikely that the investigators would only need to have screened 102 patients to achieve three groups, each containing approximately 30 participants who met the inclusion/exclusion criteria. Furthermore, there is no mention of 'not meeting eligibility criteria' as a reason for non-recruitment; this is implausible. In particular, finding individuals who vape 'without a previous history of tobacco usage' is extremely challenging and we would expect that this would have required screening of very large numbers of e-cigarette users to identify those who had not previously used any other tobacco products.

Important information is absent from the methods. For example, no information is provided on where the study took place. Some definitions are vague and subjective e.g. no *'habitual use of smokeless-tobacco products'* (exclusion criterion 'c'). With respect to the power calculation, no justification is given for the target differences of 0.5 mm and 1 mm in probing depths, or indeed, for which of these two values the study was powered. Furthermore, the assumed standard deviation, essential for this calculation, is not given or justified.

The results are presented as pairwise comparisons of means; 24 comparisons were made for the 'intra-group' analyses and 36 for the 'intergroup' analyses. The methods used for these pairwise comparisons are not specified and although it was stated that the Bonferroni adjustment would be employed there is no evidence this was implemented. Without an adjustment for the multiplicity the probability of concluding that any mean difference is statistically significant is *much higher* than the threshold for a single test of a hypothesis of no difference which is set at 0.05 here [2]. Further, a P-value alone does not convey the size of the observed difference or the uncertainty associated with it; confidence intervals should be presented so that the range of possible 'true' values that would be compatible with the data can be considered and interpreted in the context of what would be considered to be clinically meaningful [2]. Given the results discuss mean differences it may be that t-tests were used to perform the pairwise comparisons; if so these should have been paired t-tests for the intra-group comparisons and independent t-tests for the intergroup comparisons – this isn't specified. However, given the assumed observational repeated measures design, the overall analysis strategy is inappropriate. It would have been more appropriate to employ a hierarchical multivariable statistical model for each outcome of interest which would allow for imbalance across the groups at baseline (in both the outcome of interest and pre-specified possible confounding variables) and account for the correlated nature of the data. It was also stated that a Kruskall-Wallis test was used for the between group comparisons, but no results of these analyses are reported.

There are a number of inconsistencies and unusual findings in the results. For example, clinical attachment loss (CAL) was reported as zero in all participants, at all time points. This is highly unusual in a group of patients, a third of whom smoke tobacco, and all of whom have received full-mouth ultrasonic scaling. This study is reported to be a 'continuation' of a previously published study from Javed et al. [3], which was a cross-sectional comparison between three groups (cigarette smokers, e-cigarette users and never-smokers), with the implication that the participants from Javed et al. [3] were followed prospectively in ALHarthi et al. [1]. However, in Javed et al. [3], mean CAL values of 1-2mm were reported, and these data therefore appear to be incompatible with those that are presented in the current study [1], assuming that the baseline data in the present study correspond to those that were published in Javed et al. [3] and involve the same participants. Further inconsistencies in the data between the two studies are identifiable, for example the % of sites with probing depths ≥4mm, and the duration of smoking habit in group 1. It is notable that both studies were conducted between June 2016 and February 2017, and appear to involve the same participants, yet the data reported in the two studies appear inconsistent and contradictory.

Other indicators of poor reporting and/or methodology are also evident. For example, probing depths are presented as a 'mean %' (Table 2) and we presume this is an error and should be 'mean mm'. It is unusual that not a single site, in a single participant, in the vaping or never-smoker groups had a probing depth ≥4mm after the ultrasonic scaling. It is also atypical to observe 100% follow-up rates at 6 months, as there is almost always loss to follow-up in prospective clinical studies. It is odd that all participants were required to have bleeding on probing >30% (inclusion criterion 'e') yet the mean bleeding on probing scores at baseline in groups 1 and 2 were 17.2 ± 3.3% and 11.6 ± 4.5%, respectively.

In summary, although this is a novel research area, it is important that high standards of research and reporting are maintained, to ensure that the scientific literature has value, and to avoid confusion. We consider that this paper falls short of this journal's high standards and includes several fundamental errors.

Declaration of interest: The authors of this letter (apart from BC) have already published concerns [4] about the previous study [3] in this series. We highlighted methodological concerns, many of which also apply to the current study. Javed et al. [3] declined to respond to this previous letter. The authors report no other conflicts of interest.

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