Reviewer's report

Title: Face-to-face individual counseling versus online groups: a study protocol testing two modes of motivational interviewing for improving oral health

Version: 2
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Reviewer: Bente Appel Esbensen

Reviewer's report:

Will the study design adequately test the hypothesis?

• I recommend the authors to be consistent on the aim. The aim of this trial is not identical in the abstract and in the manuscript (page 7). E.g. at page 7 the authors also want “to evaluate” which is not emphasized in the abstract. Furthermore, in the abstract the authors claim that this study is “prevailing health education (HE), fact-to-face individual MI and online group MI…” and furthermore: “…will be randomly assigned to three groups…” – this is not consistent with what is written at page 7 about the aim. Here only two different interventions will be tested, namely face-to-face individual MI and online group MI. Nevertheless, from the sample size we can deduct, that the study intervention will be conducted in three different groups.

• It is of significance that the authors argue why oral health (or bad oral health) is a major concern and why/if this is a specific problem for adolescents 12-13 years old.

• Reference #5 a systematic review is from 1998 (17 years old). Is this study repeated or are a newer more up-to-date review available? If not, the authors are recommended to make notice in the background, that the review is fairly old, and to take this into account.

• Page 5: “Nevertheless, its effectiveness in changing adolescents’ dental behaviors and protecting their oral health is yet to be investigated”. This is an interesting perspective, though; the authors need to argue why especially adolescents’ (12-13 years old) dental behaviors are of importance and a problem.

• A number of references are quite old: #4, #5, #15, and #27. Please check if newer references are available and possibly could replace these.

• It would be of importance if the authors follow the “SPIRIT” recommendations for reporting clinical trial protocols. Right now the section “methods/design” starts with “sample size calculation” followed by “participant recruitment and randomization”. A flow chart showing the participant timeline is recommended.

• What simple questionnaire will be used for identification of the participants? Considerations about whether adolescents will answer in accordance with the “truth” are needed. It is not a given matter that anyone will admit to having a bad oral health.
• It is not clear from the section “Outcome measures” what the primary and the secondary outcome measures are. Though, from Table 1 we learn that the primary outcomes are two: 1) “Gingival health” and 2) “Caries increment” which is also what the sample size calculation is based on. However, more adequate information about the outcome measures is needed. The questions used to measure both self-efficacy and changes in health behavior are insufficiently described. The authors are recommended to describe what questionnaires will be used to measure the secondary outcomes. The issues to be addressed are for example: Are the instruments validated, who developed the instruments, what about reliability? How will the adolescents answer the questionnaire? In paper form or an electronic version taking the adolescents in to account that they are used to the electronic media.

Is the planned statistical analysis appropriate?

Some information is missing.

• The sample size calculation is based the primary outcome to be: 1) new carious teeth and 2) the gingival bleeding score – and on an effect size of 0.4 as considered clinically significant. Though, there is missing a reference that refers to the effect size of 0.4 to be significant and is it effect size on both variables? Please make sure that it is both practical and appropriate with two primary outcomes for this study.

• Information about scoring of the questionnaires is missing.

• Information such as will data be reported in P-values and 95% confidence intervals (95% CI), is also missing. Will a ‘per protocol’ analysis be used?

Are sufficient details provided to allow replication of the work or comparison with related analyses? If not, what is missing?

• Better overview over the interventions, such as for how long times will each the intervention last, need to be described. In some groups there is apparently a follow-up phone call, but not in all groups. This needs to be explained and the arguments to make such interventions argued.

• A discussion about how to handle the not unlikely situation, that not all adolescents complete the entire intervention related to each of the three groups.

• The instruments including the two primary outcomes are not adequately described and following difficult to replicate.

Is the writing acceptable?

OK.

Declaration of competing interests:

I declare that I have no competing interests