PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	A motivational interview intervention delivered at home to improve the oral health literacy and reduce the morbidity of Chilean disadvantaged families: A study protocol for a community trial.
AUTHORS	Cartes-Velasquez, Ricardo; Araya, Carlos; Flores, Raúl; Luengo, Luis; Castillo, Francisca; Bustos, Alex

VERSION 1 - REVIEW

REVIEWER	Dr Sharon Curtin UCC Ireland
REVIEW RETURNED	05-Apr-2016

GENERAL COMMENTS	In the introduction the authors need to provide more information on how MI can support and helping the person to examine and resolve conflicting ideas, emotions and attitudes thus enabling them to increase a person's awareness of the potential problems caused, consequences experienced, and risks. I would also suggest that the authors change the wording promotional strategy to therapeutic intervention when describing MI. Given the suggested time duration of each family visit, is it a brief MI intervention that is being delivered. Is the psychologist trained in Motivational Interviewing? If so, at what level? As the word [expert] has been used. What is the role of the 2 dentist in the delivery of the MI training course? In the section 'training in MI' I feel this would be better placed in the methodology section as it is part of the study and there are specific criteria for inclusion of applicants for training in MI.

REVIEWER	Anne Wilson University of Colorado, USA
REVIEW RETURNED	29-Apr-2016

GENERAL COMMENTS	No results are reported and the methodology design and level of description are not appropriate for the outcome measures.

REVIEWER	Daniela Harnacke Institute of Medical Psychology, Justus-Liebig-University Giessen, Germany
REVIEW RETURNED	06-Jun-2016

GENERAL COMMENTS	General comment: The study is designed as a community trial to test the improvement

	in caries and oral health literacy after an MI intervention. A special focus is set on disadvantaged families here. There is no doubt about the necessity for improvement, especially concerning disadvantaged families, but there are some points in the study protocol that need modification and clarification (e.g. missing randomization of the participants; values concerning reduction of caries and increase of OHL level). Objectives and hypotheses o page 5: How did you determine the values concerning reduction of caries and increase of OHL levels? Please add this to the study protocol. Methods: o The lack of randomization is a critical issue that complicates the analysis of the study and increase potential biases; you should randomize the participants, to avoid uncontrollable side effects and to reduce the variables you have to control and therefore reduce the risk of biases. o Patient recruitment - page 7: It is very important to inform the caregivers about the study, but you should be aware that very detailed information can affect the study outcome, too; expectation effects. o OHL questionnaires: Are the values of internal consistencies and temporal stability of the adapted questionnaires are comparable to the original questionnaires? Please add this aspect. o Intervention - page 10: the intervention group receives besides the MI some materials; will the control group receive the same materials? Does the control group receive also additional visits at home that do not contain MI intervention elements? Otherwise a potentially observed effect cannot only be attributed to MI. Statistical analysis o page 11: You describe that you will use multiple linear regression analysis, but there is no explanation which variables are considered to be predictor and/or criterion variables; additionally this is not mentioned as a hypotheses or additional analysis; please add this in the study protocol. o Referring to the hypothesis you want to test: OHL increases/caries decreases to a defined value; considering the OHL it is difficult to test percent, if the scales of the questionnaires might not measured on ratio scale, therefore you should use effect sizes instead of percent. o Please explain why you would like to use the t-test for independent sample rather than the analysis of covariance. Requests for clarifications - Abstract: o The first sentence of the abstract is contradictory to the sentence in the discussion (page 4) “This is a great challenge, considering that most public health intervention have little impact on inequities”. o “…interventions have been identified as cost-efficient”; do you refer here on public interventions? Please clarify this sentence. o Please point out in “Methods and analysis” that the intervention will take place “at home”, because this is not mentioned in the abstract yet. - Introduction: o Page 4 “This is a point of concern in developed countries” and in developing countries? o Page 4: the Stages of Change is a part of the Transtheoretical Model.

	Other minor comments - Please add a founding statement and a competing interest statement - Please add the keyword Motivational Interviewing - Please add where the trial has been registered - Strengths and Limitations: o Please add limitations here, e.g. no additional visits for the control group etc.

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1. Reviewer Name: Dr Sharon Curtin. Institution and Country: UCC, Ireland.
In the introduction the authors need to provide more information on how MI can support and helping the person to examine and resolve conflicting ideas, emotions and attitudes thus enabling them to increase a person's awareness of the potential problems caused, consequences experienced, and risks. I would also suggest that the authors change the wording promotional strategy to therapeutic intervention when describing MI.

Thank you for the suggestion. We include the following paragraph:

Motivational interviewing (MI) is a promotional strategy seeking to support and help a person in examining and resolving conflicting ideas, emotions and attitudes, thus facilitating an increase in the person's awareness of the potential problems, consequences and risks through improvement of the intrinsic motivation to change and resolve ambivalence by means of steering a person-centred approach. The person is invited to verbalize what behaviour changes they are willing to make, focusing on the movement and commitment toward that change. [21]

With regard to changing the wording from 'promotional strategy' to 'therapeutic intervention', we have the conviction that this is neither therapy nor prevention: the focus of this intervention is the promotion of healthy habits, neither threatening nor preventing oral disease.

Given the suggested time duration of each family visit, is it a brief MI intervention that is being delivered.

Thank you for the comment. The duration and number of visits is based on other MI interventions in the dental field [2, 4, 21–24]. In the literature, we found that brief interventions typically include one/two visits/phone calls lasting approximately 30 minutes. However, our project delivers four to six visits, lasting a total of approximately 120–150 minutes. Therefore, we think this is not a brief intervention.

Is the psychologist trained in Motivational Interviewing? If so, at what level? As the word [expert] has been used. What is the role of the 2 dentist in the delivery of the MI training course?
In the section 'training in MI' I feel this would be better placed in the methodology section as it is part of the study and there are specific criteria for inclusion of applicants for training in MI.

Thank you for the comment. The section 'Training in MI' is in the methodology section. The psychologist was trained in MI courses delivered by the Ministry of Health, and has ten years of experience delivering MI interventions. As the psychologist has no formal training in dentistry, the two dentists have a secondary role describing some typical scenarios of dental care or oral health promotion. We include the following paragraph:

The course will have theoretical and practical sections, and will be taught by an expert psychologist

trained in MI courses delivered by the Ministry of Health, who has ten years of experience delivering MI interventions. Two dentists with Master's degrees in Public Health and experience in dental primary care help the psychologist by describing some typical scenarios of dental care and oral health promotion.

Reviewer: 2. Reviewer Name: Anne Wilson. Institution and Country: University of Colorado, USA.
No results are reported and the methodology design and level of description are not appropriate for the outcome measures.

This is only the protocol, thus we only include the rationale, methods and discussion about the project.

Reviewer: 3. Reviewer Name: Daniela Harnacke. Institution and Country: Institute of Medical Psychology, Justus-Liebig-University Giessen, Germany.

General comment:
The study is designed as a community trial to test the improvement in caries and oral health literacy after an MI intervention. A special focus is set on disadvantaged families here. There is no doubt about the necessity for improvement, especially concerning disadvantaged families, but there are some points in the study protocol that need modification and clarification (e.g. missing randomization of the participants; values concerning reduction of caries and increase of OHL level).
Objectives and hypotheses
o page 5: How did you determine the values concerning reduction of caries and increase of OHL levels? Please add this to the study protocol.

Thank you for the comment. We include the following paragraph in the Objectives and Hypotheses section:

These values are based on previous studies using MI interventions [2, 4, 23, 24] and the criteria of our research group for what is a relevant improvement in the oral health status and OHL of this population.

Methods:
o The lack of randomization is a critical issue that complicates the analysis of the study and increase potential biases; you should randomize the participants, to avoid uncontrollable side effects and to reduce the variables you have to control and therefore reduce the risk of biases.

Thank for the comment and for the opportunity to clarify. We can (should) not randomize at the individual level because of the obvious risk of contamination. This is explained in the study design:

This is a single blind community/cluster trial. The clusters or groups to be randomised will be the entire communities and not kindergartens or other smaller groups, as in similar research [2, 3]. This design was chosen because of the strong chance of contamination by the experimental group of the control group by some aspect of the MI intervention. The main chance of contamination could affect the children of the different groups attending different kindergartens but living close to one another, or their parents being related by family or friendship.

o Patient recruitment - page 7: It is very important to inform the caregivers about the study, but you should be aware that very detailed information can affect the study outcome, too; expectation effects.

Thank you for the comment. We agree, and we only provide basic information about the study and ethical issues. We include the following paragraph:

To avoid expectation effects, we only provide basic information about the study and ethical issues.

o OHL questionnaires: Are the values of internal consistencies and temporal stability of the adapted questionnaires are comparable to the original questionnaires? Please add this aspect.

Thank you for the comment. Yes, the values are comparable. We include the following paragraphs:

These values are comparable to the original OHLI, which has a Cronbach's alpha of 0.854 and an intraclass correlation coefficient of >0.6 [35].

These values are comparable to the original REALD-30, which has a Cronbach's alpha of 0.87 [36].

o Intervention - page 10: the intervention group receives besides the MI some materials; will the control group receive the same materials? Does the control group receive also additional visits at home that do not contain MI intervention elements? Otherwise a potentially observed effect cannot only be attributed to MI.

Thank you for the comment. MI interventions use materials to support the change, giving information about health status and health habits. We do only provide materials to support the change as an essential part of MI intervention. We do not give these materials to the control group, but similar materials are given to both groups by the programme "Sembrando Sonrisas" ("Sowing smiles") of the Oral Health Department in the Ministry of Health. We include the following paragraph:

We do not give these materials to the control group, but similar materials are given to both groups by the programme "Sembrando Sonrisas" ("Sowing smiles") of the Oral Health Department in the Ministry of Health.

Statistical analysis
o page 11: You describe that you will use multiple linear regression analysis, but there is no explanation which variables are considered to be predictor and/or criterion variables; additionally this is not mentioned as a hypotheses or additional analysis; please add this in the study protocol.

Thank you for the comment. We include the following paragraph:

To compare the incidence of caries and changes in the level of OHL (intervention effect) the ANCOVA and multiple linear regression models will be used. In both cases, relevant confounding variables [2–5, 14–20] will be considered: sex, parents' age, parents' education level, child's age, monthly per capita income, and baseline values for caries and OHL.

o Referring to the hypothesis you want to test: OHL increases/caries decreases to a defined value; considering the OHL it is difficult to test percent, if the scales of the questionnaires might not measured on ratio scale, therefore you should use effect sizes instead of percent.

Thank for the comment. Both instruments can be summarized as a percentage value (correct responses/total responses) [35, 36].

o Please explain why you would like to use the t-test for independent sample rather than the analysis of covariance.

Thank you for the suggestion. We include the following paragraph:

To compare the incidence of caries and changes in the level of OHL (intervention effect), the ANCOVA and multiple linear regression models will be used. In both cases, relevant confounding variables [2–5, 14–20] will be considered: sex, parents' age, parents' education level, child's age, monthly per capita income, and baseline values for caries and OHL.

Requests for clarifications

- Abstract:

o The first sentence of the abstract is contradictory to the sentence in the discussion (page 4) "This is a great challenge, considering that most public health intervention have little impact on inequities".

Thank you for the comment. The sentence in the abstract refers to particular interventions with particular populations. In those cases, the interventions were successful, but not at the large scale level. In order to avoid confusion, we have rephrased the sentence in the abstract to read:

Oral health education/promotion interventions have been identified as cost-efficient tools to improve the oral health of the population.

o "…interventions have been identified as cost-efficient"; do you refer here on public interventions? Please clarify this sentence.

Thank you for the comment. We refer to particular interventions with particular populations: in those cases, the interventions were successful, but not at the large scale level.

o Please point out in "Methods and analysis" that the intervention will take place "at home", because this is not mentioned in the abstract yet.

Thank you for the comment, we add "at home".

- Introduction:

o Page 4 "This is a point of concern in developed countries" and in developing countries?

Thank you for the comment, we add "and in developing countries".

o Page 4: the Stages of Change is a part of the Transtheoretical Model.

Thank you for the comment, we re-phrased to "the Stages of Change as a part of the Transtheoretical Model[8,9]".

Other minor comments

- Please add a founding statement and a competing interest statement

This is on page 19.

- Please add the keyword Motivational Interviewing

We add "Motivational Interviewing" to keywords.

- Please add where the trial has been registered

This is on page 2.

- Strengths and Limitations:

o Please add limitations here, e.g. no additional visits for the control group etc.

We add the following limitation: “There are no home visits for the control group, which makes it difficult to assess the pure impact of the motivational interviewing intervention.”

VERSION 2 – REVIEW

REVIEWER	Daniela Harnacke Institute of Medical Psychology, University of Giessen, Germany
REVIEW RETURNED	30-Aug-2016

GENERAL COMMENTS	Thank you for revising the study protocol. You addressed most of my concerns, but there is one major concern of randomization that is really worth of being reconsidered. A randomization will be able to reduce the risk of further and possibly severe biases and this will justify accepting a possible “contamination” you have mentioned. I still think that it is worth to risk a potential "contamination", because just talking about the MI-intervention should not be as effective as the MI itself.

VERSION 2 – AUTHOR RESPONSE

Reviewer: 3. Reviewer Name: Daniela Harnacke. Institution and Country: Institute of Medical Psychology, University of Giessen, Germany
Dear Dr. Dr. Ricardo Cartes- Velásquez, dear Co-Authors,
Thank you for revising the study protocol. You addressed most of my concerns, but there is one major concern of randomization that is really worth of being reconsidered.
A randomization will be able to reduce the risk of further and possibly severe biases and this will justify accepting a possible “contamination” you have mentioned. I still think that it is worth to risk a potential "contamination", because just talking about the MI-intervention should not be as effective as the MI itself.

Thank for the comment and for the opportunity to clarify. As we already mentioned, we can (should) not randomize at the individual level because of the obvious (not just potential) risk of contamination. This is explained in the study design:

This is a single blind community/cluster trial. The clusters or groups to be randomised will be the entire communities and not kindergartens or other smaller groups, as in similar research [2, 3]. This design was chosen because of the strong chance of contamination by the experimental group of the control group by some aspect of the MI intervention. The main chance of contamination could affect the children of the different groups attending different kindergartens but living close to one another, or their parents being related by family or friendship.

We agree that aim is to reduce as much as possible the risk of bias. As a research team we have weighted those risks, and we have concluded that contamination means a greater risk. Please consider that almost all confounding variables (education, health literacy and socioeconomics) are included in the data collection, thus we can control them in the statistical analysis stage. However, if we make a randomization at the individual level and the contamination occurs (and we think is very likely), we have little chance to control that bias in the analysis. Besides, our aim is to test the MI-intervention in our setting in order to potentially be implemented at regional or national level.