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A motivational interview intervention delivered at home to improve the oral health literacy and reduce the morbidity of Chilean disadvantaged families: A community trial.

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ABSTRACT

Introduction: Oral health education/promotion interventions have been identifed as cost-efficient tools to improve the oral health of the population, especially in the disadvantaged, and children. These interventions are regularly made in contexts where the target population is captive, for example, in health centres. In Chile, there are no oral health interventions delivered at home.

Methods and analysis: This community trial covers two disadvantaged urban areas in the province of Concepción. Both sectors have public preschool education coverage with a traditional programme (TP) to promote oral health. The intervention will comprise four to six visits by dental hygienists trained in the delivery of a standardised oral health promotion programme using motivational interviewing (MI). The experimental group will receive TP and MI, while the control group will receive only TP. If a positive and significant effect of MI is found, this will be administered to the control group. For a 50% reduction in the incidence of caries, a sample size of 120 preschoolers per group is estimated. Data will be gathered on demographic and socioeconomic variables; oral health outcomes using WHO oral health indicators (the prevalence and severity of caries, periodontal disease, dentofacial anomalies, and oral hygiene); the oral health literacy of caregivers, measured by the Rapid Estimation of Adult Literacy in Dentistry and the Oral Health Literacy Instrument, both validated for the Chilean population. Assessments will take place at baseline, and at 12-month follow-up.

Ethics and dissemination: The university bioethics committee approved this study (EI/21/2014). We will submit the trial´s results for presentation at international scientific meetings, and to peer-reviewed journals.

Trial registration number ACTRN12615000450516.

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STRENGTHS AND LIMITATIONS OF THIS STUDY

- This project seeks to involve the entire family or, at least, all caregivers, whereas other studies have focused only on mothers; to achieve this goal, the project introduces flexibility in the schedule of visits.
- The incidence of caries between two and four years of age in this population is high, so these strategies could have a greater impact than those obtained in developed countries where incidence is lower
- This project will use validated instruments to measure oral health literacy, giving a objective measure of the intervention´s impact.
- Most previous studies have been conducted by using continuous monitoring and contact with the patients, making it difficult to estimate the real impact of the pure intervention.

INTRODUCTION

Rationale

Dental caries remains one of the most prevalent chronic diseases in the world, demonstrating inequity in its distribution similar to other diseases. Worldwide, the disadvantaged population shows the greatest burden of oral disease.[1] A specific aspect of this inequity is the increased prevalence and severity of early childhood caries. This is a point of concern in developed countries.[2-4]

To explain the development of dental caries in children, several models have been proposed. Fischer-Owens et al.[5] proposed a conceptual model with five domains: genetic and biological factors, social environment, physical environment, health behaviours, and medical and dental care. These factors interact at three levels: child, family, and community; providing the opportunity to intervene at one or more points before the appearance of oral disease.

The biological domain has been historically addressed through the adoption of policies such as water fluoridation combined with other clinical preventative measures (e.g. sealants and topical fluorinations). In recent years, however, research into psychosocial and behavioural aspects has increased, using a health promotion approach.[4,5]

The practice of this new approach has been based on psychological theories seeking behaviour change in order to maintain and/or strengthen health.[6] The most important of these include the Health Belief Model,[7] the Transtheoretical Model,[8] the Stages of Change,[9] the Theory of Reasoned Action,[10] the concept of self-efficacy in Bandura´s Social Cognitive Theory,[11] and the sense of coherence in the Salutogenic Model of Antonovsky.[12]

The central target of these theories is some form of health literacy (HL). Health literacy is crucial; there is ample evidence indicating that low levels of HL is a risk factor for the appearance, perpetuation and aggravation of various diseases that bring functional, psychological, social, and economic consequences.[13]

Oral health literacy (OHL) focuses on dental aspects.[14] Research in OHL has been consistent with the findings regarding HL.[15] Several studies have found an association between caregivers´ OHL and the oral health outcomes of their children in

terms of the need for dental treatment,[16] the use of dental sealants,[17] oral health related quality of life,[18] deleterious habits,[19] and dental emergency expenses.[20]

Despite the above, promotional strategies focused on dental patients have only recently been considered.[2-4] Motivational interviewing (MI) is a promotional strategy seeking to improve the intrinsic motivation to change and resolve ambivalence by a steering person-centred approach.[21] Motivational interviewing has shown good results in different dental settings.[2,4,22,23] However, these results are transitory and have negligible impact on the incidence of caries.[22,24]

Currently, there is scarce evidence on the effects of interventions delivered at home on OHL and the oral health outcomes of preschool children, although home visiting interventions have been sucessful in other child/pregnancy health outcomes.[25-28] The Chilean Ministry of Health is implementing an oral health intervention for preschoolers in kindergartens,[29] without plans (or evidence) to extend these programmes to home.

Objective and hypotheses

The main objective of this community trial is to evaluate at a 12-month follow-up the oral health impact, measured by the incidence of caries in preschoolers and OHL levels in caregivers, of an MI intervention delivered in the homes of disadvantaged families in Chile.

The hypotheses is that an MI intervention will achieve a decrease in the incidence of caries by 50% in preschoolers, and an increase of OHL levels by 30% in caregivers, at a 12-month follow-up.

METHODS

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 each other, or their parents being related by family or friendship.

Since this intervention involves visiting the homes of the preschoolers, we may not achieve masking of patients or who delivered the MI intervention. The professionals who will remain blinded will comprise only those involved in the assessment at the 12-month follow-up.

The study does not include interim assessments because, considering the nature of the health promotional interventions, any contact or reminder to participants could act as a health intervention in itself.

Participants and selection criteria.

Participants comprise preschoolers and their caregivers living in the communities of Boca Sur at San Pedro de la Paz (MI intervention), and Los Cerros at Talcahuano (control group). Both communities have similar characteristics in terms of size and socioeconomic conditions. Both show high levels of social vulnerability and are separated by approximately 25 kilometers.

Participants must meet the following inclusion criteria: children aged between two and four years at the time of initiating the intervention, attending JUNJI (National Kindergarten Board, *Junta Nacional de Jardines Infantiles*) or Integra kindergartens in the communities mentioned above, and with a family member in charge (caregiver). The JUNJI and Integra kindergartens are the main organisations delivering preschool education at national level in Chile; both work in alliance with the Chilean Ministry of Health in oral health issues.[29]

Exclusion criteria were: preschoolers who are receiving dental treatment at the secondary level of care, and children or caregivers presenting with any physical and/or mental conditions that preclude the delivery of the MI intervention.

Sample size

For the calculation of sample size was considered a design effect[30] based on an intracluster correlation coefficient (ICC, denoted as ρ) of 0.01. There are no data available for these communities, so we used a ρ of 0.009, as described in previous research,[3] what had rounded up to 0.01 in this study.

Considering recent oral health research in similar Chilean groups of preschoolers,[31-34] the one-year incidence of caries, as assessed by the decay, missing, filled teeth (DMFT) index and the standard deviation (SD), were estimated at 4.

Consequently, the goal was estimated at 2 in order to reduce by 50% the incidence of caries in the MI intervention group.

Therefore, the sample size estimation was made in four steps:

1. Students t-test for independent samples (two-sided, alpha=5%, power=80%, means difference=2, SD=4) gave an ni=64.
2. The design effect (de) is estimated as described elsewhere[30] (1+(ni-1)ρ), giving a de=1.63.
3. Loss rate during follow-up is estimated at 15%.
4. The final sample size is calculated as: 64 x 1.63 x 1.15 = 120 preschoolers with their caregivers per group. The minimum sample size to assess at 12-month follow-up is therefore 104 preschoolers with their caregivers, per group.

Patient recruitment

In order to obtain administrative support, all related institutions with the oral health of the preschoolers were contacted. The first contact was with the District Department of Health of San Pedro de la Paz, and Talcahuano; and the Province Office of Integra, and JUNJI. All agreed to participate in the study.

Secondly, the directors of all kindergartens in the two communities were contacted. All agreed to participate in the study and authorised us to participate in the monthly caregivers´ meetings and/or to send invitations to preschoolers´ homes in order to inform caregivers about the study.

The information in the meetings will be delivered through a PowerPoint presentation, including the study´s aim, intervention, contacts, and ethical considerations. The information in the invitations includes the same information as in the PowerPoint presentation, plus a date and time for data collection in the kindergartens or at the family health centre of the respective community. Patient recruitment will be stopped when the sample size is reached.

Variables

The study includes three groups of variables: socioeconomic and demographics, oral health outcomes, and OHL.

The *socioeconomic and demographics* variables will describe:

Firstly, the household composition, with a description of the preschooler´s nuclear family using a Genogram. The gender, age, occupation and level of education of each member will be included, and the relationships between them.

Secondly, each household's economic situation, with information on the income received by paid work of each member of the family, and state aid received from social programmes (Puente, Chile Solidario, and similar).

Oral health outcomes:

Caries: Assessment was made using the International Caries Detection System Assessment (ICDAS). The ICDAS codes will be transformed to DMFT and DMFT indicators.

Periodontal disease: Assessment was made using the Community Periodontal Index in adults. For preschoolers, ginigival inflammation was assessed at three levels: none, local, and generalised.

Dentofacial anomalies: Assessment was made using the Dental Aesthetic Index in adults. This variable was not considered in preschoolers.

Oral hygiene: Assessment was made using the Oral Simplified Hygiene index (OHI-S).

Oral health literacy: Assessment of caregivers´ OHL was made using two instruments.

The Oral Health Literacy Instrument (OHLI):[35] This is comprised of 57 items, divided into a first section of 38 missing words in a paragraph (Cloze procedure) about tooth decay and periodontal disease, and a second section of 19 items focused on numerical skills about medical prescriptions and instructions after dental procedures. For this study, a validated version of the OHLI for the Chilean population was used; this version shows a Cronbach's alpha of 0.886 and an intraclass correlation coefficient of >0.6 for temporal stability [publication under peer-review].

Rapid Estimate of Adult Literacy in Dentistry, 30 items (REALD-30):[36] This comprises 30 words from the American Dental Association Glossary of Common Dental Terminology, and dental materials commonly available in dental clinics, arranged in order of increasing difficulty. For this study, a validated version of the OHLI for the Chilean

population was used; this version shows a Cronbach's alpha of 0.876 and an intraclass correlation coefficient of 0.789 for temporal stability [publication under peer-review].

Data collection

Data collection will be carried out at baseline (pre-intervention) and at a 12-month follow-up. An initial calibration will be made to assure the reliability of the data (see the flowchart).

Calibration: The dentists and social workers will go through a calibration process consisting of an information day about the study and the instruments and indicators. Clinical calibration will performed at the Universidad de Concepción School of Dentistry with a sample of 12 preschoolers and their caregivers, recruited from the family health centres of Concepción.

Baseline: All assessments will be made directly at the kindergartens or the family health centre of the respective community. The caregivers will be informed, and they will sign the informed consent form; the assent of the preschoolers will also be obtained. The study will accord with the conditions set by the WHO to carry oral health surveys.[37]

Each respondent (caregiver and preschooler) will be given an oral health care kit consisting of toothpaste and toothbrushes.

Data will be collected by a dentist and a dental assistant concerning oral health outcomes, and a social worker for socioeconomic and demographic data and OHL.

12-month follow-up: All assessments will be made at the Universidad de Concepción School of Dentistry (approximately 20 kilometers distant from both sectors). The procedure will be the same as in the baseline assessment, but the assessment will be made by professionals blinded to the allocation of the participant to the control or experimental group to assure the single blind of the trial.

Caregivers will be contacted by telephone to arrange an appointment for the follow-up assessment. Transportation and other associated expenses incurred by travel to and from the School of Dentistry will be compensated with CLP $10,000 (USD $15). The caregiver will be instructed not to inform their community or indicate their group allocation to the professionals.

Training in motivational interviewing

A training course will be carried out with a duration of 40 hours spread over five days. The course will have theoretical and practical sections, and will be taught by an expert psychologist with experience in MI, and two dentists with Masters degrees in Public Health and experience in dental primary care. Those who pass will receive a certificate from the Universidad de Concepción School of Dentistry.

Applicants for the course will be selected according to their professional background and an interview. The course will have a maximum availability of 12 places; all will be assigned a full scholarship by the School of Dentistry. Preference will be given to dental assistants and dental hygienists working in the family health centres of the participating communities.

Four students will be selected from those who pass the course and obtain the highest grades to apply the MI intervention.

Intervention

Both the MI intervention and the control group will receive oral health interventions at kindergartens using the programme *"Sembrando Sonrisas"* ("Sowing smiles")[29] of the Oral Health Department in the Ministry of Health.

The MI intervention in this study comprises four to six home visits with the following characteristics:

1. The visits follow the principles of MI,[21] that seek to generate motivation and goals from the client and not the delivery of advice by the health worker.
2. The visits will be adjusted to the needs of the families themselves, covering at least self-care and oral health care, as recommended by the Chilean Ministry of Health.[29]
3. The visits will be made by couples of dental hygienists previously trained in the delivery of a standardised oral health promotion through MI.
4. The visits will have a duration of 15-45 minutes; normally, the first visit will be longer.
5. Besides the MI, some materials will be given to families: a leaflet about oral health, a dental colouring book with crayons, a Colgate® Dr. Rabbit DVD, stickers to remind participants about toothbrushing, and four to six plaque disclosing tablets to check the toothbrushing.

6. The first visit will take place during the three weeks after the baseline assessment. The appointment for the remaining three to five visits will be agreed with each family, separated by 7-14 days.
7. The times and days of the visits will be adjusted to the availability of families, trying to ensure the participation of the preschooler´s caregivers, within a schedule from 8.00 to 21.00 hours from Monday to Saturday.

Statistical analysis

Univariate description of all variables (baseline and follow-up) will be performed using frequency tables (qualitative variables), summary measures (of central tendency and dispersion for quantitative variables), accompanied by relevant graphics (pie-charts, bars and histograms).

Regarding the psychometric properties of OHLI and REALD-30, the Cronbach´s alpha coefficient for internal consistency of the scales will be used. Regarding the calibration of the dentists and social workers, the strength of agreement will be determined with Kappa or Lin coefficients, depending on the nature of the variables.

To analyse the association between qualitative variables, the chi-square test will be used; and for the association of quantitative variables, the Pearson correlation coefficient. To compare the incidence of caries and changes in the level of OHL (intervention effect) the t-test for independent samples and multiple linear regression models will be used. If the necessary assumptions for parametric tests are not met, the corresponding non- parametric tests will be used.

Statistical significance will be set at $p<0.05$. The analysis will be made with Stata/SE 14 for Windows (StataCorp, TX, USA).

ETHICS AND DISSEMINATION

Ethical considerations

The study adheres strictly to the Declaration of Helsinki,[38] as well as the Chilean laws #20120 (research in humans),[39] and #20584 (rights and duties of the patient).[40]

All patients are informed about the aim of the study and they will give their informed consent in order to participate in the study.

If a positive and significant effect of the MI intervention is found, this will be administered to the control group.

Dissemination

We will submit the trial´s results for presentation at international scientific meetings, and to peer-reviewed journals. We will become freely available the statistical codes, and anonymised data upon request to corresponding author.

4. DISCUSSION

In many developed countries, there is concern about the increase in the prevalence and severity of early childhood caries.[2-4] Caries in preschoolers is associated not only with high expense, but a strong functional, aesthetic and psychological impact on the children and their families.[41] Previous studies in disadvantaged communities of Chile show that the prevalence and severity of early childhood caries is high,[34-37] so strategies are needed to address it.

This project is motivated by the development, assessment and (prospective) implementation in Chile of new strategies to promote oral health. The target population is preschool children of disadvantaged communities of Chile, as other similar populations across the world. This is a great challenge, considering that most public health interventions have had little impact on inequities in oral health at national,[41,42] and worldwide level.[1,43] Bearing these difficulties in mind, a pro-active approach is proposed, delivering oral health promotion directly to the home. This approach is based on the positive results of home visits in other health areas.[25-28]

Nowadays in Chile, the promotional aspect of oral health care is a secondary component of curative and preventative care. Most oral health care is delivered to specific groups (6-, 12-, and 60-years-old population, pregnant women, and those requiring urgent dental care) through the GES program (Explicit Health Guarantees, *Garantías Explícitas en Salud*).[41] Recently, an oral health intervention at the JUNJI and Integra´s kindergartens using the programme *"Sembrando Sonrisas"* has been introduced.[29] This intervention is focused on achieving better results in the oral health status of children when they are enrolled in the GES program at six years of age.

However, there are no explicit programmes involving caregivers in the oral health care of their children in Chile, despite the good results of a mother-child preventative dental programme developed in the country.[45] The evidence suggests that, if the adults responsible for the care of children are not committed, qualified and empowered with strategies to reinforce learning at home,[15-20] behavioural interventions performed at the schools are insufficient to improve the children´s oral health.[46] Within this context, there is a need to develop cost-effective interventions that impact on adult OHL in order to continue the virtuous circle started at the school or the kindergarten; otherwise, school-based interventions could be useless.

At the international level, many studies have been developed to assess strategies to promote oral health through MI,[2-4,21-24] and home visits,[25-28] aimed at the disadvantaged population. However, they have all been conducted in developed countries, namely: Australia,[2,4] Canada,[3] and the United States.[24] To our knowledge, there are no studies published from Latin American countries or other populations with similar socioeconomic and idiosyncratic conditions.

Despite the similarities with studies in developed countries, there are some relevant differences to mention: a) this project seeks to involve the entire family or, at least, all caregivers, whereas other studies have focused only on mothers; to achieve this goal, the project introduces flexibility in the schedule of visits; b) other studies have used a low number of visits; in this study, a minimum of four and a maximum of six visits over three to ten weeks is planned; c) the incidence of caries between two and four years of age in this population is high, so these strategies could have a greater impact than those obtained in developed countries where incidence is lower; d) this project will use validated instruments to measure oral health literacy, giving a objective measure of the intervention´s impact on OHL; e) most previous studies have been conducted by using continuous monitoring and contact with the patients, making it difficult to estimate the real impact of the isolated intervention due to the implicit Hawthorne effect.[47]

In Chile, previous research on this matter has focused on preventative oral health care from pregnancy up to ten years later.[45] However there are some issues not addressed by this approach: a) a large proportion of the preschool Chilean population has not been followed from pregnancy; b) interventions have been used with mother-child dyads,

omitting fathers or other caregivers; c) the promotional aspect of the intervention focuses on prescribing the "right behaviour"; this has little impact on oral health and the empowerment of the population.[6]

In summary, the main innovation of this study is the thorough assessment of an MI intervention at the community level, involving the caregivers of preschoolers in disadvantaged communities. Although this is the first trial of this intervention in a Latin American country, the recommendations generated from similar studies in disadvantaged populations of developed countries have been considered. This community trial will provide local evidence on the effectiveness on MIs in improving oral health outcomes and literacy in our disadvantaged population.

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Contributors

RCV, CA, RF, LL, FC and AB designed the study. LL provided statistical advice. RCV and RF wrote the manuscript. All authors proofed and edited the manuscript.

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Funders have no role in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication.

Funder contact: Ms. Cielo Amestica Aguilar, e-mail: camestica@conicyt.cl.

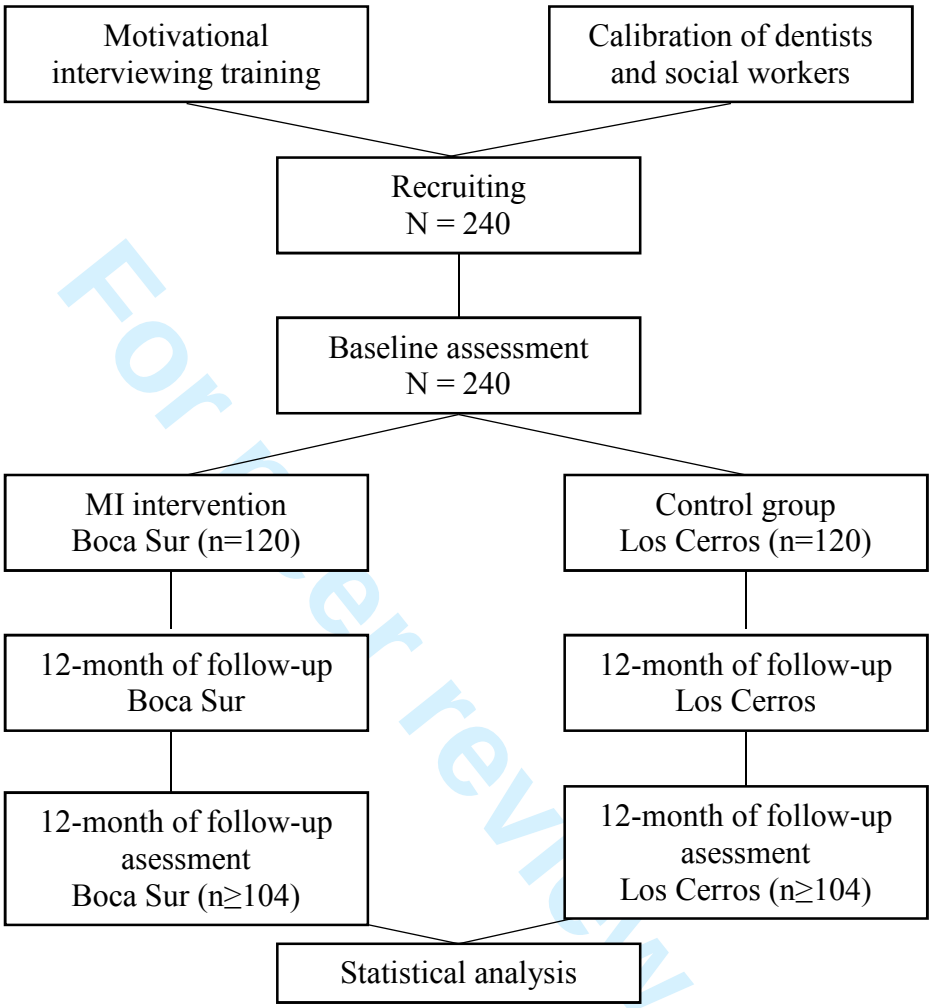
Competing interests

None declared.

Ethics approval

The study protocol was approved by the Bioethics Committee at the Universidad de Concepción School of Medicine with the code EI/21/2014.

FLOWCHART



Universidad de Concepción

FONIS N° SA14ID0162

Documento de Consentimiento Informado

Investigador Principal: Ricardo Cartes Velásquez
Organización: Departamento de Prevención y Salud Pública Odontológica, Universidad de Concepción
Patrocinador: FONIS
Proyecto: "Evaluación de una intervención de promoción en salud bucal desarrollada en el núcleo familiar de preescolares en sectores vulnerables urbanos. San Pedro de la Paz y Talcahuano. Ensayo comunitario."

Este Documento de Consentimiento Informado tiene dos partes:
– Información (proporciona información sobre el estudio)
– Formulario de Consentimiento (para firmar si está de acuerdo en participar)
Se le dará una copia del Documento completo de Consentimiento Informado como garantía de las condiciones de la participación de su institución.

PARTE I: Información

Introducción Mi nombre es Ricardo Cartes, dentista y docente del Departamento de Prevención y Salud Pública Odontológica, Universidad de Concepción, soy el investigador principal de un Proyecto de Investigación sobre el efecto de una intervención de promoción en salud bucal sobre la incidencia de caries después de un año, al cual le invita a participar.
Propósito Este estudio tiene como objetivo determinar el impacto sanitario medido a través de la incidencia de caries y niveles de alfabetismo en salud bucal luego de 12 meses de una intervención de promoción en salud bucal desarrollada en el núcleo familiar de preescolares en el sector de Boca Sur de San Pedro de la Paz en comparación a un grupo control en el sector Los Cerros de Talcahuano.
Tipo de Intervención La intervención de este proyecto consiste en 4 a 6 visitas domiciliarias con las siguientes características:

- Las visitas son realizadas siguiendo los lineamientos de la Entrevista Motivacional (EM) que busca la generación de motivos y metas por parte del mismo paciente y no la entrega de consejos por el agente sanitario.
- El desarrollo de la EM durante las visitas se ajustará a las necesidades de las propias familias con una cobertura mínima de los contenidos de: autocuidado en salud bucal y atención en el nivel de atención primaria de salud.
- Las visitas serán realizadas por 2 parejas conformadas por 2 técnicos en odontología previamente capacitados en la técnica de EM para salud bucal.
- Las visitas tienen una duración de 20 a 60 minutos.
- La primera visita se realizará durante las 3 semanas iniciales la intervención, las restantes visitas (3 a 5) serán acordadas con cada familia con una separación mínima de 1 semana y máxima de 2 semanas entre ellas.
- El horario y días de las visitas se ajustará a la disponibilidad de las familias intentando asegurar la participación de la mayor cantidad de padres y/o apoderados a cargo del preescolar, dentro de un horario de 8.00 a 21.00 horas de lunes a sábado.

Selección de participantes Se invitará a todos los preescolares y sus familias que residan en los sectores de Boca Sur en San Pedro de La Paz y Los Cerros en Talcahuano.
Participación Voluntaria Su participación será de carácter voluntario, mediado por un proceso de consentimiento informado.
Duración El proyecto tendrá una duración de 2 años, en los que deberá participar en un examen completo de su salud bucal y conocimientos, en 4 a 6 intervenciones de promoción y luego de 12 meses en un nuevo control de su salud bucal y conocimientos.
Riesgos Esta investigación no implica riesgos en contra de su bienestar físico o mental.

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Beneficios Los beneficios serán mejorar su nivel de conocimientos y niveles de salud bucal, derivados de los resultados se podrán implementar programas que beneficien a toda la población preescolar nacional y sus familias.

Incentivos Los participantes (no) recibirán retribución económica por su participación.

Confidencialidad se le solicitará identificarse con su RUT para relacionar los datos de las distintas encuestas, pero su confidencialidad será resguardada codificando la identidad de todos los participantes, la que sólo será conocida por el Investigador Principal y no será considerada durante el procesamiento de los datos ni en ningún otro momento. Además, los datos serán almacenados en ordenadores resguardados con clave.

Difusión de los Resultados Las publicaciones generadas a partir del proyecto, mantendrá el anonimato de la identidad de todos los estudiantes e instituciones participantes. Se le proporcionará un resumen ejecutivo si Ud. lo solicita.

Derecho a negarse o retirarse El rechazo a participar o el retiro en cualquier momento de la investigación no tendrán ningún tipo de castigo o consecuencia.

A Quién Contactar Cualquier pregunta respecto al desarrollo de la investigación o sobre los resultados de ésta, parcial o final, puede contactar con el investigador principal **Ricardo Cartes,** (*correo electrónico:* rcartes@udec.cl; *fono:* 41-2204386).

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FONIS N° SA14ID0162

PARTE II: Formulario de Consentimiento

He sido invitado(a) a participar en una investigación, enmarcada en el proyecto FONIS N° SA14ID0162 titulado "***Evaluación de una intervención de promoción en salud bucal desarrollada en el núcleo familiar de preescolares en sectores vulnerables urbanos. San Pedro de la Paz y Talcahuano. Ensayo comunitario. percepción del Clima académico en el ciclo clínico de Odontología de la UdeC"***, cuyo investigador es el Dr. Ricardo Cartes y que tiene como objetivo determinar el impacto en los conocimientos y salud bucal de una intervención de promoción en salud bucal desarrollada en el núcleo familiar de preescolares en el sector de Boca Sur de San Pedro de la Paz en comparación a un grupo control en el sector Los Cerros de Talcahuano.

Por este motivo, se requiere mi participación respondiendo encuestas y completando un examen de salud bucal al inicio y al término del proyecto, así como participando en 4 a 6 intervenciones de promoción en mi hogar.

Asimismo, declaro que se me informó que mi participación será de carácter voluntario y mediado por un proceso de consentimiento informado. Para poder parear mis respuestas de las distintas, se solicita que me identifique con mi RUT al inicio de cada instrumento. No obstante, los investigadores se comprometen a que la información que entregaré en estos instrumentos sólo será utilizada para responder a los objetivos de este estudio, será confidencial, que los datos serán manejados exclusivamente por los investigadores, almacenados en ordenadores resguardados con clave y que en ningún caso serán analizados individualmente, pues a este estudio sólo le interesan el efecto a nivel general de la intervención en promoción.

En este mismo sentido, sólo se me hará entrega, si lo solicito, de un resumen ejecutivo con los resultados generales del estudio sin identificar a los participantes.

También se me ha garantizado que el estudio no implica exponerme a situaciones que atenten en contra de mi bienestar físico o mental y que no perjudicará mi atención en salud.

Si en algún momento siento que el proceso de encuestaje me incomoda puedo solicitar que se detenga inmediatamente la recolección.

Estoy al tanto que la participación que se me solicita es voluntaria, que no recibiré pago alguno por mi colaboración y que puedo negarme a participar o retirarme en cualquier etapa de la investigación, sin necesidad de dar explicaciones y que esto no tendrá ningún tipo de consecuencias para mí.

Por último, he sido informado que puedo pedir mayor información del estudio al investigador, **Dr. Ricardo Cartes,** escribiéndole a su correo rcartes@udec.cl.

A partir de los antecedentes antes mencionados acepto voluntariamente participar en este estudio.

Nombre del participante (Adulto) _____ RUT: _____

Nombre del participante (Preescolar) _____ RUT: _____

Firma del participante _____

Fecha: _____

Notas:

Usted se quedará con una copia de este consentimiento como garantía de las condiciones de su participación.

Si usted siente que sus derechos fueron vulnerados en este estudio puede comunicarse con el Comité de Bioética de la Facultad de Medicina de la Universidad de Concepción, escribiéndole a Liliana Ortiz al correo lilianaortiz@udec.cl o llamándole al fono (41) 2207083.

Si desea recibir un resumen ejecutivo de los resultados del estudio una vez que éste se encuentre terminado, indique su dirección de correo electrónico, o, si no posee una, indique su dirección de correo postal:

Correo electrónico: _____

Equipo investigador

Universidad de Concepción

FONIS N° SA14ID0162

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También se me ha garantizado que el estudio no implica exponerme a situaciones que atenten en contra de mi bienestar físico o mental y que no perjudicará mi atención en salud.

Si en algún momento siento que el proceso de encuestaje me incomoda puedo solicitar que se detenga inmediatamente la recolección.

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Firma del participante _____

Fecha: _____

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Correo electrónico: _____

Equipo investigador

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
	2b	All items from the World Health Organization Trial Registration Data Set	2
Protocol version	3	Date and version identifier	2
Funding	4	Sources and types of financial, material, and other support	19
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	19
	5b	Name and contact information for the trial sponsor	19
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	19
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	19

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4-5
	6b	Explanation for choice of comparators	4-5
Objectives	7	Specific objectives or hypotheses	5
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	5
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	6
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	10
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	NA
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	NA
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	NA
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	5,7,8
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	20

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	6-7
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	7
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	NA
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	NA
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	NA
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	5
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	NA
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	9-10
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	NA

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	9
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	11
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	11
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	11
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	NA
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	NA
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	11-12
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	NA
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	19
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	11-12

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	11-12
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	11-12
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	11-12
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	19
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	12
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	11-12
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	11-12
	31b	Authorship eligibility guidelines and any intended use of professional writers	11-12
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	11-12
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Appendix 1
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	11-12

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

A motivational interview intervention delivered at home to improve the oral health literacy and reduce the morbidity of Chilean disadvantaged families: A community trial.

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2016-011819.R1
Article Type:	Protocol
Date Submitted by the Author:	19-Jul-2016
Complete List of Authors:	Cartes-Velasquez, Ricardo; Universidad de Concepcion, Preventive and Public Health Dentistry Araya, Carlos; Universidad de Concepcion, Preventive and Public Health Dentistry Flores, Raúl; Universidad de Concepcion, Preventive and Public Health Dentistry Luengo, Luis; Universidad de Concepcion, Preventive and Public Health Dentistry Castillo, Francisca; Universidad de Concepcion, Preventive and Public Health Dentistry Bustos, Alex; Universidad de Concepcion, Preventive and Public Health Dentistry
Primary Subject Heading:	Dentistry and oral medicine
Secondary Subject Heading:	Public health, Paediatrics, Health services research
Keywords:	Oral health literacy, Caries, Children, Home visits, Chile, Motivational interviewing

A motivational interview intervention delivered at home to improve the oral health literacy and reduce the morbidity of Chilean disadvantaged families: A community trial.

Ricardo Cartes-Velásquez[a*]; Carlos Araya[a]; Raúl Flores[a]; Luis Luengo[a]; Francisca Castillo[a]; Alex Bustos[a].

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Keywords: Oral health literacy; Caries; Children; Home visits; Chile; Motivational interviewing.

Word count: 3746.

ABSTRACT

Introduction: Oral health education/promotion interventions have been identified as cost-efficient tools to improve the oral health of the population. These interventions are regularly made in contexts where the target population is captive, for example, in health centres. In Chile, there are no oral health interventions delivered at home.

Methods and analysis: This community trial covers two disadvantaged urban areas in the province of Concepción. Both sectors have public preschool education coverage with a traditional programme (TP) to promote oral health. The intervention will comprise four to six visits by dental hygienists trained in the delivery of a standardised oral health promotion programme using motivational interviewing (MI) at home. The experimental group will receive TP and MI, while the control group will receive only TP. If a positive and significant effect of MI is found, this will be administered to the control group. For a 50% reduction in the incidence of caries, a sample size of 120 preschoolers per group is estimated. Data will be gathered on demographic and socioeconomic variables; oral health outcomes using WHO oral health indicators (the prevalence and severity of caries, periodontal disease, dentofacial anomalies, and oral hygiene); the oral health literacy of caregivers, measured by the Rapid Estimation of Adult Literacy in Dentistry and the Oral Health Literacy Instrument, both validated for the Chilean population. Assessments will take place at baseline, and at 12-month follow-up.

Ethics and dissemination: The university bioethics committee approved this study (EI/21/2014). We will submit the trial´s results for presentation at international scientific meetings, and to peer-reviewed journals.

Trial registration number ACTRN12615000450516.

Protocol version: 2, January 6 2016.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- This project seeks to involve the entire family or, at least, all caregivers, whereas other studies have focused only on mothers; to achieve this goal, the project introduces flexibility in the schedule of visits.
- The incidence of caries between two and four years of age in this population is high, so these strategies could have a greater impact than those obtained in developed countries where incidence is lower
- This project will use validated instruments to measure oral health literacy, giving a objective measure of the intervention´s impact.
- Most previous studies have been conducted by using continuous monitoring and contact with the patients, making it difficult to estimate the real impact of the pure intervention.
- There are no home visits for the control group, which makes it difficult to assess the pure impact of the motivational interviewing intervention.

INTRODUCTION

Rationale

Dental caries remains one of the most prevalent chronic diseases in the world, demonstrating inequity in its distribution similar to other diseases. Worldwide, the disadvantaged population shows the greatest burden of oral disease.[1] A specific aspect of this inequity is the increased prevalence and severity of early childhood caries. This is a point of concern in developed and in developing countries.[2-4]

To explain the development of dental caries in children, several models have been proposed. Fischer-Owens et al.[5] proposed a conceptual model with five domains: genetic and biological factors, social environment, physical environment, health behaviours, and medical and dental care. These factors interact at three levels: child, family, and community; providing the opportunity to intervene at one or more points before the appearance of oral disease.

The biological domain has been historically addressed through the adoption of policies such as water fluoridation combined with other clinical preventative measures (e.g. sealants and topical fluorinations). In recent years, however, research into psychosocial and behavioural aspects has increased, using a health promotion approach.[4,5]

The practice of this new approach has been based on psychological theories seeking behaviour change in order to maintain and/or strengthen health.[6] The most important of these include the Health Belief Model,[7] the Stages of Change as a part of the Transtheoretical Model,[8,9] the Theory of Reasoned Action,[10] the concept of self-efficacy in Bandura´s Social Cognitive Theory,[11] and the sense of coherence in the Salutogenic Model of Antonovsky.[12]

The central target of these theories is some form of health literacy (HL). Health literacy is crucial; there is ample evidence indicating that low levels of HL is a risk factor for the appearance, perpetuation and aggravation of various diseases that bring functional, psychological, social, and economic consequences.[13]

Oral health literacy (OHL) focuses on dental aspects.[14] Research in OHL has been consistent with the findings regarding HL.[15] Several studies have found an association between caregivers´ OHL and the oral health outcomes of their children in

terms of the need for dental treatment,[16] the use of dental sealants,[17] oral health related quality of life,[18] deleterious habits,[19] and dental emergency expenses.[20]

Despite the above, promotional strategies focused on dental patients have only recently been considered.[2-4] 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] Motivational interviewing has shown good results in different dental settings.[2,4,22,23] However, these results are transitory and have negligible impact on the incidence of caries.[22,24]

Currently, there is scarce evidence on the effects of interventions delivered at home on OHL and the oral health outcomes of preschool children, although home visiting interventions have been sucessful in other child/pregnancy health outcomes.[25-28] The Chilean Ministry of Health is implementing an oral health intervention for preschoolers in kindergartens,[29] without plans (or evidence) to extend these programmes to home.

Objective and hypotheses

The main objective of this community trial is to evaluate at a 12-month follow-up the oral health impact, measured by the incidence of caries in preschoolers and OHL levels in caregivers, of an MI intervention delivered in the homes of disadvantaged families in Chile.

The hypotheses is that an MI intervention will achieve a decrease in the incidence of caries by 50% in preschoolers, and an increase of OHL levels by 30% in caregivers, at a 12-month follow-up. 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

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.

Since this intervention involves visiting the homes of the preschoolers, we may not achieve masking of patients or who delivered the MI intervention. The professionals who will remain blinded will comprise only those involved in the assessment at the 12-month follow-up.

The study does not include interim assessments because, considering the nature of the health promotional interventions, any contact or reminder to participants could act as a health intervention in itself.

Participants and selection criteria.

Participants comprise preschoolers and their caregivers living in the communities of Boca Sur at San Pedro de la Paz (MI intervention), and Los Cerros at Talcahuano (control group). Both communities have similar characteristics in terms of size and socioeconomic conditions. Both show high levels of social vulnerability and are separated by approximately 25 kilometers.

Participants must meet the following inclusion criteria: children aged between two and four years at the time of initiating the intervention, attending JUNJI (National Kindergarten Board, *Junta Nacional de Jardines Infantiles*) or Integra kindergartens in the communities mentioned above, and with a family member in charge (caregiver). The JUNJI and Integra kindergartens are the main organisations delivering preschool education at national level in Chile; both work in alliance with the Chilean Ministry of Health in oral health issues.[29]

Exclusion criteria were: preschoolers who are receiving dental treatment at the secondary level of care, and children or caregivers presenting with any physical and/or mental conditions that preclude the delivery of the MI intervention.

Sample size

For the calculation of sample size was considered a design effect[30] based on an intracluster correlation coefficient (ICC, denoted as ρ) of 0.01. There are no data available for these communities, so we used a ρ of 0.009, as described in previous research,[3] what had rounded up to 0.01 in this study.

Considering recent oral health research in similar Chilean groups of preschoolers,[31-34] the one-year incidence of caries, as assessed by the decay, missing, filled teeth (DMFT) index and the standard deviation (SD), were estimated at 4. Consequently, the goal was estimated at 2 in order to reduce by 50% the incidence of caries in the MI intervention group.

Therefore, the sample size estimation was made in four steps:

1. Students t-test for independent samples (two-sided, alpha=5%, power=80%, means difference=2, SD=4) gave an ni=64.
2. The design effect (de) is estimated as described elsewhere[30] (1+(ni-1)ρ), giving a de=1.63.
3. Loss rate during follow-up is estimated at 15%.
4. The final sample size is calculated as: 64 x 1.63 x 1.15 = 120 preschoolers with their caregivers per group. The minimum sample size to assess at 12-month follow-up is therefore 104 preschoolers with their caregivers, per group.

Patient recruitment

In order to obtain administrative support, all related institutions with the oral health of the preschoolers were contacted. The first contact was with the District Department of Health of San Pedro de la Paz, and Talcahuano; and the Province Office of Integra, and JUNJI. All agreed to participate in the study.

Secondly, the directors of all kindergartens in the two communities were contacted. All agreed to participate in the study and authorised us to participate in the monthly caregivers´ meetings and/or to send invitations to preschoolers´ homes in order to inform caregivers about the study. To avoid expectation effects, we only provide basic information about the study and ethical issues.

The information in the meetings will be delivered through a PowerPoint presentation, including the study´s aim, intervention, contacts, and ethical considerations. The information in the invitations includes the same information as in the PowerPoint

presentation, plus a date and time for data collection in the kindergartens or at the family health centre of the respective community. Patient recruitment will be stopped when the sample size is reached (See the Figure 1).

Variables

The study includes three groups of variables: socioeconomic and demographics, oral health outcomes, and OHL.

The *socioeconomic and demographics* variables will describe:

Firstly, the household composition, with a description of the preschooler´s nuclear family using a Genogram. The gender, age, occupation and level of education of each member will be included, and the relationships between them.

Secondly, each household's economic situation, with information on the income received by paid work of each member of the family, and state aid received from social programmes (Puente, Chile Solidario, and similar).

Oral health outcomes:

Caries: Assessment was made using the International Caries Detection System Assessment (ICDAS). The ICDAS codes will be transformed to DMFT and DMFT indicators.

Periodontal disease: Assessment was made using the Community Periodontal Index in adults. For preschoolers, ginigival inflammation was assessed at three levels: none, local, and generalised.

Dentofacial anomalies: Assessment was made using the Dental Aesthetic Index in adults. This variable was not considered in preschoolers.

Oral hygiene: Assessment was made using the Oral Simplified Hygiene index (OHI-S).

Oral health literacy: Assessment of caregivers´ OHL was made using two instruments.

The Oral Health Literacy Instrument (OHLI):[35] This is comprised of 57 items, divided into a first section of 38 missing words in a paragraph (Cloze procedure) about tooth decay and periodontal disease, and a second section of 19 items focused on numerical skills about medical prescriptions and instructions after dental procedures. For this study, a validated version of the OHLI for the Chilean population was used; this version shows a

Cronbach's alpha of 0.886 and an intraclass correlation coefficient of >0.6 for temporal stability [publication under peer-review]. 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].

Rapid Estimate of Adult Literacy in Dentistry, 30 items (REALD-30):[36] This comprises 30 words from the American Dental Association Glossary of Common Dental Terminology, and dental materials commonly available in dental clinics, arranged in order of increasing difficulty. For this study, a validated version of the OHLI for the Chilean population was used; this version shows a Cronbach's alpha of 0.876 and an intraclass correlation coefficient of 0.789 for temporal stability [publication under peer-review]. These values are comparable to the original REALD-30, which has a Cronbach's alpha of 0.87 [36].

Data collection

Data collection will be carried out at baseline (pre-intervention) and at a 12-month follow-up. An initial calibration will be made to assure the reliability of the data (See the Figure 1).

Calibration: The dentists and social workers will go through a calibration process consisting of an information day about the study and the instruments and indicators. Clinical calibration will performed at the Universidad de Concepción School of Dentistry with a sample of 12 preschoolers and their caregivers, recruited from the family health centres of Concepción.

Baseline: All assessments will be made directly at the kindergartens or the family health centre of the respective community. The caregivers will be informed, and they will sign the informed consent form (See the Appendix 1); the assent of the preschoolers will also be obtained. The study will accord with the conditions set by the WHO to carry oral health surveys.[37]

Each respondent (caregiver and preschooler) will be given an oral health care kit consisting of toothpaste and toothbrushes.

Data will be collected by a dentist and a dental assistant concerning oral health outcomes, and a social worker for socioeconomic and demographic data and OHL.

12-month follow-up: All assessments will be made at the Universidad de Concepción School of Dentistry (approximately 20 kilometers distant from both sectors).

The procedure will be the same as in the baseline assessment, but the assessment will be made by professionals blinded to the allocation of the participant to the control or experimental group to assure the single blind of the trial (See the Figure 1).

Caregivers will be contacted by telephone to arrange an appointment for the follow-up assessment. Transportation and other associated expenses incurred by travel to and from the School of Dentistry will be compensated with CLP $10,000 (USD $15). The caregiver will be instructed not to inform their community or indicate their group allocation to the professionals.

Training in motivational interviewing

A training course will be carried out with a duration of 40 hours spread over five days. 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. Those who pass will receive a certificate from the Universidad de Concepción School of Dentistry.

Applicants for the course will be selected according to their professional background and an interview. The course will have a maximum availability of 12 places; all will be assigned a full scholarship by the School of Dentistry. Preference will be given to dental assistants and dental hygienists working in the family health centres of the participating communities.

Four students will be selected from those who pass the course and obtain the highest grades to apply the MI intervention.

Intervention

Both the MI intervention and the control group will receive oral health interventions at kindergartens using the programme *"Sembrando Sonrisas"* ("Sowing smiles")[29] of the Oral Health Department in the Ministry of Health.

The MI intervention in this study comprises four to six home visits with the following characteristics:

1. The visits follow the principles of MI,[21] that seek to generate motivation and goals from the client and not the delivery of advice by the health worker.

2. The visits will be adjusted to the needs of the families themselves, covering at least self-care and oral health care, as recommended by the Chilean Ministry of Health.[29]
3. The visits will be made by couples of dental hygienists previously trained in the delivery of a standardised oral health promotion through MI.
4. The visits will have a duration of 15-45 minutes; normally, the first visit will be longer.
5. Besides the MI, some materials will be given to families: a leaflet about oral health, a dental colouring book with crayons, a Colgate® Dr. Rabbit DVD, stickers to remind participants about toothbrushing, and four to six plaque disclosing tablets to check the toothbrushing. 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.
6. The first visit will take place during the three weeks after the baseline assessment. The appointment for the remaining three to five visits will be agreed with each family, separated by 7-14 days.
7. The times and days of the visits will be adjusted to the availability of families, trying to ensure the participation of the preschooler´s caregivers, within a schedule from 8.00 to 21.00 hours from Monday to Saturday.

Statistical analysis

Univariate description of all variables (baseline and follow-up) will be performed using frequency tables (qualitative variables), summary measures (of central tendency and dispersion for quantitative variables), accompanied by relevant graphics (pie-charts, bars and histograms).

Regarding the psychometric properties of OHLI and REALD-30, the Cronbach´s alpha coefficient for internal consistency of the scales will be used. Regarding the calibration of the dentists and social workers, the strength of agreement will be determined with Kappa or Lin coefficients, depending on the nature of the variables.

To analyse the association between qualitative variables, the chi-square test will be used; and for the association of quantitative variables, the Pearson correlation coefficient.

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. If the necessary assumptions for parametric tests are not met, the corresponding non-parametric tests will be used.

Statistical significance will be set at $p<0.05$. The analysis will be made with Stata/SE 14 for Windows (StataCorp, TX, USA).

ETHICS AND DISSEMINATION

Ethical considerations

The study adheres strictly to the Declaration of Helsinki,[38] as well as the Chilean laws #20120 (research in humans),[39] and #20584 (rights and duties of the patient).[40]

All patients are informed about the aim of the study and they will give their informed consent (See the Appendix 1) in order to participate in the study.

If a positive and significant effect of the MI intervention is found, this will be administered to the control group.

Dissemination

We will submit the trial´s results for presentation at international scientific meetings, and to peer-reviewed journals. We will become freely available the statistical codes, and anonymised data upon request to corresponding author.

4. DISCUSSION

In many developed countries, there is concern about the increase in the prevalence and severity of early childhood caries.[2-4] Caries in preschoolers is associated not only with high expense, but a strong functional, aesthetic and psychological impact on the children and their families.[41] Previous studies in disadvantaged communities of Chile show that the prevalence and severity of early childhood caries is high,[34-37] so strategies are needed to address it.

This project is motivated by the development, assessment and (prospective) implementation in Chile of new strategies to promote oral health. The target population is

preschool children of disadvantaged communities of Chile, as other similar populations across the world. This is a great challenge, considering that most public health interventions have had little impact on inequities in oral health at national,[41,42] and worldwide level. [1,43,44] Bearing these difficulties in mind, a pro-active approach is proposed, delivering oral health promotion directly to the home. This approach is based on the positive results of home visits in other health areas.[25-28]

Nowadays in Chile, the promotional aspect of oral health care is a secondary component of curative and preventative care. Most oral health care is delivered to specific groups (6-, 12-, and 60-years-old population, pregnant women, and those requiring urgent dental care) through the GES program (Explicit Health Guarantees, *Garantías Explícitas en Salud*).[41] Recently, an oral health intervention at the JUNJI and Integra´s kindergartens using the programme *"Sembrando Sonrisas"* has been introduced.[29] This intervention is focused on achieving better results in the oral health status of children when they are enrolled in the GES program at six years of age.

However, there are no explicit programmes involving caregivers in the oral health care of their children in Chile, despite the good results of a mother-child preventative dental programme developed in the country.[45] The evidence suggests that, if the adults responsible for the care of children are not committed, qualified and empowered with strategies to reinforce learning at home,[15-20] behavioural interventions performed at the schools are insufficient to improve the children´s oral health.[46] Within this context, there is a need to develop cost-effective interventions that impact on adult OHL in order to continue the virtuous circle started at the school or the kindergarten; otherwise, school-based interventions could be useless.

At the international level, many studies have been developed to assess strategies to promote oral health through MI,[2-4,21-24] and home visits,[25-28] aimed at the disadvantaged population. However, they have all been conducted in developed countries, namely: Australia,[2,4] Canada,[3] and the United States.[24] To our knowledge, there are no studies published from Latin American countries or other populations with similar socioeconomic and idiosyncratic conditions.

Despite the similarities with studies in developed countries, there are some relevant differences to mention: a) this project seeks to involve the entire family or, at least, all

caregivers, whereas other studies have focused only on mothers; to achieve this goal, the project introduces flexibility in the schedule of visits; b) other studies have used a low number of visits; in this study, a minimum of four and a maximum of six visits over three to ten weeks is planned; c) the incidence of caries between two and four years of age in this population is high, so these strategies could have a greater impact than those obtained in developed countries where incidence is lower; d) this project will use validated instruments to measure oral health literacy, giving a objective measure of the intervention´s impact on OHL; e) most previous studies have been conducted by using continuous monitoring and contact with the patients, making it difficult to estimate the real impact of the isolated intervention due to the implicit Hawthorne effect.[47]

In Chile, previous research on this matter has focused on preventative oral health care from pregnancy up to ten years later.[45] However there are some issues not addressed by this approach: a) a large proportion of the preschool Chilean population has not been followed from pregnancy; b) interventions have been used with mother-child dyads, omitting fathers or other caregivers; c) the promotional aspect of the intervention focuses on prescribing the "right behaviour"; this has little impact on oral health and the empowerment of the population.[6]

In summary, the main innovation of this study is the thorough assessment of an MI intervention at the community level, involving the caregivers of preschoolers in disadvantaged communities. Although this is the first trial of this intervention in a Latin American country, the recommendations generated from similar studies in disadvantaged populations of developed countries have been considered. This community trial will provide local evidence on the effectiveness on MIs in improving oral health outcomes and literacy in our disadvantaged population.

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Contributors

RCV, CA, RF, LL, FC and AB designed the study. LL provided statistical advice. RCV and RF wrote the manuscript. All authors proofed and edited the manuscript.

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Funder contact: Ms. Ximena González, e-mail: xgonzalez@conicyt.cl.

Competing interests

None declared.

Ethics approval

The study protocol was approved by the Bioethics Committee at the Universidad de Concepción School of Medicine with the code EI/21/2014.

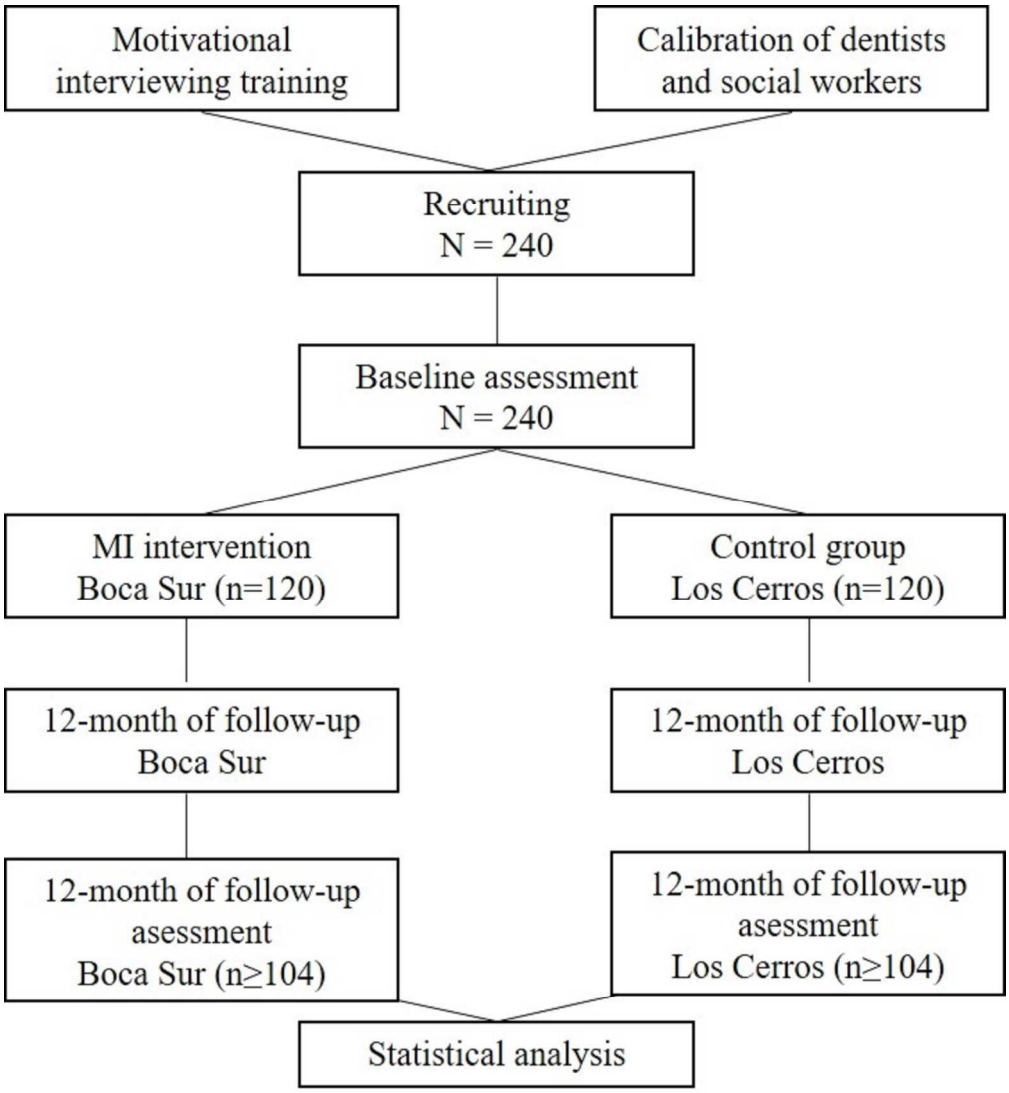

Figure 1
Figure 1
244x266mm (300 x 300 DPI)

Universidad de Concepción

FONIS N° SA14ID0162

Documento de Consentimiento Informado

Investigador Principal: Ricardo Cartes Velásquez
Organización: Departamento de Prevención y Salud Pública Odontológica, Universidad de Concepción
Patrocinador: FONIS
Proyecto: "Evaluación de una intervención de promoción en salud bucal desarrollada en el núcleo familiar de preescolares en sectores vulnerables urbanos. San Pedro de la Paz y Talcahuano. Ensayo comunitario."

Este Documento de Consentimiento Informado tiene dos partes:
– Información (proporciona información sobre el estudio)
– Formulario de Consentimiento (para firmar si está de acuerdo en participar)
Se le dará una copia del Documento completo de Consentimiento Informado como garantía de las condiciones de la participación de su institución.

PARTE I: Información

Introducción Mi nombre es Ricardo Cartes, dentista y docente del Departamento de Prevención y Salud Pública Odontológica, Universidad de Concepción, soy el investigador principal de un Proyecto de Investigación sobre el efecto de una intervención de promoción en salud bucal sobre la incidencia de caries después de un año, al cual le invita a participar.
Propósito Este estudio tiene como objetivo determinar el impacto sanitario medido a través de la incidencia de caries y niveles de alfabetismo en salud bucal luego de 12 meses de una intervención de promoción en salud bucal desarrollada en el núcleo familiar de preescolares en el sector de Boca Sur de San Pedro de la Paz en comparación a un grupo control en el sector Los Cerros de Talcahuano.
Tipo de Intervención La intervención de este proyecto consiste en 4 a 6 visitas domiciliarias con las siguientes características:

- Las visitas son realizadas siguiendo los lineamientos de la Entrevista Motivacional (EM) que busca la generación de motivos y metas por parte del mismo paciente y no la entrega de consejos por el agente sanitario.
- El desarrollo de la EM durante las visitas se ajustará a las necesidades de las propias familias con una cobertura mínima de los contenidos de: autocuidado en salud bucal y atención en el nivel de atención primaria de salud.
- Las visitas serán realizadas por 2 parejas conformadas por 2 técnicos en odontología previamente capacitados en la técnica de EM para salud bucal.
- Las visitas tienen una duración de 20 a 60 minutos.
- La primera visita se realizará durante las 3 semanas iniciales la intervención, las restantes visitas (3 a 5) serán acordadas con cada familia con una separación mínima de 1 semana y máxima de 2 semanas entre ellas.
- El horario y días de las visitas se ajustará a la disponibilidad de las familias intentando asegurar la participación de la mayor cantidad de padres y/o apoderados a cargo del preescolar, dentro de un horario de 8.00 a 21.00 horas de lunes a sábado.

Selección de participantes Se invitará a todos los preescolares y sus familias que residan en los sectores de Boca Sur en San Pedro de La Paz y Los Cerros en Talcahuano.
Participación Voluntaria Su participación será de carácter voluntario, mediado por un proceso de consentimiento informado.
Duración El proyecto tendrá una duración de 2 años, en los que deberá participar en un examen completo de su salud bucal y conocimientos, en 4 a 6 intervenciones de promoción y luego de 12 meses en un nuevo control de su salud bucal y conocimientos.
Riesgos Esta investigación no implica riesgos en contra de su bienestar físico o mental.
Beneficios Los beneficios serán mejorar su nivel de conocimientos y niveles de salud bucal, derivados de los resultados se podrán implementar programas que beneficien a toda la población preescolar nacional y sus familias.
Incentivos Los participantes (no) recibirán retribución económica por su participación.

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Confidencialidad se le solicitará identificarse con su RUT para relacionar los datos de las distintas encuestas, pero su confidencialidad será resguardada codificando la identidad de todos los participantes, la que sólo será conocida por el Investigador Principal y no será considerada durante el procesamiento de los datos ni en ningún otro momento. Además, los datos serán almacenados en ordenadores resguardados con clave.

Difusión de los Resultados Las publicaciones generadas a partir del proyecto, mantendrá el anonimato de la identidad de todos los estudiantes e instituciones participantes. Se le proporcionará un resumen ejecutivo si Ud. lo solicita.

Derecho a negarse o retirarse El rechazo a participar o el retiro en cualquier momento de la investigación no tendrán ningún tipo de castigo o consecuencia.

A Quién Contactar Cualquier pregunta respecto al desarrollo de la investigación o sobre los resultados de ésta, parcial o final, puede contactar con el investigador principal **Ricardo Cartes,** (*correo electrónico:* rcartes@udec.cl; *fono:* 41-2204386).

Universidad de Concepción

FONIS N° SA14ID0162

PARTE II: Formulario de Consentimiento

He sido invitado(a) a participar en una investigación, enmarcada en el proyecto FONIS N° SA14ID0162 titulado "***Evaluación de una intervención de promoción en salud bucal desarrollada en el núcleo familiar de preescolares en sectores vulnerables urbanos. San Pedro de la Paz y Talcahuano. Ensayo comunitario. percepción del Clima académico en el ciclo clínico de Odontología de la UdeC"***, cuyo investigador es el Dr. Ricardo Cartes y que tiene como objetivo determinar el impacto en los conocimientos y salud bucal de una intervención de promoción en salud bucal desarrollada en el núcleo familiar de preescolares en el sector de Boca Sur de San Pedro de la Paz en comparación a un grupo control en el sector Los Cerros de Talcahuano.

Por este motivo, se requiere mi participación respondiendo encuestas y completando un examen de salud bucal al inicio y al término del proyecto, así como participando en 4 a 6 intervenciones de promoción en mi hogar.

Asimismo, declaro que se me informó que mi participación será de carácter voluntario y mediado por un proceso de consentimiento informado. Para poder parear mis respuestas de las distintas, se solicita que me identifique con mi RUT al inicio de cada instrumento. No obstante, los investigadores se comprometen a que la información que entregaré en estos instrumentos sólo será utilizada para responder a los objetivos de este estudio, será confidencial, que los datos serán manejados exclusivamente por los investigadores, almacenados en ordenadores resguardados con clave y que en ningún caso serán analizados individualmente, pues a este estudio sólo le interesan el efecto a nivel general de la intervención en promoción.

En este mismo sentido, sólo se me hará entrega, si lo solicito, de un resumen ejecutivo con los resultados generales del estudio sin identificar a los participantes.

También se me ha garantizado que el estudio no implica exponerme a situaciones que atenten en contra de mi bienestar físico o mental y que no perjudicará mi atención en salud.

Si en algún momento siento que el proceso de encuestaje me incomoda puedo solicitar que se detenga inmediatamente la recolección.

Estoy al tanto que la participación que se me solicita es voluntaria, que no recibiré pago alguno por mi colaboración y que puedo negarme a participar o retirarme en cualquier etapa de la investigación, sin necesidad de dar explicaciones y que esto no tendrá ningún tipo de consecuencias para mí.

Por último, he sido informado que puedo pedir mayor información del estudio al investigador, **Dr. Ricardo Cartes,** escribiéndole a su correo rcartes@udec.cl.

A partir de los antecedentes antes mencionados acepto voluntariamente participar en este estudio.

Nombre del participante (Adulto) _____ RUT: _____

Nombre del participante (Preescolar) _____ RUT: _____

Firma del participante _____

Fecha: _____

Notas:

Usted se quedará con una copia de este consentimiento como garantía de las condiciones de su participación.

Si usted siente que sus derechos fueron vulnerados en este estudio puede comunicarse con el Comité de Bioética de la Facultad de Medicina de la Universidad de Concepción, escribiéndole a Liliana Ortiz al correo lilianaortiz@udec.cl o llamándole al fono (41) 2207083.

Si desea recibir un resumen ejecutivo de los resultados del estudio una vez que éste se encuentre terminado, indique su dirección de correo electrónico, o, si no posee una, indique su dirección de correo postal:

Correo electrónico: _____

Equipo investigador

Universidad de Concepción

FONIS N° SA14ID0162

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A partir de los antecedentes antes mencionados acepto voluntariamente participar en este estudio.

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Nombre del participante (Preescolar) _____ RUT: _____

Firma del participante _____

Fecha: _____

Notas:

Usted se quedará con una copia de este consentimiento como garantía de las condiciones de su participación.

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Correo electrónico: _____

Equipo investigador

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
	2b	All items from the World Health Organization Trial Registration Data Set	2
Protocol version	3	Date and version identifier	2
Funding	4	Sources and types of financial, material, and other support	19
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	19
	5b	Name and contact information for the trial sponsor	19
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	19
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	19

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4-5
	6b	Explanation for choice of comparators	4-5
Objectives	7	Specific objectives or hypotheses	5
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	5
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	6
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	10
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	NA
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	NA
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	NA
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	5,7,8
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	20

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	6-7
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	7
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	NA
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	NA
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	NA
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	5
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	NA
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	9-10
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	NA

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	9
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	11
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	11
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	11
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	NA
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	NA
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	11-12
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	NA
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	19
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	11-12

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	11-12
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	11-12
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	11-12
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	19
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	12
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	11-12
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	11-12
	31b	Authorship eligibility guidelines and any intended use of professional writers	11-12
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	11-12
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Appendix 1
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	11-12

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

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.

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Keywords:	Oral health literacy, Caries, Children, Home visits, Chile, Motivational interviewing

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.

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Keywords: Oral health literacy; Caries; Children; Home visits; Chile; Motivational interviewing.

Word count: 3746.

ABSTRACT

Introduction: Oral health education/promotion interventions have been identified as cost-efficient tools to improve the oral health of the population. These interventions are regularly made in contexts where the target population is captive, for example, in health centres. In Chile, there are no oral health interventions delivered at home.

Methods and analysis: This community trial covers two disadvantaged urban areas in the province of Concepción. Both sectors have public preschool education coverage with a traditional programme (TP) to promote oral health. The intervention will comprise four to six visits by dental hygienists trained in the delivery of a standardised oral health promotion programme using motivational interviewing (MI) at home. The experimental group will receive TP and MI, while the control group will receive only TP. If a positive and significant effect of MI is found, this will be administered to the control group. For a 50% reduction in the incidence of caries, a sample size of 120 preschoolers per group is estimated. Data will be gathered on demographic and socioeconomic variables; oral health outcomes using WHO oral health indicators (the prevalence and severity of caries, periodontal disease, dentofacial anomalies, and oral hygiene); the oral health literacy of caregivers, measured by the Rapid Estimation of Adult Literacy in Dentistry and the Oral Health Literacy Instrument, both validated for the Chilean population. Assessments will take place at baseline, and at 12-month follow-up.

Ethics and dissemination: The university bioethics committee approved this study (EI/21/2014). We will submit the trial´s results for presentation at international scientific meetings, and to peer-reviewed journals.

Trial registration number ACTRN12615000450516.

Protocol version: 2, January 6 2016.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- This project seeks to involve the entire family or, at least, all caregivers, whereas other studies have focused only on mothers; to achieve this goal, the project introduces flexibility in the schedule of visits.
- The incidence of caries between two and four years of age in this population is high, so these strategies could have a greater impact than those obtained in developed countries where incidence is lower
- This project will use validated instruments to measure oral health literacy, giving a objective measure of the intervention´s impact.
- Most previous studies have been conducted by using continuous monitoring and contact with the patients, making it difficult to estimate the real impact of the pure intervention.
- There are no home visits for the control group, which makes it difficult to assess the pure impact of the motivational interviewing intervention.

INTRODUCTION

Rationale

Dental caries remains one of the most prevalent chronic diseases in the world, demonstrating inequity in its distribution similar to other diseases. Worldwide, the disadvantaged population shows the greatest burden of oral disease.[1] A specific aspect of this inequity is the increased prevalence and severity of early childhood caries. This is a point of concern in developed and in developing countries.[2-4]

To explain the development of dental caries in children, several models have been proposed. Fischer-Owens et al.[5] proposed a conceptual model with five domains: genetic and biological factors, social environment, physical environment, health behaviours, and medical and dental care. These factors interact at three levels: child, family, and community; providing the opportunity to intervene at one or more points before the appearance of oral disease.

The biological domain has been historically addressed through the adoption of policies such as water fluoridation combined with other clinical preventative measures (e.g. sealants and topical fluorinations). In recent years, however, research into psychosocial and behavioural aspects has increased, using a health promotion approach.[4,5]

The practice of this new approach has been based on psychological theories seeking behaviour change in order to maintain and/or strengthen health.[6] The most important of these include the Health Belief Model,[7] the Stages of Change as a part of the Transtheoretical Model,[8,9] the Theory of Reasoned Action,[10] the concept of self-efficacy in Bandura´s Social Cognitive Theory,[11] and the sense of coherence in the Salutogenic Model of Antonovsky.[12]

The central target of these theories is some form of health literacy (HL). Health literacy is crucial; there is ample evidence indicating that low levels of HL is a risk factor for the appearance, perpetuation and aggravation of various diseases that bring functional, psychological, social, and economic consequences.[13]

Oral health literacy (OHL) focuses on dental aspects.[14] Research in OHL has been consistent with the findings regarding HL.[15] Several studies have found an association between caregivers´ OHL and the oral health outcomes of their children in

terms of the need for dental treatment,[16] the use of dental sealants,[17] oral health related quality of life,[18] deleterious habits,[19] and dental emergency expenses.[20]

Despite the above, promotional strategies focused on dental patients have only recently been considered.[2-4] 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] Motivational interviewing has shown good results in different dental settings.[2,4,22,23] However, these results are transitory and have negligible impact on the incidence of caries.[22,24]

Currently, there is scarce evidence on the effects of interventions delivered at home on OHL and the oral health outcomes of preschool children, although home visiting interventions have been sucessful in other child/pregnancy health outcomes.[25-28] The Chilean Ministry of Health is implementing an oral health intervention for preschoolers in kindergartens,[29] without plans (or evidence) to extend these programmes to home.

Objective and hypotheses

The main objective of this community trial is to evaluate at a 12-month follow-up the oral health impact, measured by the incidence of caries in preschoolers and OHL levels in caregivers, of an MI intervention delivered in the homes of disadvantaged families in Chile.

The hypotheses is that an MI intervention will achieve a decrease in the incidence of caries by 50% in preschoolers, and an increase of OHL levels by 30% in caregivers, at a 12-month follow-up. 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

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.

Since this intervention involves visiting the homes of the preschoolers, we may not achieve masking of patients or who delivered the MI intervention. The professionals who will remain blinded will comprise only those involved in the assessment at the 12-month follow-up.

The study does not include interim assessments because, considering the nature of the health promotional interventions, any contact or reminder to participants could act as a health intervention in itself.

Participants and selection criteria.

Participants comprise preschoolers and their caregivers living in the communities of Boca Sur at San Pedro de la Paz (MI intervention), and Los Cerros at Talcahuano (control group). Both communities have similar characteristics in terms of size and socioeconomic conditions. Both show high levels of social vulnerability and are separated by approximately 25 kilometers.

Participants must meet the following inclusion criteria: children aged between two and four years at the time of initiating the intervention, attending JUNJI (National Kindergarten Board, *Junta Nacional de Jardines Infantiles*) or Integra kindergartens in the communities mentioned above, and with a family member in charge (caregiver). The JUNJI and Integra kindergartens are the main organisations delivering preschool education at national level in Chile; both work in alliance with the Chilean Ministry of Health in oral health issues.[29]

Exclusion criteria were: preschoolers who are receiving dental treatment at the secondary level of care, and children or caregivers presenting with any physical and/or mental conditions that preclude the delivery of the MI intervention.

Sample size

For the calculation of sample size was considered a design effect[30] based on an intracluster correlation coefficient (ICC, denoted as ρ) of 0.01. There are no data available for these communities, so we used a ρ of 0.009, as described in previous research,[3] what had rounded up to 0.01 in this study.

Considering recent oral health research in similar Chilean groups of preschoolers,[31-34] the one-year incidence of caries, as assessed by the decay, missing, filled teeth (DMFT) index and the standard deviation (SD), were estimated at 4. Consequently, the goal was estimated at 2 in order to reduce by 50% the incidence of caries in the MI intervention group.

Therefore, the sample size estimation was made in four steps:

1. Students t-test for independent samples (two-sided, alpha=5%, power=80%, means difference=2, SD=4) gave an ni=64.
2. The design effect (de) is estimated as described elsewhere[30] (1+(ni-1)ρ), giving a de=1.63.
3. Loss rate during follow-up is estimated at 15%.
4. The final sample size is calculated as: 64 x 1.63 x 1.15 = 120 preschoolers with their caregivers per group. The minimum sample size to assess at 12-month follow-up is therefore 104 preschoolers with their caregivers, per group.

Patient recruitment

In order to obtain administrative support, all related institutions with the oral health of the preschoolers were contacted. The first contact was with the District Department of Health of San Pedro de la Paz, and Talcahuano; and the Province Office of Integra, and JUNJI. All agreed to participate in the study.

Secondly, the directors of all kindergartens in the two communities were contacted. All agreed to participate in the study and authorised us to participate in the monthly caregivers´ meetings and/or to send invitations to preschoolers´ homes in order to inform caregivers about the study. To avoid expectation effects, we only provide basic information about the study and ethical issues.

The information in the meetings will be delivered through a PowerPoint presentation, including the study´s aim, intervention, contacts, and ethical considerations. The information in the invitations includes the same information as in the PowerPoint

presentation, plus a date and time for data collection in the kindergartens or at the family health centre of the respective community. Patient recruitment will be stopped when the sample size is reached (See the Figure 1).

Variables

The study includes three groups of variables: socioeconomic and demographics, oral health outcomes, and OHL.

The *socioeconomic and demographics* variables will describe:

Firstly, the household composition, with a description of the preschooler´s nuclear family using a Genogram. The gender, age, occupation and level of education of each member will be included, and the relationships between them.

Secondly, each household's economic situation, with information on the income received by paid work of each member of the family, and state aid received from social programmes (Puente, Chile Solidario, and similar).

Oral health outcomes:

Caries: Assessment was made using the International Caries Detection System Assessment (ICDAS). The ICDAS codes will be transformed to DMFT and DMFT indicators.

Periodontal disease: Assessment was made using the Community Periodontal Index in adults. For preschoolers, ginigival inflammation was assessed at three levels: none, local, and generalised.

Dentofacial anomalies: Assessment was made using the Dental Aesthetic Index in adults. This variable was not considered in preschoolers.

Oral hygiene: Assessment was made using the Oral Simplified Hygiene index (OHI-S).

Oral health literacy: Assessment of caregivers´ OHL was made using two instruments.

The Oral Health Literacy Instrument (OHLI):[35] This is comprised of 57 items, divided into a first section of 38 missing words in a paragraph (Cloze procedure) about tooth decay and periodontal disease, and a second section of 19 items focused on numerical skills about medical prescriptions and instructions after dental procedures. For this study, a validated version of the OHLI for the Chilean population was used; this version shows a

Cronbach's alpha of 0.886 and an intraclass correlation coefficient of >0.6 for temporal stability [publication under peer-review]. 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].

Rapid Estimate of Adult Literacy in Dentistry, 30 items (REALD-30):[36] This comprises 30 words from the American Dental Association Glossary of Common Dental Terminology, and dental materials commonly available in dental clinics, arranged in order of increasing difficulty. For this study, a validated version of the OHLI for the Chilean population was used; this version shows a Cronbach's alpha of 0.876 and an intraclass correlation coefficient of 0.789 for temporal stability [publication under peer-review]. These values are comparable to the original REALD-30, which has a Cronbach's alpha of 0.87 [36].

Data collection

Data collection will be carried out at baseline (pre-intervention) and at a 12-month follow-up. An initial calibration will be made to assure the reliability of the data (See the Figure 1).

Calibration: The dentists and social workers will go through a calibration process consisting of an information day about the study and the instruments and indicators. Clinical calibration will performed at the Universidad de Concepción School of Dentistry with a sample of 12 preschoolers and their caregivers, recruited from the family health centres of Concepción.

Baseline: All assessments will be made directly at the kindergartens or the family health centre of the respective community. The caregivers will be informed, and they will sign the informed consent form (See the Appendix 1); the assent of the preschoolers will also be obtained. The study will accord with the conditions set by the WHO to carry oral health surveys.[37]

Each respondent (caregiver and preschooler) will be given an oral health care kit consisting of toothpaste and toothbrushes.

Data will be collected by a dentist and a dental assistant concerning oral health outcomes, and a social worker for socioeconomic and demographic data and OHL.

12-month follow-up: All assessments will be made at the Universidad de Concepción School of Dentistry (approximately 20 kilometers distant from both sectors).

The procedure will be the same as in the baseline assessment, but the assessment will be made by professionals blinded to the allocation of the participant to the control or experimental group to assure the single blind of the trial (See the Figure 1).

Caregivers will be contacted by telephone to arrange an appointment for the follow-up assessment. Transportation and other associated expenses incurred by travel to and from the School of Dentistry will be compensated with CLP $10,000 (USD $15). The caregiver will be instructed not to inform their community or indicate their group allocation to the professionals.

Training in motivational interviewing

A training course will be carried out with a duration of 40 hours spread over five days. 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. Those who pass will receive a certificate from the Universidad de Concepción School of Dentistry.

Applicants for the course will be selected according to their professional background and an interview. The course will have a maximum availability of 12 places; all will be assigned a full scholarship by the School of Dentistry. Preference will be given to dental assistants and dental hygienists working in the family health centres of the participating communities.

Four students will be selected from those who pass the course and obtain the highest grades to apply the MI intervention.

Intervention

Both the MI intervention and the control group will receive oral health interventions at kindergartens using the programme *"Sembrando Sonrisas"* ("Sowing smiles")[29] of the Oral Health Department in the Ministry of Health.

The MI intervention in this study comprises four to six home visits with the following characteristics:

1. The visits follow the principles of MI,[21] that seek to generate motivation and goals from the client and not the delivery of advice by the health worker.

2. The visits will be adjusted to the needs of the families themselves, covering at least self-care and oral health care, as recommended by the Chilean Ministry of Health.[29]
3. The visits will be made by couples of dental hygienists previously trained in the delivery of a standardised oral health promotion through MI.
4. The visits will have a duration of 15-45 minutes; normally, the first visit will be longer.
5. Besides the MI, some materials will be given to families: a leaflet about oral health, a dental colouring book with crayons, a Colgate® Dr. Rabbit DVD, stickers to remind participants about toothbrushing, and four to six plaque disclosing tablets to check the toothbrushing. 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.
6. The first visit will take place during the three weeks after the baseline assessment. The appointment for the remaining three to five visits will be agreed with each family, separated by 7-14 days.
7. The times and days of the visits will be adjusted to the availability of families, trying to ensure the participation of the preschooler´s caregivers, within a schedule from 8.00 to 21.00 hours from Monday to Saturday.

Statistical analysis

Univariate description of all variables (baseline and follow-up) will be performed using frequency tables (qualitative variables), summary measures (of central tendency and dispersion for quantitative variables), accompanied by relevant graphics (pie-charts, bars and histograms).

Regarding the psychometric properties of OHLI and REALD-30, the Cronbach´s alpha coefficient for internal consistency of the scales will be used. Regarding the calibration of the dentists and social workers, the strength of agreement will be determined with Kappa or Lin coefficients, depending on the nature of the variables.

To analyse the association between qualitative variables, the chi-square test will be used; and for the association of quantitative variables, the Pearson correlation coefficient.

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. If the necessary assumptions for parametric tests are not met, the corresponding non-parametric tests will be used.

Statistical significance will be set at $p<0.05$. The analysis will be made with Stata/SE 14 for Windows (StataCorp, TX, USA).

ETHICS AND DISSEMINATION

Ethical considerations

The study adheres strictly to the Declaration of Helsinki,[38] as well as the Chilean laws #20120 (research in humans),[39] and #20584 (rights and duties of the patient).[40]

All patients are informed about the aim of the study and they will give their informed consent (See the Appendix 1) in order to participate in the study.

If a positive and significant effect of the MI intervention is found, this will be administered to the control group.

Dissemination

We will submit the trial´s results for presentation at international scientific meetings, and to peer-reviewed journals. We will become freely available the statistical codes, and anonymised data upon request to corresponding author.

4. DISCUSSION

In many developed countries, there is concern about the increase in the prevalence and severity of early childhood caries.[2-4] Caries in preschoolers is associated not only with high expense, but a strong functional, aesthetic and psychological impact on the children and their families.[41] Previous studies in disadvantaged communities of Chile show that the prevalence and severity of early childhood caries is high,[34-37] so strategies are needed to address it.

This project is motivated by the development, assessment and (prospective) implementation in Chile of new strategies to promote oral health. The target population is

preschool children of disadvantaged communities of Chile, as other similar populations across the world. This is a great challenge, considering that most public health interventions have had little impact on inequities in oral health at national,[41,42] and worldwide level. [1,43,44] Bearing these difficulties in mind, a pro-active approach is proposed, delivering oral health promotion directly to the home. This approach is based on the positive results of home visits in other health areas.[25-28]

Nowadays in Chile, the promotional aspect of oral health care is a secondary component of curative and preventative care. Most oral health care is delivered to specific groups (6-, 12-, and 60-years-old population, pregnant women, and those requiring urgent dental care) through the GES program (Explicit Health Guarantees, *Garantías Explícitas en Salud*).[41] Recently, an oral health intervention at the JUNJI and Integra´s kindergartens using the programme *"Sembrando Sonrisas"* has been introduced.[29] This intervention is focused on achieving better results in the oral health status of children when they are enrolled in the GES program at six years of age.

However, there are no explicit programmes involving caregivers in the oral health care of their children in Chile, despite the good results of a mother-child preventative dental programme developed in the country.[45] The evidence suggests that, if the adults responsible for the care of children are not committed, qualified and empowered with strategies to reinforce learning at home,[15-20] behavioural interventions performed at the schools are insufficient to improve the children´s oral health.[46] Within this context, there is a need to develop cost-effective interventions that impact on adult OHL in order to continue the virtuous circle started at the school or the kindergarten; otherwise, school-based interventions could be useless.

At the international level, many studies have been developed to assess strategies to promote oral health through MI,[2-4,21-24] and home visits,[25-28] aimed at the disadvantaged population. However, they have all been conducted in developed countries, namely: Australia,[2,4] Canada,[3] and the United States.[24] To our knowledge, there are no studies published from Latin American countries or other populations with similar socioeconomic and idiosyncratic conditions.

Despite the similarities with studies in developed countries, there are some relevant differences to mention: a) this project seeks to involve the entire family or, at least, all

caregivers, whereas other studies have focused only on mothers; to achieve this goal, the project introduces flexibility in the schedule of visits; b) other studies have used a low number of visits; in this study, a minimum of four and a maximum of six visits over three to ten weeks is planned; c) the incidence of caries between two and four years of age in this population is high, so these strategies could have a greater impact than those obtained in developed countries where incidence is lower; d) this project will use validated instruments to measure oral health literacy, giving a objective measure of the intervention´s impact on OHL; e) most previous studies have been conducted by using continuous monitoring and contact with the patients, making it difficult to estimate the real impact of the isolated intervention due to the implicit Hawthorne effect.[47]

In Chile, previous research on this matter has focused on preventative oral health care from pregnancy up to ten years later.[45] However there are some issues not addressed by this approach: a) a large proportion of the preschool Chilean population has not been followed from pregnancy; b) interventions have been used with mother-child dyads, omitting fathers or other caregivers; c) the promotional aspect of the intervention focuses on prescribing the "right behaviour"; this has little impact on oral health and the empowerment of the population.[6]

In summary, the main innovation of this study is the thorough assessment of an MI intervention at the community level, involving the caregivers of preschoolers in disadvantaged communities. Although this is the first trial of this intervention in a Latin American country, the recommendations generated from similar studies in disadvantaged populations of developed countries have been considered. This community trial will provide local evidence on the effectiveness on MIs in improving oral health outcomes and literacy in our disadvantaged population.

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Contributors

RCV, CA, RF, LL, FC and AB designed the study. LL provided statistical advice. RCV and RF wrote the manuscript. All authors proofed and edited the manuscript.

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Funder contact: Ms. Ximena González, e-mail: xgonzalez@conicyt.cl.

Competing interests

None declared.

Ethics approval

The study protocol was approved by the Bioethics Committee at the Universidad de Concepción School of Medicine with the code EI/21/2014.

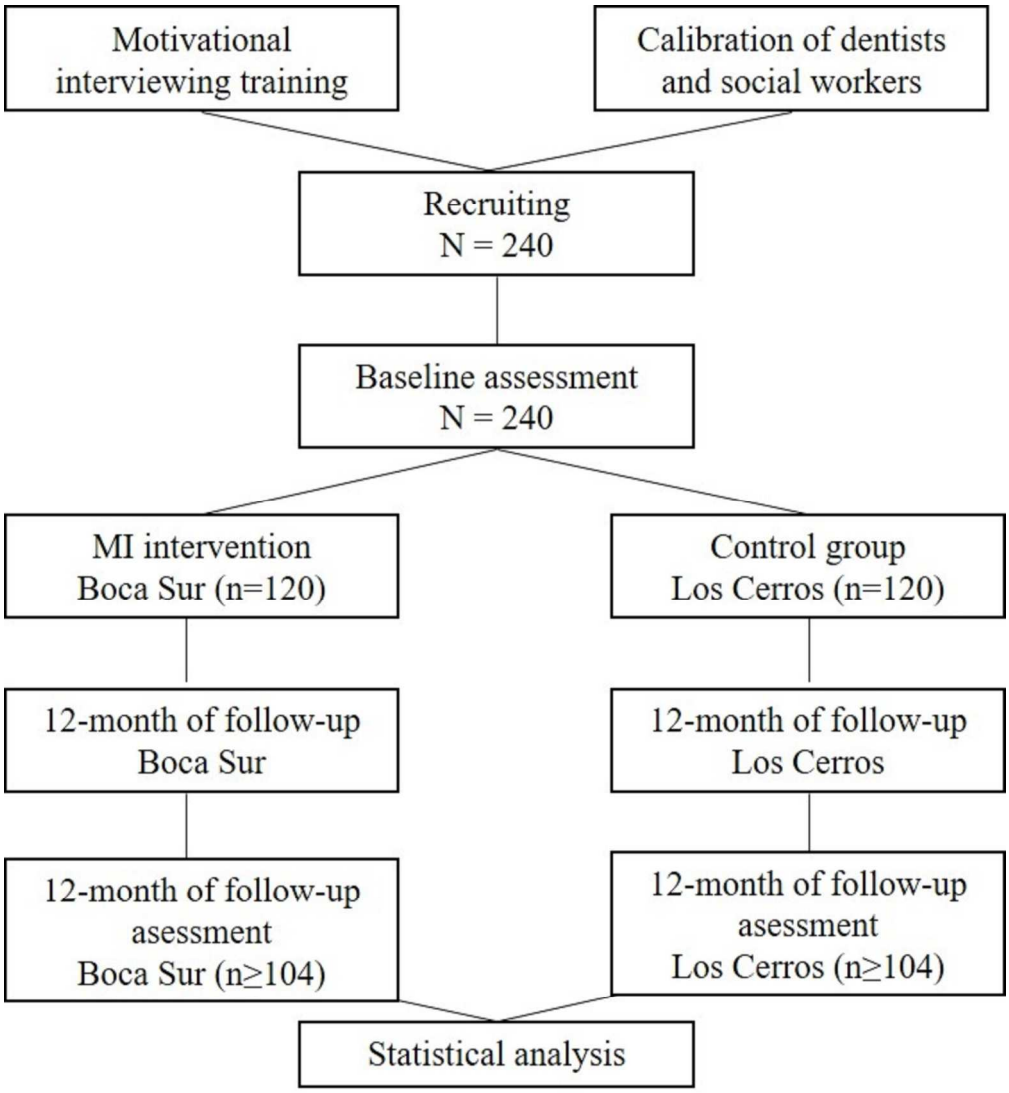

Figure 1
Figure 1
244x266mm (300 x 300 DPI)

Universidad de Concepción

FONIS N° SA14ID0162

Documento de Consentimiento Informado

Investigador Principal: Ricardo Cartes Velásquez
Organización: Departamento de Prevención y Salud Pública Odontológica, Universidad de Concepción
Patrocinador: FONIS
Proyecto: "Evaluación de una intervención de promoción en salud bucal desarrollada en el núcleo familiar de preescolares en sectores vulnerables urbanos. San Pedro de la Paz y Talcahuano. Ensayo comunitario."

Este Documento de Consentimiento Informado tiene dos partes:
– Información (proporciona información sobre el estudio)
– Formulario de Consentimiento (para firmar si está de acuerdo en participar)
Se le dará una copia del Documento completo de Consentimiento Informado como garantía de las condiciones de la participación de su institución.

PARTE I: Información

Introducción Mi nombre es Ricardo Cartes, dentista y docente del Departamento de Prevención y Salud Pública Odontológica, Universidad de Concepción, soy el investigador principal de un Proyecto de Investigación sobre el efecto de una intervención de promoción en salud bucal sobre la incidencia de caries después de un año, al cual le invita a participar.
Propósito Este estudio tiene como objetivo determinar el impacto sanitario medido a través de la incidencia de caries y niveles de alfabetismo en salud bucal luego de 12 meses de una intervención de promoción en salud bucal desarrollada en el núcleo familiar de preescolares en el sector de Boca Sur de San Pedro de la Paz en comparación a un grupo control en el sector Los Cerros de Talcahuano.
Tipo de Intervención La intervención de este proyecto consiste en 4 a 6 visitas domiciliarias con las siguientes características:

- Las visitas son realizadas siguiendo los lineamientos de la Entrevista Motivacional (EM) que busca la generación de motivos y metas por parte del mismo paciente y no la entrega de consejos por el agente sanitario.
- El desarrollo de la EM durante las visitas se ajustará a las necesidades de las propias familias con una cobertura mínima de los contenidos de: autocuidado en salud bucal y atención en el nivel de atención primaria de salud.
- Las visitas serán realizadas por 2 parejas conformadas por 2 técnicos en odontología previamente capacitados en la técnica de EM para salud bucal.
- Las visitas tienen una duración de 20 a 60 minutos.
- La primera visita se realizará durante las 3 semanas iniciales la intervención, las restantes visitas (3 a 5) serán acordadas con cada familia con una separación mínima de 1 semana y máxima de 2 semanas entre ellas.
- El horario y días de las visitas se ajustará a la disponibilidad de las familias intentando asegurar la participación de la mayor cantidad de padres y/o apoderados a cargo del preescolar, dentro de un horario de 8.00 a 21.00 horas de lunes a sábado.

Selección de participantes Se invitará a todos los preescolares y sus familias que residan en los sectores de Boca Sur en San Pedro de La Paz y Los Cerros en Talcahuano.
Participación Voluntaria Su participación será de carácter voluntario, mediado por un proceso de consentimiento informado.
Duración El proyecto tendrá una duración de 2 años, en los que deberá participar en un examen completo de su salud bucal y conocimientos, en 4 a 6 intervenciones de promoción y luego de 12 meses en un nuevo control de su salud bucal y conocimientos.
Riesgos Esta investigación no implica riesgos en contra de su bienestar físico o mental.
Beneficios Los beneficios serán mejorar su nivel de conocimientos y niveles de salud bucal, derivados de los resultados se podrán implementar programas que beneficien a toda la población preescolar nacional y sus familias.
Incentivos Los participantes (no) recibirán retribución económica por su participación.

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Confidencialidad se le solicitará identificarse con su RUT para relacionar los datos de las distintas encuestas, pero su confidencialidad será resguardada codificando la identidad de todos los participantes, la que sólo será conocida por el Investigador Principal y no será considerada durante el procesamiento de los datos ni en ningún otro momento. Además, los datos serán almacenados en ordenadores resguardados con clave.

Difusión de los Resultados Las publicaciones generadas a partir del proyecto, mantendrá el anonimato de la identidad de todos los estudiantes e instituciones participantes. Se le proporcionará un resumen ejecutivo si Ud. lo solicita.

Derecho a negarse o retirarse El rechazo a participar o el retiro en cualquier momento de la investigación no tendrán ningún tipo de castigo o consecuencia.

A Quién Contactar Cualquier pregunta respecto al desarrollo de la investigación o sobre los resultados de ésta, parcial o final, puede contactar con el investigador principal **Ricardo Cartes,** (*correo electrónico:* rcartes@udec.cl; *fono:* 41-2204386).

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PARTE II: Formulario de Consentimiento

He sido invitado(a) a participar en una investigación, enmarcada en el proyecto FONIS N° SA14ID0162 titulado "***Evaluación de una intervención de promoción en salud bucal desarrollada en el núcleo familiar de preescolares en sectores vulnerables urbanos. San Pedro de la Paz y Talcahuano. Ensayo comunitario. percepción del Clima académico en el ciclo clínico de Odontología de la UdeC"***, cuyo investigador es el Dr. Ricardo Cartes y que tiene como objetivo determinar el impacto en los conocimientos y salud bucal de una intervención de promoción en salud bucal desarrollada en el núcleo familiar de preescolares en el sector de Boca Sur de San Pedro de la Paz en comparación a un grupo control en el sector Los Cerros de Talcahuano.

Por este motivo, se requiere mi participación respondiendo encuestas y completando un examen de salud bucal al inicio y al término del proyecto, así como participando en 4 a 6 intervenciones de promoción en mi hogar.

Asimismo, declaro que se me informó que mi participación será de carácter voluntario y mediado por un proceso de consentimiento informado. Para poder parear mis respuestas de las distintas, se solicita que me identifique con mi RUT al inicio de cada instrumento. No obstante, los investigadores se comprometen a que la información que entregaré en estos instrumentos sólo será utilizada para responder a los objetivos de este estudio, será confidencial, que los datos serán manejados exclusivamente por los investigadores, almacenados en ordenadores resguardados con clave y que en ningún caso serán analizados individualmente, pues a este estudio sólo le interesan el efecto a nivel general de la intervención en promoción.

En este mismo sentido, sólo se me hará entrega, si lo solicito, de un resumen ejecutivo con los resultados generales del estudio sin identificar a los participantes.

También se me ha garantizado que el estudio no implica exponerme a situaciones que atenten en contra de mi bienestar físico o mental y que no perjudicará mi atención en salud.

Si en algún momento siento que el proceso de encuestaje me incomoda puedo solicitar que se detenga inmediatamente la recolección.

Estoy al tanto que la participación que se me solicita es voluntaria, que no recibiré pago alguno por mi colaboración y que puedo negarme a participar o retirarme en cualquier etapa de la investigación, sin necesidad de dar explicaciones y que esto no tendrá ningún tipo de consecuencias para mí.

Por último, he sido informado que puedo pedir mayor información del estudio al investigador, **Dr. Ricardo Cartes,** escribiéndole a su correo rcartes@udec.cl.

A partir de los antecedentes antes mencionados acepto voluntariamente participar en este estudio.

Nombre del participante (Adulto) _____ RUT: _____

Nombre del participante (Preescolar) _____ RUT: _____

Firma del participante _____

Fecha: _____

Notas:

Usted se quedará con una copia de este consentimiento como garantía de las condiciones de su participación.

Si usted siente que sus derechos fueron vulnerados en este estudio puede comunicarse con el Comité de Bioética de la Facultad de Medicina de la Universidad de Concepción, escribiéndole a Liliana Ortiz al correo lilianaortiz@udec.cl o llamándole al fono (41) 2207083.

Si desea recibir un resumen ejecutivo de los resultados del estudio una vez que éste se encuentre terminado, indique su dirección de correo electrónico, o, si no posee una, indique su dirección de correo postal:

Correo electrónico: _____

Equipo investigador

Universidad de Concepción

FONIS N° SA14ID0162

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He sido invitado(a) a participar en una investigación, enmarcada en el proyecto FONIS N° SA14ID0162 titulado "***Evaluación de una intervención de promoción en salud bucal desarrollada en el núcleo familiar de preescolares en sectores vulnerables urbanos. San Pedro de la Paz y Talcahuano. Ensayo comunitario. percepción del Clima académico en el ciclo clínico de Odontología de la UdeC"***, cuyo investigador es el Dr. Ricardo Cartes y que tiene como objetivo determinar el impacto en los conocimientos y salud bucal de una intervención de promoción en salud bucal desarrollada en el núcleo familiar de preescolares en el sector de Boca Sur de San Pedro de la Paz en comparación a un grupo control en el sector Los Cerros de Talcahuano.

Por este motivo, se requiere mi participación respondiendo encuestas y completando un examen de salud bucal al inicio y al término del proyecto, así como participando en 4 a 6 intervenciones de promoción en mi hogar.

Asimismo, declaro que se me informó que mi participación será de carácter voluntario y mediado por un proceso de consentimiento informado. Para poder parear mis respuestas de las distintas, se solicita que me identifique con mi RUT al inicio de cada instrumento. No obstante, los investigadores se comprometen a que la información que entregaré en estos instrumentos sólo será utilizada para responder a los objetivos de este estudio, será confidencial, que los datos serán manejados exclusivamente por los investigadores, almacenados en ordenadores resguardados con clave y que en ningún caso serán analizados individualmente, pues a este estudio sólo le interesan el efecto a nivel general de la intervención en promoción.

En este mismo sentido, sólo se me hará entrega, si lo solicito, de un resumen ejecutivo con los resultados generales del estudio sin identificar a los participantes.

También se me ha garantizado que el estudio no implica exponerme a situaciones que atenten en contra de mi bienestar físico o mental y que no perjudicará mi atención en salud.

Si en algún momento siento que el proceso de encuestaje me incomoda puedo solicitar que se detenga inmediatamente la recolección.

Estoy al tanto que la participación que se me solicita es voluntaria, que no recibiré pago alguno por mi colaboración y que puedo negarme a participar o retirarme en cualquier etapa de la investigación, sin necesidad de dar explicaciones y que esto no tendrá ningún tipo de consecuencias para mí.

Por último, he sido informado que puedo pedir mayor información del estudio al investigador, **Dr. Ricardo Cartes,** escribiéndole a su correo rcartes@udec.cl.

A partir de los antecedentes antes mencionados acepto voluntariamente participar en este estudio.

Nombre del participante (Adulto) _____ RUT: _____

Nombre del participante (Preescolar) _____ RUT: _____

Firma del participante _____

Fecha: _____

Notas:

Usted se quedará con una copia de este consentimiento como garantía de las condiciones de su participación.

Si usted siente que sus derechos fueron vulnerados en este estudio puede comunicarse con el Comité de Bioética de la Facultad de Medicina de la Universidad de Concepción, escribiéndole a Liliana Ortiz al correo lilianaortiz@udec.cl o llamándole al fono (41) 2207083.

Si desea recibir un resumen ejecutivo de los resultados del estudio una vez que éste se encuentre terminado, indique su dirección de correo electrónico, o, si no posee una, indique su dirección de correo postal:

Correo electrónico: _____

Equipo investigador

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
	2b	All items from the World Health Organization Trial Registration Data Set	2
Protocol version	3	Date and version identifier	2
Funding	4	Sources and types of financial, material, and other support	19
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	19
	5b	Name and contact information for the trial sponsor	19
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	19
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	19

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4-5
	6b	Explanation for choice of comparators	4-5
Objectives	7	Specific objectives or hypotheses	5
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	5
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	6
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	10
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	NA
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	NA
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	NA
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	5,7,8
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	20

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	6-7
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	7
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	NA
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	NA
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	NA
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	5
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	NA
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	9-10
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	NA

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	9
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	11
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	11
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	11
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	NA
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	NA
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	11-12
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	NA
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	19
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	11-12

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	11-12
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	11-12
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	11-12
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	19
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	12
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	11-12
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	11-12
	31b	Authorship eligibility guidelines and any intended use of professional writers	11-12
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	11-12
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Appendix 1
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	11-12

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.