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Avaliação da Promoção da Autorregulação em saúde: estudo no contexto do Programa Saúde na Escola no Rio Grande do Sul/Brasil.

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Tese submetida ao Programa de Pós-Graduação em Ciências da Saúde da Universidade Federal de Ciências da Saúde de Porto Alegre como requisito para a obtenção do grau de Doutor

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Dedico este estudo a todos os trabalhadores, profissionais da saúde e da educação que acreditam e lutam todo dia para construir espaços com uma educação emancipatória, que seja propulsora de autonomia, que ajude a pensar e não a executar e que seja promotora de saúde.

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RESUMO

Este estudo se situa no campo da promoção da autorregulação para a saúde entre escolares. No domínio da saúde, o construto da autorregulação pode contribuir para a compreensão de hábitos de vida que contribuem para melhorias na saúde dos indivíduos. Diante disso, este estudo teve o objetivo de realizar e avaliar um programa de intervenção de promoção da autorregulação nas temáticas de alimentação saudável e saúde bucal, sob perspectiva da teoria social cognitiva, em atividades relacionadas ao Programa Saúde na Escola (PSE). O estudo foi desenvolvido nos anos de 2015 a 2018, no município de Sapucaia do Sul-RS, e recebeu financiamento da CAPES, pelo Programa Ciência Sem Fronteiras, no Edital 09/2014, Processo: 88881.068058/2014-01. **Métodos e análises:** Trata-se de um ensaio clínico randomizado (ClinicalTrials.gov: NCT03222713) com a população de turmas do 5º ano de escolas municipais de Sapucaia do Sul/RS Brasil, estruturado em duas fases. Na fase 1, os professores e profissionais da saúde participaram de um Programa de Formação em Promoção de Autorregulação em Saúde e, na fase 2, foi realizado um Programa de Intervenção em Autorregulação (PARS) com os escolares. Os participantes foram randomizados em três grupos (grupo Experimental I - G2, Experimental II - G3 e grupo controle - G1). Para medidas de avaliação da eficácia do programa de intervenção (PARS) com os alunos, foram utilizados: um desenho de pre-post de medidas repetidas, empregando questionário alimentar do dia anterior (QUADA); um questionário de conhecimento declarativo sobre alimentação saudável e saúde bucal; uma escala de autorregulação para a saúde, uma escala de autoeficácia para a saúde e duas avaliações de medidas físicas, índice de massa corporal (IMC) e índice de higiene oral simplificado (IHOS). Todos os instrumentos foram validados para o contexto brasileiro em outro estudo à parte e utilizados nesta pesquisa. **Resultados:** Os dados dos escolares selecionados, de onze escolas do ensino fundamental, foram alocados nos grupos de tratamento e medidos em cinco momentos (antes do início da intervenção, após 3 meses de intervenção, após 6 meses intervenção, final da intervenção e 6 meses após final da intervenção) considerando seis variáveis dependentes (AR_AL e AR SB - autorregulação alimentação saudável e saúde bucal; AE_AL e AE SB - autoeficácia alimentação saudável e saúde bucal; CD_AL e CD SB - conhecimento declarativo

alimentação saudável e saúde bucal; FV_AL FV SB - frutas e legumes alimentação saudável e saúde bucal; IMC_AL - índice de massa corporal; UP_AL e UP SB - alimentos ultraprocessados alimentação saudável e saúde bucal; e IHOS_SB - índice de higiene oral simplificado). Como as médias do Grupo de alunos participantes do PARS (G 3) aumentaram (AR_AL e SB, AE_AL e SB, CD_AL e SB, FV_AL e SB e IHOS_SB - boa higiene oral) ou diminuíram (IMC_AL - sobrepeso e obesidade e UP_AL) ao longo do tempo, parece haver uma melhora consistente nas medidas dos participantes ao longo do tempo. Portanto, nesse caso, o tempo de implementação do programa foi crucial para avaliar a eficácia da intervenção.

Conclusões: A atuação intersetorial de promoção de saúde (PSE) e da autorregulação focaliza a contribuição para a construção de novos dispositivos para mudança de comportamento e hábitos saudáveis. O PARS ajudou a reduzir os problemas de saúde das crianças (por exemplo, aumentar o consumo de frutas e vegetais e melhorar a higiene e escovação em relação à saúde bucal), bem como reforçou as políticas públicas de promoção da alimentação saudável e de saúde bucal nas escolas, pois auxiliou a mudar os hábitos de saúde.

Palavras-chave: Autorregulação para a saúde; Programa Saúde na Escola (PSE), alimentação saudável, saúde bucal.

Abstract

This study is located in the field of promoting self-regulation for health among school children. In the field of health, the self-regulation construct can contribute to the understanding of life habits that contribute to the improvement of individuals' health. The objective of this study was to perform and evaluate an intervention program to promote self - regulation in the themes of healthy eating and oral health, under the lens of the perspective of cognitive social theory, in activities related to the School Health Program (Programa Saúde na Escola -PSE). The study was developed in the years 2015 to 2018, in the city of Sapucaia do Sul-RS and was financially suported by CAPES, by the Science without Borders Program in Public Notice 09/2014, Process: 88881.068058 / 2014-01. **Methods and analysis**: This is a randomized clinical trial (ClinicalTrials.gov: NCT03222713), with the population of classes of the 5th year of municipal schools in Sapucaia do Sul / RS Brazil, structured in two phases. In phase 1, teachers and health professionals participated in a training

program to promote self-regulation in health and in phase 2 an intervention program in self-regulation (PSRH) was carried out. Participants were randomized into three groups (Experimental group I – G2, Experimental group II – G3 and control group – G1). For measures to evaluate the effectiveness of the intervention program with the students, a pre-post design of repeated measures was used, using a Previous Day Food Questionnaire (PFDQ); a declarative knowledge questionnaire on healthy eating and oral health; a scale of self-regulation for health and a scale of self-efficacy for health and two evaluations of physical measures, body mass index - BMI and simplified oral hygiene index - IHOS. All the instruments were validated for the Brazilian context in another study a used in this research. **Results:** Data from selected schoolchildren from eleven elementary schools were allocated to the treatment groups and measured at five times and six dependent variables (AR_AL and AR SB - self-regulation of healthy food and oral health, AE_AL and AE SB - self-efficacy healthy eating and oral health, CD_AL and CD SB - declarative knowledge healthy eating and oral health, FV_AL FV SB - fruits and vegetables healthy eating and oral health, IMC_AL - body mass index, UP_AL and UP SB - ultraprocessed foods and oral health and IHOS_SB - simplified oral hygiene index). As the means of Group 3 increased (AR_AL and SB, AE_AL and SB, CD_AL and SB, FV_AL and SB and IHOS_SB - good oral hygiene) or decreased (IMC_AL - overweight and obesity and UP_AL) over time, there seems to be an improvement consistent with participants' measures over time. Therefore, in this case, the program implementation time is crucial to evaluate the effectiveness of the intervention.

Conclusions: This intersectorial action of health promotion (PSE) and self-regulation focuses on the contribution to the construction of new devices for behavior change and healthy habits. PSRH has helped to reduce children's health problems, as well as strengthened public policies to promote healthy eating and oral health in schools, as well as helped to change health habits (eg increase fruit and vegetable consumption and improve hygiene and toothbrushing in relation to oral health).

Keywords: Self-regulation for health; Health in School Program (PSE), healthy eating and oral health

SUMÁRIO

1 APRESENTAÇÃO

Este trabalho consiste na Tese de Doutorado intitulada “Avaliação da Promoção da Autorregulação em saúde: estudo no contexto do Programa Saúde na Escola no Rio Grande do Sul/Brasil”, apresentada ao Programa de Pós-Graduação em Ciências da Saúde da Universidade Federal de Ciências de Saúde de Porto Alegre. O trabalho é apresentado em três partes.

Na primeira parte, a Contextualização, a Revisão da Literatura e os Objetivos nos capítulos 2, 3 e 4, respectivamente.

Na segunda parte, os Artigos oriundos da Tese: Artigo I - Artigo de protocolo que descreve a metodologia do programa do estudo e sua base teórica (já publicado na revista *Frontiers in Psychology*); Artigo II - Artigo empírico que apresenta os dados, da temática da alimentação saudável, relacionados à avaliação do programa do estudo; e Artigo III - Artigo empírico que apresenta os dados, da temática de saúde bucal, relacionados à avaliação do programa do estudo, a ser submetido para publicação.

Na terceira parte, as Considerações Finais são apresentadas. Após, as Referências e, por fim, os documentos de apoio, incluindo o Parecer do Comitê de Ética em Pesquisa e os instrumentos utilizados na pesquisa, que são apresentados nos Anexos. Os instrumentos estão disponíveis de forma parcial, pois ainda não foram publicados.

2 CONTEXTUALIZAÇÃO

O sistema Brasileiro de saúde, o Sistema Único de Saúde (SUS), é regulado pela Lei nº 8.080 de 1990, que traz o dever do Estado na garantia da saúde, por meio da formulação e execução de políticas econômicas e sociais que visem à redução de riscos de doenças e de outros agravos, assegurando acesso universal e igualitário às ações e aos serviços para a sua promoção, proteção e recuperação (BRASIL, 1990). Saúde esta que possui diversos determinantes e condicionantes, como a alimentação, o meio ambiente, a educação, a atividade física, o lazer e o acesso aos bens e serviços essenciais (BRASIL, 1990). Em função dessa complexidade, é necessário que a atuação intersetorial e, portanto, o envolvimento de outros setores parceiros, seja essencial para que se concretizem ações mais amplas e com o objetivo de integralidade da saúde da população. Para o desenvolvimento dessas ações e a implantação de atividades de promoção, prevenção e atenção à saúde, a escola torna-se um dos principais espaços de protagonismo. Essa mostra-se um espaço para a convivência social e para o estabelecimento de relações favoráveis à promoção da saúde pelo viés de uma Educação Integral (FIGUEIREDO, 2010).

Na década de 1990, foram constituídas e estabelecidas algumas das principais referências para a educação formal no Brasil, entre elas, os Parâmetros Curriculares Nacionais (PCNs). (BRASIL, 1997). O Ministério da Educação, por meio desse documento, incentiva que as escolas assumam de forma transdisciplinar os temas transversais, conferindo atenção especial aos temas ética, saúde, meio ambiente, orientação sexual, pluralidade cultural, trabalho e consumo (BRASIL, 1997). Também na década de 1990, a Organização Pan-Americana de Saúde (OPAS) estimulou a implantação da Iniciativa Regional Escolas Promotoras de Saúde (IREPS). Organizadas com o foco no trabalho articulado entre educação, saúde e sociedade, essas passaram a encarar a estratégia de promoção da saúde no espaço escolar com enfoque integral, tendo três componentes relacionados entre si: educação para a saúde com foco na integralidade, incluindo o desenvolvimento de habilidades para a vida; criação e manutenção de ambientes físicos e psicossociais saudáveis; e oferta de serviços de saúde, alimentação saudável e vida ativa (BRASIL, 2007).

Entretanto, a educação em saúde na escola ainda tem sido compreendida, usualmente, como objeto de intervenções pontuais e como lugar de aplicação de controle e prevenção de

doenças, por ser a escola encarada como um lugar onde os alunos seriam um grupo passivo para a realização de ações de saúde (BRASIL, 2007a; FIGUEIREDO, 2010). Assim, procurando modificar esse panorama da saúde escolar no Brasil, tendo como norteadoras as experiências e diretrizes anteriormente citadas, o Ministério da Saúde e o da Educação, em 2007, instituí o Programa Saúde na Escola (PSE). Apesar dos esforços e da reorganização de uma proposta de trabalho focada na melhoria da saúde dos escolares, algumas situações de saúde (como a saúde bucal e o estado nutricional) ainda são consideradas como problemas de saúde pública no País (WORLD HEALTH ORGANIZATION, 2016).

Diante disso, os governos têm assumido uma posição de tomar medidas mais normativas em relação a políticas públicas, principalmente no que se refere à alimentação saudável, que possam auxiliar o Programa Saúde na Escola a reverter esse quadro. Nessa lógica, no ano de 2007, foi aprovado, pela Câmara dos Deputados, o projeto de lei (PL) nº 1.755/2007, que proíbe a comercialização de refrigerantes em escolas públicas e privadas na educação básica, envolvendo do ensino infantil ao médio (BRASIL, 2007c). Da mesma forma, nessa perspectiva, recentemente, foi alterada a LDB (lei 9.394 de 1996), que estabelece as diretrizes para a educação nacional do país, para inclusão, no art. 24, do § 9º A que inclui a Educação Alimentar e Nutricional (EAN) como tema transversal no currículo escolar (BRASIL, 1996; BRASIL, 2018).

Portanto, diante desse cenário, torna-se relevante pesquisar dispositivos que possam potencializar as estratégias desenvolvidas no âmbito do PSE e que também ofereçam novas ferramentas para subsidiar o trabalho interdisciplinar entre a saúde e a educação. Essa articulação interdisciplinar, em prol de ações de promoção de saúde, e a possível criação de novos dispositivos para mudança de comportamento na direção de hábitos saudáveis, podem auxiliar na redução de problemas de saúde na população infantil, assim como na diminuição de gastos públicos com tratamentos de recuperação e reabilitação da saúde nessa área.

Face ao exposto, o que objetiva essa investigação é a compreensão e implementação da promoção da autorregulação em saúde (ARS), para escolares, no contexto do Programa Saúde na Escola, propiciando a ampliação do processo de educação em saúde e hábitos mais saudáveis de vida para essa população. Dessa forma, faz-se necessário discutir sobre marcos teóricos que contextualizam e orientam o desenvolvimento da pesquisa, como a base dos processos de promoção de saúde de educação em saúde, o Programa Saúde na Escola como Política Pública, a Teoria Social Cognitiva, que embasa o contruto da Autorregulação em

saúde para esse trabalho e a utilização das narrativas como potente recurso para a promoção da ARS.

3 REVISÃO DA LITERATURA

3.1 Promoção e Educação em Saúde

A promoção de saúde vem sendo desenvolvida em vários âmbitos no cuidado em saúde e, principalmente, em atividades de educação em saúde (HEIDMANN et al., 2006). Desde a carta de Ottawa, a proposta de educação em saúde integra, em parte, a compreensão do conceito de promoção à saúde, englobando cinco estratégias em sua concepção: “políticas públicas saudáveis, ambientes favoráveis à saúde, reorientação dos serviços de saúde, reforço da ação comunitária e desenvolvimento de habilidades pessoais”. (HEIDMANN et al., p.356 , 2006).

Para que a promoção da saúde ocorra de maneira eficiente, com o objetivo de ampliação de cuidado e com a instrumentalização da educação em saúde, é importante que, além da compreensão da temática a ser trabalhada, dos conceitos e dos aspectos que ela abrange, aconteça a associação dessa prática à comunicação, à informação, à educação e a uma escuta qualificada. Dessa forma os processos de educação devem provocar, além da oferta de informações e conhecimento, a relação desse conhecimento com os contextos de vida das pessoas, auxiliando a construção de sentido no seu cuidado em saúde. (SALCI et al., 2013). Portanto, a educação torna-se um dos pontos fundamentais para a saúde e, dessa forma, a promoção da saúde auxilia o desenvolvimento pessoal e social através da divulgação de informações, educação em saúde e aperfeiçoamento das habilidades vitais dos indivíduos e dos coletivos (BOEHS et al., 2007; WORLD HEALTH ORGANIZATION, 1986).

A educação em saúde tem estabelecido como foco prioritário a mudança do comportamento individual ou de aspectos intrapessoais, como atitudes e crenças, avaliadas como possíveis determinantes do comportamento, com o intuito de auxiliar a promover um melhor estado de saúde (BENNETT & MURPHY, 1999). De acordo com Tonnes & Tilford

(1994), a educação para a saúde é definida como qualquer atividade que possa ser planejada com o objetivo de promover aprendizagem em relação à saúde ou doença, ou seja, qualquer modificação relativamente permanente na competência ou disponibilidade para o cuidado em saúde de um indivíduo.

Essa temática vem sendo abordada em instituições escolares, visto que essas têm sido consideradas como espaços ideais de aprendizagem, por meio de programas educacionais para a saúde que objetivam ofertar ferramentas que favoreçam o desenvolvimento de habilidades para o cuidado em saúde nos estudantes e, portanto, contribuam para o seu desenvolvimento integral (MANTILLA-URIBE et al., 2015). As fases de desenvolvimento da infância e adolescência, acompanhadas com proximidade no cenário escolar, são de extrema importância para a construção de estilos de vida saudáveis, uma vez que os hábitos desenvolvidos e adquiridos nessas etapas de vida podem ser mantidos e perpetuados para a vida adulta (FRIEDRICH et al., 2014). Os investimentos em hábitos saudáveis nessas faixas etárias devem ser prioridade para os setores educacionais e sociais, principalmente para os espaços da escola, por serem locais privilegiados para a elaboração de programas de intervenção voltados para a saúde, já que reúnem a maioria das crianças e adolescentes do país, considerando que, aproximadamente, 56,5 milhões de alunos estão matriculados nos Ensinos Fundamental e Médio da rede pública (INEP, 2017).

Como já referido anteriormente, a criação do PSE foi estratégica para a implementação de práticas e ações sistematizadas no contexto escolar. A dinâmica de atividades desenvolvidas no PSE está pautada nos processos de educação em saúde e na implantação de ações de promoção de saúde nos diferentes âmbitos da situação de saúde dos escolares, sendo as temáticas de alimentação saudável e saúde bucal consideradas como dois dos temas centrais (BRASIL, 2015).

3.2 Programa Saúde na Escola – PSE

O Programa Saúde na Escola (PSE) tem como objetivo a integração e a articulação da educação e da saúde de modo permanente, a fim de contribuir para a formação integral dos estudantes da rede pública de educação básica. O Programa propõe que as ações devem ser firmadas entre a escola, a partir de seu projeto político-pedagógico, e a unidade básica de saúde, considerando o contexto escolar e social e o diagnóstico local em saúde do escolar. Para alcançar esses propósitos, o PSE se constituiu, entre outros, pelos componentes: a)

Avaliação das Condições de Saúde das crianças, adolescentes e jovens que estão na escola pública; b) Promoção da Saúde e de atividades de Prevenção; c) Educação Permanente e Capacitação dos Profissionais da Educação e da Saúde e de Jovens (BRASIL, 2015).

A partir da Portaria Interministerial nº 1.911/2011, que estabelece critérios para transferência de recursos aos municípios credenciados ao Programa Saúde na Escola (PSE), os Ministérios da Saúde e Educação ampliam as ações do PSE, sendo possíveis a adesão e a transferência de recursos vinculados à execução do programa a todos os municípios brasileiros. Como exemplo da potencialidade de alcance e disseminação de ações do PSE, no ano de 2012, 2495 municípios brasileiros aderiram e foram realizadas, no eixo "alimentação saudável", 6.361.998 avaliações antropométricas e ainda 9.162.825 educandos participaram de ações de promoção da alimentação saudável (BRASIL, 2013). Em 2017, mais de 20 milhões de estudantes, em 85,7 mil escolas, foram envolvidos, em atividades como atualização vacinal, prevenção à obesidade e cuidados com a saúde bucal. O programa faz parceria com mais de 36 mil equipes da atenção primária em saúde (BRASIL, 2017).

Em todas as regiões do país, demonstra-se um número expressivo de atividades desenvolvidas pelo Programa. Porém, essas ações ainda não ocorrem de forma sistemática e com a mesma proporção, sendo a região Norte a área que mais executa atividades relacionadas ao PSE (80,5%) enquanto que as regiões Sul e Sudeste são as áreas com menor percentual de atividades (69,4%) (MACHADO et al., 2015). Para a concretização dessas ações, a colaboração e o envolvimento de todos os atores são essenciais para o desenvolvimento pleno das metas e atividades do PSE. Nesse campo, um dos desafios para essa implementação é a formação dos profissionais da área da educação para construir e trabalhar com educação em saúde (SILVA et al., 2014).

No entanto, é necessário destacar que não é suficiente somente oportunizar o espaço para o desenvolvimento de promoção e educação em saúde de forma intersetorial (educação e saúde), mas, também, construir, com os usuários, a relação sobre a importância da corresponsabilidade nessas práticas, ressaltando a participação dos estudantes na mobilização, formação e ampliação de aprendizagem de habilidades individuais e sociais para lidar com os processos saúde-doença (ARASH & CARPENTIER, 2014). Nessa lógica, torna-se essencial que essas ações e atividades estejam coerentes com os pressupostos orientadores da promoção de saúde, o que se coloca como um desafio, visto que as práticas

predominantes ainda estão pautadas em características curativistas e individualistas. (MACHADO et al., 2015).

Dessa forma, a manutenção e a sustentabilidade do PSE, para além de somente um programa de governo dentro de uma perspectiva de uma política de Estado, provocam uma superação do modelo biomédico, curativista e individualista de atenção e cuidado ofertados aos estudantes, para uma proposta de promoção de saúde com a participação concreta de todos os atores envolvidos, gestores, profissionais das Estratégias de Saúde da Família - ESF, escola e comunidade escolar (estudantes, pais, comunidade dos territórios) no enfrentamento de suas necessidades. Com isso, desenvolve-se um trabalho com capacidades individuais e coletivas existentes (FERREIRA et al., 2014). Diante dessa perspectiva, é fundamental que se possa planejar, estruturar e implementar as ações, voltadas para as temáticas da alimentação saudável e saúde bucal, seguindo os pressupostos teóricos discutidos dentro do cenário da Educação em Saúde.

3.2.1 Educação em Saúde: alimentação saudável

Estudos com propostas próximas à temática da alimentação saudável, que buscaram avaliar ações no campo da educação alimentar e nutricional no ambiente escolar no Brasil, são escassos e apresentam uma maior concentração a partir do ano de 2009, mostrando o crescente interesse pela área em estudo, possivelmente motivado pela também crescente atenção das políticas públicas para promoção em saúde no ambiente escolar (RAMOS et al., 2013; BRASIL 2007a; BRASIL 2007b). Apesar do crescimento e interesse por esse campo, são poucas as intervenções com escolares que objetivam atividades de educação nutricional para a diminuição de fatores de risco à saúde de crianças e adolescentes. Além disso, as metodologias, tipos de intervenção, efetividade e os impactos na saúde dessa população são pouco divulgados e/ou conhecidos (FARIAS et al., 2009; SILVA et al., 2013).

Uma revisão mais recente da literatura, compreendendo os estudos no Brasil, nos anos de 2000-2011, encontrou 13 publicações sobre a temática (RAMOS et al., 2013). Os principais métodos de avaliação das ações empregadas por esses estudos analisados foram a avaliação antropométrica, do conhecimento e do consumo alimentar. As autoras da revisão sistemática da literatura questionam a utilização desses métodos, assim como o critério de eficácia de uma ação de educação alimentar e nutricional a ser considerado, pois esses instrumentos não permitiriam a avaliação crítica do processo educativo e suas complexidades, mas somente

dos resultados objetivos (RAMOS et al., 2013). Uma pesquisa de revisão mais atualizada analisou estudos de intervenção programada, no Brasil, com atividades físicas e/ou atividades nutricionais que tivessem como objetivo diminuir fatores de risco à saúde de crianças e adolescentes (sobrepeso/obesidade e alterações no perfil metabólico) com pré e pós-teste e encontrou, no final do levantamento, apenas cinco estudos. Nesses, os principais apontamentos foram em relação à diminuição da adiposidade corporal e aos efeitos positivos identificados em todas as pesquisas, independentemente do tempo da intervenção. Porém, também se destaca que, em todos os estudos, o escore em relação ao desenho metodológico da intervenção foi baixo (divisão dos grupos e presença de grupo controle), demonstrando que poucos estudos apresentaram transparência e estruturação consistentes em relação à proposta metodológica da intervenção (GUIMARÃES et al., 2015).

Estudos de revisão abordando a relação ou utilização dos jogos digitais para a promoção de saúde e ampliação do conhecimento em relação à alimentação saudável em escolares apresentaram evidências em relação ao potencial desse recurso para favorecer o desenvolvimento de competências para o autocuidado em saúde no ambiente escolar. No entanto, identificou-se a necessidade de programar intervenções com duração mais prolongada, com período de *follow up* mais extenso e realização de medidas repetidas durante o processo de intervenção, com vistas a explorar os processos de aprendizagem disparados pelos jogos digitais (STRACK et al., 2016).

No que se refere à avaliação do estado nutricional, a avaliação antropométrica pelo Índice de Massa Corporal (IMC), por ser um dos métodos menos invasivos e de maior aplicabilidade, com técnicas e pontos de cortes já estabelecidos (WORLD HEALTH ORGANIZATION, 2006; BRASIL, 2008), é o método mais amplamente utilizado, principalmente em intervenções que tenham o enfoque na prevenção da obesidade. (BOGART, et al 2014; FRIEDRICH et al., 2012; KAMATH et al., 2014, SILVEIRA, 2002). Os estudos de validação desse instrumento são limitados em quantidade. Um estudo de validação interna e externa demonstrou estimativas válidas em relação ao peso dos sujeitos avaliados por esta escala (DEURENBERG et al., 1991).

Em relação à avaliação de mudanças de práticas alimentares, os questionários de frequência alimentar são os instrumentos mais comumente utilizados, pois são métodos simples e que garantem outras opções ao inquérito recordatório e ao questionário de frequência. Além disso, demonstram ser mais práticos e com um melhor custo-benefício para

avaliações de programas comunitários e escolares (EDMUNDS & ZIEBLAND, 2002; ASSIS et al., 2009; ENGLE-STONE et al., 2015; WINPENNY et al., 2017). Esforços vêm sendo realizados para a elaboração de instrumentos mais sensíveis para cada contexto, levando em consideração a faixa etária destinada, a identificação com alimentos pertencentes à cultura alimentar e que possibilitem a sua utilização no contexto escolar. (ASSIS et al., 2009, 2010).

Outras revisões sobre intervenções em escolas, com enfoque maior na prevenção da obesidade, têm chamado atenção para o fator tempo de intervenção como ponto crucial para a eficácia das ações. Nessas análises, tem-se evidenciado que atividades com duração menor do que um ano não promovem mudanças mensuráveis, principalmente sobre os aspectos da composição corporal. (BOGART, et al 2014; FRIEDRICH et al., 2012; KAMATH et al., 2014; SILVEIRA, 2002). Em outro estudo de revisão, os autores mencionam que, quanto maior o tempo de duração da intervenção, maiores serão os benefícios proporcionados à saúde e que esses terão maiores possibilidades de ser inseridos no cotidiano das crianças e adolescentes. (SUN et al., 2013).

3.2.2 Educação em Saúde: Saúde Bucal

Em relação aos estudos envolvendo a temática saúde bucal, uma revisão da produção científica sobre “programação em saúde bucal”, compreendendo o período entre 1992 e 2001, identificou quatro tendências nessa área de investigação: ações curativas e preventivas com práticas educativas; ações preventivas com bochechos fluorados e práticas educativas pontuais; práticas educativas com foco na informação e no uso de recursos mobilizadores; prevenção e práticas educativas de conscientização. (PAULETO et al, 2004). As autoras discutem que, embora diversos programas de educação em saúde bucal venham sendo propostos nos últimos anos, esses ainda baseiam-se, na maioria das vezes, em tratamentos preventivos medicalizadores e curativos em detrimento da educação. Além disso, mesmo os que propõem ações de educação, muitas vezes não possibilitam o diálogo nem a participação efetiva dos alunos, necessários à construção de um conhecimento emancipatório que produza autonomia em relação aos cuidados com a saúde bucal, abrindo espaço para uma prática participativa em que os alunos possam ser protagonistas do processo de ensino-aprendizagem (PAULETO et al, 2004).

A instituição de atividades educativas de saúde bucal na escola tem se mostrado de grande valor na prevenção de doenças bucais biofilme-dependentes. Em seu estudo, Barreto et al (2013) mostra que uma atividade educativo-preventiva com escolares e pré-escolares, mesmo em curto prazo, é eficaz na redução de placa visível e sangramento gengival, mas enfatiza que, para que os resultados positivos possam ser perpetuados, um programa educativo-preventivo de longo prazo deve ser instituído. Estudos que avaliaram a efetividade de programas educativo-preventivos em saúde bucal obtiveram resultados positivos tanto em abordagens de curto quanto de longo prazo de intervenção. Esses retornos ocorreram em situações com medidas de avaliação realizadas após as intervenções educativo-preventivas e até 2 anos de acompanhamento depois do término da intervenção. Porém, nesses estudos, é apontado como destaque que a melhora nos níveis de higiene oral está associada diretamente à duração da atividade de educação proposta, sendo necessário o seguimento da atividade para a manutenção de melhores níveis de saúde bucal. (SILVEIRA et al., 2002; TOASSI et al., 2002; MIGLIATO et al., 2008; BARRETO et al., 2013).

Estudos que buscam avaliar a eficácia de programas de abordagem coletiva em saúde bucal têm utilizado, como parâmetro para avaliação da saúde bucal, medidas de controle de biofilme dental. (CASTRO, 2006; MIGLIATO et al., 2008). Essa é uma medida de qualidade de higiene oral que tem como base o biofilme dental, um dos principais agentes etiológicos da cárie e da doença periodontal. (PEREIRA, 2003). O IHOS (Índice de Higiene Oral Simplificado), de Greene e Vermillion (1964), é uma medida clássica usada em estudos que procuram medir o impacto da educação em saúde sobre o autocuidado em higiene oral. (RIOS, 2012; CARDOSO, 2011; SCOPEL, et al 2011, MURIETA-PRUNEDA, 2013; GONZALES, 2007). O IHOS é um índice simples e rápido, utilizado para classificar a higiene oral (ROVIDA et al., 2010), no qual são examinadas superfícies de 6 dentes, observando a presença de biofilme dentário e classificando-os de acordo com o índice encontrado. Foi proposto originalmente da seguinte forma: boa- 0,0 a 0,6; regular- 0,7 a 1,8; ruim- 1,9 a 3,0. Estudo de Moimaz et al (2001) indica o uso do (IHOS) e sua reprodutibilidade associada a outros 3 índices de higiene oral, como medidas apropriadas em ações de saúde bucal. Em outro estudo com o objetivo de avaliar a frequência de higiene oral e sua relação com o comportamento e cuidado em saúde bucal, o IOHS também foi utilizado como forma de avaliação física, por esse ser reconhecido como um índice de mensuração da educação em

saúde bucal em sistemas públicos escolares (MBAWALLA et al., 2010, MAHESWARI, et al 2014; SANDEEP JAIN et al., 2016).

3.3 Teoria Social Cognitiva e o Construto da Autorregulação da Aprendizagem

A Teoria Social Cognitiva, proposta por Bandura, explica o comportamento humano pela interação de três fatores, a saber, fatores pessoais, ambientais e comportamentais, que se influenciam mutuamente de maneira dinâmica (BANDURA, 1986). Portanto, considera-se que os comportamentos não são determinados apenas pelo seu contexto, pois o indivíduo possui papel atuante nesse processo, estabelecendo planos de acordo com os seus objetivos, metas e expectativas a curto, médio e longo prazo (MURPHY & EISENBERG, 1997).

Nessa perspectiva, existem elementos na Teoria Social Cognitiva que podem ser relevantes para os processos de promoção de saúde: papel das expectativas como determinantes dos comportamentos; o processo de aprendizagem vicariante; e a influência do bom resultado de saúde como aspecto motivador para o comportamento (MURPHY & EISENBERG, 1997). Soma-se a esse contexto, na educação e na saúde, uma preocupação crescente entre os estudiosos pela explicação da variabilidade de estados de saúde da população, sobretudo no que tange aos seus determinantes, comportamento e estilos de vida individuais (BANDURA, 2005).

As pesquisas nessa área têm reforçado a importância da implicação e da participação ativa dos indivíduos na adoção de comportamentos saudáveis como meio de preservar a sua saúde e bem-estar, bem como prevenir doenças, tendo como argumento central que “o indivíduo é capaz de fazer escolhas, bem como agir sobre si próprio e sobre o meio, para alcançar resultados desejados” (SILVA e PEREIRA, 2012, p. 287). Esta assunção da responsabilidade pessoal na condução dos comportamentos, a agência, tem sido o foco central das investigações no âmbito da autorregulação, com o objetivo de mapear as variáveis intervenientes no processo de construção da autonomia e responsabilidade (ROSÁRIO et al., 2012, 2013, 2014; ZIMMERMAN, 2008), mas, também, desenhar projetos de intervenção que promovam os processos autorregulatórios de modo a incrementar a implicação pessoal no agir e melhorar as performances. (ZIMMERMAN, 2000; NÚÑEZ et al., 2013; ROSÁRIO et al., 2014).

De acordo com Rosário (2004a), a autorregulação é definida como um processo ativo, em que os alunos organizam objetivos que norteiam o seu processo de aprendizagem,

tentando monitorar, regular e gerenciar as suas cognições, motivações, emoções e comportamentos, com o intuito de alcançá-los. Dessa forma, esse conceito descreve o grau em que os alunos são metacognitivamente, motivacionalmente, e comportamentalmente envolvidos em seus próprios processos de aprendizagem (ZIMMERMAN, 1989).

A investigação nos últimos dez anos tem dado apoio empírico ao pressuposto de que crianças mais novas podem participar em atividades que promovam a autorregulação na sua aprendizagem (PERRY et al., 2002) e que são as que mais se beneficiam desse treino de competências (DIGNATH et al., 2008). A grande vantagem de ensinar as crianças como autorregular a sua aprendizagem no início da escolaridade obrigatória se deve ao fato de que, durante esses anos cruciais de aprendizagem, as crianças criam atitudes de aprendizagem e de autoeficácia (WHITEBREAD et al, 2004) que são mais fáceis de modificar do que quando já são mais velhas e já desenvolveram estilos próprios de aprendizagem (HATTIE et al, 1996; DIGNATH et al., 2008; ROSÁRIO et al., 2012, 2013).

A autoeficácia é uma variável essencial no processo de autorregulação, pois está relacionada com as percepções das crianças a respeito das suas próprias capacidades de organização e efetivação de recursos necessários para atingir determinado objetivo ou meta. (BANDURA, 1986). Se a criança sente que é capaz de concretizar determinada atividade, é mais provável que desenvolva um maior interesse por essa atividade (ROSÁRIO, 2004a). Portanto, a autoeficácia e a atitude são construtos que os profissionais da saúde precisam estar atentos quando estão no processo de gestão de programas, de promoção ou prevenção da saúde, para que esses impactem positivamente na população escolar. (MELO-HURTADO; JAIMES-VALENCIA, 2015).

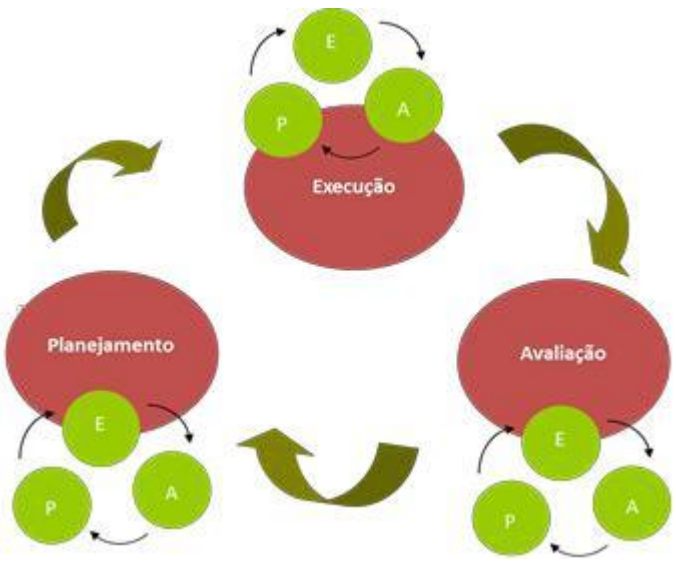
3.3.1 Autorregulação da Aprendizagem e o Modelo PLEA

A aprendizagem autorregulada é um dos temas primordiais da prática educativa e assunto central de investigação no campo educacional, pois têm focalizado a sua atenção para a compreensão das habilidades e competências a serem desenvolvidas para proporcionar um melhor desempenho e satisfação no ambiente escolar das crianças e adolescentes (ROSÁRIO et al., 2004a). Os estudos e pesquisas nessa perspectiva foram desenvolvidos no “domínio da aprendizagem escolar” (BOEKAERTS e CORNOl, 2005), sobretudo nas áreas de metacognição e motivação, para explicação e compreensão do papel ativo do aluno nas suas próprias aprendizagens, com resultados muito positivos para a criação

de instrumentos de avaliação e a aplicação de programas de intervenção no campo educativo. (NÚÑEZ et al., 2013; ROSÁRIO et al., 2014; NÚÑEZ et al., 2006).

A autorregulação da aprendizagem é um processo cíclico, que acontece em três etapas principais: etapa prévia, etapa “controle volitivo” e etapa da autorreflexão. Esses processos são interdependentes, portanto, não seguem uma hierarquia no percurso das fases e, por esse fato, cada etapa recebe a influência da outra como forma preparatória ao processo de aprendizagem da criança (ZIMERMANN, 2002). Com base nesse modelo sociocognitivo, proposto por Zimermann, da autorregulação, ROSÁRIO (2004b) desenvolveu um modelo explicativo da autorregulação para aprender: o PLEA - Planejamento, Execução e Avaliação (Figura 1). Esse expõe um seguimento do processo autorregulatório, no qual cada fase operacionaliza em si própria o mesmo processo cíclico. Portanto, o processo não só se organiza do planejamento para avaliação, passando pela execução, como também, em cada uma das fases, o mesmo funcionamento é atualizado, fortalecendo o racional teórico do processo autorregulatório (ROSÁRIO et al., 2007, 2008, 2010). Estas dinâmicas estruturantes reforçam o movimento cíclico autorregulatório, possibilitando a vivência do processo autorregulatório como um todo, em qualquer uma das suas fases (ROSÁRIO, 2004b, SCHUNK & ZIMMERMAN, 2008).

Figura 1 - Modelo autorregulado da aprendizagem (PLEA)



Fonte: ROSÁRIO et al. (2004b).

Analisando de maneira mais detalhada cada uma das fases, evidencia-se que a fase do planejamento acontece quando o aluno pensa e analisa, antecipadamente, a atividade ou tarefa que vai realizar e elenca um conjunto de estratégias de aprendizagem para alcançar os objetivos estabelecidos. Nesse percurso, por meio dessa apreciação, a criança pode avaliar os seus recursos pessoais e os do ambiente em que está inserida, estabelecer os objetivos diante da atividade ou tarefa e elaborar um plano com o intuito de garantir um desenvolvimento adequado da tarefa até a sua concretização final. (ROSÁRIO et al, 2003; ROSÁRIO et al., 2007, NÚNEZ et al, 2014). A segunda fase, a da execução, relaciona-se com o momento em que o aluno põe em prática o plano estabelecido, através da implementação de um repertório de estratégias, controlando e realizando o monitoramento da sua eficácia para, assim, consolidar o que havia planejado. (ROSÁRIO et al., 2007, NÚNEZ, et al, 2013). Esse processo de colocar em prática o plano requer da criança elaboração e reflexão contínuas sobre o que está sendo feito e como está sendo feito, com o automonitoramento presente. A terceira e última fase, a da avaliação, versa sobre determinar se as tarefas ou atividades de aprendizagem foram bem-sucedidas. Isso ocorre através da análise da relação entre o produto e o resultado final e as metas e objetivos estabelecidos. Essa é a fase do processo autorregulatório que implica em pensar, refletir depois da ação feita (ROSÁRIO et al., 2007) e suas consequências no presente e em ações futuras, utilizando novamente o PLEA, refletido, resignificado (PINA et al, 2010).

3.3.2 Autorregulação em Saúde

No domínio da saúde, o construto da autorregulação contribui para a compreensão dos processos de promoção de hábitos saudáveis, na medida em que auxilia na compreensão dos hábitos de vida que cooperem para melhorias da saúde e bem-estar pessoal nos indivíduos. (SILVA e PEREIRA, 2012). Embora com finalidades diferentes (hábitos de estudo ou hábitos de vida) em ambos os domínios, o que se tem em comum são as metodologias e as ações desenvolvidas para o alcance de metas e objetivos pessoais. Esses processos implicam algum grau de regulação por parte do indivíduo, com a conjugação de recursos internos e externos (do meio), de forma intencional e estratégica (SILVA e PEREIRA, 2012).

A literatura tem indicado e sugerido a eficácia do uso da estrutura da autorregulação também para o domínio da área da saúde. Alguns estudos, com o foco em doenças crônicas, demonstram que intervenções com programas que utilizam sistemas de autogestão e outras

estratégias autorregulatórias durante o tratamento são eficazes para melhorar a saúde, diminuir hospitalizações, aumentar a adesão, diminuir o absenteísmo escolar, causado muitas vezes pelo adoecimento, e melhorar o nível acadêmico no que se refere ao desempenho escolar (HASKELL et al., 1994; WEST et al., 1997; FU et al., 2003; CLARK et al., 2005). Apesar desses estudos apontarem uma eficácia de programas de autorregulação na melhoria da saúde e tratamentos, ainda carece, de modelos criativos, que possam compreender uma aplicação social desse processo no campo da promoção de saúde (BANDURA, 2005). Existe evolução teórica e atenção voltada para a validade preditiva da teoria da autorregulação, mas pouco para o entendimento e a intervenção de como isso pode ser demonstrado na ótica da promoção da saúde (BANDURA, 2005).

Outros estudos no campo, sobre hábitos saudáveis e conhecimento sobre alimentação saudável com crianças, indicaram que essas mantêm hábitos alimentares pouco saudáveis, embora tenham conhecimento sobre o que é uma alimentação saudável, sugerindo que a grande dificuldade para mudança desse comportamento de saúde está em aprender ou desenvolver competências autorregulatórias para isso (GASPAR et al., 2014; ANDERSON et al., 2007). Portanto, esses estudos indicam e sugerem que intervenções em escolas, que possam abordar esses temas, devem desenvolver um conjunto de habilidades de autorregulação necessárias para a construção de processos de promoção de saúde e autocuidado (ANDERSON et al., 2007). Outro estudo com essa temática identificou que as práticas parentais alimentares também influenciam as habilidades de autorregulação das crianças em relação à alimentação e que essas possuem implicações importantes para os comportamentos alimentares das crianças (FRANKEL et al., 2018).

Bub e colaboradores, em estudo para investigar o quanto que o papel de um conjunto mais amplo de habilidades de autorregulação pode influenciar na promoção não apenas de um peso mais saudável, mas, também, de melhores comportamentos gerais relacionados à saúde, identificaram resultados que sugerem que existem benefícios a longo prazo da autorregulação relacionados com a saúde das crianças. As crianças com melhores habilidades de autorregulação demonstraram menor aumento nos escores padronizados do índice de massa corporal (IMC) e mantiveram maior saúde, conforme relatado pela mãe, durante a infância e a adolescência (BUB et al., 2016).

Dessa forma, estudos que deem conta de melhor evidência empírica e compreensão dos processos autorregulatórios e sua contribuição na promoção da saúde, sobretudo na

infância, são esperados e promissores na busca de uma melhor saúde e qualidade de vida da população.

3.4 As Histórias como dispositivo de promoção da autorregulação

A prática de contar histórias já se tornou uma tradição educativa em diversas culturas e pode ser uma forma de organizar conhecimento e contribuir com instrumentos sobre alguns conteúdos, sendo uma metodologia reconhecida no processo educativo (ROSÁRIO et al., 2007). O potencial norteador para a aprendizagem é inerente a própria dinâmica da história. Cada pessoa escuta com seus ouvidos condicionados a sua própria experiência e, portanto, "lê" a história conforme as suas necessidades para aquele momento. Essa natureza relativa da estruturação do conhecimento possibilita ao aluno explorar aquela história em todas as suas dimensões, mas, também, reinventá-la, organizando a narrativa pela sua experiência, para dar-lhe um sentido conforme a realidade vivida. (ROSÁRIO, et al 2003; GONÇALVES, 2000).

O processo de escutar histórias propicia às crianças um envolvimento dentro de uma estrutura narrativa que pode ser utilizada como modelagem para organização, para uma sequência lógica, para imaginação e tomada de decisões. (ALNA, 1999). Um estudo realizado nos Estados Unidos identificou que crianças que tinham como hábito ouvir histórias em sala de aula apresentaram resultados superiores em testes de linguagem e de compreensão quando comparadas às crianças que não possuíam essa metodologia no seu processo educativo. (WALKER, 2001). Isbell e colaboradores (2004), em um estudo com o objetivo de identificar como a narrativa e a leitura de histórias influenciam o desenvolvimento da linguagem e a compreensão em crianças de três a cinco anos de idade, indicaram que a contação e a leitura de histórias produziram ganhos positivos na linguagem oral e que as crianças que ouviram as histórias relatadas demonstraram melhor compreensão da história em sua recontagem, refletido na sua complexidade de linguagem.

A análise da narrativa pode provocar que os alunos articulem os conhecimentos da aprendizagem autorregulada. Esses conhecimentos podem ser adquiridos na escola, em conversa com familiares, com colegas e na televisão (ROSÁRIO et al., 2003). Dessa forma, através da análise da narrativa pela lógica autorregulatória, o aluno é convidado a tomar consciência e refletir sobre os processos e as estratégias de autorregulação e como esses podem ser utilizados em seus processos de aprendizagem. A missão do protagonista da

história, nesse aspecto sempre configurado como o personagem do “herói”, é ensinar a lição aprendida e apresentar a sua diferente versão após essa “transformação”, ou seja, explicitando alguma mensagem aprendida e que pode ser aplicada em outras realidades (ROSÁRIO et al., 2003; CAMPBELL, 1949).

Pelo marco teórico sociocognitivo, a aprendizagem através da observação auxilia no desenvolvimento ou ampliação de um repertório de estratégias autorregulatórias de aprendizagem. Portanto, os personagens das narrativas, que tiverem demonstrado a utilização de competências e estratégias autorregulatórias no caminho para alcançar os seus objetivos, poderão servir de modelos sempre que seus comportamentos e pensamentos forem analisados em relação à realidade e ao cotidiano dos alunos. (ROSÁRIO et al., 2003). Dessa forma, a autorregulação pode ser agenciada por meio da modelação da aprendizagem e da experiência em diferentes oportunidades. As crianças/leitoras podem vivenciar uma aprendizagem vicariante por meio das histórias apresentadas, além de aprender um modelo autorregulatório que lhes oferece possibilidade de reflexão a respeito das aprendizagens e vivências do seu cotidiano (SILVA e PEREIRA et al., 2012).

A literatura relacionada a estudos com a utilização de narrativas como ferramentas em programas para a promoção da autorregulação tem demonstrado a eficácia desse dispositivo para a promoção de autonomia e autorregulação das crianças na educação infantil. Nessa mesma perspectiva, um estudo sobre o uso de narrativas com o objetivo de promoção de estratégias autorregulatórias para alunos do quinto e do sexto ano, desenvolvido no sistema educativo de Portugal, demonstrou que 70% dos alunos que participaram do programa melhoraram os comportamentos de estudo autorregulados. Esse resultado indica os ganhos autorregulatórios em comportamentos de aprendizagem com a utilização das narrativas como dispositivo (ROSARIO, et al 2004a; ROSARIO et al.,2004).

3.4.1 Projeto “As Travessuras do Amarelo”

O projeto do livro “As Travessuras do Amarelo”, de Rosário et al. (2012), adota como referencial a Teoria Social Cognitiva de Bandura (1986) e o construto da autorregulação da aprendizagem (ZIMMERMANN, 1986, 1989), tendo como base o modelo proposto por Rosário et al. (2017), que visa promover competências autorregulatórias em crianças de até 10 anos. Esse constitui-se em um instrumento educativo, que equipa as crianças com um repertório de

estratégias de aprendizagem, que, por sua vez, as auxilia a enfrentar diariamente as suas tarefas de aprendizagem com mais qualidade, profundidade, responsabilidade e de forma autônoma. O programa do projeto encontra-se em um livro já editado para o contexto brasileiro e consiste numa narrativa que descreve um conjunto de aventuras vividas pelas cores do arco-íris em busca do seu amigo Amarelo, perdido no bosque. “Todos são importantes”, “não se pode deixar ninguém para trás” e “quem não desistir, há de conseguir” são exemplos de mensagens trabalhadas com as crianças no projeto das Travessuras do Amarelo.

O projeto do livro está dividido em três etapas em cada uma delas, existem objetivos e competências específicas a serem alcançadas junto com as crianças (ROSÁRIO et al., 2017). Nessa perspectiva, o trabalho com o livro é desenvolvido seguindo a lógica da aquisição de competências, objetivadas em cada etapa que se encontram as histórias. Na primeira etapa do livro (dos capítulos 1 ao 7 aproximadamente), a criança deverá: ser capaz de definir as três fases do processo autorregulatório (planejar, executar e avaliar – PLEA); colocar em prática as diferentes fases do processo autorregulatório em situações do cotidiano; analisar essas fases pela ótica da resolução de problemas e experimentar a resolução de problemas em atividades específicas; selecionar os recursos disponíveis e ajuda mútua que sejam coerentes com as necessidades das tarefas e resolução dos problemas; analisar e antecipar as consequências dos comportamentos adotados; valorizar a importância do trabalho em grupo e também identificar de maneira adequada os seus sentimentos; refletir sobre a relevância das estratégias autorregulatórias nos processos de aprendizagem; e refletir sobre as aprendizagens vivenciadas. Após essa etapa, na segunda parte do livro (capítulos 8 a 12), além das competências acima descritas, a criança também deve: já ser capaz de aplicar o PLEA a outras situações e histórias do cotidiano; organizar objetivos coerentes para as atividades apresentadas; realizar uma atividade a partir de um plano; analisar comportamentos e sentimentos, admitindo as responsabilidades sobre seus atos; respeitar a comunicação, as regras e a opinião dos outros, utilizando argumentações com um discurso coerente e organizado; e refletir e experimentar as diferentes fases da resolução de problemas, buscando desenvolver a reflexibilidade por meio do controle da impulsividade e experimentando as etapas de tomada de decisão. Já na terceira etapa do livro (capítulos 13 ao 17 - final do livro), depois de trabalhar junto com as crianças todas essas competências, a criança deverá ser capaz de transferir as aprendizagens sobre os processos da

autorregulação para outros domínios (cuidado em saúde, alimentação saudável e saúde bucal) e refletir sobre a importância das estratégias de autorregulação e aprendizagens já então realizadas.

A história tem um estilo não prescritivo, humorado e desafiador e oferece às crianças a oportunidade de adquirir um vasto leque de estratégias de aprendizagens que, por sua vez, as fará refletir sobre diversas situações e ideias idênticas as suas. Essa proximidade de experiências facilita, então, a discussão e a reflexão nos participantes, promovendo, para além de um conjunto de processos e estratégias de autorregulação, aspectos emocionais e comportamentais (ROSÁRIO et al., 2007; 2010, 2014) que podem envolver aspectos gerais da vida, como questões de saúde e estilos de vida, por exemplo.

Dessa forma, este estudo adotou como ferramenta didática o livro de histórias “As Travessuras do Amarelo” com o propósito de promover estratégias autorregulatórias na aprendizagem e na promoção de saúde em contexto de formação de educadores e profissionais de saúde e na intervenção com escolares do 5º ano da Educação Básica.

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5 OBJETIVOS

5.1 Objetivo Geral

Realizar e avaliar uma intervenção na temática “promoção da autorregulação em saúde”, sob a lente da perspectiva da Teoria Social Cognitiva, em atividades relacionadas ao Programa Saúde na Escola, no Município de Sapucaia-RS/Brasil.

5.1.1 Objetivos Específicos:

a) realizar oficinas de formação com os profissionais, participantes do PSE (professores e profissionais da Atenção Básica) sobre as temáticas alimentação saudável, saúde bucal e autorregulação da saúde;
b) monitorar, ao longo de um ano letivo, o programa de promoção à saúde com ênfase na promoção dos comportamentos de autorregulação dos hábitos alimentares e da saúde bucal desenvolvido pelos professores e pelos profissionais de saúde;
c) analisar, ao longo de um ano de intervenção do Programa de promoção de saúde, as mudanças ocorridas em relação à autorregulação e à promoção de saúde das crianças participantes do estudo quanto à perspectiva da alimentação saudável e saúde bucal;
d) avaliar, após 6 meses do final do Programa de intervenção, a manutenção das mudanças ocorridas em relação à autorregulação e à promoção de saúde das crianças participantes do estudo quanto à perspectiva da alimentação saudável e saúde bucal.

6 ARTIGOS

frontiers in Psychology

PROTOCOLS
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Promoting Self-Regulation in Health Among Vulnerable Brazilian Children: Protocol Study

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The Health and Education Ministries of Brazil launched the Health in School Program (Programa Saúde na Escola - PSE) in 2007. The purpose of the PSE is two-fold: articulate the actions of the education and health systems to identify risk factors and prevent them; and promote health education in the public elementary school system. In the health field, the self-regulation (SR) construct can contribute to the understanding of life habits which can affect the improvement of individuals' health. This research aims to present a program that promotes SR in health (SRH). This program (PSRH) includes topics on healthy eating and oral health from the PSE; it is grounded on the social cognitive framework and uses story tools to train 5th grade Brazilian students in SRH. The study consists of two phases. In Phase 1, teachers and health professionals participated in a training program on SRH, and in Phase 2, they will be expected to conduct an intervention in class to promote SRH. The participants were randomly assigned into three groups: the Condition I group followed the PSE program, the Condition II group followed the PSRH (i.e., PSE plus the SRH program), and the control group (CG) did not enroll in either of the health promotion programs. For the baseline of the study, the following measures and instruments were applied: Body Mass Index (BMI), Simplified Oral Hygiene Index (OHI-S), Previous Day Food Questionnaire (PFDQ), and Declarative Knowledge for Health Instrument. Data indicated that the majority are eutrophic children, but preliminary outcomes showed high percentages of children that are overweight, obese and severely obese. Moreover, participants in all groups reported high consumption of ultraprocessed foods (e.g., soft drinks, artificial juices, and candies). Oral health data from the CI and CII groups showed a prevalence of regular oral hygiene, while the CG presented good oral hygiene. The implementation of both PSE and PSRH are expected to help reduce health problems in school, as well as the public expenditures with children's health (e.g., Obesity and oral diseases).

Keywords: self-regulation, promotion health, school health program, healthy eating, oral health

INTRODUCTION

Health promotion for children has been receiving the attention of educators and researchers, and there has been a particular focus on oral health and eating habits (Yekaninejad et al., 2012; World Health Organization, 2016). According to the WHO report, the prevalence of obesity among children under the age of five has increased from 4.8 to 6.1% between 1990 and 2014; this entails that the number of children affected by this phenomenon has grown from 31 million to 41 million (World Health Organization, 2016).

Oral health involves health and well-being in an integral way, and despite being a preventable situation, oral diseases are considered endemic (Yekaninejad et al., 2012). Notwithstanding some improvements in oral health in developed countries, oral diseases such as dental plaque, gingival bleeding and dental caries are prevalent among schools worldwide, and are still considered public health problems (Yekaninejad et al., 2012).

In 2007, the Ministries of Health and Education from Brazil created the Health in School Program (Programa Saúde na Escola—PSE) with the aim of improving the school health system in Brazil (Brasil, 2007). The PSE is a school-based program built on the articulation of the educational and health systems to promote the education of health for the public schools students (Brasil, 2007). The main objective of the PSE is to detect risk factors and identify acts of preventive care while promoting the health of public elementary school students (e.g., assessing nutritional status, early incidence of hypertension and diabetes, caries control, visual and auditory acuity) (Brasil, 2015).

The social cognitive framework provides a relevant theoretical framework to the present study (Bandura, 1986). Social cognitive researchers have been specifically stressing the importance of people's agency as a construct of the assumption of one's personal responsibility in one's own behaviors (Bandura, 1986).

This has been the major focus of the research in the field of Self-Regulation in Health—SRH—(Bandura, 1986). Extant research has been focused on mapping the intervening variables in the process of building autonomy and responsibility (Zimmerman, 1986; Rosário et al., 2012a, 2015). Moreover, the design of intervention projects to promote self-regulatory processes as well as individuals' implications on their own health issues and the health outcomes have been receiving researchers' attention (Bandura, 2005; Silva and Pereira, 2012).

Self-regulation (SR) models have three customary sub-functions: (i) self-control of health-related behaviors and the cognitive and social conditions attached, (ii) adoption of objectives and strategies to achieve this self-control and (iii) self-reactivity, which involves self-motivating stimuli and social support networks that sustain healthy practices (Bandura, 2005). When focused on health, the SR construct can help build understanding of the processes involved in promoting lifelong habits. Thus, the promotion of SR is likely to improve individuals' health and personal well-being (Bandura, 2005). Extant literature has shown the efficacy of using the SR framework in health programs (e.g., the use of self-management strategies during the treatment of chronic diseases) (West et al., 1997; Fu et al., 2003; Clark et al., 2005) designed for improving health, decreasing the need for hospitalizations, and increasing the adherence to treatment (Haskell et al., 1994; West et al., 1997; Fu et al., 2003; Clark et al., 2005). However, research on the efficacy of school-based programs focused on promoting SR competencies in the health domain is still lacking (e.g., interventions targeting health eating and oral health) (Bandura, 2005).

School Health Program—PSE Programa Saúde Na Escola

The PSE is offered to Brazilian cities by the central government, and it involves the combined efforts of primary health care units and public schools (Brasil, 2007). The program has three components: (a) evaluation of the health conditions of the children and adolescents enrolled in public schools, (b) training on a set of activities of health promotion and risk prevention, and (c) the professional development and ongoing training of professionals from the educational and health systems (Brasil, 2015). To develop these actions, health professionals [nurses, community health workers (CHWs), dentists] conduct anthropometric evaluations (weight and height) and health assessments (healthy eating habits, oral health, and visual acuity) to students from all school grades (Brasil, 2015).

Program to Promote Self-Regulation in Health (PSRH)

The PSRH is a program designed to promote the SR of health. The health contents of the PSRH are the same as those of the PSE (i.e. healthy eating and oral health habits). Moreover, the program is rooted on the social cognitive framework and the construct of SR (Rosário et al., 2012b). Both components are the theoretical ground for the story-tool, *Yellow's Trials and Tribulations*, which will be used to deliver the health contents and SR strategies (Rosário et al., 2017).

This story-tool aims to promote SR skills in children aged up to 10 years by teaching them learning strategies designed to accompany activities proposed by the PSRH. The book tells the story of the disappearance of the Yellow color from the Rainbow and the adventures of the other rainbow colors as they search for their missing friend (Rosário et al., 2012c). This story-tool addresses many practical examples of how children can use SR strategies to resolve their daily difficulties by increasing their autonomy in a responsible manner (Núñez et al., 2014; Rosário et al., 2017).

The present study should be interpreted as a response to three current issues: the health of Brazilian children, which in general is showing a negative trajectory despite the efforts of the PSE; the difficulties of children in developing systematic actions involving routine follow-up activities in PSE; and the lack of actions to promoting healthcare (Machado et al., 2015). To address the latter, this research aims to present a program that promotes SR in health. This program includes topics on healthy eating and oral health from the PSE; it is based on the social cognitive framework and uses story tools (Cabanach et al., 2009; Rosário et al., 2017) to train SRH in 5th grade students from the South of Brazil. The current program aims to promote the development of

self-regulatory skills, which are considered essential for changing health-related behaviors (Bandura, 2005).

METHODS

The current paper is a protocol study that describes a quasi-experimental study (Bedard et al., 2017). The development of the project will have two phases: Phase I: Deliver Training in Health Self-Regulation; and Phase II: Set an Intervention Program to Promote Self-regulation in Health (**Figure 1**).

Contextualization of the Study Site

The study will be conducted in a city in the south of Brazil (i.e., Sapucaia do Sul). This city has ~138,357 inhabitants and a lower average monthly income compared to neighboring cities in the region (IBGE, 2016). The high social vulnerability of the inhabitants of the city was the reason this town was chosen for the investigation. Sapucaia has 23 elementary schools working with Primary Health Care Units that employ doctors, nurses, nursing technicians, CHWs, dentists and oral health technicians (Sapucaia do Sul, 2016). Of these, 16 elementary schools are currently engaged with the PSE program. To engage in PSE, elementary schools and the primary health care units should form a dyad: each school has a health care unit partner to work with regarding health issues (Sapucaia do Sul, 2016). For the current study, the schools enrolled should have two classes in 5th grade. Only 14 out of 16 elementary schools in Sapucaia engaged in PSE met this criterion. All were invited to participate. Finally, seven dyads (school-health care unit) agreed to participate in the current investigation (response rate of 50%). Seven elementary schools which were not enrolled in PSE were contacted to participate as CG, but only three agreed (**Figure 2**). The reasons given by the schools for not enrolling in the research were not related with the nature or goals of the intervention, but with social and administrative limitations (e.g., general strikes that paralyzed public schools for several months, high workload and low salaries). The latter are examples that reflect the actual educational political environment in Brazil and stresses the relevance of developing research projects with vulnerable children, to help them with learning and health issues (Ribeiro, 2013; Casemiro et al., 2014).

Recruitment and Randomization

The school boards of 10 elementary schools agreed to participate. Participants were students and teachers from seven PSE elementary schools and health units, and three non-PSE schools. Finally, these schools were randomized into three groups: Control Group—CG—(eight classes)—schools not participating in PSE, Condition I—CI—(eight classes)—schools participating PSE; and Condition II—CII—(nine classes)—schools participating in the Phases I and II of the project.

Study Participants

Six hundred and twenty-five fifth grade students and their parents were contacted through face-to-face contacts (parent meetings and meetings with the teachers). Finally, 429 students [215 girls] were enrolled. These students are nested in 24 classes and their allocation to the three conditions was as follows: 8 classes with 118 students [62 girls] not enrolled in the PSE participated as CG; the remaining 17 classes were randomly split into two groups, 9 classes with 198 students [92 girls] in the CII, and 8 classes with 113 students [61 girls] in the CI.

Inclusion Criteria

To be enrolled in this study, participants must meet the following criteria:

Teachers must teach a 5th grade class in a public elementary school;

Health professionals must be working in a primary care unit; Students must be enrolled in the 5th grade in a public elementary school;

Parents/guardians: must be responsible for a child enrolled in a 5th grade class in a public elementary school;

All participants (parents and children) must be volunteers and must sign the Free and Informed Consent Term and Free and Informed Consent Term for parents/guardians authorizing their children to participate in the study. All subjects gave written informed consent in accordance with the Declaration of Helsinki.

Exclusion Criteria

Potential participants who do not meet all the inclusion criteria, including 5th grade students with special educational needs that limit their cognitive autonomy, will be excluded from the study.

STEPWISE PROCEDURE

Program Rationale

The PSRH is grounded in the SR framework which describes the degree in which students are metacognitively, motivationally, and behaviorally engaged in their own learning processes (Zimmerman, 1989). SR processes may be described as open and dynamic processes proceeding through three main phases (i.e., forethought phase, the performance phase, and the self-reflection phase) (Zimmerman, 2002). The cyclical nature of this model aims to explain how students initiate, keep and control their behaviors, thoughts, and emotions toward specific goals. Motivational beliefs and task analysis are the two areas of the forethought phase, and they describe processes prior to learning efforts (e.g., goal setting, self-efficacy beliefs) (Rosário et al., 2013). The performance phase, describes the processes used by students' during learning. For example, self-instruction is a strategy that may help students focus their attention on homework assignments and eliminate distractors; and self-recording notes is a strategy that may help students self-monitor their performance (Zimmerman, 1989). Both strategies may facilitate self-control and self-observation, which are key components of the performance phase (Zimmerman, 2002). Lastly, the self-reflection phase describes methods intended to help students understand the processes that may have led to the outcomes and the reactions to these outcomes (Zimmerman, 1989). Self-judgments and self-reactions are the two areas of this last phase of the SR cycle (Zimmerman, 2002). For the purposes of the current work, the PLEE model, which is a SR model grounded on the model by Zimmerman (2002), will be used

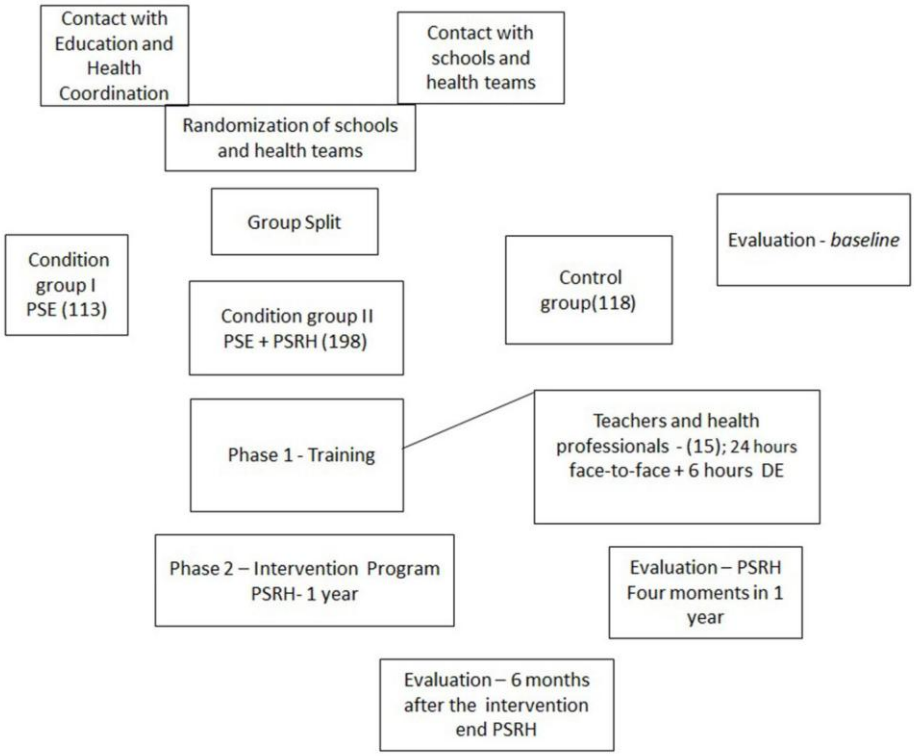

FIGURE 1 | Promoting self-regulation in health among vulnerable Brazilian children: protocol study. Flow diagram for study procedures. PSE, Programa Saude na Escola; PSRH, Program to Promote Self-regulation in Health.

(Rosário et al., 2012a; Núñez et al., 2013). The abbreviation PLEE stands for the three phases that comprise the structure of the model: planning, task execution and evaluation (Pina et al., 2010). In this model, the logic and the cyclic movement is present at all times; during the planning phase, the execution and evaluation phases are still carried out (Rosário et al., 2017). For example, when children plan what they want to eat for lunch, they fulfill the execution phase by placing healthier foods in their lunch pack and they complete the self-reflection phase by evaluating their choices based on their learned experiences regarding nutrition.

Phase 1—Training in Self-Regulation in Health

During this stage, the training aimed to equip the participating professionals with the skills needed to conduct a program in SR focused on healthy eating and oral health habits. This training occurred in 2017 and was delivered by the authors and research assistants who have knowledge and skills in SR of health. The training duration was a total of 24 h, divided into 3 months (4 h sessions every 2 weeks of each month). The participants were health professionals (dentists, nurses, nursing technicians, CHWs) and 5th grade teachers of the CII schools. These sessions addressed the theoretical content related to SR, healthy eating, oral health and the chapters of the story-tool, *Yellow's Trials and Tribulations*, which was to be read and discussed (Rosário et al., 2012c). The sessions also included hands-on activities to build the support materials needed to work with children (e.g., drawings, worksheets, food maps;) (see **Figure 3**).

Phase 2—Intervention: Program to Promote Self-Regulation in Health

The intervention program with children will be run by teachers and health professionals (CII) in 50-min biweekly sessions that will take place in class throughout the 2018 school year. During these sessions, the children will discuss the chapters of *Yellow's Trials and Tribulations* (Rosário et al., 2012b), one chapter per week, as well as the discussions and activities related to the topics of healthy eating and oral health (**Table A1** in Appendix section).

The practice of storytelling has become an educational tradition that occurs in a variety of cultures. One of the reasons for using this technique may be related to the fact that stories are efficient ways of organizing knowledge (Rosário et al., 2017). When children become involved in a narrative, through reading or listening, they are likely to learn how to organize the information in a logical sequence (Alna, 1999).

Extant research indicates that discussion and interpretation of narratives may contribute to children's awareness of SR behaviors, which may be translated into their learning processes (Núñez et al., 2013). This process takes place through the development of vicarious learning by observing and expanding upon behaviors and expressions that help structure future modulations (Bandura, 1986; Schunk, 2000).

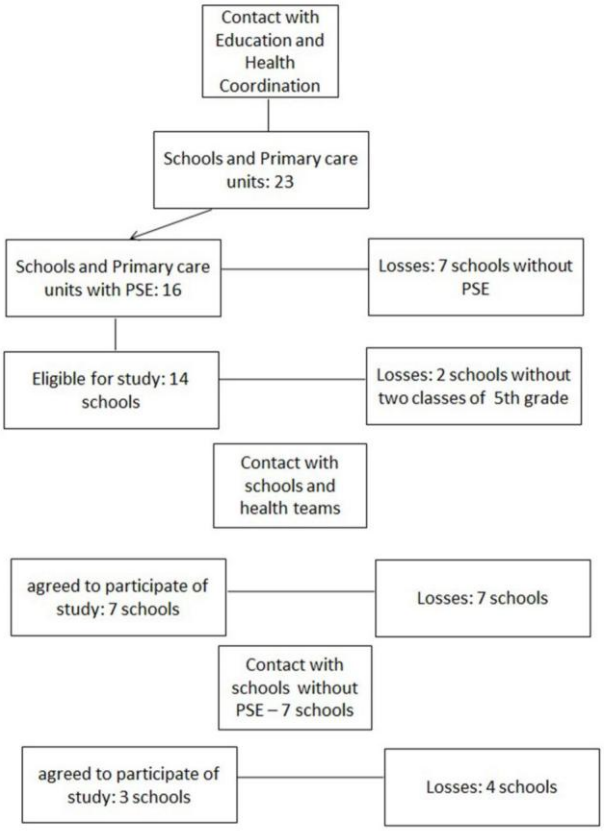

FIGURE 2 | Promoting self-regulation in health among vulnerable Brazilian children: protocol study. Flow diagram to recruitment. PSE, Programa Saude na Escola.

The *Yellow's Trials and Tribulations* story-tool is divided into three steps, each of them with specific goals and contents to be learned by children. By the end of the first step of the book (i.e., Chapters 1–7), the children are expected to be able to define the three phases of the SR process (PLEE) (Rosário et al., 2012a). After completing the second step (i.e., Chapters 8–12), the children are expected to be able to apply the PLEE model to situations of their everyday lives (Rosário et al., 2017). After completing the entire assigned reading, children are expected to be able to reflect on the importance of the SR strategies learned and transfer this knowledge to distinct domains of their lives (e.g., behavior in class, healthy food habits, time management; oral hygiene).

Monitoring

The program will be monitored by researchers through case discussions and theoretical group meetings with teachers and health professionals which will occur during the biweekly visits to classes. Students in the three groups will be assessed five times throughout the year: before the initiation of the intervention program, 3 and 6 months later, at the end of the intervention, and 6 months post-intervention to check for the impact of the program on children's health.

Ethics Statement

This project was approved in the Ethics Committee of the Federal University of Health Sciences of Porto Alegre/Brazil—UFCSPA, n° 1.151.220 and through the Coordination for the Improvement of Higher Education Personnel (CAPES), Brazilian Federal agency for the Support and Evaluation of Graduate Education. The participation of children and parents, as well as their parents' consent was voluntary and unrewarded. Finally, informed consent was obtained from all parents/guardians regarding authorization of their children to participate in this study. All subjects (children, parents and consent of parents/guardians) gave written informed consent in accordance with the Declaration of Helsinki.

MATERIALS AND EQUIPMENT

Instruments and Measures

The effectiveness of the intervention will be assessed five times throughout the program. Ten self-reports (e.g., Food Preference Instrument, Students' Attitudes and Perceptions and Parents' Perceptions and Influences on the Health Instrument, Food Availability and Oral Health Instrument, Self-Regulation for Health Scale, Self-Efficacy for Health Scale) and two physical measures (e.g., BMI and OHI-S) will be used.

To characterize the baseline of this study, two questionnaires were used in 2016, before the start the program: Previous Day Food Questionnaire—*PDFQ;* and *Declarative Knowledge* and physical measures assessments (BMI e OHI-S) (Greene and Vermillion, 1964; World Health Organization and Multicentre Growth Reference Study Group, 2006; Penkilo et al., 2008; Assis et al., 2009; Wall et al., 2012).

Body Mass Index (BMI)

This anthropometric evaluation is one of the less invasive methods and has well established cutting techniques and points (Greene and Vermillion, 1964; World Health Organization and Multicentre Growth Reference Study Group, 2006; Brasil, 2008). It is the most commonly used method in interventions that focus on obesity prevention (Kamath et al., 2008; Friedrich et al., 2012; Bogart et al., 2014). Validation studies of this instrument are limited in quantity. An internal and external validation study showed valid estimates regarding the weight of the subjects evaluated by this scale (Deurenberg et al., 1991). The data were obtained by determining the weight and height of the students by using an electronic scale and stadiometer for each measurement respectively. The devices were calibrated in the Nutrition Laboratory of the Federal University of Health Sciences of Porto Alegre and operated by nutrition researchers from these labs. To guarantee the reliability of the measures, all researchers followed the same protocol throughout evaluations. To classify the nutritional status of the schoolchildren, the data on height/age z scores (E/I) and body mass/age index (BMI/I) were used, following the standards of the World Health Organization and Multicentre Growth Reference Study Group (2006). We used the following cut-off points for E/I: $z < -3$ (low height), $-3 \leq z < -2$ (low height), $z \geq -2$ (height suitable); the following cut-off points were used for BMI/3 (thinness): $-3 \leq z$

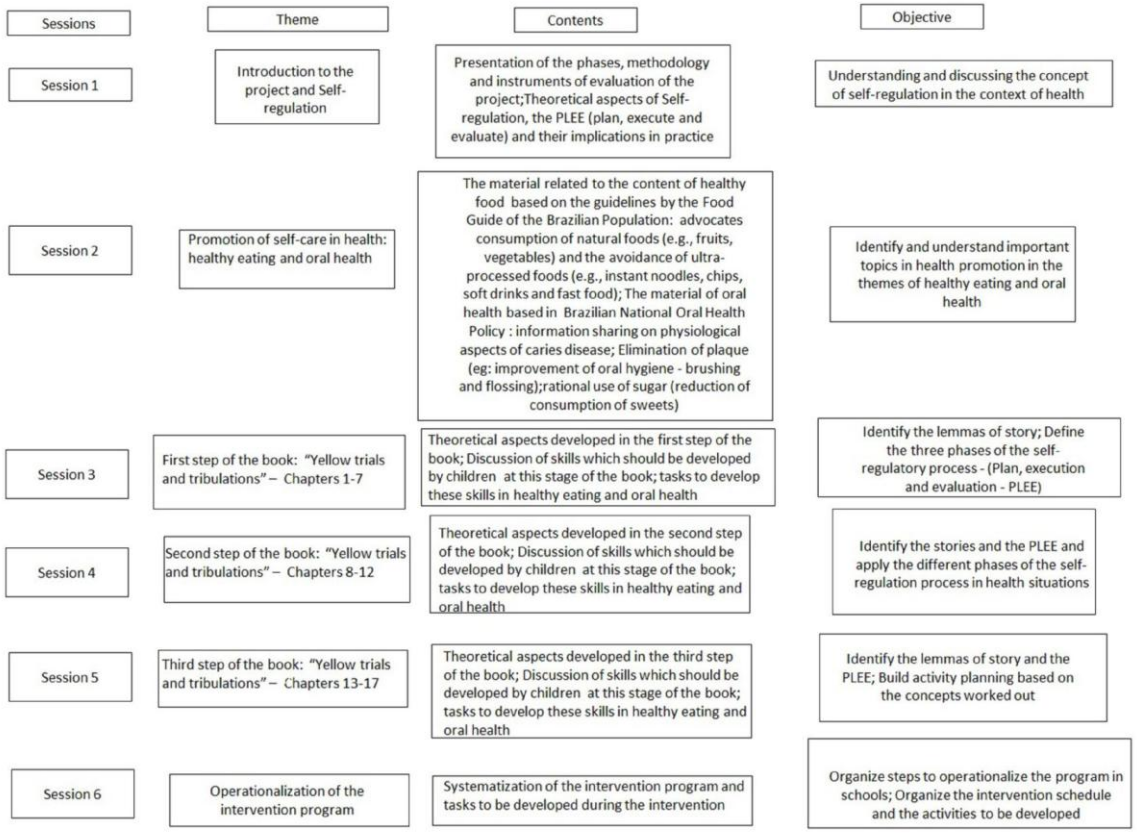

FIGURE 3 | Promoting self-regulation in health among vulnerable Brazilian children: protocol study. Training Actives. PLEE, Plan, execution and evaluation.

<−2 (severe thinness), −2 ≤ z < +1 (eutrophic/normal), +1 ≤ z < +2 (overweight), +2 ≤ z < +3 (obesity), Z ≥ + 3 (severe obesity) (World Health Organization and Multicentre Growth Reference Study Group, 2006).

Simplified Oral Hygiene Index

OHI-S is a classic measure used to determine the impact of health education on oral hygiene (Greene and Vermillion, 1964; Silveira et al., 2002; Cardoso et al., 2011; Scopel et al., 2011). To assess the oral health condition the index OHI-S was used. This index measures plaque accumulation on six dental surfaces (16, 11, 26 and lingual vestibular of 31, 36, 46) (Greene and Vermillion, 1964). Each surface is evaluated according to the scores on a scale from 0 to 3: 0—The surface is free of plaque; 1—Less than 1/3 of the tooth covered per plate; 2—Between 1/3 and 2/3 of the tooth is covered per plate; 3—More than 2/3 of the tooth is covered per plate. The final result of this evaluation is obtained by dividing the sum of the values by the number of surfaces evaluated (Greene and Vermillion, 1964). The values obtained indicate the oral health on a range between good and poor hygiene: values from 0.0 to 0.6 indicate good hygiene, values from 0.7 to 1.8 indicate regular hygiene, and values from 1.9 to 3.0 indicate poor hygiene (Greene and Vermillion, 1964). Oral Hygiene Index (OHIS) is recognized to be a useful index for evaluation of dental health education in public school systems. Literature has been stating that OHIS is a sensitive method that can be used to evaluate oral hygiene of population groups with confidence (Greene and Vermillion, 1964; Mbawalla et al., 2010).

Previous Day Food Questionnaire (PFDQ)

The PFDQ is an illustrated instrument that seeks information from schoolchildren about the food they consumed on the day prior (Assis et al., 2009). The meals were arranged in chronological order: breakfast, mid-morning snack, lunch, afternoon snack, dinner, and evening snack (Assis et al., 2009). Each meal was illustrated by 21 individual foods and some food groups: dry beans, rice, milk, coffee with milk, chocolate milk, cheese, yogurt, beef or poultry, pasta, bread or crackers, French fries, pizza or hamburger, leafy vegetables, starchy vegetables, vegetable soup, fruits, sweets, chips, fish/sea foods, soft drinks, and fruit juices (Assis et al., 2009). The reliability of this instrument to assess the foods consumed was 70.2% and the non-consumed food was 96.2%. In Brazil, studies were also conducted using multivariate logistic regression. Data showed that the frequency of discordance ranged from 3.7 to 39.6% (Assis et al., 2009). Children in 5th grade classes will complete this questionnaire three times a week in class and at home, the latter with the parents/guardians acting as responsible mediators.

Declarative Knowledge for Health Instrument (DKH)

In this study, the Declarative Knowledge for Health (DKH) is an adaptation of the Nutritional Monitoring questionnaire (Penkilo et al., 2008; Assis et al., 2009). Questions aim to evaluate children's knowledge about healthy eating and oral health (Penkilo et al., 2008; Wall et al., 2012). This instrument consists of 20 questions (10 questions for each theme). In the current study, the coefficient of Alpha of Cronbach indicated an internal consistency of 0.71 for healthy eating and 0.76 for oral health.

PROPOSED ANALYSIS

Data will be analyzed with linear mixed models using IBM SPSS Statistics version 22 with alpha levels set at $p \leq 0.05$. It is expected that at the end of the intervention significant differences will occur with an increase in SRH, self-efficacy, and declarative knowledge in both domains (healthy eating and oral health) for CII in relation to the other two groups (CI and CG). Moreover, in relation to healthy eating, at the end of the program it is expected that the consumption of fruits and vegetables may increase, and the consumption of ultraprocessed foods may decrease; consequently a reduction in obesity and overweightness is expected. While focusing on oral health, at the end of the intervention it is expected for the CII group to show better brushing and care in relation to oral health and consequently an improvement in the health situation reflected in dental plaque reduction (and possible oral diseases prevention). These hypotheses will be studied through the intragroup analysis and intergroup with ANOVA of repeated measures, during the five moments of evaluation of the program. Differences between conditional and control groups at baseline were examined using Chi-square test (χ^2) of heterogeneity comparing the proportions between the groups, significance levels were set at $p < 0.05$, and descriptive analysis of frequencies, mean, and standard deviation were done.

ANTICIPATED RESULTS Baseline

The preliminary outcomes show the first application of PFDQ, DKH, and physical measurement evaluation (BMI and OHI-S) (Greene and Vermillion, 1964; Penkilo et al., 2008; Assis et al., 2009; Wall et al., 2012; World Health Organization, 2016). These data were collected prior to the beginning of the project in order to characterize the baseline.

In terms of the anthropometric data, 429 students (198 from the CII, 113 from the CI and 118 from the CG) participated in data collection. The mean age of participants was 10.61 years (*SD*−1.06). When assessing the nutritional status of children, according to z-score of BMI/weight and height/ age, the researchers observed that there were no differences between groups (World Health Organization and Multicentre Growth Reference Study Group, 2006). The prevalence of eutrophic/normal children with adequate heights for their age was 96 (24.5%), 57 (14.5%), and 67 (17.1%), respectively. However, there were high percentages of overweight, obesity and severe obesity in all groups (**Table 1**).

TABLE 1 | Data of BMI/weight and Height for age, Z-score (Z) (World Health Organization and Multicentre Growth Reference Study Group, 2006).

BMI CLASSIFICATION DATA	CII (198)	CI (113)	CG (118)	Total (429)
Eutrofhy/height suitable for age	94 (24.5%)	57 (14.5%)	67 (17.1%)	218 (50.8%)
Eutrofhy/low height for age	2 (1.07%)	–	–	2 (0.5%)
Overweight/height suitable for age	47 (12.0%)	30 (7.7%)	19 (4.8%)	96 (22.4%)
Obesity/ height suitable for age	25 (6.4%)	18 (4.6%)	24 (6.1%)	67 (15.7%)
Severe obesity/height suitable for age	10 (5.0%)	5 (4.4%)	4 (3.4%)	19 (4.4%)
Thinness/height suitable for age	4 (1.0%)	2 (0.5%)	2 (1.7%)	8 (1.9%)
Severe thinness/low height for age	–	–	2 (1.7%)	2 (0.4%)

BMI, Body Mass Index; CII, condition II group; CI, condition I group; CG control group.

Regarding the Declarative Knowledge in health, we did not observe statistically significant differences in the number of correct answers between healthy eating and oral health in the participating groups (the level of significance was 0.05). Focusing on the knowledge related to the theme of healthy eating, only two items (3 and 5) presented significant differences in the number of correct answers between the groups [item 3: $\chi^2 = 7.20$, $p = 0.027$ and Item 5: $\chi^2 = 12.38$, $p = 0.002$]. These questions relate to fruits and vegetables (e.g., "It is necessary to eat fruits and vegetables but not all days") and biscuits with sugar (e.g., "Biscuits with sugar are industrial foods"). In the two items, the CI Group (schools enrolled in the PSE), had more correct answers than the other two groups. This may indicate that this content knowledge had already been addressed during the PSE sessions run by the primary care teams (Brasil, 2015) as well as by the teachers in science classes (Brasil, 2016).

Regarding the oral health data, a difference was found between the groups. Globally, the CII and CI groups showed a prevalence of regular oral hygiene, 103 (25.0%) and 58 (14.1%), respectively; while the CG presented a good oral hygiene, 67 students (16.3%), as shown in **Table 2**. This good oral hygiene status of the CG may be due to more frequent and adequate brushing techniques used. Regarding the oral health topic, three items presented differences between the groups in terms of the number of correct answers (item 1: $\chi^2 = 9.15$, $p = 0.010$; Item 8: $\chi^2 = 8.50$, $p = 0.014$ and item 9: $\chi^2 = 7.35$, $p = 0.025$). These items regard caries disease (e.g., "Carie is not caused by bacterias"), toothbrush cleanliness (e.g., "I need to change my toothbrush once per year") and bacterial plaque (e.g., "Bacterial plaque can be removed by brushing teeth"). The highest number of correct answers was obtained by CI and CII groups.

The outcomes related to the previous day food questionnaire (PDFQ) describe the food that was consumed on 3 days of the week (1 weekend day and 2 weekdays), six meals per day (breakfast, mid-morning snack, lunch, afternoon snack, dinner,

TABLE 2 | Data Simplified Oral Hygiene Index – OHI-S (Greene and Vermillion, 1964).

OHI-S DATA	CII (198)	CI (113)	CG (118)
Poor	8 (1.9%)	16 (3.9%)	1 (0.2%)
Regular	103 (25.0%)	58 (14.1%)	50 (12.1%)
Good	71 (17.2%)	38 (9.2%)	67 (16.3%)

CII, condition II group; CI, condition I group; CG control group.

and evening snack) (Assis et al., 2009). Data were organized and analyzed as follows: the 21 foods depicted in the PDFQ were collected in ten large food groups in accordance to the Food Guide of the Brazilian Population, which describes the food groups that should have highest prevalence for each meal (**Table 3**) (Assis et al., 2009; Brasil, 2014). Moreover, the students in the three groups reported the food they had consumed within the previous 3 days prior to the questionnaire. The food that was most commonly consumed for breakfast and mid-morning snack meals included the following: dairy products (milk, yogurt, cheese, chocolate), cereals (bread, wafer, rice, pasta), and fruit (fruit and fruit juices) groups. Another observation worth noting is that for snacks, the children tended to consume candies (cakes and sweets in general), soft drinks (and artificial juices), and chips (Currie et al., 2012). The most frequent food groups reported in lunch and dinner were cereals (bread, crackers, rice, pasta, and potatoes), proteins (meats in general, eggs) and soft drinks (**Table 4**). It should be noted that the vegetable groups had a lower prevalence than that of soft drinks (and artificial juices). The afternoon and evening snacks included the following as main food groups: cereals, milk and dairy products, with an emphasis on fast food in the evening (e.g., chips, hamburgers, pizza, and ultra-processed snacks) (CGI−26%, CGII−18%, CG−27%, see **Table 4**) (Brasil, 2014).

DISCUSSION

The data found are consistent with general data from the Brazilian population-based studies involving school children: findings show a low rate of nutritional deficits and an increase in overweightness and obesity (Ruiz et al., 2009). In a study involving 3,387 school children between the ages of seven and ten, in the public school system of Rio de Janeiro, data showed that the students had a prevalence of eutrophy/normal weight, followed by overweightness and obesity (Anjos et al., 2003). Percentages of overweightness and obesity were identified in all groups as well as unhealthy eating habits such as the following: the consumption of soft drinks and artificial juices for almost all meals; the consumption of snacks, candies and fast food for breakfast; and the higher consumption of soft drinks and candies over vegetables. These eating behaviors, particularly low consumption of fruits and vegetables and high consumption of sweets, candies, and beverages rich in sugar and fats, have been indicated by literature as significant risk factors for overweightness and obesity (Neutzling et al., 2007; Tarek et al., 2008; Bertin et al., 2010).

Declarative knowledge describes how people define their knowledge. It is comprised of the process of information and how people understand concepts (Rosário et al., 2017). Data on declarative knowledge about healthy eating have indicated that children maintain unhealthy eating habits even though they have knowledge about healthy eating (Gaspar et al., 2014). This may suggest that children have difficulties in regulating their eating behavior (Anderson et al., 2007). Therefore, school interventions in this topic may wish to develop a set of self-regulatory skills needed to develop healthy eating habits (Anderson et al., 2007).

Data for oral health were also gathered from all the groups enrolled. The students in the groups that participated previously in PSE showed lower oral hygiene than the students in the control group; the latter will not participate in school activities systematically implemented on this topic. This finding was unexpected because the students in Condition I and Condition II participated in the PSE activities and had several opportunities to practice oral care, while students in the Control group did not have this training.

This good practice prevents the generation of plaque on the surfaces of the teeth as well as, overall, oral disease. Prior research indicates that adequate oral hygiene is related to the absence of caries in school children (Anagnostopoulos et al., 2011). Another study pointed out that educational-preventive activities with school children and preschoolers, even for a short period, may be effective for reducing visible plaque and gingival bleeding (Barreto et al., 2013). However, the current study findings suggest that to maintain positive results, the intervention program must be long-term (Pauleto et al., 2004).

In recent years, the number of oral health programs offered to school children has increased. However, the programs still hold an approach more focused on medicalized treatments than on educational promotion, for example stressing students agent role in their health (Pauleto et al., 2004). Notwithstanding, even school-based programs with an educational approach lack opportunities to discuss and reflect on health behaviors and improve SR. The SR practices are important because they are likely to promote autonomy and instigate good oral health care (Pauleto et al., 2004). Initial data allows us to conclude that children's participation in the PSE intervention for 4 years (from 1st to 4th grade) and the acquisition of knowledge on healthy eating and oral health is not enough to promote and sustain good health habits. Data seem to be indicating that besides the health knowledge learnt with the PSE intervention, children may need intentional educational training on SR to help them change their health behavior. Present findings indicate the need to expand PSE interventions while emphasizing the development of SR competences for self-management and self-control of health-related behaviors. This training is expected to help children set goals and display strategies to achieve, and afterwards sustain, good health practices.

TABLE 3 | Food Consumption information– PFDQ (Assis et al., 2009).

Meals	nº meals/week			Food groups consumed					
	CI	CII	CG	CI		CII		CG	
Breakfast	296	422	295	Milk/derivatives	227 (76.68%)	Milk/derivatives	307 (72.74%)	Milk/derivatives	265 (89.83%)
				Cereals	218 (73.64%)	Cereals	267 (63.27%)	Cereals	226 (76.61%)
				Fruits	62 (20.94%)	Fruits	58 (13.74%)	Fruits	44 (14.91%)
				Candies	19 (6.41%)	Candies	48 (11.37%)	Candies	22 (7.45%)
				Soft drinks	19 (6.41%)	Soft drinks	36 (8.53%)	Soft drinks	17 (5.76%)
Mid-morning snack	239	318	220	Milk/derivatives	109 (45.60%)	Milk/derivatives	117 (36.79%)	Milk/derivatives	71 (32.27%)
				Cereals	91 (38.07%)	Cereals	87 (27.35%)	Cereals	70 (31.81%)
				Fruits	75 (31.38%)	Fruits	78 (24.52%)	Fruits	61 (27.72%)
				Candies	44 (18.41%)	Candies	53 (16.66%)	Candies	60 (27.27%)
				Soft drinks	42 (17.57%)	Soft drinks	50 (15.72%)	Soft drinks	43 (19.54%)
				Salty snacks (chips)	29 (12.13%)	Salty snacks (chips)	45 (14.15%)	Salty snacks (chips)	33 (15%)
Lunch	335	527	347	Cereals	295 (88.05%)	Cereals	437 (82.92%)	cereals	316 (91.06%)
				Proteins	233 (69.55%)	Proteins	355 (67.36%)	Proteins	267 (76.94%)
				Legume	188 (56.11%)	Legume	269 (51.04%)	Legume	213 (61.38%)
				Soft drink	114 (34.92%)	Soft drink	156 (29.60%)	Soft drink	97 (27.95%)
				Vegetables	88 (26.26%)	Vegetables	133 (25.23%)	Vegetables	88 (25.36%)
				Fruits	50 (14.92%)	Fruits	82 (15.55%)	Fruits	54 (15.56%)
				Fast food	32 (9.55%)	Fast food	35 (6.64%)	Fast food	29 (8.35%)

PFDQ, Previous Day Food Questionnaire; CI, condition I group; CII, condition II group; CG control group.

TABLE 4 | Food Consumption information– PFDQ (Assis et al., 2009).

Afternoon snack	320	487	322	Cereals	176 (55%)	Cereals	244 (50.10%)	Cereals	155 (48.13%)
				Milk/derivates	150 (46.87%)	Milk/derivates	214 (43.94%)	Milk/derivates	137 (42.54%)
				Candies	81 (25.31%)	Candies	125 (25.66%)	Candies	98 m(30.43%)
				Fruits	77 (24.06%)	Fruits	96 (19.71%)	Fruits	92 (28.57%)
				Soft drinks	72 (22.5%)	Soft drinks	92 (18.89%)	Soft drinks	78 (24.22%)
				Salty snack (chips)	51 (15.93%)	Salty snack (chips)	56 (11.49%)	Salty snack (chips)	43 (13.35%)
				Fast food	28 (8.75%)	Fast food	24 (4.92%)	Fast food	29 (9%)
Dinner	321	488	328	Cereals	251 (78.19%)	Cereals	343 (70.28%)	Cereals	259 (78.96%)
				Proteins	189 (58.87%)	Proteins	240 (49.18%)	Proteins	187 (57.01%)
				Legume	161 (50.15%)	Legume	178 (36.47%)	Legume	150 (45.73%)
				Soft drinks	95 (29.59%)	Soft drinks	134 (27.45%)	Soft drinks	91 (27.74%)
				Vegetables	86 (26.79%)	Vegetables	112 (22.95%)	Vegetables	79 (24.08%)
				Fruits	41 (12.77%)	Fruits	77 (15.77%)	Fruits	46 (14.02%)
				Fast food	37 (11.52%)	Fast food	72 (14.75%)	Fast food	47 (14.32%)
				Milk/derivates	21 (6.54%)	Milk/derivates	31 (6.35%)	Milk/derivates	16 (4.87%)
Evening snack	246	313	230	Milk/derivates	87 (35.36%)	Milk/derivates	104 (33.22%)	Milk/derivates	77 (33.47%)
				Candies	74 (30.06%)	Candies	91 (29.07%)	Candies	72 (31.30%)
				Fruits	69 (28.04%)	Fruits	68 (21.72%)	Fruits	64 (27.82%)
				Cereals	61 (24.79%)	Cereals	68 (21.72%)	Cereals	58 (25.21%)
				Soft drinks	61 (24.79%)	Soft drinks	64(20.44%)	Soft drinks	43(18.69%)
				Salty snacks (chips)	24 (9.75%)	Salty snacks (chips)	24 (7.66%)	Salty snacks (chips)	27 (11.73%)
				Fast food	26 (10.56%)	Fast food	18 (5.75%)	Fast food	20 (8.69%)

PFDQ, Previous Day Food Questionnaire.

LIMITS

The possible limitations of this study may stem from the restricted numbers of participants enrolled and the design, as follows: the study was restricted to only one city with their schools and health services; data collection may be impacted by the possible loss of participation, especially considering that this investigation will be run throughout a school-year and per losses of the schools who did not agree to participate in the study.

The biweekly monitoring of the Condition II, the training program and the guidance of materials are among the several strategies expected to help solve these possible external situations (e.g., stoppages due to teachers strikes, withdrawal of study participation, transfers of students and school teachers).

CONCLUSIONS

The present study is expected to contribute to understand the impact of a health public policy implemented all over the country. The findings are expected to help reinforce the importance of the multidisciplinary action of health and education professionals, and this interdisciplinary articulation favors health promotion. The PSRH is designed to respond to this call. This program aims to equip the students with the skills and knowledge to improve their self-care habits, their organization in their daily life and their overall autonomy. Moreover, it can be further used as a tool to train teachers and health professionals so that they help students throughout the stages and processes of SR (e.g., PLEE) (Núñez et al., 2013). It is hoped that the training provided on SRH for health professionals and teachers, and the implementation of the PSRH in schools help children to become more autonomous and responsible regarding their self-care on healthy eating and oral health. In consequence, PSRH is expected to help reduce children's health problems, as well as public expenditures with children's health (e.g., obesity and oral diseases).

AUTHOR CONTRIBUTIONS

LM, CM, PR, MB, and MS: contributed to the build design and conduct the training of the Program; MM and AB: contributed to the organization and analysis of data; CR, CM, and PR: contributed to the writing, discussion, and approval of the manuscript.

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Conflict of Interest Statement: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

APPENDIX

TABLE A1 | Examples of activities 1 month in three groups.

	Activities	**Periodicity**	**Methodology**	**Responsible**
CGI	Educational activity on healthy eating	Monthly	Lecture	Health care professional
	Educational activity on oral health	Monthly	Lecture	Dentist or oral health technician
CGII	Educational activity on healthy eating	Monthly	Lecture	Health care professional
	Educational activity on oral health	Monthly	Lecture	Dentist or oral health technician
	Reading chapter 1 and reflection;	Weekly	Collective reading and discussion in a large group	5th grade teacher—trained by PSR
	"Colors" activity; Identification with the colors of the students' history and characteristics	Weekly	Discussion in small and large groups	5th grade teacher and health professional—trained by PSR
	Reading chapter 2 and reflection;	Weekly	Collective reading and discussion in a large group	5th grade teacher—trained by PSR
	Activity: "Order of things"—reflect on order of things in life, health care (healthy eating and oral health)	Weekly	Discussion in a large group	5th grade teacher and health professional—trained by PSR
	- Reading chapter 3 and reflection	Weekly	Collective reading and discussion in a large group	5th grade teacher—trained by PSR
	- Activity: "What would happen if ... "—reflect on the role of all (healthy eating and oral health)	Weekly	Discussion in a large group	5th grade teacher and health professional—trained by PSR
	Reading chapter and reflection	Weekly	Collective reading and discussion in a large group	5th grade teacher—trained by PSR
	Activity: Planning—Reflect on the importance of planning actions (health care)	Weekly	Reading and working in small groups	5th grade teacher and health professional—trained by PSR
CG	Curricular school activities	weekly	Exhibition classes; Group discussions	5th grade teacher—trained by PSR

ARTIGO 2 -

Promoting self-regulation in healthy eating among vulnerable Brazilian children: a randomized clinical trial

Self-regulation in children healthy eating

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Abstract

Objective: This study aims to evaluate the effectiveness of a program to promote Self-Regulation in healthy eating.

Design: The current paper reports a randomized clinical trial (Clinical Trials NCT03222713) The research had two phases: Phase I: Training in Self-Regulation in Health; and Phase II: Implementation of the Self-Regulation Program of Health (PSRH). The classes were randomly assigned into three groups: PSE program (G2), PSE plus PSRH program (G3) and a control group (G1) of participants in classes which did not enroll in either program. Measures and instruments used: Previous Day Food Questionnaire, Declarative Knowledge for Health Instrument, Self-Regulation for Health Scale, Self-Efficacy for Health Scale, and body mass index. Participants in all conditions were measured across five time-points in six dependent variables (i.e., self-regulation - SR, self-efficacy SE, declarative knowledge DK, reported consumption of fruits and vegetables, and ultraprocessed foods, and body mass index BMI).

Setting: South of Brazil.

Subjects: The participants of study were 5th grade students from public elementary schools.

Results: Findings indicates that the means of Group 3 increased (SR healthy eating, SE healthy eating, DK healthy eating, fruits and vegetable) or decreased (BMI and Ultraprocessed foods) across time, there appears to be consistent improvement across time. Therefore, in this case, the time of implementation of the program is crucial to judge the efficacy of the intervention.

Conclusions: PSRH helped change the health habits (e.g., increase consumption of fruits and vegetable, and reduce children's health problems. Moreover, globally, data stressed the value of public policies focused on the promotion of healthy eating that help vulnerable children stay healthy and succeed in school.

Keywords: Self- regulation, healthy eating, public elementary schools.

Introduction

Health promotion targeting children with a particular focus on eating habits has been receiving the attention of educators and researchers [1]. According to the WHO report, the prevalence of obesity among children under the age five has increased from 4.8% to 6.1% between 1990 and 2014; this entails that the number of children affected has grown from 31 million to 41 million [1]. These changes of health condition have resulted, in increases in noncommunicable chronic diseases (e.g., diabetes, hypertension, heart disease and certain types of cancer) in all population groups [2,3]. The nutritional education of the population is a complex process, influenced by many personal and societal variables. For example, the food consumption habits of the Brazilian population in the last years, replacing "in natura" (e.g., beans, rice, potato, vegetables and manioc) with ready-to-eat industrialized products (e.g., cookie stuffed, fast food, instant noodles), may help explain the aforementioned health condition scenario. The promotion of healthy eating in the school has the potential to lead to significant changes in the health eating habits of the population, because eating habits developed in childhood and adolescence are likely to last into adulthood [4,5].

Aiming to improve the school health in Brazil, the Ministries of Health and Education launched the Health in School Program (PSE)[6]. The PSE is a school-based program built on the articulation of the educational and health systems to promote the education for health public schools [6]. The main goal of the PSE is to analyze the risk factors of the populations and set preventive care interventions in the public elementary school to promote students health (e.g., assessing nutritional status, early incidence of hypertension and diabetes, caries control, visual and auditory acuity and health eating activities)[7]. These activities are developed by primary care professionals (nurses, nursing technicians and community health agents) along with teachers [7]. However, and despite the political efforts displayed over the last years to set the PSE program in action by developing health activities integrating school and health systems, the low nutritional state Brazilian children has not regressed [8]. In fact, according to a recent report by Brazilian Ministry of Health, 15.6% of the

Brazilian children aged between 5 and 10 years old are overweight and 13.7% are obese [9].

Furthermore, what may help to explain these scenario, extant research has reported difficulties to develop joint activities involving school and health teams to promote healthy eating on a regular basis [10]. In order to contribute for this question the current research aimed to investigate the promotion of healthy eating in elementary school, under a health promotion perspective, based on Bandura model of self-regulation (SR)[11] , which provides a relevant theoretical framework to the present study. SR in health addresses individuals efforts to exercise control over their motivation and health behaviors[11], and throughout the years has gained the attention of researchers interested in processes of health behavioral changes (e.g., self-control of health-related behaviors; setting objectives and strategies focused on health promotion and on sustaining healthy practices) [12, 3] . Focused on health, the SR framework can help build understanding of the processes involved in the promotion of lifelong habits [13]; moreover, the promotion of SR is likely to improve individuals' health and personal well-being [14,15]. Specially, displaying adequate levels of SR predicts long-term success in achieving goals on healthy eating interventions [16, 17]. In fact, the development of SR skills was identified as the best predictor of healthy nutritional behavior in studies with adults, children and adolescents populations [18-21].

The current study is grounded on the SR framework, and addresses three goals: 1) the promotion of health of Brazilian children which shows a negative trajectory, despite the efforts of the PSE; 2) the difficulties children and teachers report to engage in the activities of the PSE; and the 3) lack of interventions under the SR framework to promote healthcare in Brazilian context [18, 8]. Therefore this research aims to assess the efficacy of a program to promote SR in healthy eating.

Methods

The paper reports a randomized clinical trial. Elementary public schools from the south of Brazil were enrolled in the current research, and were randomly assigned to an experimental condition: PSE program; SRL Program, and control condition. Each condition will be further explained in the following section.

The research had two phases: Phase I: Training in Self-Regulation in Health; and Phase II: Self-Regulation Program of Health (Figure 1).

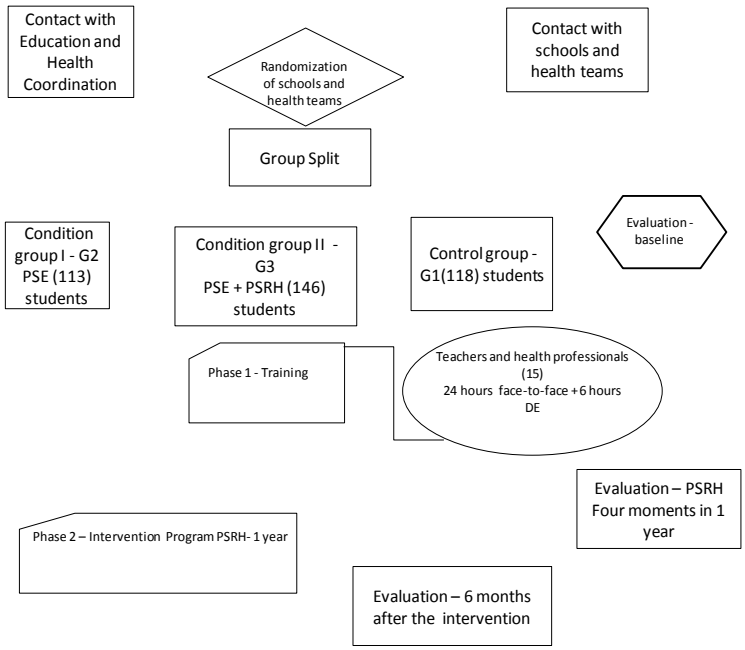

FIGURE 1. Promoting self-regulation in healthy eating among vulnerable Brazilian children: a randomized clinical trial. Flow diagram for study procedures.
PSE, Programa Saúde na Escola; PSRH, Program to Promote Self-regulation in Health, DE, distance education.

Contextualization of the study

The study was conducted in Sapucaia do Sul, a city in the South of Brazil. That has approximately 138,357 inhabitants and a low average monthly income compared to neighboring cities in the same region [22]. The high social vulnerability of the inhabitants of the city explains why it was chosen for running the investigation. Sapucaia do Sul has 42 elementary public schools and 23 Primary Health Care Units. The latter employs doctors, nurses, nursing technicians, community health workers (CHW), dentists and oral health technicians [23]. Elementary schools and the primary health care units are expected to form a dyad as a condition to engage in the PSE. This means that each school enrolled in the PSE is working with a health care unit regarding health issues [23].

Recruitment and randomization process

Specific requisites for be enrolled in the current study were for schools with 5th grade classes and working together with a Fourteen health care unit of the 16 elementary schools engaged in PSE which met these criteria, were invited to participate seven schools agreed to participate (response rate of

50%). Seven elementary schools which were not enrolled in PSE were contacted to participate as Control Group, but only three agreed (response rate of 43%) (Figure 2). The reasons given by the schools for not enrolling in the research were not related with the nature or goals of the intervention, but with social and administrative limitations (e.g., general strikes that paralyzed public schools for several months, high workload and low salaries of the teachers and health staff). The latter are examples that reflect the actual educational and public health scenario in Brazil and stress the relevance of developing research projects with vulnerable children, to help them improve health and school success [24, 25].

The school boards of ten elementary schools agreed to participate. Seven out of the ten elementary schools were enrolled in PSE. The classes from these schools were randomized into two groups: Condition I – G2 - (eight classes) – schools participating in the PSE; and Condition II – G3 - (nine classes) – schools participating in the Promotion of Self-regulation in Health program (PSRH) (figure 2). The three schools non enrolled in PSE (eight classes) participated as Control Group – G1.

Inclusion criteria

To be enrolled in this study, participants must meet the following criteria: All participants must be volunteers; teachers must be teaching a 5th grade class in a public elementary school; health professionals must be working in a primary care unit; students must be enrolled in the 5th grade in a public elementary school.

Parents/guardians signed a informed consent term authorizing their children to participate in the study, and teachers and health professionals also signed the informed consent term. All the written informed consents are in accordance with the Declaration of Helsinki.

Exclusion criteria

Potential participants who did not meet all the inclusion criteria, including 5th grade students with special educational needs that limited their cognitive autonomy, were excluded from the study.

Participants

Six hundred and twenty-five fifth grade students and their parents were contacted through face-to-face contacts (parent meetings and meetings with

teachers). Finally, 377 students [215 girls] were enrolled in this research project. These students were nested in 24 classes and their allocation to the three conditions was as follows: 8 classes with 118 students [62 girls] in CG; 8 classes with 113 students [61 girls] in the CI, and 9 classes with 146 students [92 girls] in the CII.

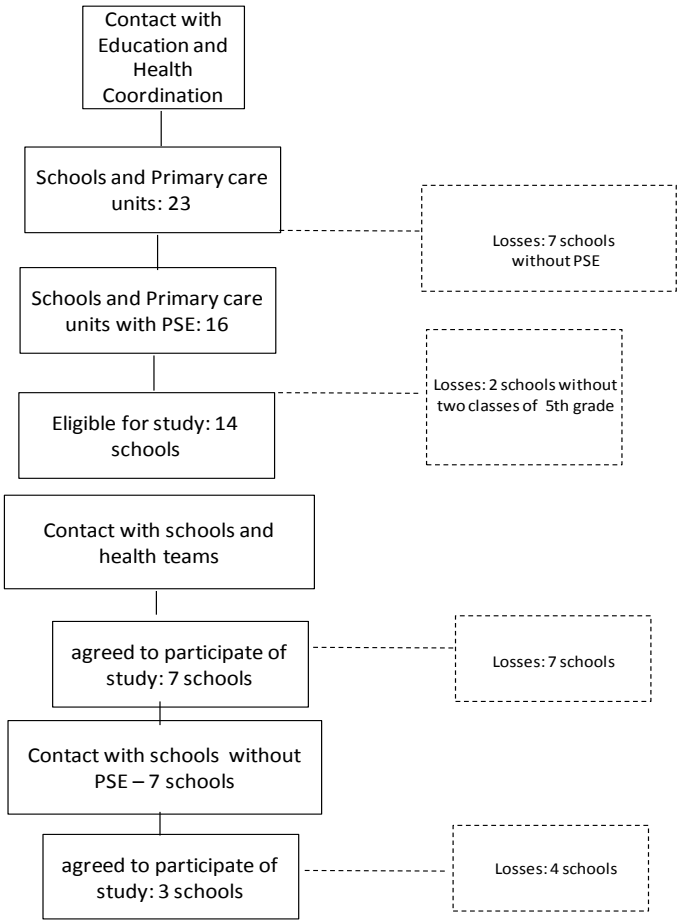

FIGURE 2. Promoting self-regulation in healthy eating among vulnerable Brazilian children: a randomized clinical trial. Flow diagram to recruitment. PSE, Programa Saúde na Escola.

Program Rationale

The PSRH is grounded in the social cognitive framework of SR which addresses the degree in which children are metacognitively, motivationally, and behaviorally engaged in their own learning and health [26]. For the purposes of this investigation, SR focus was set on health behaviors. SR processes may be described as open and dynamic processes proceeding through three main phases (i.e., forethought phase, the performance phase, and the self-reflection phase) [27]. The cyclical nature of this model aims to explain how children initiate, keep and control their behaviors, thoughts, and emotions towards

specific goals. Motivational beliefs and task analysis are the two areas of the forethought phase, and they describe processes prior to behavior efforts (e.g., goal setting, self-efficacy beliefs) [28]. The performance phase describes the processes used by children during their health behaviors. For example, self-instruction is a strategy that may help children focus their attention on healthy food choices and eliminate distractors [26]. Both strategies may facilitate self-control and self-observation, which are key components of the performance phase [27]. Lastly, the self-reflection phase describes methods intended to help children understand the processes that may have led to the outcomes and the reactions to these outcomes [29]. Self-judgments and self-reactions are the two areas of this last phase of the SR cycle [27]. For the purposes of the current research, we used the PLEE model, which is a SR model grounded on the Zimmerman model [27, 30, 31]. The abbreviation PLEE stands for the three phases that comprise the structure of the model: planning, task execution and evaluation [32]. In this model, the logic and the cyclic movement is present within each phase [33]. For example, when children plan what they want to eat for lunch, they fulfill the execution phase by placing healthier foods in their lunch pack and they complete the self-reflection phase by evaluating their choices based on their learned experiences regarding nutrition.

Program to Promote Self-regulation in Health (PSRH)

The PSRH is a program designed to promote the SR of healthy eating. The health contents of the PSRH are the same as those of the PSE (i.e. healthy eating habits). Moreover, the program is rooted on the social cognitive framework of SR [34]. This framework grounded the story-tool, *Yellow Trials and Tribulations* used to approach the health contents and the SR strategies [33].

This story-tool aims to promote SR skills in children aged up to ten years by teaching them SR strategies. The book tells the story of the disappearance of the Yellow color from the Rainbow and the adventures of the other rainbow colors as they search for their missing friend [35]. This story-tool addresses many practical examples of how children can use SR strategies to resolve their daily difficulties by increasing their autonomy in a responsible manner [36,33] .

Phase 1 – Training in Self-regulation in Health

This stage aimed at equipping the professionals with the skills needed to conduct a program in SR of healthy eating habits. This training was delivered by the authors and lasted for three months.

Training was comprised of 24 hours of in-person sessions (4 hour sessions every two weeks of each month). The participants were health professionals (dentists, nurses, nursing technicians and community health workers) and 5th grade teachers of the classes enrolled in the CII condition. These sessions addressed the theoretical contents related to SR, healthy eating and the story-tool, Yellow Trials and Tribulations, which was read and discussed [37, 38, 31]. The sessions also included hands-on activities to build the support materials needed to the work with children (e.g., drawings, worksheets, food maps; See Fig 3. Training activities).

Phase 2 – Intervention program to promote SR in health

The intervention program with children was run by teachers and health professionals (CII) in 50-minute biweekly sessions that were take place throughout the 2016 school year. During these school sessions, the children was completed the assigned chapters of *Yellow Trials and Tribulations* (one chapter per week) as well as participated in discussions and activities related to healthy eating [34] .

The story-tool is divided into three steps, each of them with specific goals and contents to be learned by. By the end of the first step of the book (i.e. Chapers 1-7), the children should be able to define the three phases of the SR process (PLEE) [31]. After completing the second step (i.e. Chapters 8-12), the children should be able to apply the PLEE model to situations of their everyday lives [33]. After completing the entire assigned reading, children should be able to reflect on the importance of the SR strategies learned and transfer to this knowledge to distinct domains of their lives (e.g., behavior in class, healthy food habits, time management).

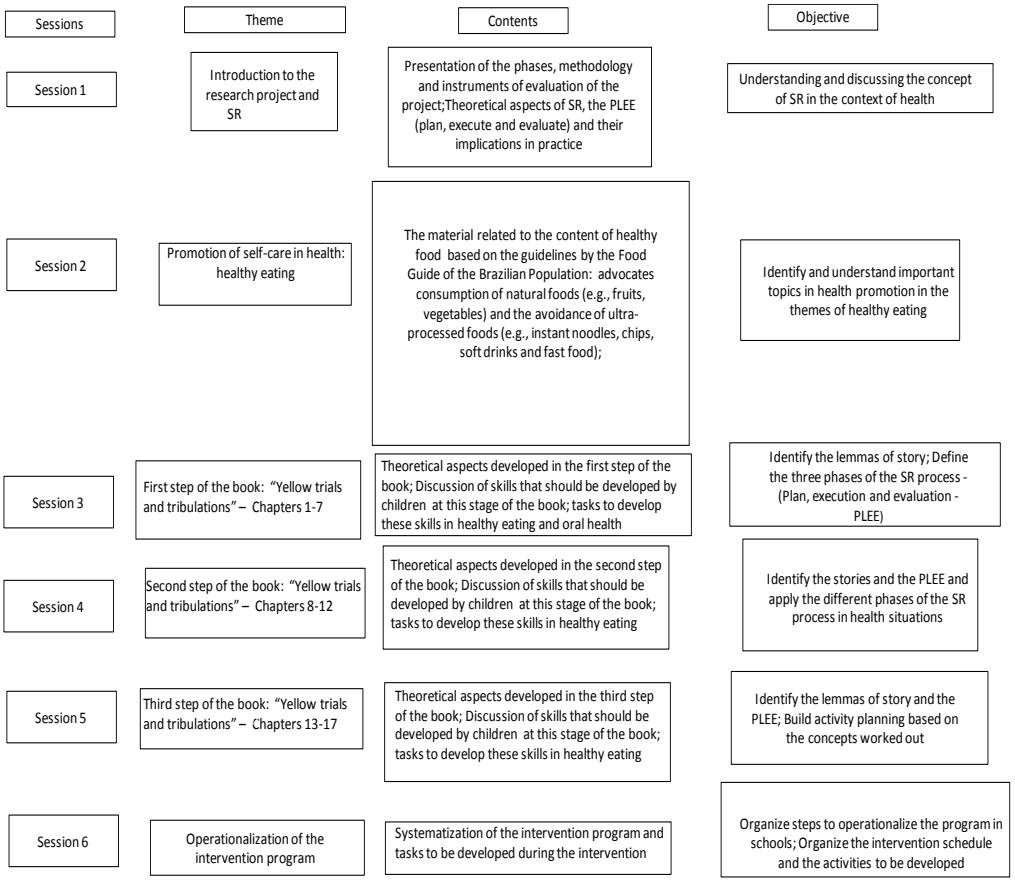

FIGURE 3. Promoting self-regulation in healthy eating among vulnerable Brazilian children: a randomized clinical trial . Training Activities.
PLEE, Plan, execution and evaluation model (Mattos et al, 2018)

Monitoring

The monitoring of the program was done through biweekly visits by the researchers with case discussions and theoretical group meetings. Moreover, students in the three groups were assessed four times throughout the school year (before the beginning of the intervention program, after three months of intervention, after six months of intervention, after nine months of intervention), and 6 months after the conclusion of intervention in the following year, to check the maintenance or changes in relation to SR, self-care and health promotion in the perspective of healthy eating.

Material and measures

The effectiveness of the intervention was assessed five times throughout the program, with three self-reports: SR for Health Scale, Self-Efficacy for Health Scale, Previous Day Food Questionnaire *(PFDQ)*, Declarative Knowledge for Health Instrument (DKHI) and physical measure (Body Mass

Index - BMI). The instruments were validated for the Brazilian context, in another study to be used as an evaluation in this study [39].

SR for Health Scale – This instrument was originally constructed with the objective of evaluating the self-regulation of the learning of school children aged 10 and 11 years [39-41, 33]. The original scale was adapted by the research teams with the purpose of validation to Brazil and for the theme of healthy eating. Cronbach's Alpha coefficient indicated an internal consistency of 0.73. This aims to assess the extent to which children can self-regulate their health in terms of nutrition, being self-administered and composed of nine questions.

Self-Efficacy for Health Scale – This instrument was originally developed for of verifying the perception of self-efficacy of children of elementary school regarding the change in the consumption of fruits and vegetables, after being submitted to a nutritional intervention program [42]. This instrument was adapted and contextualized, by the research team, to the Brazilian scenario and to the theme of healthy eating. Cronbach's Alpha coefficient indicated an internal consistency of 0.77. It is suitable for children between 10 and 11 years old, self-administered and composed of 10 questions.

Previous Day Food Questionnaire *(PFDQ)* – The PFDQ is an illustrated instrument that seeks information from school children about the food they consumed on the day prior [43]. The meals are arranged in chronological order: breakfast, mid-morning snack, lunch, afternoon snack, dinner and evening snack[43] . Each meal was illustrated by 21 individual foods and some food groups: dry beans, rice, milk, coffee with milk, chocolate milk, cheese, yogurt, beef or poultry, pasta, bread or crackers, french fries, pizza or hamburger, leafy vegetables, starchy vegetables, vegetable soup, fruits, sweets, chips, fish/sea foods, soft drinks and fruit juices [43]. The reliability of this instrument to assess the foods consumed was 70.2% and the non-consumed food was 96.2%. In Brazil, studies were also conducted using multivariate logistic regression. Data showed that the frequency of discordance ranged from 3.7% to 39.6% [43].

Declarative Knowledge for Health Instrument (DKH) - In the current study, instrument is an adaptation of the Nutritional Monitoring Questionnaire [44, 43]. Questions aim to evaluate children's knowledge about healthy eating [44, 45].

This instrument consists of ten questions for healthy eating and the coefficient of Cronbach's Alpha coefficient indicated (0.71).

Body Mass Index (BMI)

This anthropometric evaluation is one of the less invasive methods and has well established cutting techniques and points [46,47]. It is the most commonly used method in interventions that focus on obesity prevention [48-50]. Validation studies of this instrument are limited in quantity. An internal and external validation study showed valid estimates regarding the weight of the subjects evaluated by this scale [51]. The data were obtained by determining the weight and height of the students by using an electronic scale and stadiometer for each measurement respectively. The devices were calibrated in the Nutrition Laboratory of the Federal University of Health Sciences of Porto Alegre and operated by nutrition researchers from these lab. To guarantee the reliability of the measures, all researchers followed the same protocol throughout evaluations. To classify the nutritional status of the schoolchildren, the data on height / age z scores (E / I) and body mass / age index (BMI / I) were used, following the standards of the World Health Organization [46].

Data analysis

In the current investigation, we used a longitudinal cluster randomized trials design. Cluster randomized trials is a natural design choice for testing many educational research questions. This design comprises groups of individuals (e.g., classes) rather than individuals themselves, which are randomly assigned to experimental conditions and where repeated measurements are made on individuals from the same clusters over time.

A wide variety of methods based on classical linear models can be applied to the analysis of longitudinal data. However, the presence of imbalance, due to missing responses from some subjects or due to observations from the same subject being generally correlated, can lead to erroneous conclusions regarding hypotheses of interest. Among other reasons, this is why multilevel hierarchical linear models have become the method of choice for modeling the change in response over time and the factors influencing the change ([52]).

Likelihood-based mixed-effects regression models (MRM), both multivariate and univariate, were used in the analysis of current data. The MRM modeling approach provides an appropriate general analytic framework to determine whether the change in response profiles over time is different among the treatment groups and facilitates that the treatment groups can be compared at the selected values of time. Under the assumption of missing at random (MAR) data, this model is probably the most widely used method for analyzing longitudinal data. Because the missing data mechanism cannot reasonably be assumed ignorable, we performed sensitivity analyses via pattern-mixture models (PMM) and shared-parameter models (SPM) to explore the impact of deviations from the MAR assumption on the conclusions. For the purposes of this research, the time was considered as a quantitative variable centered on initial status (i.e., measured in months beginning at 0 months for the baseline assessment), rather than a classification variable. Dataset was analyzed using MRM with maximum likelihood (ML) estimation as implemented in SAS PROC MIXED [(53)] and the most general mixed model using SAS PROC NLMIXED. Furthermore, Cohen's *d* was calculated as a measure of standardized effect size using the approach described by Vallejo, Ato, Fernández, and Livavic-Rojas [(54)] for growth curve models with attrition.

Initially, we modeled the effect of the intervention considering three different models in competition; each statistical model extends a prior model in some sensible and convenient way. In the first option (hereafter, Model A), the data was analyzed assuming that the 377 students selected from ten middle schools were assigned to the treatment groups and measured across five time-points in six dependent variables (i.e., SR_AL - self-regulation, SE_AL – self-efficacy, DK_AL - declarative knowledge, FV_AL – fruits and vegetables, BMI_AL – body mass index, and UP_AL – ultraprocessed foods). In this first option, the variable class was not included in the random part of model, so the analysis was conducted ignoring clustering in the data at the classroom level. In the analysis of the second option (hereafter, Model B), we analyzed the data from 377 students nested in 25 arbitrarily selected classes from eleven middle schools, with the restriction that seven or eight classes were randomly assigned to each type of treatment, and measured across time in six dependent variables. Finally, simultaneously considering all dependent variables we

analyzed the data from 377 students assuming a quadratic three-level regression model. The three-level model described allows to empirically assess the influence of the class on the observations of the student. If the class effect is observed to be negligible, then analysis by the two-level model for longitudinal data is appropriate, otherwise, the results from the two-level model may be misleading.

Results

Observed outcomes (i.e., SR_AL, SAE_AL, DK_AL, BMI_AL, and UP_AL) means, standard deviations, and sample sizes across the five study time points are given in Table 1. Because the means of Group 3 are increasing (SR_AL, SE_AL, DK_AL, and FV_AL) or decreasing (BMI_AL and UP_AL) across time, there appears to be consistent improvement across time. However, the improvement it is not similar for all the dependent variables. Additionally, the UP_AL means of Group 2 decreased across time.

Table 1. Observed Dependent Variables Means, Standard Deviations, and N Across Time

		Group 1 (PSE)					Group 2 (PSE + PSRH)					Group 3 (Control Group)				
		T_0	T_3	T_6	T_9	T_15	T_0	T_3	T_6	T_9	T_15	T_0	T_3	T_6	T_9	T_15
SR_AL	Mean	3.52	3.41	3.46	3.39	3.41	3.46	3.47	3.47	3.45	3.41	3.35	3.42	3.58	3.79	3.92
	SD	0.76	0.84	0.94	0.95	0.83	0.77	0.80	0.76	0.85	0.86	0.72	0.90	0.82	0.83	0.71
	N	118	112	108	93	92	113	106	99	93	87	146	134	124	118	111
SE_AL	Mean	3.37	3.38	3.42	3.32	3.35	3.39	3.40	3.38	3.30	3.38	3.32	3.39	3.41	3.60	3.76
	SD	0.51	0.50	0.63	0.63	0.62	0.49	0.49	0.52	0.59	0.52	0.56	0.54	0.53	0.43	0.33
	N	118	114	108	94	92	113	106	100	93	88	146	135	128	119	112
DK_AL	Mean	6.65	6.56	6.58	6.18	6.15	6.18	6.37	6.20	6.17	6.47	6.41	6.84	7.29	7.46	7.66
	SD	1.77	1.62	1.66	1.85	1.46	1.77	1.80	1.85	1.60	1.58	1.85	2.04	1.89	1.53	1.63
	N	118	112	108	93	87	113	106	99	93	79	146	134	123	116	106
FV_AL	Mean	4.40	4.32	4.04	3.70	4.06	4.40	4.54	4.00	4.05	4.42	4.22	4.35	4.68	5.54	5.89
	SD	3.01	2.99	3.07	2.47	2.43	3.43	3.70	2.76	2.76	2.25	2.83	2.89	2.26	2.59	3.36
	N	118	107	97	85	77	113	100	95	88	77	146	127	113	108	91
BMI_AL	Mean	2.12	2.11	2.11	2.17	2.14	2.06	2.10	2.00	2.14	2.04	2.04	2.10	2.08	2.02	1.77
	SD	1.20	1.23	1.28	1.30	1.31	1.25	1.31	1.32	1.30	1.17	1.23	1.27	1.27	1.26	1.03
	N	118	97	92	91	83	113	93	93	93	83	146	134	128	124	109
	Mean	6.62	7.19	6.39	6.26	6.31	6.89	5.21	5.30	4.58	5.29	6.56	5.72	5.47	5.21	5.36

UP_AL	*SD*	4.69	6.00	4.78	4.10	4.35	5.22	4.12	3.45	3.15	4.82	4.10	3.63	3.97	3.62	3.74
	N	118	112	108	93	92	113	105	100	93	87	146	130	123	115	110

It is also important to note that, despite the total number of participants in this study (377), the number of those which filled in all measures at each time of evaluation fluctuated. Specifically, the number of subjects were ranged from 377 to 377 at time 0 (baseline for all dependent variables), 324 to 355 at time 3 months, 305 to 336 at time 6 months, 281 to 306 at time 9 months, and 245 to 292 at time 15 months. Of the 377 subjects, only 245 completed data for all dependent variables at all-time points; the remaining 132 subjects did not respond the questionnaires due to various reasons, such as miss school because sickness, and external factors unrelated to the program (i.e., change of residence). Therefore, complete-case analysis under repeated measures multivariate analysis of variance, for example, would have discard approximately one-third of the dataset. MRM, alternatively, uses the data that are available from all 377 subjects.

To test whether the missing data on each of the dependent variables are missing completely at random (MCAR) or not, the Little's test [(55)], which divides the sample into groups based on the patterns of data absence for the study outcome, was used. The likelihood ratio test statistic yielded a χ^2 value of 19.1204 on 10 *df* (p = 0.0387) for observed measurement occasions of the SR_AL variable, a χ^2 value of 7.3256 on 10 *df* (p = 0.6944) for SE_AL variable, a χ^2 value of 8.5925 on 10 *df* (p = 0.5712) for DK_AL variable, a χ^2 value of 65.0751 on 10 *df* (p < 0.0001) for FV_AL, a χ^2 value of 16.3306 on 10 *df* (p = 0.0905) for BMI_AL, and a χ^2 value of 12.0912 on 10 *df* (p = 0.2789) for personal UP_AL variable, which suggests that the MCAR model provides an adequate fit to the data of SE_AL, DK_AL, BMI_AL and UP_AL variables. However, based on Little's test, it was found that the missing data mechanism of the SR_AL and FV_AL were not MCAR. This was confirmed by examining a plot of estimates as a function of the time of dropout. In addition to Little's test, we also performed a comparison of the likelihood-based ignorable model (i.e., MRM) with the pattern-mixture model that only stratifies subjects by dropout status (completers vs. dropouts). The likelihood ratio test statistic yielded a χ^2 value of 9.8 on 4 *df* (p = 0.0439) for observed measurement occasions of the

SR_AL variable and a χ^2 value of 63.1 on 4 *df* ($p < 0.0001$) for FV_AL, which suggests that the MAR model provides an inadequate fit to the data. When the missing data mechanism cannot reasonably be assumed to be MAR, it is advisable to carry out a sensitivity analysis.

Fitting Competing Models

Table 2 shows the results obtained from the three types of multivariate MRM (i.e., Model A, B, and C). Model A was chosen as our "final model" after assessing model fit with likelihood-based AIC and BIC criteria. Empirical results presented by Vallejo, Fernández, Livacic-Rojas and Tuero-Herrero [(56)] showed the appropriateness of ML for selecting the best mean structure using information criteria. This same conclusion was obtained when comparing the three models using likelihood ratio tests. The deviance statistic and number of estimated parameter between parentheses for Models A, B and C were 43079.9 (44), 43079.8 (45) and 43054.2 (63), respectively. Comparing Models A and B, which differ only by the class term, we found a trivial difference in deviance of 0.1 on 1 degree of freedom (*df*). Comparing the Model A to Model C, which differ by the class term and the quadratic change of trajectory, we found that the deviance statistic declines 25.7, which is less the associated .05 critical value of 30.144 (*df* =19). These findings provide an argument for using a simpler, two-level analysis with within-student measurements at level 1 and students at level 2, ignoring the class's effects. However, because the classes were randomized to study conditions, one could argue that the unit of assignment must remain in the model regardless of significance.

Table 2. Results of fitting three multivariate Mixed-Effects Regression Model analyses

	Model A		Model B		Model C	
Fixed Effect	F value	Pr > F	F value	Pr > F	F value	Pr > F
Var	$F_{6,6332}$ = 1782.00	<.0001	$F_{6,766}$ = 1720.24	<.0001	$F_{6,1177}$ =1370.52	<.0001
Var×Sex	$F_{6,4012}$ = 7.29	<.0001	$F_{6,3916}$ = 7.29	<.0001	$F_{6,3916}$ = 7.29	<.0001
Var×Group	$F_{12,7552}$ = 1.46	.2580	$F_{12,966}$ = 1.21	.2724	$F_{12,1468}$ = 0.40	.9630
Var×Time	$F_{6,9346}$ = 9.93	<.0001	$F_{6,9345}$ = 9.93	<.0001	$F_{6,9300}$ = 6.46	<.0001
Var×Group×Time	$F_{12,9344}$ = 6.44	<.0001	$F_{12,9348}$ = 6.45	<.0001	$F_{12,9301}$ = 2.22	.0086

Var×Time^2					$F_{6,9290}$ = 2.61	.0742
Var×Group×Time^2					$F_{12,9290}$ = 1.49	.1394
Random Effect	Estimate	SE	Estimate	SE	Estimate	SE
Level-1 (within-subject variance)						
Residual	5.0064***	0.0736	5.0063***	0.0736	4.9866***	0.0733
Level-2 (between students within classes variances)						
Intercept	0.2598***	0.0335	0.2582***	0.0348	0.2588***	0.0348
Level-3 (between-classes variances)						
Intercept			0.0015	0.0099	0.0015	0.0099
Goodness-of-fit						
Deviance	43079.9		43079.8		43054.2	
Number parameter	44.0		45.0		63.0	
AIC	43167.9		43168.7		43180.2	
BIC	43340.7		43346.5		43427.6	

Note: SE = standard error.

*p < .05 *p < .01; ***p < .001.

Multivariate MRM analyses

Table 2 shows that: 1) sex is a variable that a statistically significant effect on all the above dependent variables simultaneously; 2) as expected, due to randomization, the mean response of treatment groups did not differ significantly from each other at baseline [F (12, 7552) = 1.46, p = 0.2580], in the set of the six dependent variables considered simultaneously; 3) averaged across the treatment groups, there is a significant [F (6, 9346) = 9.33, p < .0001] increase in the mean response over time when considering all dependent variables; that is, on average, participants improved across time. Finally, it is very important to note that there is a significant [F (12, 9344) = 6.44, p < .0001] difference between the treatment conditions over time in the set of the six dependent variables considered simultaneously (i.e., the pattern of change in the variables measured over time is not the same in the three groups). Table 3 shows pairwise comparisons among the three treatment groups evaluated at a specific time. There are no significant differences among groups at times 0, 3, and 6 after treatment. In addition, the means of groups 1 and 2 are not

significantly different for times 9 and 15, but group 3 means are significantly different from the mean of groups 1 and 2 for times 9 and 15.

Table 3. Comparisons of Group × Time Least-Squares Means by simultaneously considering all dependent variables

Effect	Group	Group	Time	Estimate	SE	DF	t value	Pr > |t|
Group	1	2	0	-0.03693	0.1462	211.0	-0.25	0.8008
Group	1	3	0	0.07692	0.1414	165.0	0.54	0.5871
Group	2	3	0	0.11394	0.1399	168.0	0.81	0.4168
Group	1	2	3	-0.02877	0.1179	92.2	-0.24	0.8078
Group	1	3	3	-0.04552	0.1142	71.8	-0.40	0.6913
Group	2	3	3	-0.01675	0.1130	73.6	-0.15	0.8825
Group	1	2	6	-0.02061	0.1065	61.5	-0.19	0.8473
Group	1	3	6	-0.16803	0.1031	47.8	1.63	0.1098
Group	2	3	6	-0.14742	0.1019	48.3	-1.45	0.1545
Group	1	2	9	-0.01244	0.1169	88.6	-0.11	0.9155
Group	1	3	9	-0.29041	0.1129	68.5	-2.57	0.0123
Group	2	3	9	-0.27805	0.1113	68.5	-2.50	0.0150
Group	1	2	15	0.00388	0.1816	457.0	0.02	0.9829
Group	1	3	15	0.53530	0.1751	360.0	3.06	0.0024
Group	2	3	15	-0.53928	0.1722	359.0	-3.13	0.0019

Note: DF = degree of freedom.

Univariate MRM analyses for each dependent variable

Follow-up univariate MRM analyses were performed to determine which dependent variables are responsible for the significant test of group by time interaction. Table 4 includes results of the hypothesis tests for the outcome response measurement data.

Table 4. Results of Mixed-Effects Regression analysis of each of the dependent variables

Fixed Effects					Random Effects				
AR_AL									
Effect	df_N	df_D	F-value	Pr > F	VC	Estimate	SE	Z-value	Pr > Z
Group	2	375	1.74	.1777	τ_{00}	.3578	.0413	8.63	<.0001

Time	1	326	9.12	.0027	τ_{01}	-.0058	.0028	-2.05	.0399
Group×Time	2	326	25.57	<.0001	τ_{11}	.0055	.0003	1.90	.0286
					σ^2	.3528	.0160	22.06	<.0001

AE_AL

Effect	df_N	df_D	F-value	Pr > F	VC	Estimate	SE	Z-value	Pr > Z
Group	2	371	1.05	.3514	τ_{00}	.1631	.0189	8.63	<.0001
Time	1	339	12.92	.0004	τ_{01}	-.0059	.0014	-4.11	<.0001
Group×Time	2	339	23.54	<.0001	τ_{11}	.0005	.0002	3.46	.0003
					σ^2	.1594	.0072	22.15	<.0001

CD_AL

Effect	df_N	df_D	F-value	Pr > F	VC	Estimate	SE	Z-value	Pr > Z
Sex	1	363	4.23	.0403	τ_{00}	1.4693	.1952	7.53	<.0001
Group	2	373	2.15	.1176	τ_{01}	-0.0352	.0141	-2.49	.0127
Time	1	328	9.24	.0026	τ_{11}	0.0004	.0015	0.29	.3846
Group×Time	2	328	26.15	<.0001	σ^2	1.9785	.0901	21.96	<.0001

FV_AL

Effect	df_N	df_D	F-value	Pr > F	VC	Estimate	SE	Z-value	Pr > Z
Sex	1	378	9.54	.0022	τ_{00}	4.1763	.5357	8.64	<.0001
Group	2	384	0.38	.6862	τ_{01}	-0.1591	.0456	-3.49	.0005
Time	1	302	0.13	.8563	τ_{11}	0.0165	.0054	3.05	.0012
Group×Time	2	302	15.94	<.0001	σ^2	5.0704	.2448	20.72	<.0001

IMC_AL

Effect	df_N	df_D	F-value	Pr > F	VC	Estimate	SE	Z-value	Pr > Z
Group	2	379	0.06	.9413	τ_{00}	1.3547	.1140	11.88	<.0001
Time	1	333	1.50	.2209	τ_{01}	-.0278	.0055	-5.05	<.0001
Group×Time	2	298	3.94	.0204	τ_{11}	.0023	.0044	5.15	<.0001
					σ^2_1	.2660	.0224	11.88	<.0001
					σ^2_2	.4961	.0431	11.42	<.0001
					σ^2_3	.2938	.0202	14.54	<.0001

UP_AL

Effect	df_N	df_D	F-value	Pr > F	VC	Estimate	SE	Z-value	Pr > Z
Group	2	370	0.90	.4071	τ_{00}	12.0673	1.3022	9.27	<.0001
Time	1	328	15.47	<.0001	τ_{01}	-.4407	.0926	-4.76	<.0001

Group×Time	2	328	0.81	.4474	τ_{11}	.0335	.0093	3.60	.0002
					σ^2	9.4569	.4332	21.83	<.0001

Note: VC = variance component.

Table 4 shows that the null hypothesis of no differences between treatment conditions with respect to their average growth rates is rejected at a level of significance of no more than 2% for all outcome variables, consumption of ultra-processed food products excluded [$F(2, 326) = 25.57$, $p < .0001$; $F(2, 339) = 23.54$, $p < .0001$; $F(2, 328) = 26.15$, $p < .0001$; $F(2, 302) = 15.94$, $p <.0001$; $F(2, 298) = 3.94$, $p = .0204$; $F(2, 328) = 0.81$, $p =.4474$]. As a whole, these data indicate that the efficacy of the intervention is observed when taking into account the temporal moment of the observation. Therefore, in this case, the time of implementation of the program is crucial to judge the efficacy of the intervention.

The next step addresses the group × time interaction in a manner consistent with the objectives of the research. Linear combinations of means are estimated and compared for this purpose using the LSMEANS statement of the PROC MIXED. The least-squares means are estimates of the three groups evaluated at 0, 3, 6, 9 and 15 times after initiation of the treatments for each dependent variable. These means are graphed in Figure 4. As one would expect, there are no significant differences among the three groups at time 0 (baseline). The means of treatment groups 1 and 2 are not significantly different for times 3 to 15, but the mean of treatment group 3 is significantly different from the means of groups 1 and 2 for times 6 to 15 under the response variables SE_AL, DK_AL and FV_AL. On the other hand, at times 9 and 15 was observed a like behavior to the described with the response variables SR_AL and BMI_AL. As regards to dependent variable UP_AL, it should be noted the all group comparisons tend to become no significant over time. Table 5 summarizes the results of the analysis.

Table 5. Comparisons of Group × Time Least-Squares Means for each Dependent Variable

		SR_AL		SE_AL		DK_AL		FV_AL		BMI_AL	
Group	Time	Estimate	SE	Estimate	SE	Estimate	SE	Estimate	SE	Estimate	SE
1-2	0	.0002	.1001	-.0187	.0661	.3984	.2116	.0498	.3547	.0595	.1666
1-3	0	.1477	.0946	.0664	.0622	.0458	.1901	.2705	.3335	.0273	.1564
2-3	0	.1475	.0923	.0852	.0631	-.3526	.2019	.2207	.3378	-.0323	.1583
1-2	3	-.0147	.0886	-.0168	.0563	.2722	.1812	-.0418	.2978	.0883	.1530
1-3	3	.0001	.0837	-.0301	.0530	-.3122	.1707	-.2766	.2803	.1016	.1436
2-3	3	.0147	.0825	-.0133	.0537	-.5844**	.1730	-.2348	.2842	.0133	.1453
1-2	6	-.0298	.0835	-.0149	.0509	-.1461	.1636	-.1333	.2780	.1171	.1454
1-3	6	-.1477	.0789	-.1267**	.0479	-.6702***	.1541	-.8237**	.2616	.1759	.1363
2-3	6	-.1181	.0782	-.1117*	.0487	-.8162***	.1563	-.6903**	.2646	.0588	.1377
1-2	9	-.0445	.0861	-.0131	.0513	.0199	.1629	-.2249	.3027	.1459	.1446
1-3	9	-.2954***	.0815	-.2232***	.0484	-1.0481***	.1533	-1.3707***	.2842	.2797*	.1367
2-3	9	-.2509**	.0803	-.2102***	.0491	-1.0379***	.1558	-1.1458***	.2861	.1044	.1365
1-2	15	-.0743	.1105	-.0093	.0678	-0.2325	.2089	-0.4080	.4222	.2034	.1632
1-3	15	-.5908***	.1048	-.4164***	.0639	-1.7442***	.1959	-2.4648***	.4161	.4062**	.1484
2-3	15	-.5165***	.1008	-.4070***	.0648	.1.5117***	.1998	-2.0589***	.4160	.1955	.1530

Note: *p < .05 *p < .01; ***p < .001.

Standardized effect size

Adopting the approach described by Vallejo et al. (2018), Cohen's *d* local effect sizes are reported in Table 6 for significant group by times interaction effects as appropriate for multilevel modelling analysis. These values were calculated separately at the three-month, six-month and end-of-treatment, nine-month, and fifteen-month follow-up.

Table 6. Standardized effect size for significant interaction effects of each of the outcome variables at the evaluated values of times

Effect	Group	_Group	Time	SR_AL	SR_AL	DK_AL	FV_AL	BMI_AL
Group	1	2	3	0.013	0.032	0.148	0.016	0.074
Group	1	3	3	0.001	0.057	0.169	0.095	0.089
Group	2	3	3	0.014	0.024	0.317	0.079	0.016
Group	1	2	6	0.043	0.027	0.071	0.053	0.108

Group	1	3	6	0.222	0.282	0.433	0.335	0.167
Group	2	3	6	0.180	0.255	0.504	0.282	0.059
Group	1	2	9	0.071	0.021	0.012	0.089	0.142
Group	1	3	9	0.447	0.514	0.716	0.575	0.245
Group	2	3	9	0.375	0.493	0.703	0.485	0.103
Group	1	2	15	0.100	0.015	0.102	0.123	0.173
Group	1	3	15	0.667	0.734	1.020	0.794	0.320
Group	2	3	15	0.567	0.721	0.917	0.671	0.146

Note. According to Cohen's guidelines, *d* values of 0.2, 0.5, and .8 are considered small, medium, and large effect sizes, respectively

Ad-Hoc Sensitivity Analysis

Since the possibility of the presence of a non-ignorable dropout mechanism in the AR_AL and FV_AL dependent variables is difficult to role out, it is important to evaluate the robustness of the findings of joint models for non-ignorable missingness (i.e., shared parameter-SPM and pattern-mixture models-PMM), with the findings of ignorable standard likelihood and quasi-likelihood-based methods (i.e., mixed-effects regression model-MRM, generalized estimating equations with multiple imputation-MI-GEE and weighted GEE-WGEE). A summary of the results obtained by using statistical analyses based on MAR (i.e., MRM, MI-GEE, and WGEE) and not MAR (i.e., SPM and PMM) mechanisms is given in Table 7. Inspection of the estimates in Table 7 reveals that all procedures examined provide similar statistical inferences on both response variables, sex factor excluded.

Table 7. Summary of results from the MAR primary analyses and the NMAR models

	MRM		MI-GEE		WGEE		SPM		PMM	
Effect	Estimate	SE	Estimate	SE	Estimate	SE	Estimate	SE	Estimate	SE
Summary of results from AR_AL dependent variable										
Intercept	3.5891***	.1007	3.5769***	.0994	3.5922***	.2856	3.5671***	.1031	3.5896***	.1253
Group	-.0765	.0451	-.0731	.0444	-.0704	.0795	-.0654	.0448	-.0922	.0532
Time	-.0378***	.0084	-.0384***	.0081	-.0676***	.0154	-.0409***	.0091	-.1641***	.0159
Group×Time	.0243***	.0037	.0245***	.0036	.0379***	.0067	.0252***	.0032	.0930***	.0180

Summary of results from FV_AL dependent variable										
Intercept	5.5315***	.4780	5.2489***	.4763	5.1551***	.4867	4.3800***	.3839	5.3110***	.4721
Sex	-.6751**	.2156	-.5649*	.2170	-.5490**	.2120	-.3240	.1910	-.4164*	.2073
Group	-.1411	.1612	-.0985	.1510	-.0544	.1511	-.1323	.1654	-.2369	.1569
Time	-.1914***	.0403	-.1563**	.0391	-.1410***	.0378	-.2522***	.0413	-.2363***	.0530
Group×Time	.0968***	.0178	.0848***	.0164	.0790***	.0178	.0891***	.0171	.1175***	.0252

Note. MRM = mixed-effects regression model; MI-GEE = generalized estimating equations with multiple imputation; WGEE = weighted GEE; SHM = shared-parameter model; PMM = pattern-mixture model. Analyses were implemented using the SAS procedures MIXED (MRM and PMM), MI-GENMOD-MIANALYZE (MI-GEE), GENMOD (WGEE), and NLMIXED (SPM).

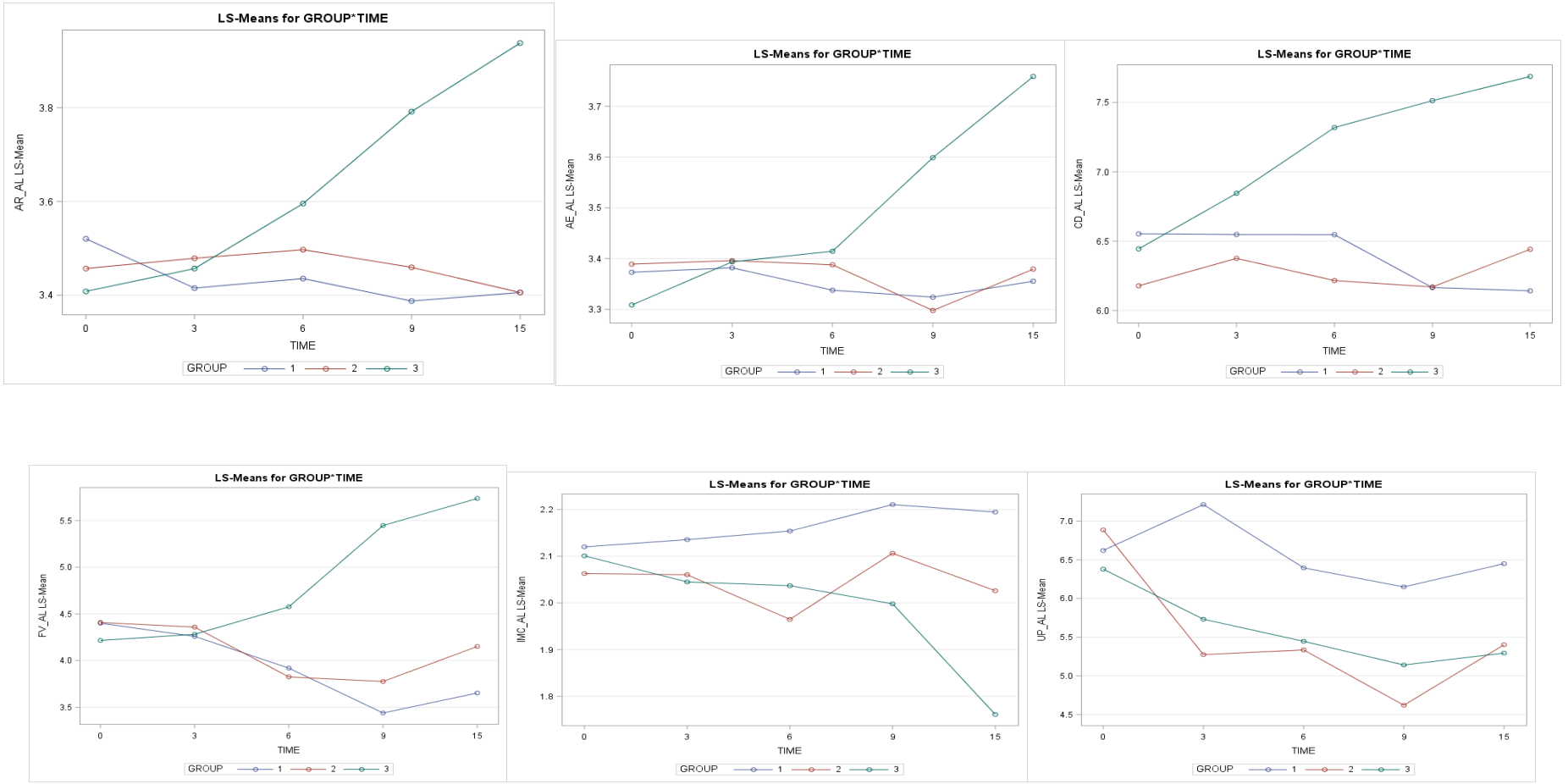

Figure 4 Interactions Plots: Least-Squares Means over Time by Groups for each type of Dependent Variable (i.e., SR_AL, SE_AL, DK_AL, FV_AL, BMI_AL and UP_AL)

Discussion

Findings indicate that participants in G3, when compared to their counterparts in the other two groups (G2 and G1), showed a significant increase in declarative knowledge, self-efficacy, self-regulation and fruits and vegetables consumption throughout the intervention. These differences between the groups were likely to be developed throughout the intervention, because baseline data were similar across the study variables, with no significant differences between groups.

The baseline result is itself interesting because students in G2 and G3, contrary to students in G1, had learnt information about healthy eating during the activities developed in the Health Program at School – PSE. School and health administrators could be willing to analyze this unexpected data and further examine the work being done in the PSE program.

Despite similar results in the first assessment, after three months of intervention students in G3, compared to students in G2, showed statistically significant differences in the declarative knowledge, SR, self-efficacy and consumption of fruits and vegetables, but not they did not decrease their consumption of ultraprocessed foods. The latter finding is consistent with data by Stok, [57] who reported a gap between the children's knowledge on healthy eating and their daily eating habits. In fact, despite youth declarative knowledge about healthy eating they are likely to keep unhealthy eating habits [18, 12]. This may suggest that youth have difficulties coping with social distractors related with food (e.g., advertisements, fast food restaurants were they meet friends) and regulating their eating behaviors [18]. Nureeva and colleagues [58] examined this phenomenon and found that adolescents with low self-regulation showed high daily intakes of unhealthy snacks and low consumption of fruits and vegetables, and recommended the need to promote SR.

The PSRH responded to this challenge by developing SR skills, using a story tool grounded in the social cognitive SR framework. Children were encouraged to transfer the SR contents learned while discussing the narrative to their eating habits diet (e.g., increase consumption of fruits and vegetables - foods in natura). Findings indicated that students in G3 showed a significant increase in fruit and vegetables intake after the third month of intervention, when compared with participants in the other two groups. These data adds the corpus of knowledge[19], stressing that health promotion programs and policies should address information related to the food environment, but also help set opportunities to develop strategies to promote health behaviors. School-based interventions focused on this topic may wish to offer

training on SR skills needed to develop healthy eating habits [18]. Current data regarding the consumption of fruits and vegetables indicates that children in G3 increased their declarative knowledge, but also developed strategies to increase the consumption of fruits and vegetables. This change in eating habits is essential in this age group, moreover the consumption of fruits and vegetables is considered a protective factor for the development of non-communicable diseases such as cardiovascular diseases, cancer, asthma and other respiratory diseases in childhood [59,60].

The significant differences between the groups that already had some type of education and information about healthy eating (i.e. G2 and G3) can also be explained by the possibility of discussing vicarious learning experiences using the characters of the story tool [61]. The practice of storytelling has become an educational tradition within a variety of cultures, because stories help think and organize knowledge [33]. In fact, when children become involved in a narrative, through reading or listening, they can learn how to organize the information in a logical and articulated sequence [62]. Extant research indicates that the discussion and interpretation of narratives may contribute to children's awareness of SR behaviors, which hopefully is translated to their learning processes [33]. This reflection process occurs while analyzing and exploring the characters behaviors [63,64]. These data corroborate with the results found in a systematic review study that showed that psychosocial correlations that showed a greater association with eating behavior were modeling and intentions for dietary change [66].

Thus, in addition to the children having access to the declarative knowledge (e.g., what is a healthy eating) already offered during the Health in the School Program, it was possible through the PSRH, in each session and for each SR strategy in each learning situation, students reported their declarative knowledge, procedural knowledge regarding the strategy, and conditional knowledge [30]. Declarative knowledge is factual knowledge (e.g., to know what is healthy eating). The procedural knowledge is the knowledge of how to implement the learning strategies (e.g., to know how to have healthy eating in daily). Finally, conditional knowledge is related to when one should use a learning strategy in a particular context (e.g., considering the prepare of school snack, when and how the use of this strategy may or may not be effective) [33]. Hands-on practice with a set of SR strategies helps students to become increasingly aware of their agent role as learners, and focus their attention on the contents learned. Thus developing SR

strategies for the domain of healthy eating in their daily lives and make a change in consumption and eating habits.

Another fact that was highlighted in this study was the importance of the intervention time for the development of SR competences and increase of means in all variables of the study. This long-term intervention (one year), as well as the story-tools programs with the instructional sequence that can be summarized in three steps (reading of the stories, reflection on the stories and solving practical tasks), also allowed that these acquisitions could be maintained even after months of the end of the program. This may indicate that educators guided discussions, explained how students could expand their strategy repertoire, instigating their agency and personal control, and helped them to project consequences onto their performance, promoting lifelong skills [33].

Regarding the variables of body mass index (BMI_AL) and consumption of ultraprocessed foods (UP_AL), no large differences were identified between the groups. Body mass index showed small G3 differences in relation to the other groups, more specifically from six months of intervention, and consumption of ultraprocessed foods from three months onwards, but decreasing again throughout the intervention and after its end. This fact corroborates results found in previous studies that indicate that SR competencies and planning and organization strategies are more associated with visualizing the long-term benefits of healthy eating [21]. The unhealthy snacking (eg, candies, soft drinks and other ultraprocessed foods) usually require little organization time to be consumed and the consumption of fruits and vegetables requires more planning and organization [66, 67]. As a consequence, the small differences in the decrease in the BMI_AL variable (decrease in overweight and obesity) between the groups may be related to non-decrease or non-constant decrease in the consumption of ultraprocessed foods. Some studies have already indicated the association between body mass and obesity on the consumption of fast food, soft drink and the frequency of consumption of other ultraprocessed foods in the daily diet among children, adolescents and adults [68,69, 70].

In addition, no differences were found of the variables between G1 (control group) and between G2 (experimental group I). Therefore, even though G2 students are already participating in health promotion activities related to the topic of healthy eating developed within the school health program, their impact on the students' health situations could not be measured and / or evidenced in this study.

Conclusions

The findings help to reinforce the importance of the multidisciplinary action of health and education professionals, as this interdisciplinary articulation favors health promotion. This program aims to equip the students with the skills and knowledge to improve their self-care habits, their organization in their daily life and their overall autonomy. Moreover, it can be further used as a tool to train teachers and health professionals so that they help students throughout the stages and processes of SR (e.g., PLEE) [30]. The limitations of this study may stem from the restricted numbers of participants enrolled and the design, as follows: the study was restricted to only one city of South Brazil with their schools and health services; data collection was impacted by the possible loss of participation, especially considering that this investigation run throughout a school-year and per losses of the schools who did not agree to participate in the study. Another limitation is the use weight and height to calculate BMI, of this age group, since this measure may become more fragile as it be influenced by the large changes in body composition that occur in adolescence [71, 19, 72].

Despite this, the training provided on SRH for health professionals and teachers, and the implementation of the PSRH in schools, helped children to become more autonomous and responsible regarding their self-care on healthy eating. In consequence, PSRH helped to reduce children's health problems, as well as reinforces public policy of promotion healthy eating in schools and helped change the health habits (e.g., increase the consumption of fruits and vegetables).

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Conflict of Interest

The authors declare that they have no competing interests.

Authors Contributions

LB.M, C. R.M, P.R, M.S.B and M.S contributed to the build design and conduct the training of the Program. M.B.M and C.S contributed to the organization and analysis of data. C.R, C.M and P.R contributed to the writing, discussion and approval of the manuscript.

Ethical Standards Disclosure

This project was approved in the Ethics Committee of the Federal University of Health Sciences of Porto Alegre/Brazil – UFCSPA, nº 1.151.220, and through the Coordination for the Improvement of Higher Education Personnel (CAPES), Brazilian Federal agency for the Support and Evaluation of Graduate Education. The participation of children and parents, as well as their parents' consent was voluntary and unrewarded. Informed consent was obtained from all parents/guardians regarding authorization of their children to participate in this study. All subjects (children, parents and consent of parents/guardians) gave written informed consent in accordance with the Declaration of Helsinki.

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ARTIGO 3 –

Promoting self-regulation in oral health among vulnerable Brazilian children: a randomized clinical trial

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Abstract

Background: The Health and Education Ministries of Brazil launched the Health in School Program (PSE – Programa Saúde na Escola). The purpose of the PSE is twofold: articulate the actions of the education and health systems to identify risk factors and prevent them. In the health field, the self-regulation (SR) construct can contribute to the understanding of life habits which can affect the improvement of individuals' health. Therefore this study aims to evaluate the effectiveness of a program to promote SR in oral health. **Methods:** A randomized clinical trial with 5th grade students from public elementary schools in the south of Brazil. The study has two phases. In Phase 1, training program on Self-regulation in health - SRH(teachers and health professionals) and in Phase 2, an intervention with students about the Promotion of SRH conducted by teacher and health professionals. The participants were randomly assigned into three groups: the Condition I (G2) group followed the PSE program, the Condition II group (G3) followed the PSE and the SRH program, and the control group (G1) that did not enroll in either health promotion programs. These measures and instruments were applied: Simplified Oral Hygiene Index (OHI-S), Declarative Knowledge for Health Instrument, Self-Regulation for Health Scale, Self-Efficacy for Health Scale and Previous Day Food Questionnaire **Results:** 372 students selected from eleven middle schools were assigned to the treatment groups and evaluated across five time-points in six dependent variables (i.e., SR_SB - self-regulation, SE_SB – self-efficacy, DK_SB - declarative knowledge , FV_SB – fruits and vegetables, IHOS_SB - Simplified Oral Hygiene Index, and UP_SB – ultraprocessed foods). Because the means of Group 3 are increasing (SR_SB, SE_SB, DK_SB, FV_SB and IHOS_SB) or decreasing UP_SB across time, there appears to be consistent improvement across time. Therefore, in this case, the time of implementation of the program is crucial to judge the efficacy of the intervention. **Conclusions:** PSRH helped reduce children's health problems, as well as reforce public policy of promotion of oral health in schools and helped change the health habits (e.g., increase good hygiene oral).

Trial registration: Clinical Trials NCT03222713. 17 May 2017, Retrospectively registered.

Keywords: Self-regulation, promotion of health, School Health program, oral health

Background

Oral health involves health and well-being in an integral way and, despite being a preventable situation, oral diseases yet are considered endemic [1]. Notwithstanding some improvements in oral health in developed countries, oral diseases such as dental plaque, gingival bleeding and dental caries are prevalent among schools worldwide, and are still considered as public health problems [1,2]. This pattern is being observed in several parts of the world in parallel to the transition to modern diets (e.g., more industrialized foods) and lifestyle changes [3].

In 2007, the Ministries of Health and Education from Brazil created the Health in School Program (Programa Saúde na Escola - PSE) with the aim of improving the school health system in Brazil [4]. The PSE is a school-based program built on the articulation of the educational and health systems to promote the education for health of the public schools students [4]. The main objective of the PSE is to detect risk factors and identify acts of preventive care while also promoting health for public elementary school students (e.g., assessing nutritional status, early incidence of hypertension and diabetes, caries control, visual and auditory acuity) [5]. In the PSE, oral health activities could be promotional and preventive nature (e.g., educational activities with information on oral health care, collective and individual supervised brushing) or clinical (e.g. clinical examination and follow-up and / or treatment when necessary) [5]. These activities are developed by primary care professionals (dentists, oral health technicians and community health agents) along with school teachers [5].

Despite the efforts of this governamental Program, the various activities promoted over the years between school and health and recent declining trends in dental caries in children with twelve years old, the oral health state of children in Brazil remains a health problem [6,2,7]. In fact, around 56% of children at age 12 are still affected by caries disease [8] . However, this oral health situation, especially in childhood, can be avoided by planning and controlling adequate feeding (reduction of free sugar intake) and with the use of prevention strategies [3]. These aspects indicate the importance of oral health promotion program developed during childhood, since it can impact on the reduction of risk factors and the promotion of healthier habits [9]. The oral health programs offered to

school children, although has increased, still hold an approach more focused on medicalized treatments than on educational promotion, for example stressing students agent role in their health [10]. This paradigm of prevention related to oral health, adopts educational measures that assumes and the transmission of information is enounce to change behaviors [11]. However, this approach to health education (information-based and expert advice) is largely ineffective in achieving its goals [12,13].

To overcome evaluation, researchers' efforts to understand how behavioral and psychological determinants may be related to children's oral health have grown in the last years [9]. In this regard, SR has gained more importance in processes of behavioral change in recent years [14], especially, because identifying adequate levels of self-regulation predicts long-term success in achieving our goals of a plan [15]. Self-regulation (SR) models have three customary subfunctions: (i) self-control of health-related behaviors and the cognitive and social conditions attached, (ii) adoption of objectives and strategies to achieve this self-control and (iii) self-reactivity, which involves self-motivating stimuli and social support networks that sustain healthy practices [16,17]. Thus, when focused on health, the SR construct can help build understanding for the processes involved in promoting lifelong habits; thus, the promotion of SR is likely to improve individuals' health and personal well-being [18,7].

Self-efficacy for oral hygiene is likely to influence the choice of tasks and the constitution goals, as well as the persistence and purposeful effort, especially when facing obstacles or unpleasant situations [19,9]. Literature in this area has demonstrated that interventions with SR strategies, perceived self-efficacy, action planning and coping planning increase the use of daily dental flossing and brushing [20,21]. These results have indicated that these behavioral changes have an impact on the oral health condition and the reduction of oral diseases of the study participants [22,23].

Howing this background, the present study aims to present and to evaluate a program for promotes SR in oral health. This program includes content on oral healthy approached in the PSE; it is based on the social cognitive framework and uses story tools to train 5th grade students, from elementary schools in the South of Brazil, in SR competencies.

Methods

The current study that describes a randomized clinical trial. The development of the project had two phases: Phase I: Training SR in health; and Phase II: SR in health Program (PSRH) (figure 1). The participants were students and teachers from seven PSE elementary schools and health units, and three non-PSE schools.

Contextualization of the study

The study was conducted in a city in the south of Brazil (i.e. Sapucaia do Sul). This city has approximately 138,357 inhabitants and a lower average monthly income compared to neighboring cities in the same region [24]. The high social vulnerability of the inhabitants of the city is the reason of choice for running the investigation at this city. Sapucaia do Sul has 42 elementary schools and 23 Primary Health Care Units that employ doctors, nurses, nursing technicians, community health workers (CHW), dentists and oral health technicians [25]. To engage in PSE, elementary schools and the primary health care units should form a dyad: each school has a health care unit partner to work with regarding health issues [25].

Recruitment process

For the current study, the schools enrolled should have two classes in 5th grade. Only 14 out of 16 public elementary schools in Sapucaia do Sul engaged in PSE met this criterion. All were invited to participate. Finally, seven dyads (school-health care unit) agreed to participate in the current investigation (response rate of 50%). Seven elementary schools which were not enrolled in PSE were contacted to participate as CG, but only three agreed (Figure 1). The reasons given by the schools for not enrolling in the research were not related with the nature or goals of the intervention, but with social and administrative limitations (e.g., general strikes that paralyzed public schools for several months, high workload and low salaries).

The school boards of ten elementary schools agreed to participate. Finally, these schools were randomized into three groups: Control Group – G1 - (eight classes) - schools not participating in PSE, Condition I– G2 - (eight classes) – schools participating in PSE; and Condition II – G3 - (nine classes) – schools participating in the Phases I and II of the intervention (PSRH).

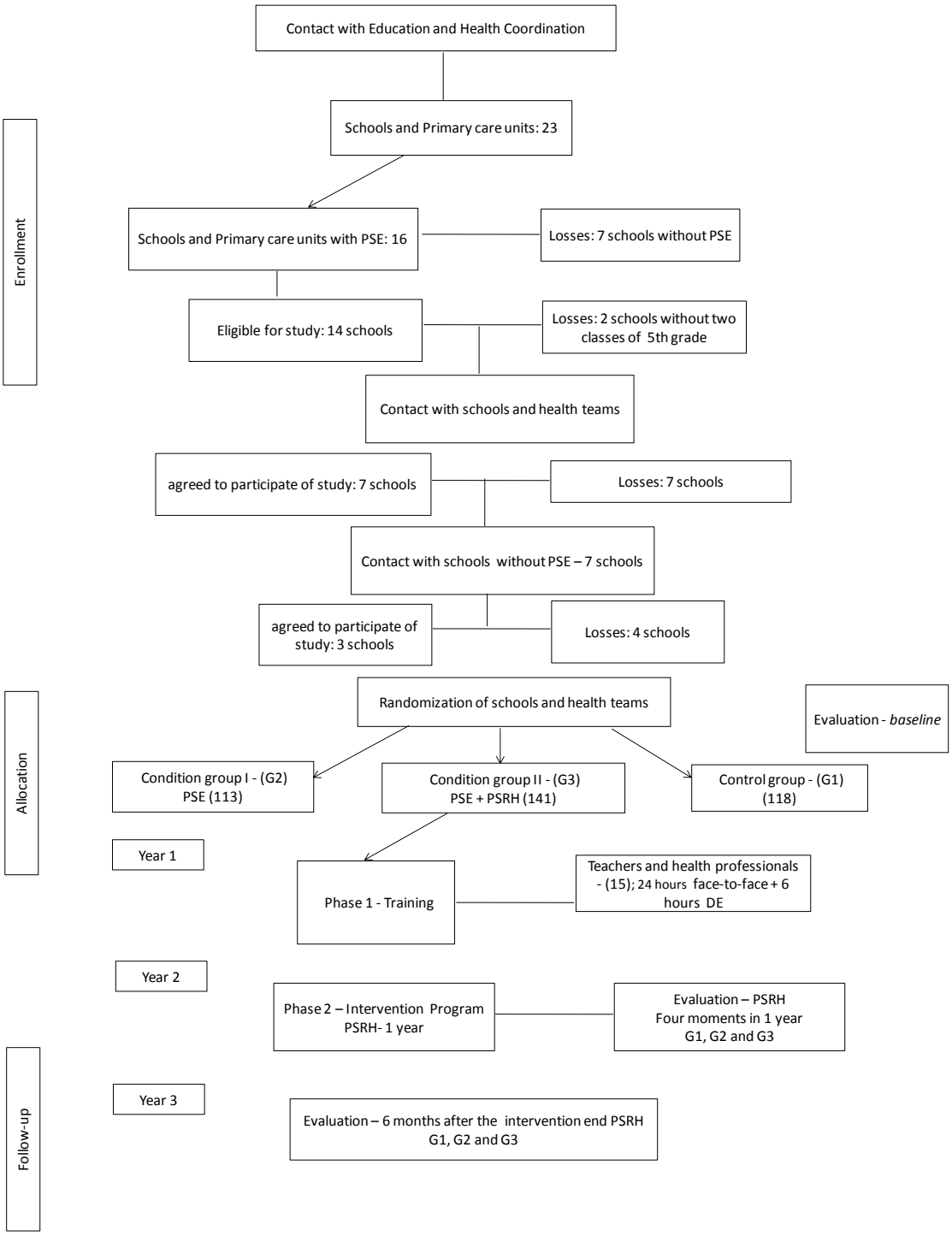

FIGURE 1. Promoting self-regulation in oral health among vulnerable Brazilian children: a randomized clinical trial. Flow diagram for study procedures.
PSE - Programa Saúde na Escola; PSRH - Program promote self-regulation in health ; DE, distance education

P**articipants**

Six hundred and twenty-five 5th grade students and their parents were contacted through face-to-face contacts (parent meetings and meetings with teachers). Finally, 372 students [215 girls] were enrolled. These students are nested in 24 classes and their allocation to the three conditions was as follows: 8 classes with 118 students [62 girls] not enrolled in the PSE participated as G1; the remaining 17 classes were randomly split into two groups, 9 classes with 141 students [92 girls] in the G3, and 8 classes with 114 students [61 girls] in the G2.

Inclusion criteria

To be enrolled in this study, participants must meet the following criteria: Teachers must teach a 5th grade class in a public elementary school; Health professionals must be working in a primary care unit; Students must be enrolled in the 5th grade in a public elementary school; Parents/guardians: must be responsible for a child enrolled in a 5th grade class in a public elementary school;

All participants (parents and children) must be volunteers and must sign the Free and Informed Consent Term and Free and Informed Consent Term for parents/guardians authorizing their children to participate in the study.

Exclusion criteria

Potential participants who do not meet all the inclusion criteria, including 5th grade students with special educational needs that limit their cognitive autonomy, will be excluded from the study.

Program Rationale

The PSRH is grounded in the SR framework which describes the degree in which students are metacognitively, motivationally, and behaviorally engaged in their own learning processes [26]. SR processes may be described as open and dynamic processes proceeding through three main phases (i.e., forethought phase, performance phase, self-reflection phase) [27]. The cyclical nature of this model aims to explain how students initiate, keep and control their behaviors, thoughts, and emotions towards specific goals. Motivational beliefs and task analysis are the two areas of the forethought phase, and they describe processes prior to learning efforts (e.g., goal setting, self-efficacy beliefs) [28]. The performance phase, describes the processes used by students' during learning. For example, self-instruction is a strategy that may help students focus their attention on homework assignments and eliminate distractors; and self-recording notes is a strategy that may help students self-monitor their performance [29]. Both strategies may facilitate

self-control and self-observation, which are the key components of the performance phase [27]. Lastly, the self-reflection phase describes methods intended to help students understand the processes that may have led to the outcomes and their reactions to these outcomes [26]. Self-judgments and self-reactions are the two areas of this last phase of the SR cycle [27]. For the purposes of the current work, the PLEE (Plan, execution and evaluation) model, which is a SR model grounded on the Zimmerman model [27] will be used [30,31]. The abbreviation PLEE stands for the three phases that comprise the structure of the model: planning, task execution and evaluation [32]. In this model, the logic and the cyclic movement is present at all times; during the planning phase, the execution and evaluation phases are still carried out [33]. For example, For instance, when children plan doing oral hygiene, they fulfill the execution phase brushing yours tooths and they complete the self-reflection phase by evaluating their choices based on their learned experiences with brushing.

Program to Promote SR in Health (PSRH)

The PSRH is a program designed to promote the SR of oral health. The health contents of the PSRH are the same as those of the PSE (i.e. oral health habits). Moreover, the program is rooted on the social cognitive framework and the construct of SR [34]. Both components are the theoretical ground for the story-tool, *Yellow Trials and Tribulations*, which is used to deliver the health contents and SR strategies [33]. This story-tool aims to promote SR skills in children aged up to ten years by teaching them learning strategies that are designed to accompany activities proposed by the PSRH. The book tells the story of the disappearance of the Yellow color from the Rainbow and the adventures of the other rainbow colors as they search for their missing friend [35]. This story-tool addresses many practical examples of how children can use SR strategies to resolve their daily difficulties by increasing their autonomy in a responsible manner

[36,33].

Training in SR in Health (Phase I)

The training was aimed to equipping the participating professionals with the skills needed to conduct a program in SR of oral healthy habits for students. The training was delivered by the authors and research assistants for three months.

There were being 24 hours of face-to-face sessions and six hours of virtual activities which was distributed into four hour sessions every two weeks of each month. The participants were including the health professionals (dentists, nurses, nursing technicians, community health workers) and the 5th grade teachers of the

G3 schools. These sessions addressed the theoretical contents related to SR, oral health and the chapters of the story-tool Yellow Trials and Tribulations [5,31]. The sessions also included hands-on activities to build the support materials needed to the work with children (e.g., drawings, worksheets, food maps; See Fig 2. Training activities).

Program to promote self-regulation in health – PSRH (Phase II)

The intervention program with children was runned by teachers and health professionals (G3) in 50-minute biweekly sessions that was took place in class throughout the 2016 school year. During these sessions, the children completed the assigned chapters of *Yellow Trials and Tribulations* (one chapter per week) as well as the discussions and activities related to oral health [34]. The story-tool is divided into three steps, each of them with specific goals and contents to be learned by children. By the end of the first step of the book (i.e. Chapers 1-7), the children should be able to define the three phases of the SR process (PLEE) [31]. After completing the second step (i.e. Chapters 8-12), the children should be able to apply the PLEE model to situations of their everyday lives [33]. After completing the entire assigned reading, children should be able to reflect on the importance of the SR strategies learned and transfer to this knowledge to distinct domains of their lives (e.g., behavior in class, oral health habits, time management).

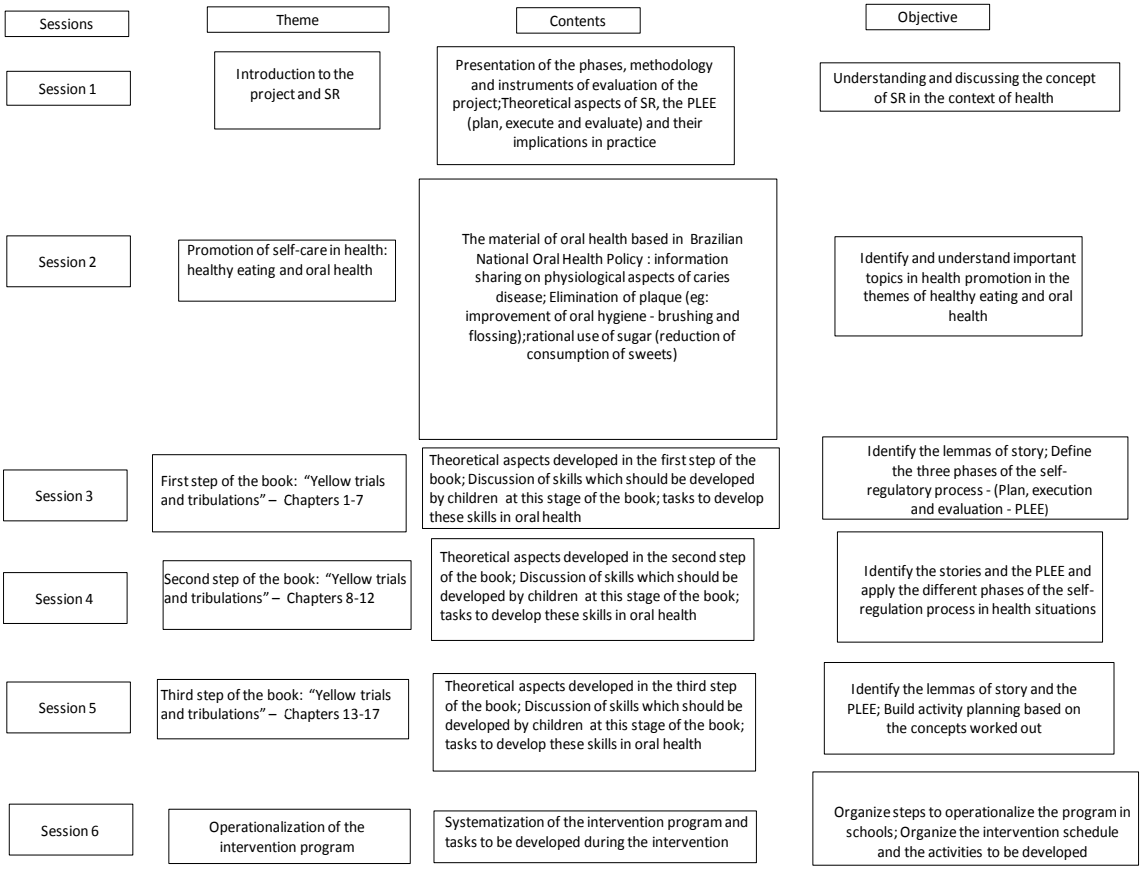

FIGURE 2. Promoting SR in health among vulnerable Brazilian children: protocol study. Training Activies.
PLEE, Plan, execution and evaluation (Mattos, et al, 2018)

Monitoring

The monitoring of the program was made by researchers through biweekly visits the with case discussions and theoretical group meetings. Students in the three groups was assessed four times throughout the year (before the begging of the intervention program, after three months of intervention, after six months of intervention, after nine months of intervention), and 6 months after the end of intervention in the following year, to check the maintenance or changes in relation to SR, self-care and health promotion of the study in the perspective of oral health.

Ethics statement

This project was approved by Ethics Committee of Ethics in Research of the Federal University of Health Sciences of Porto Alegre/Brazil – UFCSPA, nº 1.151.220 and by the Coordination for the Improvement of Higher Education Personnel (CAPES), Brazilian Federal agency for the Support and Evaluation of Graduate Education. The participation of children and parents, as well as their parents' consent was voluntary and unrewarded. Finally, informed consent was obtained from all parents/guardians regarding authorization of their children to participate in this study. All subjects (children, parents and consent of

parents/guardians) gave written informed consent in accordance with the Declaration of Helsinki.

Material and measures

The effectiveness of the intervention was assessed five times throughout four self-reports: SR for Health Scale, Self-Efficacy for Health Scale, Declarative Knowledge for Health Instrument (DKH) and Previous Day Food Questionnaire *(PFDQ)*. Also a physical measures (e.g. IOH-S) was be used. These instruments are validated for the Brazilian context, this process was reported in another study [37].

SR for Health Scale – This instrument was originally constructed with the objective of evaluating the self-regulation of the learning of schoolchildren aged 10 and 11 years [37,38,33,39]. The original scale was adapted by researchers to Brazilian context and for the theme of oral health. Cronbach's Alpha coefficient indicated of 0.74. These aims to assess the extent to which children can self-regulate their health in terms of oral health, being self-administered and composed of nine items.

Self-Efficacy for Health Scale – This instrument was originally developed for verifying the perception of self-efficacy of children of elementary school regarding the change in the consumption of fruits and vegetables, after being submitted to a nutritional intervention program [40]. This instrument was adapted and contextualized, by the researchers, to the Brazilian scenario and to the theme of oral health. Cronbach's Alpha coefficient indicated of 0.77 It is suitable for children between 10 and 11 years old, self-administered and composed of ten questions.

Declarative Knowledge for Health Instrument (DKH) – In this study, the is an adaptation of the Nutritional Monitoring questionnaire [41,42]. Questions aim to evaluate children knowledge have about oral health [41]. This instrument consists of ten questions. The coefficient of Alpha of Cronbach indicated an internal consistency 0.76.

Previous Day Food Questionnaire *(PFDQ)* – The PFDQ is an illustrated instrument that seeks information from schoolchildren about the food they consumed on the day prior [42]. The meals were arranged in chronological order: breakfast, mid-morning snack, lunch, afternoon snack, dinner and evening snack [42]. Each meal was illustrated by 21 individual foods and some food groups: dry beans, rice, milk, coffee with milk, chocolate milk, cheese, yogurt, beef or poultry, pasta, bread or crackers, french fries, pizza or hamburger, leafy vegetables, starchy vegetables, vegetable soup, fruits,

sweets, chips, fish/sea foods, soft drinks and fruit juices [42]. The reliability of this instrument to assess the foods consumed was 70.2% and the non-consumed food was 96.2%. In Brazil, studies were also conducted using multivariate logistic regression. Data showed that the frequency of discordance ranged from 3.7% to 39.6% [42].

Simplified Oral Hygiene Index (OHI-S) - OHI-S is a classic measure used to determine the impact of health education on oral hygiene [43-46]. This index was used to assess the oral health condition. It measures plaque accumulation on six dental surfaces (16, 11, 26 and lingual vestibular of 31, 36, 46) [43]. Each surface is evaluated according to the scores on a scale from 0 to 3: 0 – The surface is free of plaque; 1 - Less than 1/3 of the tooth covered per plate; 2 – Between 1/3 to 2/3 of the tooth is covered per plate; 3 - More than 2/3 of the tooth is covered per plate. The final result of this evaluation is obtained by dividing the sum of the values by the number of surfaces evaluated [43]. The values obtained indicate the oral health on a range between good and poor hygiene: values from 0.0 to 0.6 indicate good hygiene, values from 0.7 to 1.8 indicate regular hygiene, and values from 1.9 to 3.0 indicate poor hygiene [43]. (OHIS) is recognized to be a useful index for evaluation of dental health education in public school systems because is a sensitive method used to evaluate oral hygiene of population groups with confidence [43, 47-50].

Data analysis

The present investigation used a longitudinal cluster randomized trials design. Cluster randomized trials, where groups of individuals (small and larger groups) rather than individuals themselves, are randomly assigned to experimental conditions and where repeated measurements are made on individuals from the same clusters over time, is a natural design choice for testing many educational research questions [51]. Likelihood-based mixed-effects regression models (MRM), both multivariate and univariate, were used in the analysis of data. The MRM modeling approach provides an appropriate general analytic framework to determine whether the change in response profiles over time is different among the treatment groups and facilitates that the treatment groups can be compared at the selected values of time. Under the assumption of missing at random (MAR) data, this model is probably the most widely used method for analyzing longitudinal data. In the current investigation, time was treated as a quantitative variable centered on initial status (i.e., measured in months beginning at 0 months for the baseline assessment), rather than a classification variable. Dataset was analyzed using

MRM with maximum likelihood (ML) estimation as implemented in SAS PROC MIXED [52] and the most general mixed model using SAS PROC NLMIXED. Furthermore, Cohen's *d* was calculated as a measure of standardized effect size using the approach described by Vallejo, Ato, Fernández, and Livavic-Rojas [53] for growth curve models with attrition.

Initially, we modeled the effect of the intervention considering three different models in competition; each statistical model extends a prior model in some sensible and convenient way. In the first option (hereafter, Model A), we analyzed the data assuming that the 372 students selected from eleven middle schools were assigned to the treatment groups and measured across five time-points in six dependent variables (i.e., SR_SB - self-regulation, SE_SB - self-efficacy, DK_SB - declarative knowledge, FV_SB - fruits and vegetables, IHOS_SB - Simplified Oral Hygiene Index, and UP_SB - ultraprocessed foods). In this first option, the variable class was not included in the random part of model, so the analysis was conducted ignoring clustering in the data at the classroom level. In the analysis of the second option (hereafter, Model B), we analyzed the data from 372 students nested in 25 arbitrarily selected classes from eleven middle schools, with the restriction that seven or eight classes were randomly assigned to each type of treatment, and measured across time in six dependent variables. Finally, simultaneously considering all dependent variables, we analyzed the data from 372 students assuming a quadratic three-level regression model. The three-level model described helped to learn the influence of the class on the observations of the students. If the class effect is found to be negligible, then the two-level model for longitudinal data is appropriate, otherwise, the results from the two-level model may be misleading.

Results

Observed outcomes (i.e., SR_SB, SE_SB, DK_SB, FV_SB, IHOS_SB, and UP_SB) means, standard deviations, and sample sizes across the five study time points are given in Table 1. Because the means of Group 3 are increasing (SR_SB, SE_SB, DK_SB, FV_SB and IHOS_SB) or decreasing (UP_SB) across time, there appears to be consistent improvement across time. However, the improvement is not similar for all the dependent variables. Additionally, from the results summarised in Table 1, it is clear that the UP_SB means of Group 2 are also decreasing across time.

Table 1. Observed Dependent Variables Means, Standard Deviations, and N Across Time

		Group 1					Group 2					Group 3				
		T_0	T_3	T_6	T_9	T_15	T_0	T_3	T_6	T_9	T_15	T_0	T_3	T_6	T_9	T_15
AR_SB	Mean	4.02	4.02	4.09	3.35	3.61	4.07	4.16	4.10	3.87	3.87	4.03	4.12	4.20	4.12	4.21
	SD	0.78	0.83	0.84	0.62	0.91	0.74	0.76	0.72	0.67	0.89	0.67	0.72	0.65	0.57	0.57
	N	118	112	108	93	93	114	108	99	93	87	141	135	124	118	111
AE_SB	Mean	3.27	3.25	3.28	327	3.22	3.26	3.27	3.23	3.28	3.31	3.21	3.34	3.36	3.45	3.56
	SD	0.59	0.66	0.71	0.77	0.72	0.60	0.64	0.64	0.67	0.73	0.62	0.61	0.63	0.61	0.52
	N	118	112	108	93	93	113	107	99	93	87	141	135	128	119	111
CD_SB	Mean	6.58	6.63	6.51	6.84	7.01	6.61	6.70	6.92	6.73	7.16	6.36	7.39	7.70	7.68	7.99
	SD	1.37	1.75	1.81	1.84	1.74	1.37	1.60	1.56	1.60	1.32	1.46	1.58	1.51	1.62	1.19
	N	118	112	108	93	90	113	107	99	93	86	141	135	124	117	109
FV_SB	Mean	4.54	4.27	3.98	3.73	4.09	4.85	4.64	4.06	4.01	4.51	4.34	4.30	4.94	5.65	6.06
	SD	3.00	3.02	3.09	2.47	2.39	3.35	4.04	2.79	2.76	2.32	2.83	2.88	2.41	2.76	3.42
	N	118	111	97	75	63	113	100	89	78	66	141	129	111	92	80
IHOS_SB	Mean	2.32	2.48	2.44	2.41	2.30	2.27	2.41	2.46	2.45	2.42	233	2.47	2.49	2.48	2.69
	SD	0.70	0.70	0.65	0.69	0.70	0.67	0.59	0.64	0.60	0.67	0.58	0.53	0.52	0.52	0.50
	N	118	109	102	94	86	113	93	93	93	88	141	129	127	126	112
UP_SB	Mean	6.69	7.32	6.65	6.66	6.86	6.85	5.43	5.56	5.20	5.84	6.18	6.07	6.01	5.73	5.87
	SD	4.60	5.86	4.66	3.79	4.33	5.11	3.95	3.32	2.93	3.76	4.18	3.41	3.92	3.37	3.77
	N	118	112	107	89	73	113	104	96	84	69	141	134	120	110	92

It is also important to note that, although the total number of subjects in this study was 372, the number of subjects with all measures at each evaluation time fluctuated. Of the 372 subjects, only 209 filled in all the questionnaires; the remaining 163 subjects fail do fill in data for various reasons such as miss school, and external factors unrelated to the program (i.e., change of residence).

To test whether the missing data on each of the dependent variables are missing completely at random (MCAR) or not, we applied Little's test [54], which divides the sample into groups based on the patterns of data absence for the study outcome. The likelihood ratio test statistic yielded a χ^2 value of 14.1937 on 10 *df* (p = 0.1643) for observed measurement occasions of the SR_SB variable, a χ^2 value of 14.9186 on 10 *df* (p = 0.1351) for AE_SB variable, a χ^2 value of 10.7433 on 10 *df* (p = 0.3778) for DK_SB variable, a χ^2 value of 77.0733 on 10 *df* (p < 0.0001) for FV_SB, a χ^2 value of 83.7435 on 10 *df* (p = <0.0001) for IHOS_SB, and a χ^2 value of 28.0534 on 10 *df* (p = 0.0018) for personal UP_SB variable, which suggests that the MCAR model provides an adequate fit to the data of AR_SB, AE_SB, and CD_SB. However, based on Little's test, it was found that the missing data mechanism of the FV_SB, IHOS_SB, and UP_SB were not MCAR. This was confirmed by examining a plot of estimates as a function of the time of dropout. In addition to Little's test, we also performed a comparison of the likelihood-based ignorable model (i.e., MRM) with the pattern-mixture model that only stratifies subjects by dropout status (completers vs. dropouts). The likelihood ratio test statistic yielded a χ^2 value of 63.1 on 4 *df* (p < 0.0001) for observed measurement occasions of the FV_SB variable, a χ^2 value of 71.2 on 4 *df* (p < 0.0001) for observed measurement occasions of the

IHOS_SB variable, and a χ^2 value of 21.0 on 4 *df* (p = 0.0003) for UP_SB, which suggests that the MAR model provides an inadequate fit to the data. When the missing data mechanism cannot reasonably be assumed to be MAR, it is advisable to carry out a sensitivity analysis.

Fitting Competing Models

Table 2 shows the results for the three types of multivariate MRM (i.e., Model A, B, and C). Model A was chosen as our "final model" after assessing model fit with likelihood-based AIC and BIC criteria. Empirical results presented by Vallejo, Fernández, Livacic-Rojas and Tuero-Herrero [55] showed the appropriateness of ML for selecting the best mean structure using information criteria. This same conclusion was obtained when comparing the three models using likelihood ratio tests. The deviance statistic and number of estimated parameter between parentheses for Models A, B and C were 40793.90 (44), 40793.89 (45) and 40765.30 (63), respectively. When comparing Models A and B, which differ only by the class term, we found a trivial difference in deviance of 0.01 on 1 degree of freedom (*df*). Comparing the Model A to Model C, which differ in the class term and the quadratic change of trajectory, we found that the deviance statistic declines 28.6, which is less the associated .05 critical value of 30.144 (*df* =19). These findings provided an argument for using a simpler, two-level analysis with within-student measurements at level 1 and students at level 2, ignoring the class's effects. However, because the classes were randomized to study conditions, one could argue that the unit of assignment must remain in the model regardless of significance.

Table 2. Results of fitting three multivariate Mixed-Effects Regression Model analyses

	Model A		Model B		Model C	
Fixed Effect	F value	Pr > F	F value	Pr > F	F value	Pr > F
Var	$F_{6,6434}$ = 1536.67	<.0001	$F_{6, 657}$ = 1477.66	<.0001	$F_{6,975}$ = 1194.32	<.0001
Var×Sexo	$F_{6,3953}$ = 5.84	<.0001	$F_{6,3877}$ = 5.83	<.0001	$F_{6,3875}$ = 5.75	<.0001
Var×Group	$F_{12,7182}$ = 1.52	.1089	$F_{12,846}$ = 1.50	.1191	$F_{12,1248}$ = 0.99	.4515
Var×Time	$F_{6,9245}$ = 3.86	.0008	$F_{6,9245}$ = 3.86	.0008	$F_{6,9198}$ = 3.02	.0060
Var×Group×Time	$F_{12,9248}$ = 6.30	<.0001	$F_{12,9248}$ = 6.29	<.0001	$F_{12,9198}$ = 2.46	.0034
Var×Time^2					$F_{6,9191}$ = 2.06	.0545
Var×Group×Time^2					$F_{12,9191}$ = 1.47	.1279
Random Effect	Estimate	SE	Estimate	SE	Estimate	SE
Level-1 (within-subject variance)						

Residual	4.0834***	0.0603	4.0835***	0.0603	4.0709***	0.0602
Level-2 (between students within classes variances)						
Intercept	0.2759***	0.0325	0.2744***	0.0338	0.2739***	0.0338
Level-3 (between-classes variances)						
Intercept			0.0017	0.0096	0.0019	0.0097
Goodness-of-fit						
Deviance	40793.90		40793.89		40765.30	
Number parameter	44.0		45.0		63.0	
AIC	40881.9		40883.9		40891.3	
BIC	41197.0		41206.2		41342.5	

Note: SE = standard error. *p < .05 *p < .01; ***p < .001.

Multivariate MRM analyses

Table 2 shows hat: i) the variable sex has a statistically significant effect on all the above dependent variables simultaneously [F (6, 3953) = 5.84, p < .0001]; ii) as expected, due to randomization, the mean response of treatment groups did not differ significantly from each other at baseline [F (12, 7182) = 1.52, p = 0.1089], in the set of the six dependent variables considered simultaneously; iii) across the treatment groups there is a significant [F (6, 9245) = 3.86, p = .0008] increase in the mean response over time when considering all the dependent variables; that is, on average, participants improved across time. Finally, it is very important to note that there is a significant [F (12, 9248) = 6.30, p < .0001] difference between the treatment conditions over time in the set of the six dependent variables considered simultaneously.

Table 3 shows pairwise comparisons among the three treatment groups evaluated at a specific time for all the dependent variables (i.e., SR_SB, SE_SB, DK_SB, FV_SB, IHOS_SB, and UP_SB). There are no significant differences among groups at times 0, and 3, after treatment. In addition, the means of groups 1 and 2 are not significantly different for times 9, but group 3 means are significantly different from the mean of groups 1 and 2 for times 6, 9 and 15. Meanwhile, the means of groups 1 and 2 are significantly different for times 9 and 15.

Table 3. Comparisons of Group × Time Least-Squares Means by simultaneously considering all dependent variables

Effect	Group	_Group	Time	Estimate	SE	DF	t value	Pr > |t|
Group	1	2	0	-0.0394	0.1367	5107	-0.29	0.7734
Group	1	3	0	0.0512	0.1228	5049	0.42	0.6768
Group	2	3	0	0.0906	0.1013	5043	0.69	0.4881
Group	1	2	3	-0.0265	0.0969	3157	-0.27	0.7849
Group	1	3	3	-0.1417	0.0916	2881	-1.55	0.1220
Group	2	3	3	-0.1153	0.1013	3235	-1.14	0.2553
Group	1	2	6	-0.1435	0.0860	2319	-1.67	0.0952
Group	1	3	6	-0.3347	0.8131	1999	-4.12	<.0001
Group	2	3	6	-0.1912	0.0898	2249	-2.13	0.0334
Group	1	2	9	-0.2671	0.1199	3656	-2.27	0.0260
Group	1	3	9	-0.5276	0.0986	3306	-5.35	<.0001
Group	2	3	9	-0.2605	0.1049	3547	-2.48	0.0130

Group	1	2	15	-0.3430	0.1500	5273	-2.30	0.0217
Group	1	3	15	-0.7205	0.1332	5297	5.41	<.0001
Group	2	3	15	-0.3778	0.1422	5182	-2.65	0.0080

Univariate MRM analyses for each dependent variable

Follow-up univariate MRM analyses were performed to determine which dependent variables are responsible for the significant omnibus test of group by time interaction. Table 4 includes results of the hypothesis tests for the outcome response measurement data.

Table 4. Results of Mixed-Effects Regression analysis of each of the dependent variables

	Fixed Effects				Random Effects				
AR_SB									
Effect	df_N	df_D	F-value	Pr > F	VC	Estimate	SE	Z-value	Pr > Z
Sex	1	340	1.09	.2981	τ_{00}	.4898	.0382	12.83	<.0001
Group	2	369	0.42	.6589	τ_{01}	-.1110	.0113	-9.79	<.0001
Time	1	324	16.21	<.0001	τ_{11}	.0539	.0048	11.31	<.0001
Group×Time	2	324	18.24	<.0001	σ^2	.2178	.0036	60.98	<.0001
AE_SB									
Effect	df_N	df_D	F-value	Pr > F	VC	Estimate	SE	Z-value	Pr > Z
Sex	1	366	0.66	.4183	τ_{00}	.2230	.0257	8.67	<.0001
Group	2	370	0.23	.7945	τ_{01}	-.0050	.0018	-2.71	.0066
Time	1	321	10.98	.0010	τ_{11}	.0006	.0002	2.99	.0014
Group×Time	2	321	9.72	<.0001	σ^2	.2149	.0096	22.02	<.0001
CD_SB									
Effect	df_N	df_D	F-value	Pr > F	VC	Estimate	SE	Z-value	Pr > Z
Sex	1	367	0.39	.5341	τ_{00}	.6913	.0821	8.42	<.0001
Group	2	374	0.94	.3893					
Time	1	360	68.36	<.0001					
Group×Time	2	360	16.18	<.0001	σ^2	1.7579	.0690	25.34	<.0001
FV_SB									
Effect	df_N	df_D	F-value	Pr > F	VC	Estimate	SE	Z-value	Pr > Z
Sex	1	374	8.22	.0044	τ_{00}	4.4520	.5967	7.46	<.0001
Group	2	377	1.15	.3164	τ_{01}	-0.6143	.1787	-3.44	.0006
Time	1	313	1.91	.675	τ_{11}	0.2139	.0741	2.89	.0020
Group×Time	2	312	18.51	<.0001	σ^2	5.2277	.2583	20.24	<.0001
IHOS_SB									
Effect	df_N	df_D	F-value	Pr > F	VC	Estimate	SE	Z-value	Pr > Z
Sex	1	303	7.30	.0073	τ_{00}	.2464	.0298	8.24	<.0001
Group	2	363	0.41	.6624	τ_{01}	-.0366	.0084	-4.37	<.0001
Time	1	314	6.63	.0105	τ_{11}	.0103	.0003	3.46	.0003
Group×Time	2	314	9.83	<.0001	σ^2	.2231	.0104	21.56	<.0001
UP_SB									
Effect	df_N	df_D	F-value	Pr > F	VC	Estimate	SE	Z-value	Pr > Z
Sex	1	355	2.68	.1027	τ_{00}	12.3422	1.3699	9.01	<.0001
Group	2	365	1.02	.3607	τ_{01}	-1.8870	0.3665	-5.15	<.0001
Time	1	342	7.39	.0069	τ_{11}	0.5052	0.1284	3.93	<.0001
Group×Time	2	342	0.97	.3819	σ^2	9.1644	0.4291	22.06	<.0001

Note: VC = variance component.

Data in the Table 4 shows that the null hypothesis of no differences between treatment conditions with respect to their average growth rates is rejected at a level of significance of no more than 0.01% (1 per 10000) for all outcome variables, consumption of ultra-processed food products excluded [$F(2, 324) = 18.24$, $p < .0001$; $F(2, 321) = 9.72$, $p < .0001$; $F(2, 360) = 16.18$, $p < .0001$; $F(2, 312) = 18.51$, $p < .0001$; $F(2, 314) = 9.83$, $p < .0001$; $F(2, 342) = 0.97$, $p = .3819$]. As a whole, these data indicate that the efficacy of the intervention is observed when taking into account the temporal moment of the observation. Therefore, in this case, the time of implementation of the program is revealed as crucial to judge the efficacy of the intervention.

The next step is to explain the group × time interactions. As indicated in Table 5, there are no significant differences among the three groups at time 0 (as one would expect). The means of treatment groups 1 and 2 are not significantly different for times 3 to 15, when SE_SB and DK_SB were used as the dependent variables. However, it can also be seen that the means of groups 1 and 2 are significantly different from one another at times 9 and 15, when SR_SB and IHOS_SB were used as the dependent variables. On the other hand, the mean of treatment group 3 was significantly different from the means of groups 1 and 2 for times 3 to 15, when DK_SB was used as the measure of the dependent variable; and for times 6 to 15 in the remaining outcome variables, excluding the difference between groups 2 and 3 at time 6 under IHOS. As regards to dependent variable UP_SB, it should be noted the all group comparisons tend to become no significant over time. These conclusions can also be visualized by the graph in Figure 3.

Table 5. Comparisons of Group × Time Least-Squares Means for each Dependent Variable

		SR_SB		SE_SB		DK_SB		FV_SB		IOHS_SB	
Group	Time	Estimate	SE	Estimate	SE	Estimate	SE	Estimate	SE	Estimate	SE
1-2	0	-.0255	.0963	.0351	.0795	-.0714	.1753	-.2568	.3691	.0707	.0824
1-3	0	.0664	.0907	.0446	.0750	-.2212	.1653	.2714	.3481	.0538	.0774
2-3	0	.0920	.0918	.0009	.0759	-.1498	.1676	.5282	.3533	-.0169	.0786
1-2	3	-.1109	.0759	.0104	.0684	-.0880	.1467	-.2383	.2998	.0008	.0670
1-3	3	-.1251	.0715	-.0474	.0645	-.4962 ^^	.1386	-.3677	.2828	-.0520	.0629
2-3	3	-.0142	.0725	-.0578	.0654	-.4084 ^^	.1405	-.1285	.2875	-.0528	.0641
1-2	6	-.1204	.0626	-.0143	.0649	-.1042	.1400	-.2197	.2813	-.0691	.0593
1-3	6	-.3167	.0617	-.1394	.0613	-.7711	.1324	-1.0068	.2676	-.1579	.0555
2-3	6	-.1963	.0655	-.1251	.0621	-.6669	.1342	-0.7871	.2711	-.0888	.0566
1-2	9	-.2816	.0696	-.0390	.0702	.1206	.1579	-0.2011	.3225	-.1390	.0620
1-3	9	-.5082	.0657	-.2314	.0663	-1.0460	.1495	-1.6459	.3097	-.2638	.0580
2-3	9	-.2266	.0666	-.1923	.0672	-0.9255	.1514	-1.4448	.3120	-.1248	.0588
1-2	15	-.3670	.0862	-.0637	.0826	-0.1370	.1937	-0.1826	.4056	-.2090	.0740
1-3	15	-.6998 ***	.0814	-.3233 ***	.0780	-1.3210 ***	.1834	-2.2850 ***	.3912	-.3697 *	.0693
2-3	15	-.3327 ***	.0825	-.2596 ***	.0791	.1.1840 ***	.1855	-2.1025 ***	.3927	-.1607 *	.0698

Note: *p < .05 *p < .01; ***p < .001.

Standardized effect size

Adopting the approach described by Vallejo et al [53] Cohen's *d* local effect sizes are reported in Table 6 for significant group by times interaction effects as appropriate for multilevel modelling analysis. These values were calculated separately at the three-month, six-month and end-of-treatment, and fifteen-month follow-up.

Table 6. Standardized effect size for significant interaction effects of each of the outcome variables at the evaluated values of times

Effect	Group	_Group	Time	SR_AL	SR_AL	DK_AL	FV_AL	IHOS_AL
Group	1	2	3	0.146	0.016	0.056	0.081	0.001
Group	1	3	3	0.166	0.074	0.317	0.125	0.082
Group	2	3	3	0.019	0.089	0.261	0.044	0.083
Group	1	2	6	0.160	0.022	0.066	0.077	0.115
Group	1	3	6	0.444	0.220	0.493	0.355	0.262
Group	2	3	6	0.275	0.197	0.426	0.277	0.147
Group	1	2	9	0.405	0.061	0.077	0.072	0.237
Group	1	3	9	0.732	0.364	0.667	0.586	0.450
Group	2	3	9	0.326	0.303	0.590	0.514	0.213
Group	1	2	15	0.525	0.098	0.087	0.064	0.357
Group	1	3	15	1.001	0.500	0.840	0.802	0.632
Group	2	3	15	0.476	0.401	0.753	0.738	0.275

Note. According to Cohen's guidelines, *d* values of 0.2, 0.5, and .8 are considered small, medium, and large effect sizes, respectively

Ad-Hoc Sensitivity Analysis

Since the possibility of the presence of a non-ignorable dropout mechanism in the FV_SB, IOHS_SB and UP_SB dependent variables is difficult to role out, it was important to evaluate the robustness of the findings of joint models for non-ignorable missingness (i.e., shared parameter model-SPM and pattern-mixture model-PMM), with the findings of ignorable standard likelihood and quasi-likelihood-based methods (i.e., mixed-effects regression model-MRM, generalized estimating equations with multiple imputation-MI-GEE and weighted GEE-WGEE). A summary of the results obtained by using statistical analyses based on MAR (i.e., MRM, MI-GEE, and WGEE) and not MAR (i.e., SPM and PMM) mechanisms is given in Table 7. Inspection of the estimates in Table 7 reveals that all procedures examined provide similar statistical inferences on three response variables, sex factor excluded.

Table 7. Summary of results from the MAR primary analyses and the NMAR models

	MRM		MI-GEE		WGEE		SPM		PMM	
Effect	Estimate	SE	Estimate	SE	Estimate	SE	Estimate	SE	Estimate	SE
Summary of results from FV_SB dependent variable										
Intercept	5.3515***	.4780	5.2692***	.4774	5.1168***	.4789	4.3814***	.3844	5.1521***	.4841
Sex	-.6751**	.2156	-.5144*	.2149	-.4722*	.2162	-.3217	.1910	-.3955	.2114

Group	-.1411	.1612	-.0529	.1603	-.0115	.1512	-.1310	.1645	-.2154	.1605
Time	-.1914***	.0403	-.1662**	.0403	-.1532***	.0385	-.2544**	.0422	-.2352***	.0570
Group×Time	.0968***	.0178	.0831***	.0178	.0819***	.0189	.0889***	.0167	.1179***	.0262
Summary of results from IHOS_SB dependent variable										
Intercept	2.6073***	.1041	2.5552***	.0990	2.5942***	.1099	2.321***	.0872	2.6090***	.1025
Sex	-.1221*	.0463	-.1041*	.0465	-.1204*	.0472	-.1060*	.0451	-.1154**	.0441
Group	-.0244	.0366	-.0162	.0331	-.0221	.0380	-.0119	.0378	-.0249	.0362
Time	-.0272**	.0717	-.0244**	.0071	-.0276**	.0081	-.0231*	.0080	-.2503**	.0090
Group×Time	.0161***	.0162	.0154***	.0030	.0164***	.0033	.0152***	.0008	.0151***	.0041
Summary of results from UP_SB dependent variable										
Intercept	7.8940***	.7184	7.6126***	.6708	7.6916***	.8192	6.9976***	.6000	7.3522***	.7333
Sex	-.4656	.3194	-.3115	.3162	-.3051	.3227	-.2974	.3144	-.2030	.3212
Group	-.3777	.2493	-.3588	.2235	-.3754	.2639	-.3165	.2572	-.3213	.2513
Time	-.0505	.0507	-.0370	.0499	-.0637	.0587	-.0462	.0639	-.0082	.0659
Group×Time	.0022	.0022	.0016	.0232	.0051	.0245	.0203	.0276	-.0221	.0300

Note. MRM = mixed-effects regression model; MI-GEE = generalized estimating equations with multiple imputation; WGEE = weighted GEE; SHM = shared-parameter model; PMM = pattern-mixture model. Analyses were implemented using the SAS procedures MIXED (MRM and PMM), MI-GENMOD-MIANALYZE (MI-GEE), GENMOD (WGEE), and NLMIXED (SPM).

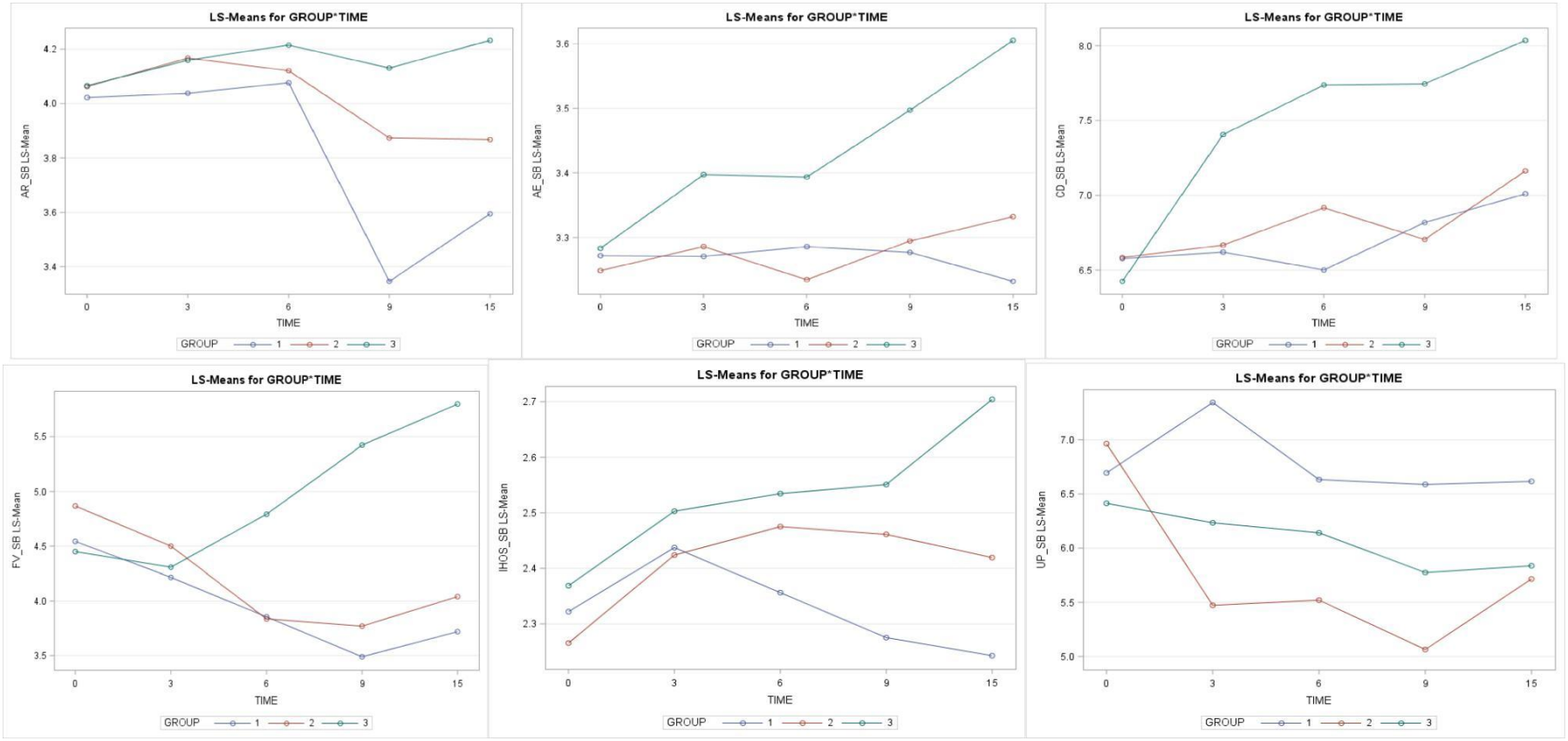

Figure 3 Interactions Plots: Least-Squares Means over Time by Groups for each type of Dependent Variable (i.e., AR_SB, AE_SB, CD_SB, FV_SB, IHOS_SB and UP_SB)

Discussion

The data of students in G3 indicated a significant increase in the means of declarative knowledge, self-efficacy, SR and oral health condition throughout the intervention compared to the other two study groups (G2 and G1). These differences between groups were established with the passing of the stages (intervention times), because at the time of baseline the groups showed a similar behavior between the study variables, and there were no significant differences between them. The similarity between the declarative knowledge-related data of students participating in G2 and G3 before beginning the intervention process is justified by the fact that these students already had contact with the theme, per education activities about oral healthy developed in the Health Program at School - PSE. However, after three months of the intervention program students in G3 increased their means in relation to G2 regarding declarative knowledge, SR and self-efficacy.

Self-efficacy was identified as an important predictor for oral hygiene care in several studies that analyzed the quality of toothbrushing, oral hygiene and flossing. This aspect indicates that decisions to brush and floss are influenced by the perception of ability to perform these actions successfully. [21,56,57]. Therefore, interventions targeting children's agency and active role in their health activities could promote children's competencies and expand their self-care skills for good oral health habits [9,34]. In relation to this, the results of the PSRH demonstrated that in the program the children had the opportunity to develop SR skills, through the narrative tool and identification with the characters of the book - PLEE, and that having the possibility to build a logic and organization for a oral health (improvement in tooth brushing, reduction of dental plaque, reduction of sugar consumption – ultraprocessed and increase consumption of fruits and vegetables). The practice of storytelling has become an educational tradition that occurs in a variety of cultures [33]. One of the reasons for using this technique may be related to the nature stories have as an efficient ways of organizing knowledge [33]. When children become involved in a narrative, through reading or listening, they can learn to organize the information in a logical sequence [58]. Extant research indicates that discussion and interpretation of narratives may contribute to children's awareness of SR behaviors, which may be translated into their learning processes [33]. This process takes place through the development of vicarious learning by observing and expanding upon behaviors and expressions that help structure future modulations [59,60]. The significant differences between the groups that already had some type of about oral health (G2 and G1) and the conditional group II – G3 - can be explained by the possibility of modeling and vicarious learning experience offered through the characters of the stories in the book *Yellow Trials and Tribulations* [61]. Thus, in addition to the children having access to the declarative knowledge (eg, what is oral health), also

offered during the Health in the School Program, it was possible through the PSRH in each session of these and for each SR strategy in each learning situation, students reported their declarative knowledge, procedural knowledge regarding the strategy, and conditional knowledge [30]. Declarative knowledge is factual knowledge (e.g., know what is good oral health). The procedural knowledge is the knowledge of how to implement the learning strategies (e.g., to know how to have good oral health in daily). Finally, conditional knowledge is related to when one should use a learning strategy in a particular context (e.g., considering a good oral health and a good tooth brushing, when and how the use of this strategy may or may not be effective) [33].

Hands-on practice with a set of SR strategies helps students to become increasingly aware of their agent role as learners, and focus their attention on the contents learned [33], developing self-regulatory strategies for the domain of oral health in their daily lives and make a change in health habits for achieve the changes (e.g. Improvement in tooth brushing and reduction of sugar consumption – ultraprocessed). These results corroborate data from other studies that have also indicated the benefits of developing self-regulatory skills and perceived self-efficacy for improving self-care in oral health [62,20]. The differences and increase of these variables in G3 in relation to the other two groups also had repercussion in the decrease of the dental plaque and increase of the good oral hygiene measured by the OHI-S, more specifically from six months of intervention. These data are in line with the results of many studies that promoted the training of teachers for the development of oral health education for schoolchildren. In these, differences were identified as a significant increase in knowledge and indicating a significant improvement in oral hygiene of the children after education process [47-50, 63].

Another fact that was highlighted in this study was the importance of the intervention time for the development of self-regulatory competences and increase of means in all variables of the study. This long-term intervention (one year), as well as the story-tools programs (reading of the stories, reflection on the stories and solving practical tasks), also allowed that these acquisitions could be maintained for month after of the end of the program. This may indicate that educators guided discussions, explained how students could expand their strategy repertoire, instigating their agency and personal control, and helped them to project consequences onto their performance, promoting lifelong skills [33].

In addition, no differences were found in the behavior of the variables between G1 (control group) and G2 (experimental group I). Therefore, even though G2 students are already participating in health promotion activities related to the topic of oral health developed within the school health program, their impact on the students' health situation could not be measured and / or evidenced in this study.

Conclusions

The findings help to reinforce the importance of the multidisciplinary action of health and education professionals, and this interdisciplinary articulation favors health promotion. The PSRH was designed to respond to this call. This program aimed to equip the students with the skills and knowledge to improve their self-care habits, their organization in their daily life and their overall autonomy. Moreover, it can be further used as a tool to train teachers and health professionals so that they help students throughout the stages and processes of SR (e.g., PLEE) [30]. The limitations of this study may stem from the restricted numbers of participants enrolled and the design, as follows: the study was restricted to only one city with their schools and health services; data collection was impacted by the possible loss of participation, especially considering that this investigation run throughout a school-year and, per losses of the schools who did not agree to participate in the study.

Despite this, the training provided on SRH for health professionals and teachers, and the implementation of the PSRH in schools, helped children to become more autonomous and responsible regarding their self-care on oral health. In consequence, PSRH helped toreduce children's health problems, as well as reinforce public policy of promotion oral health in schools and helped change the health habits (e.g., increase good oral hygiene).

List of abbreviations

PSE – Programa Saúde na Escola (School Health Program); SR – Self- regulation; SRH Self-regulation in health; OHI-S – Simplified Oral Hygiene Index; WHO – World Health Organisation; PSRH – Program to promote self-regulation in health; CHW – Community health workers, DKH – Declarative Knowledge for health; CAPES - Coordination for the Improvement of Higher Education Personnel, Brazilian Federal agency for the Support and Evaluation of Graduate Education.

Ethics approval and consent participate – This project was approved in the Ethics Committee of the Federal University of Health Sciences of Porto Alegre/Brazil – UFCSPA, nº 1.151.220 and through the Coordination for the Improvement of Higher Education Personnel (CAPES), Brazilian Federal agency for the Support and Evaluation of Graduate Education. The participation of children and parents, as well as consent from theirs parents were voluntary and unrewarded. Finally, informed consent was obtained from all the parents/guardians in regarding or authorization of theirs children to participate in this study. All subjects (children, parents and consent of parents/guardians) gave written informed consent in accordance with the Declaration of Helsinki.

Consent for publication

Not applicable

Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Author's contributions

L.B.M, C.M, P.R, M.S.B and M.S contributed to the build design and conduct the training of the Program. M.B.M and A.B contributed to the organization and analysis of data. C.R, C.M and P.R contributed to the writing, discussion and approval of the manuscript.

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7 CONSIDERAÇÕES FINAIS

A presente Tese de Doutorado teve como objetivo a construção e a avaliação de um programa de promoção de autorregulação em saúde, nas temáticas de alimentação saudável e saúde bucal em atividades relacionadas ao Programa Saúde na Escola no Município de Sapucaia-RS/Brasil.

O construto da autorregulação, que embasa a proposta desse programa, possibilita a organização de estratégias, objetivos e metas para alcançar determinadas ações e comportamentos, em um processo de construção pessoal e de interação com o meio, influenciando e sendo influenciado por ele. Dessa forma, a pesquisa utilizou como dispositivo a formação de professores e profissionais de saúde para realizar a instrumentalização dos alunos sobre as etapas e processos do modelo PLEA (ROSÁRIO et al., 2004), de modo a equipar os participantes para a ampliação da reflexão sobre o seu processo de cuidado em saúde, a organização do seu cotidiano, em diferentes domínios de sua vida, e a promoção da autonomia, potencializando as atividades do PSE.

Os três artigos apresentados na Tese abordaram o programa de autorregulação em suas diferentes perspectivas e resultados. O primeiro artigo teve como objetivo apresentar o delineamento do programa de promoção da autorregulação em saúde, nas temáticas de alimentação saudável e saúde bucal para alunos do 5º ano da Educação Básica. Neste, foram apresentados o racional do programa, com o respectivo desenho e fases, e a linha base do estudo. Como o programa desenvolveu suas fases e atividades no contexto do PSE, centrado nas temáticas de alimentação saudável e saúde bucal, nos artigos dois e três, foram apresentadas e discutidas as repercussões e os resultados do programa de intervenção bem como, seus impactos nas variáveis estudadas.

O artigo dois teve como objetivo explorar e discutir o programa e sua avaliação em relação à alimentação saudável. Para essa análise, as variáveis de autorregulação em saúde, autoeficácia, conhecimento declarativo, consumo de frutas e verduras e alimentos ultraprocessados e o índice de massa corporal foram comparados entre os grupos e avaliados durante os diferentes tempos de intervenção e após o seu término. Na mesma lógica, o artigo três ressaltou a discussão já realizada no artigo anterior e aprofundou a questão da saúde bucal na infância e sua abordagem na escola. Esse debate foi subsidiado por meio da análise do impacto do programa de intervenção de autorregulação nas variáveis relacionadas com a temática da saúde bucal, o que incluiu uma medida física, o índice de higiene oral simplificado, que demonstrou a melhora de cuidado em relação à escovação, diminuição de placa dentária e

higiene oral como um todo para os alunos participantes no programa.

Dessa forma, além de demonstrar a efetividade do programa de autorregulação para a melhora dos hábitos alimentares e aumento do consumo de frutas e verduras, o estudo também discutiu esses aspectos relacionados à higiene oral e ao contexto do PSE, buscando proporcionar algumas reflexões a respeito de como esse está estruturado, a sua sistemática e, principalmente, as estratégias utilizadas para o desenvolvimento do trabalho.

Diante disso, compreende-se que o presente estudo contribuiu para potencializar a prática e ações de uma política pública implementada no cenário nacional brasileiro, assim como para reforçar a importância da atuação multidisciplinar das diferentes profissões da saúde e da educação. Essa articulação interdisciplinar, em prol de ações de promoção de saúde e da autorregulação, que pôde ser desenvolvida durante o processo do Programa (tanto na fase de formação quanto na fase de intervenção), teve como foco a contribuição para a construção de novos dispositivos para a mudança de comportamento e hábitos, possibilitando a redução de problemas de saúde na população infantil. Nessa perspectiva, auxiliou na ampliação de capacidades e habilidades dos profissionais e alunos em relação aos temas trabalhados no PSE, aumentando as possibilidades de redução de gastos públicos com tratamentos de recuperação e reabilitação da saúde nessa área.

Além disso, o programa, construído e desenvolvido durante esse estudo, buscou mapear e conhecer a realidade do campo de intervenção. Esse mapeamento foi realizado por meio de estudo anterior implementado por integrantes do Grupo de Pesquisa (Estudos em Educação em Saúde), envolvendo entrevistas com profissionais da rede participantes do PSE (Educação e Saúde), com o objetivo de verificar as principais potencialidades e fragilidades do desenvolvimento do PSE no município. A partir disso, foi oferecida a formação com base em aspectos já destacados como coerentes à prática dos profissionais. Portanto, durante o programa, foram construídos, de forma conjunta com os participantes que conduziram a fase de intervenção, atividades e materiais que foram utilizados com os escolares. Dessa maneira, o programa, além de oferecer novos dispositivos e ferramentas de trabalho, para ser desenvolvido no Programa Saúde na Escola - PSE, também produziu e assegurou, como contrapartida para o município, materiais (livro de histórias de autorregulação em saúde, cartilha com atividades para serem desenvolvidas) inovadores na temática de autorregulação e que poderão ser utilizados nos mais diferentes contextos escolares e da promoção de saúde por todos os profissionais da rede.

Todo esse processo de formação e de intervenção ao longo de um ano, ao mesmo tempo em que auxiliou a desenvolver muitas competências (ampliação da autonomia,

competências autorregulatórias que envolvem planejamento, execução e avaliação, ampliação do cuidado em saúde, conhecimento em saúde e competências para modificações de hábitos alimentares) construção de vínculos e possibilidade de resultados mais duradouros, também gerou limitações e dificuldades para este estudo. O tempo de intervenção pode ser a justificativa para a perda de participantes ao longo do processo, por tratar-se de um programa de intervenção de longa duração, assim como também provocou configuração e organização no processo de acompanhamento do estudo muita intensas. A equipe realizou o acompanhamento, quinzenal com o objetivo de estar mais próxima dos participantes e para realizar a gestão desses processos, em virtude do longo tempo de intervenção. Dessa forma, ao mesmo tempo em que foi construída e desenvolvida uma relação muito próxima entre a equipe de pesquisa e os participantes do estudo, em função do longo tempo de desenvolvimento do Programa, percebeu-se que foi necessário realizar muitas adequações durante esse percurso e que influenciaram também no desenvolvimento e desfechos do estudo.

Esse percurso de intenso acompanhamento e deslocamento ao campo de estudo para a gestão presencial desses processos, também trouxe muitos aprendizados, enquanto pesquisadora, sobre metodologia de intervenção, pesquisa de campo, gestão dos processos de pesquisa e, principalmente, a possibilidade de acompanhar o desenvolvimento de competências e crescimento dos participantes envolvidos e, com isso, visualizar na prática a contribuição do conhecimento científico, da Universidade, para a comunidade.

Nessa constante construção e transformação como pesquisadora, foi extremamente gratificante participar de todo esse processo. Principalmente por ter tido a oportunidade de estar envolvida em todas as etapas do processo que envolve uma pesquisa: planejamento, desenvolvimento e execução, desde o primeiro contato com o campo, estruturação de materiais e instrumentos até aplicação desses no campo de prática, análise dos resultados e repercussões e momento da devolutiva para os participantes e comunidade. Todas essas etapas foram “recheadas” de muitos aprendizados, frustrações, desafios, alegrias, estudos, discussões e aprofundamentos teóricos e metodológicos e que auxiliaram muito no meu crescimento e constituição como pesquisadora. A experiência de vivenciar a construção e concretização de uma pesquisa com um grupo interdisciplinar provocou, em vários momentos, a necessidade de deslocar-me do lugar de pesquisadora Psicóloga e me experienciar no lugar de diferentes e desconhecidos saberes, auxiliando na ampliação de conhecimentos em outras áreas e pesquisa e atuação.

Ainda, cabe ressaltar a importância das análises dos dados qualitativos, oriundos do projeto maior do qual este estudo faz parte que se mostram com grande potencial para a triangulação dos dados e complementação do entendimento das temáticas, para o aprofundamento dos resultados apresentados nesta Tese.

ANEXOS

ANEXO A
TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO
(Para profissionais de saúde e professores das escolas)

O(A) Sr.(a) está sendo convidado(a) a participar do Projeto de Pesquisa "**Avaliação da Promoção da Autorregulação para o autocuidado em saúde: estudo no contexto do Programa Saúde na Escola no Rio Grande do Sul/Brasil.** Esta pesquisa objetiva realizar e avaliar um programa de formação no âmbito da Educação Permanente em Saúde na temática "autocuidado em saúde" em atividades relacionadas ao Programa Saúde na Escola, no município de Sapucaia do Sul-RS, bem como avaliar uma intervenção focada na mesma temática junto a alunos(as) do 5º ano do referido município. Se aceitar participar da pesquisa, é importante que o(a) Sr.(a) esteja ciente de que poderá participará de uma oficina de formação (de 30 horas) sobre os temas autorregulação e autocuidado em saúde, durante aproximadamente três meses (em 2015), período no qual serão realizados 2 grupos focais (no início e final da formação) com duração aproximada de uma hora. Além disso, o(a) Sr.(a) será acompanhado(a) durante outros nove meses (em 2016), quando da realização das atividades junto a alunos(as) de 5º ano.

Como parte da geração de dados, serão coletadas atividades escritas produzidas pelos(as) alunos(as), bem como material produzido pelo(a) professor(a). Serão feitos áudios e vídeos das entrevistas em grupo e/ou individuais com professores e profissionais de saúdes; registros fotográficos das atividades realizadas na escola ao longo do período da pesquisa, em especial nas atividades de formação, durante o ano da intervenção e ao final da pesquisa.

Indique, para cada item abaixo, o seu consentimento de uso dos dados gerados em áudio e vídeo, utilizando sua rubrica. Somente os dados permitidos serão utilizados:

Uso dos dados	Áudio	Vídeo	Foto	Texto transcrito
1. Os dados serão estudados pelos/as pesquisadores/as envolvidos no projeto.	(____)	(____)	(____)	(____)
2. Os dados podem ser mostrados a pessoas envolvidas em outros projetos de pesquisa.	(____)	(____)	(____)	(____)
3. Os dados podem ser usados em publicações científicas.	(____)	(____)	(____)	(____)
4. Os dados podem ser mantidos em arquivo digital à disposição de pesquisadores/as envolvidos/as ou não no	(____)	(____)	(____)	(____)

projeto.				
5. Os dados podem ser usados por pesquisadores/as em outros projetos.	(____)	(____)	(____)	(____)
6. Os dados podem ser mostrados em salas de aula, para fins de estudo.	(____)	(____)	(____)	(____)
7. Os dados podem ser mostrados em apresentações públicas de cunho acadêmico e científico, tais como congressos, seminários, simpósios, encontros e jornadas.	(____)	(____)	(____)	(____)

Todas as informações sobre você serão mantidas confidenciais através do uso de pseudônimos, para garantir o seu anonimato. Além disso, os dados não serão disponibilizados para qualquer propósito que não se encaixe nos termos da pesquisa.

Os encontros para a geração dos dados da pesquisa serão realizados presencialmente no seu local de trabalho, mediante agendamento, conforme sua disponibilidade e de acordo com as Unidades Básicas de Saúde e/ou a Direção das escolas participantes. Os dados coletados (anotações, áudio e transcrições das entrevistas) serão utilizados para este estudo e guardados para um estudo comparativo futuro, com o mesmo público ou público semelhante, que venha a ser desenvolvido por membros da equipe.

A sua participação na pesquisa é voluntária e não implica em nenhum risco ou prejuízo pessoal ou profissional para o Sr. (a), que poderá recusar-se a responder qualquer pergunta que possa lhe trazer constrangimento ou mesmo desistir de participar desta pesquisa a qualquer momento, mesmo após ter começado. Os benefícios da participação nesta pesquisa são indiretos, uma vez que ela poderá contribuir para uma melhor compreensão e atuação dos professores e profissionais de saúde na temática autocuidado em saúde no âmbito escolar. Não haverá despesas pessoais para o Sr. (a) assim como também não haverá compensação financeira relacionada a sua participação na pesquisa.

A responsabilidade do estudo fica a cargo da pesquisadora Cleidilene Ramos Magalhães. Para qualquer esclarecimento sobre a pesquisa o Sr.(a) poderá contatar a qualquer momento a Profª. Cleidilene Ramos Magalhães, pelo e-mail: cleidirm@ufcspa.edu.br ou telefone (51) 3303 8768. Caso tenha dúvidas o Comitê de Ética e Pesquisa (CEP/UFCSPA) também estará à disposição no endereço Rua Sarmento Leite, 245, Porto Alegre/RS ou pelo telefone (51) 3303 8804. Ambos os contatos podem ser feitos diariamente entre 9 e 17h.

Eu,_____
____, atesto o recebimento de uma cópia assinada deste Termo de Consentimento Livre e Esclarecido, conforme recomendações da Comissão Nacional de Ética e Pesquisa (CONEP) e concordo em participar voluntariamente desta pesquisa.

Sapucaia do Sul, ____ de _____ de _____.

_____ _____

Assinatura do participante Assinatura da pesquisadora responsável

ANEXO B
TERMO DE ASSENTIMENTO
(Para Pais, responsáveis e/ou cuidadores do aluno)

O(A) Sr.(a) está sendo convidado(a) a participar e autorizar a participação do aluno, pelo qual é responsável, no Projeto de Pesquisa "**Avaliação da Promoção da Autorregulação para o autocuidado em saúde: estudo no contexto do Programa Saúde na Escola no Rio Grande do Sul/Brasil.** Esta pesquisa objetiva realizar e avaliar um programa sobre Educação em Saúde na temática "autocuidado em saúde" em atividades relacionadas ao Programa Saúde na Escola, no município de Sapucaia do Sul-RS, bem como avaliar uma intervenção com este tema junto a alunos(as) do 5º ano deste mesmo Município.

Se concordar em participar e autorizar a participação do aluno na pesquisa, é importante que o(a) Sr.(a) esteja ciente de que:

1- responderá a três questionários, num tempo aproximado de 30 minutos, levados para casa pelo aluno em quatro momentos durante o ano letivo;

2- o(a) aluno(a) responderá a sete questionários, todos relacionados ao autocuidado em saúde, com duração aproximada de 10 minutos para cada questionário (respondido em sala de aula) em quatro momentos durante o ano letivo;

3- o(a) aluno(a) será acompanhado e avaliado no que se refere à saúde (envolvendo medidas de peso, altura e saúde bucal, individualmente, não implicando procedimento invasivo para o aluno), em quatro momentos durante o ano letivo, no horário das aulas;

4 – o(a) aluno(a) poderá ainda participar de atividades de orientação em relação à alimentação saudável e saúde bucal, desenvolvidas pelo professor, com o acompanhamento dos pesquisadores.

Todas as atividades que envolvem os alunos serão realizadas presencialmente nas escolas, mediante agendamento, conforme a disponibilidade da escola e dos alunos, no ano letivo de 2016.

Os dados coletados, como anotações e atividades escritas dos alunos, respostas dos questionários, avaliações, bem como o registro em áudio e vídeo das atividades realizadas na escola, serão utilizados para este estudo e guardados para um possível estudo comparativo futuro com alunos da mesma idade, para aprimoramento da pesquisa neste tema.

Como parte da geração de dados, serão coletadas atividades escritas produzidas pelos(as) alunos(as). Serão feitos registros fotográficos e áudios curtos com os depoimentos dos(as) alunos(as) sobre as atividades e sobre o projeto ao longo do período da pesquisa, em especial nas quatro visitas programadas e ao final do projeto.

Indique, para cada item abaixo, o seu consentimento de uso dos dados gerados em áudio e vídeo, utilizando sua rubrica. Somente os dados permitidos serão utilizados:

Uso dos dados	Áudio	Vídeo	Foto	Texto transcrito
1. Os dados serão estudados pelos/as pesquisadores/as envolvidos no projeto.	(____)	(____)	(____)	(____)
2. Os dados podem ser mostrados a pessoas envolvidas em outros projetos de pesquisa.	(____)	(____)	(____)	(____)
3. Os dados podem ser usados em publicações científicas.	(____)	(____)	(____)	(____)
4. Os dados podem ser mantidos em arquivo digital à disposição de pesquisadores/as envolvidos/as ou não no projeto.	(____)	(____)	(____)	(____)
5. Os dados podem ser usados por pesquisadores/as em outros projetos.	(____)	(____)	(____)	(____)
6. Os dados podem ser mostrados em salas de aula, para fins de estudo.	(____)	(____)	(____)	(____)
7. Os dados podem ser mostrados em apresentações públicas de cunho acadêmico e científico, tais como congressos, seminários, simpósios, encontros e jornadas.	(____)	(____)	(____)	(____)

Todas as informações sobre os(as) participantes, incluindo o(a) aluno(a) sob sua responsabilidade, serão mantidas confidenciais através do uso de pseudônimos, para garantir o seu anonimato. Além disso, os dados não serão disponibilizados para qualquer propósito que não se encaixe nos termos da pesquisa.

A participação na pesquisa é voluntária e não implica em nenhum risco ou prejuízo para o(a) Sr. (a) ou para o(a) aluno(a), que poderá recusar-se a responder qualquer pergunta que possa lhe trazer constrangimento ou mesmo desistir de participar desta pesquisa a qualquer momento, mesmo após ter começado. Os benefícios da participação nesta pesquisa são indiretos, uma vez que ela poderá contribuir para uma melhor compreensão dos processos de autocuidado em saúde e melhoria na qualidade de vida dos participantes da pesquisa. Todos os dados serão guardados sob sigilo, resguardando seu anonimato, assim como a ética profissional exige. Não haverá despesas pessoais para o(a) Sr. (a) e\ou a criança, assim como também não haverá compensação financeira relacionada à participação na pesquisa.

A responsabilidade do estudo fica a cargo da pesquisadora Cleidilene Ramos Magalhães. Para qualquer esclarecimento sobre a pesquisa o Sr.(a) poderá contatar a qualquer momento a Profª. Cleidilene Ramos Magalhães, pelo e-mail: cleidirm@ufcspa.edu.br ou telefone (51) 3303 8768. Caso tenha dúvidas o Comitê de Ética e Pesquisa (CEP/UFCSPA) também estará à disposição no endereço Rua Sarmento Leite, 245, Porto Alegre/RS ou pelo telefone (51) 3303 8804. Ambos os contatos podem ser feitos diariamente entre 9h e 17h.

Eu,_____
____, atesto o recebimento de uma cópia assinada deste Termo de Consentimento Livre e Esclarecido, conforme recomendações da Comissão Nacional de Ética e Pesquisa (CONEP) e concordo em participar voluntariamente desta pesquisa.

Assinatura do(a) responsável pelo(a) aluno(a):
_____

Sapucaia do Sul, ____ de _____ de _____.

<u>Termo de assentimento</u>:

Eu, _____ (nome do/a aluno/a), recebi as informações sobre a importância e os objetivos desta pesquisa de forma clara e concordo em participar do estudo.

Assinatura do(a) aluno(a): _____

Sapucaia do Sul, ____ de _____ de 201___.

Parecer Comitê de Ética

UNIVERSIDADE FEDERAL DE CIÊNCIAS DA SAÚDE DE PORTO ALEGRE

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: Avaliação da promoção da autorregulação para o autocuidado em saúde: estudo no contexto do Programa Saúde na Escola no Rio Grande do Sul/Brasil.

Pesquisador: Cleidilene Ramos Magalhães

Área Temática:

Versão: 1

CAAE: 46789315.0.0000.5345

Instituição Proponente: Universidade Federal de Ciências da Saúde de Porto Alegre

Patrocinador Principal: MINISTERIO DA EDUCACAO

DADOS DO PARECER

Número do Parecer: 1.151.220

Data da Relatoria: 16/07/2015

Apresentação do Projeto:

Este estudo se situa no campo da promoção da autorregulação para a saúde entre escolares. Este estudo inscreve-se no âmbito das atividades do Sistema Único de Saúde (SUS) que assegura o dever do Estado de garantir a saúde, por meio da formulação e execução de políticas econômicas e sociais que visem à redução de riscos de doenças e de outros agravos. Neste sentido, assegura o acesso universal e igualitário às ações e aos serviços para a sua promoção, proteção e recuperação e contando com a escola como lócus privilegiado para as ações de promoção à saúde, formação de cidadãos saudáveis e multiplicadores de tais ações. Trata-se de um estudo multi-métodos que pretende: i. realizar e avaliar um programa de formação no âmbito da Educação Permanente em Saúde na temática “autocuidado em saúde” em atividades relacionadas ao Programa Saúde na Escola, no município de Sapucaia do Sul-RS; ii. analisar a eficácia de ações de educação em saúde dentro do programa PSE para promover a autorregulação e autoeficácia para o autocuidado em saúde em escolares de 5o ano da Educação Básica. Para concretizar as ações descritas neste projeto, o estudo objetiva a elaboração de uma proposta ampla e inovadora de materiais didáticos (ex., ebook e jogos digitais). Estes materiais serão construídos para a intervenção e pesquisa a partir da temática do autocuidado em saúde. A eficácia do programa de intervenção com os alunos seguirá um desenho de pre-post de medidas repetidas, utilizando os questionários de

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disponibilidade, preferências e questionário alimentar do dia anterior; um questionário de crenças, influências e atitudes para a saúde; um questionário de conhecimento declarativo sobre alimentação saudável e saúde bucal; uma escala de autorregulação para a saúde e uma escala de autoeficácia para a saúde e outros como diários de campo, para captar a evolução do comportamento dos alunos ao longo do projeto. Todos os instrumentos serão validados para o contexto brasileiro em outro estudo a parte e utilizados neste projeto. O estudo será desenvolvido nos anos de 2015 a 2018, no município de Sapucaia do Sul -RS. O projeto será desenvolvido por integrantes do Grupo de Pesquisa Cadastrado no CNPq - Estudos em Educação e Saúde, Liderado pela Profa. Dra. Cleidilene Ramos Magalhães e contará com a participação do Professor Dr. Pedro Rosário, um especialista nos processos de autorregulação, contemplado como Professor Visitante Especial, pelo Programa Ciência Sem Fronteiras no Edital 09/2014 da CAPES.

Objetivo da Pesquisa:

Objetivo Primário:

Realizar a educação permanente de profissionais de saúde e professores e avaliar o processo de promoção da autorregulação e autocuidado em saúde, sob a lente da perspectiva da teoria social cognitiva, em atividades relacionadas ao Programa Saúde na Escola, no Município de Sapucaia- RS/Brasil. Objetivo Secundário:

- Elaborar material didático (e-book) de apoio para professores e profissionais da saúde utilizando a abordagem da Teoria da autorregulação, a partir do projeto “As Travessuras do Amarelo” para o desenvolvimento das temáticas “alimentação saudável e saúde bucal”, nas atividades relacionadas ao PSE;- Elaborar jogos educativos digitais fundamentados na teoria da autorregulação, com foco no autocuidado em saúde: alimentação saudável e saúde bucal; - Realizar oficinas de formação em serviço com os profissionais da Atenção Básica, participantes do PSE, e professores das escolas envolvidas sobre a temática autocuidado em saúde para formá-los na autorregulação da saúde;- Realizar grupo focal com os professores e profissionais de saúde participantes das oficinas de formação em serviço, para fins de avaliação das oficinas realizadas;- Monitorar, ao longo de um ano letivo, o programa de educação para a saúde com ênfase na promoção dos comportamentos de autorregulação dos hábitos alimentares e da saúde bucal desenvolvido pelos professores e pelos profissionais de saúde, que realizaram a formação em serviço, no contexto da escola;- Analisar, ao longo de um ano de intervenção, as mudanças ocorridas em relação à autorregulação, ao autocuidado e à promoção de saúde dos alunos participantes do estudo nas perspectivas da alimentação saudável e saúde bucal, realizadas pelos professores e profissionais de saúde;

-

Avaliar o consumo alimentar com quatro medidas repetidas, por meio da aplicação de questionário alimentar do dia anterior (adaptado de Assis et al., 2009), com alunos do 5o ano da Educação Básica participantes do estudo;- Avaliar o estado nutricional dos alunos do 5o ano da Educação Básica participantes do estudo por meio do Índice de Massa Corporal (IMC) (OMS, 2006, Brasil, 2008), com quatro medidas repetidas durante o ano; - Aplicar o Índice de Higiene Oral Simplificado (IHOS), de Greene e Vermillion (1964), para controle da placa bacteriana nos alunos do 5o ano da Educação Básica, com quatro medidas repetidas durante o ano.-Analisar, após seis meses do final da intervenção, as mudanças ocorridas em relação à autorregulação, ao autocuidado e à promoção de saúde dos alunos participantes do estudo nas perspectivas da alimentação saudável e saúde bucal, realizadas pelos professores e profissionais de saúde (medida follow-up).

Avaliação dos Riscos e Benefícios:

Riscos:

Não há riscos envolvidos na participação no estudo, a não ser eventual constrangimento em responder alguma questão, o que será respeitado.

Benefícios:

Os benefícios da participação na pesquisa são indiretos, uma vez que ela poderá contribuir para uma melhor compreensão dos processos de autocuidado em saúde e melhoria na qualidade de vida dos participantes da pesquisa.

Comentários e Considerações sobre a Pesquisa:

O presente trabalho preconiza um estudo multi-métodos que pretende i. realizar oficinas com os profissionais da Atenção Básica, participantes do PSE, e professores das escolas envolvidas sobre a temática autocuidado, preparando-os para conduzirem como formadores um programa de promoção da autorregulação da saúde destinado a alunos de 5oano da Educação Básica; ii.investigar os processos de autorregulação para o autocuidado em saúde, desenhando e avaliando a eficácia de um programa de educação em saúde promovido no âmbito do programa PSE, adotando-se como referencial a teoria da autorregulação e o “Projeto Travessuras do Amarelo” de Rosário et al. (2012) com alunos de 5o ano da Educação Básica. Coleta de dadosOs alunos do Grupo controle e do Grupo experimental 1 não participarão no programa de formação e seguirão as atividades educativas habituais sem a intervenção dos profissionais formados nas oficinas de autorregulação da saúde. Os alunos destas 28 turmas serão avaliados 4 vezes ao longo do ano letivo (nos meses de março, maio, agosto e novembro de 2016) nas seguintes áreas: autorregulação e auto-eficácia da saúde, em saúde bucal e em alimentação saudável,

Questionários de disponibilidade alimentar, Questionário de preferência alimentar, Questionário alimentar do dia anterior, Questionário de crenças, influências e atitudes para a saúde, Questionário de conhecimento declarativo sobre alimentação saudável e saúde bucal, medida de Índice de Massa Corporal (IMC) – OMS (2006) e Brasil (2008) para avaliar o estado nutricional dos alunos, medida de Índice de Higiene Oral Simplificado (IHOS), de Greene e Vermillion (1964) para controle da placa bacteriana nos alunos.Os alunos das 14 turmas do Grupo experimental 2 participarão no programa de promoção da autorregulação da saúde. O programa decorrerá numa sessão quinzenal (no horário da aula da disciplina de Ciências), conduzida pelo professor da turma e numa sessão mensal, conduzida conjuntamente pelo professor e profissionais de saúde. Tais sessões ocorrerão ao longo do ano letivo e serão organizadas pelos professores e profissionais de saúde. Ao longo do ano letivo, os pesquisadores farão monitoramento do trabalho desenvolvido por estes profissionais através de reuniões mensais com os profissionais e contatos telefônicos com o intuito de avaliar, acompanhar o processo do programa e também para discutir sobre dificuldades surgidas durante a intervenção. Estes dados serão registados em diário de campo. Os encontros para a geração dos dados da pesquisa serão realizados presencialmente no local de trabalho profissionais de saúde e professores, mediante agendamento, conforme a disponibilidade dos participantes e de acordo com as Unidades Básicas de Saúde e/ou a Direção das escolas participantes. A coleta de dados junto aso pais/responsáveis será realizada durante o ano letivo por intermédio do aluno: o aluno levará para casa e retornará para a escola os instrumentos de avaliação. Os dados coletados, como anotações e atividades escritas dos alunos, respostas dos questionários, avaliações, bem como os registros fotográficos, áudios e vídeos das atividades realizadas na escola com professores e alunos, serão utilizados para este estudo e guardados para um possível estudo comparativo futuro com alunos da mesma idade, para aprimoramento da pesquisa neste tema.

Considerações sobre os Termos de apresentação obrigatória:

São apresentados um TCLE para professores e profissionais de saúde e outro para os pais ou responsáveis das crianças. Este último também inclui um termo de assentimento a ser assinado pelas crianças.

O projeto conta com a anuência da Secretaria Municipal de Saúde e da Secretaria Municipal da Educação do Município de Sapucaia do sul - RS.

Recomendações:

Aprovar.

Conclusões ou Pendências e Lista de Inadequações:

O projeto está adequado dos pontos de vista ético e metodológico, tendo seu prazo de execução encerrando-se no mês de julho de 2018.

Situação do Parecer:

Aprovado

Necessita Apreciação da CONEP:

Não

Considerações Finais a critério do CEP:

De acordo com o parecer do Relator.

PORTO ALEGRE, 16 de Julho de 2015

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Instrumentos

1 – Parte da Escala Autorregulação em Saúde – Saúde Bucal

Questionário de Processos de Autorregulação para a Saúde SAÚDE BUCAL	Nunca	Poucas vezes	Algumas vezes	Muitas vezes	Sempre
Por exemplo: Depois que acordo, penso no que vou comer no café da manhã e no que preciso fazer para prepará-lo.	1	2	3	4	5
2. Durante o dia, em casa ou em outro local, penso no que tenho de mudar para conseguir ter uma alimentação saudável.	1	2	3	4	5
3. Gosto de cuidar o que eu como para manter a minha saúde.	1	2	3	4	5

Escala Autorregulação em Saúde – Alimentação Saudável

Questionário de Processos de Autorregulação para a Saúde ALIMENTAÇÃO SAUDÁVEL	Nunca	Poucas vezes	Algumas vezes	Muitas vezes	Sempre
1. Faço um plano para as minhas refeições. Penso no que vou comer e no que é preciso para preparar a minha refeição. *Por exemplo: Depois que acordo, penso no que vou comer no café da manhã e no que preciso fazer para prepará-lo.*	1	2	3	4	5
2. Durante o dia, em casa ou em outro local, penso no que tenho de mudar para conseguir ter uma alimentação saudável.	1	2	3	**4**	5
3. Gosto de cuidar o que eu como para manter a minha saúde.	1	2	3	4	5

2 – Autoeficácia em Saúde – Saúde Bucal

Questionário de Processos de Autoeficácia para a Saúde SAÚDE BUCAL	Com muita dificuldade	Com dificuldade	Com facilidade	Com muita facilidade
1. Eu consigo escovar os dentes após o café da manhã.	1	2	3	4
2. Eu consigo escovar os dentes após o almoço.	1	2	3	4
3. Eu consigo escovar os dentes após o lanche.	1	2	3	4
4. Eu consigo escovar os dentes após o jantar.	1	2	3	4

Autoeficácia em Saúde – Alimentação Saudável

Questionário de Processos de Autoeficácia para a Saúde ALIMENTAÇÃO SAUDÁVEL	Com muita dificuldade	Com dificuldade	Com facilidade	Com muita facilidade
No café da manhã				
1. Eu consigo comer frutas.	1	2	3	4
2. Eu consigo comer legumes e verduras.	1	2	3	4
3. Eu consigo beber um copo de suco de fruta natural, feito em casa.	1	2	3	4
4. Eu consigo beber leite ou iogurte.	1	2	3	4
5. Eu consigo comer pão ou outro alimento do grupo dos cereais.	1	2	3	4
No almoço				
6. Eu consigo comer legumes e verduras.	1	2	3	4
7. Eu consigo beber um copo de suco de fruta natural, feito em casa.	1	2	3	4

3 – Questionário de Conhecimento Declarativo em Saúde – Saúde Bucal

Questionário de Conhecimento Declarativo sobre Saúde SAÚDE BUCAL	Verdadeiro (V)	Falso (F)
1. A cárie não é causada por bactérias	V	F
2. O fio dental limpa o espaço entre os dentes, onde a escova não alcança	V	F
3. É normal sangrar a gengiva durante as escovações	V	F

Questionário de Conhecimento Declarativo em Saúde – Alimentação Saudável

Questionário de Conhecimento Declarativo sobre Saúde ALIMENTAÇÃO SAUDÁVEL	Verdadeiro (V)	Falso (F)
1. Uma criança deve beber apenas uma xícara de leite por dia.	V	F
2. Arroz, pão e outros cereais são alimentos que devem ser consumidos todos os dias.	V	F
3. É necessário comer frutas e legumes, mas não todos os dias.	V	F

4 – Questionário Alimentar do dia Anterior – QUADA

QUESTIONÁRIO ALIMENTAR DO DIA ANTERIOR (QUADA)

DADOS DE IDENTIFICAÇÃO	
Nome:	**Data:**
Escola:	**Turma:**