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Paula dos Santos Leffa

**Impacto de um programa de
atualização em alimentação infantil
para profissionais de saúde no
consumo de alimentos
ultraprocessados: ensaio de campo
randomizado por conglomerados**

Universidade Federal de Ciências da Saúde
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Orientador: Dra. Márcia Regina Vitolo

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RESUMO

Introdução: O consumo alimentar entre crianças tem sido investigado devido as intensas modificações nos padrões alimentares ao longo das últimas décadas. Recentemente foram estabelecidos critérios de classificação de alimentos de acordo com o propósito e grau de processamento industrial, que auxiliam na compreensão e análise dietética. **Objetivos:** O objetivo geral da presente dissertação foi avaliar o impacto de um programa de atualização em alimentação infantil para profissionais de saúde no consumo de alimentos ultraprocessados durante o seguimento de um grupo de crianças nas idades de 12 meses e 3 anos. **Métodos:** Ensaio de campo randomizado por conglomerados realizado em Porto Alegre (RS), Brasil. Vinte unidades de saúde foram randomizadas em grupo intervenção (n = 9) e controle (n = 11). Os profissionais das unidades de saúde do grupo intervenção receberam orientações quanto às diretrizes alimentares para lactentes do Ministério da Saúde. Aos 12 meses e 3 anos de idade das crianças, os dados dietéticos foram avaliados por meio de inquéritos recordatórios de 24 horas e os itens alimentares presentes foram classificados de acordo com o sistema NOVA. **Resultados:** Foram avaliadas 520 e 446 crianças aos 12 meses e 3 anos, respectivamente. O percentual de energia proveniente de alimentos ultraprocessados foi de $36,1 \pm 2,3$ e $46,9 \pm 12,0$ aos 12 meses e 3 anos, respectivamente. Aos 3 anos de idade, a ingestão nos valores absolutos de energia proveniente de biscoitos e salgadinhos (DM -23,5 kcal 95% IC, - 42,2 - 4,8) foram significativamente menores no grupo intervenção em relação ao controle, no qual diminuiu a ingestão energética de alimentos ultraprocessados (DM -50,3 kcal 95% IC, - 96,0 - 4,6). Consequentemente, as crianças do grupo intervenção apresentaram menores diferenças médias na ingestão energética total (DM -77,6 kcal 95% IC, -147,1 -8,1). Por outro lado, não foram observados efeito da intervenção aos 12 meses de idade. **Conclusão:** O programa de intervenção apresentou resultados positivos nas práticas alimentares durante a infância e adicionou informações sobre o consumo de alimentos ultraprocessados nos primeiros anos de vida.

Palavras-chaves: Estudos de intervenção. Criança. Consumo de alimentos. Alimentos ultraprocessados.

ABSTRACT

Introduction: Children's dietary consumption has been investigated due to the significant changes that have occurred in dietary patterns over the last decades. Criteria have recently been established to classify foods according to their degree of processing, which assists in dietary analysis and understanding. **Objectives:** The overall objective of this dissertation was to assess the impact of a training program for health professionals about children's diets and the consumption of ultra-processed foods during the follow-up by a group of children at the ages of 12 months and 3 years. **Methods:** This was a cluster-randomized field trial conducted in Porto Alegre (RS), Brazil. Twenty public health centers were randomized into an intervention group (n=9) and a control group (n=11). The health center professionals in the intervention group were trained about the Brazilian Health Ministry's feeding guidelines for infants. The children's dietary data were assessed at 12 months and 3 years of age using 24-hour dietary recalls and the dietary items present were classified according to the NOVA system. **Results:** We evaluated 520 and 446 children at 12 months and 3 years of age, respectively. The percentage of daily energy provided by ultra-processed foods was 36.1 ± 2.3 and 46.9 ± 12.0 at 12 months and 3 years, respectively. At 3 years of age, the absolute energy intake values from savoury and biscuits (MD -23.5 kcal 95% CI, - 42.2 – 4.8) were significantly lower in the intervention group compared to the control group, which decreased the energy intake values from ultra-processed foods (MD -50.3 kcal 95% CI, - 96.0 – 4.6). As a result, the children in the intervention group had smaller mean differences in daily energy intake (MD -77.6 kcal 95% CI, -147.1 -8.1). On the other hand, no intervention effect was observed at 12 months of age. **Conclusion:** The intervention program had positive effects on dietary practices during childhood and added information about the consumption of ultra-processed foods in the first years of life.

Keywords: Intervention studies. Children. Food consumption. Ultra-processed foods.

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1 INTRODUÇÃO

Nas últimas décadas, as intensas transformações na dieta, com o aumento exponencial de alimentos e bebidas processados industrialmente, modificaram o padrão de consumo na população (POPKIN, 2004; KANT & GRAUBARD, 2015; POPKIN & HAWKES, 2015). Consequentemente, estas práticas alimentares inadequadas atingem a população infantil e atualmente são considerados um problema de saúde pública, visto que estão associados à desfechos de saúde, como excesso de peso e morbidades associadas (POPKIN *et al.*, 2012; DANAEI *et al.*, 2013; POPKIN, 2015). Desta forma, o uso da classificação de alimentos baseada na extensão e propósito de processamento pode ser utilizado como ferramenta da qualidade global da dieta de uma população (VANDEVIJVERE *et al.*, 2013) e auxiliar no entendimento do comportamento alimentar.

Neste contexto, considerando os primeiros anos de vida como período crucial para formação de hábitos alimentares (VENTURA & WOROBEY, 2013; BIRCH & DOUB, 2014), os programas de intervenção que visam comportamentos saudáveis em idade precoce, como a melhoria das práticas alimentares, são essenciais para aprimorar as condições de saúde da população. Apesar da magnitude do tema, ainda são poucos os estudos que avaliam o consumo de alimentos ultraprocessados por meio do sistema de classificação de alimentos nos primeiros anos de vida, bem como o impacto de programas de intervenção na ingestão dos mesmos.

2 REVISÃO DA LITERATURA

2.1 Fatores determinantes em práticas alimentares na infância

As preferências alimentares, em desenvolvimento desde os primeiros dias de vida, apresentam fundamental importância nas escolhas alimentares, principalmente de crianças. Sabe-se que essas preferências são determinadas por uma complexa interação de fatores genéticos, ambientais e familiares (BIRCH, 1998; SCAGLIONI *et al.*, 2011). Geneticamente, as crianças são predispostas a aceitarem as substâncias de sabor doce e salgado e rejeitarem ácidos e amargos (BIRCH, 1998). Diferentes estudos revelaram que crianças preferem alimentos de alta densidade energética, com elevada concentração de açúcar e de gorduras, como sorvete, doces e bebidas adoçadas, em detrimento de verduras e frutas (BOWMAN *et al.*, 2004; FORD *et al.*, 2013; KEAST *et al.*, 2013). Essas preferências podem ser explicadas como uma função protetora, em que os sabores mais aceitos são identificados como sinal de uma fonte de energia e nutrientes enquanto os rejeitados são percebidos como um risco pela presença de toxinas (BIRCH, 1998). No entanto, essas predisposições podem tornar-se um obstáculo para a promoção da ingestão saudável em crianças. A neofobia alimentar e aversões para os alimentos azedos ou amargos podem dificultar a introdução de, por exemplo, frutas e legumes, na alimentação da criança e deste modo favorecer o consumo de alimentos com alta densidade energética e palatáveis (BIRCH & VENTURA, 2009).

Embora o ser humano tenha preferências inatas por determinados sabores, a exposição pré-natal e durante o aleitamento, através do consumo alimentar materno, assim como as primeiras exposições a alimentos, podem determinar preferências alimentares, que tendem a se perpetuar em todas as faixas etárias (BEAUCHAMP & MENNELLA, 2009). Estudos indicam que são necessárias de oito a 15 exposições a um novo alimento para que esse seja aceito (BIRCH *et al.*, 1990; SULLIVAN & BIRCH, 1994), destacando que a rejeição aos novos alimentos é fisiológica, mas após a familiarização a aceitação tende a aumentar. Dessa forma, as características genéticas e as experiências relacionadas aos alimentos, principalmente nos primeiros anos de vida, interagem durante o desenvolvimento. Contudo, é importante ressaltar que as influências genéticas podem ser modificadas e a interação com fatores ambientais serão determinantes para a formação dos hábitos alimentares dos indivíduos (BIRCH, 1999).

Neste contexto a família, especialmente os pais e cuidadores, desempenham papel crítico na formação da preferência alimentar em crianças, uma vez que estes teriam a função de influenciar as atitudes e crenças das crianças ao impor regras, oferecer informações e servindo

como um modelo de comportamento aos seus filhos (HOLSTEN *et al.*, 2012), além de controlar a qualidade da dieta que disponibilizam às crianças (DAVISON & BIRCH, 2001).

As práticas alimentares nos primeiros anos de vida são determinantes e influenciam as condições de saúde em curto e longo prazo (BARKER, 2007; SCAGLIONI *et al.*, 2011). Deste modo, os hábitos alimentares inadequados constituem-se em relevante problema de saúde pública, estando associadas à desfechos de saúde não apenas na infância, mas também na idade adulta (HANSON *et al.*, 2012; BRANDS *et al.*, 2014).

2.2 Estudos de intervenção

A importância da realização de intervenções no início da vida baseia-se nas evidências que os primeiros anos de desenvolvimento de uma criança estão diretamente relacionados com a ocorrência de doenças crônicas na vida (WHO, 2014; LANGLEY-EVANS, 2015). Neste período, a plasticidade biológica constitui-se uma oportunidade única para evitar ou reduzir possíveis mecanismos epigenéticos que aumentariam a sensibilidade para o desenvolvimento de doenças (VICKERS, 2014), deste modo, intervenções precoces para diminuir os fatores de risco ambientais são essenciais para as melhorias nas condições de saúde da população. Dentre os enfoques para o período, os programas de intervenção nutricional são cruciais considerando a formação precoce de hábitos alimentares (BIRCH & DOUB, 2014) e seu impacto na saúde. Diversos aspectos positivos são observados em estudos de intervenção direcionados aos hábitos alimentares de crianças no início da vida, como promoção do aleitamento materno (EKSTROM *et al.*, 2012; HAROON *et al.*, 2013; FU *et al.*, 2014; SIKANDER *et al.*, 2015) e melhorias na prática da alimentação complementar (SHI *et al.*, 2010; OLAYA *et al.*, 2013; DANIELS *et al.*, 2014).

No Brasil, VITOLO *et al.* (2005) realizaram estudo randomizado sobre a implementação do programa governamental denominado “Dez passos para alimentação saudável para crianças menores de 2 anos”, onde mães alocadas para o grupo intervenção receberam visitas domiciliares para orientações dietéticas de acordo com os “Dez Passos” no primeiro ano de vida de seus filhos. Os resultados mostraram impacto positivo no aleitamento materno exclusivo e na redução de guloseimas (balas, refrigerantes, salgadinhos e chocolates) no grupo intervenção. Outra publicação referente ao mesmo estudo, com as crianças na fase pré-escolar, avaliou a qualidade da dieta utilizando o *Heathy Eating Index* (KENNEDY *et al.*, 1995), e observou a efetividade do impacto dessa intervenção também nesse aspecto, pois a qualidade da

alimentação das crianças do grupo intervenção foi maior em relação às aquelas que pertenciam ao controle (VITOLO *et al.*, 2010). A eficácia a longo prazo do aconselhamento dietético no primeiro ano de vida foi observada aos 7-8 anos de idade referente ao perfil sérico de lipídeos, onde as meninas do grupo intervenção apresentaram maiores valores de HDL-colesterol e menores concentrações de triglicerídeos (LOUZADA *et al.*, 2012).

Estudos objetivando capacitar profissionais de saúde para transmitir orientações sobre alimentação saudável são oportunidades para abranger maior número de pessoas e vêm sendo observados resultados positivos destas ações. SUNGUYA *et al.* (2013) publicaram revisão sistemática que incluiu estudos que avaliaram o efeito da atualização em nutrição para profissionais de saúde sobre as práticas alimentares de crianças entre 6 e 24 meses. A revisão avaliou 10 estudos conduzidos em países de baixa e média renda. Os autores concluíram que a atualização em nutrição para profissionais da saúde apresenta potencial nas melhorias de condições nutricionais da criança, com resultados positivos na frequência da alimentação, ingestão de energia e na diversidade da dieta.

É relevante que diferentes formas de intervenção com programas nutricionais apresentem resultados satisfatórios nas práticas alimentares de crianças nos primeiros anos de vida, entretanto, esses achados vão contra uma série de limitações como aspectos culturais, comportamentais, baixo nível socioeconômico e escolaridade (HEDBERG, 2013; ICKES *et al.*, 2015). É necessário que novos estudos considerem estas barreiras como estratégias de intervenção para que resultados mais promissores possam ser alcançados.

2.3 Classificação dos alimentos baseada na extensão e propósito do processamento

A preparação dos alimentos, bem como as técnicas empregadas para o seu cultivo e preservação, permitiu a evolução e adaptação da espécie humana (WRANGHAM, 2013). Historicamente o processamento dos alimentos consolidou-se de forma lenta e gradual durante a história da humanidade. Desde a industrialização, e em particular no início da década de 80, o processamento de alimentos desenvolveu-se muito rapidamente e com intensas transformações através da ciência e tecnologia. Fatores como a globalização econômica, as transformações nos padrões de produção e consumo de alimentos, revolucionaram o padrão alimentar na maioria dos países pelo aumento da produção, disponibilidade, acessibilidade e comercialização de produtos alimentares e bebidas processadas (LUDWIG, 2011; SWINBURN *et al.*, 2011). Dietas tradicionais à base de frutas, legumes e vegetais foram substituídas por

dietas com elevada densidade energética, ricas em açúcar e sódio, com aumento do consumo de gorduras, especialmente saturadas e *trans*, carboidratos refinados e alimentos de origem animal (WHO, 2003; PIERNAS & POPKIN, 2010; LEVY *et al.*, 2012). Tais mudanças nos padrões alimentares são conhecidas como "transição nutricional" (POPKIN, 2004; 2009), sendo o aumento do consumo de alimentos processados industrialmente como característica marcante destes novos padrões dietéticos (POPKIN *et al.*, 2012).

Tradicionalmente, os estudos epidemiológicos que avaliam padrões alimentares e seus impactos na saúde utilizam como base a avaliação energética e de macro e micronutrientes da dieta. Entretanto, é de senso comum que os indivíduos não ingerem nutrientes isolados, mas refeições compostas por diferentes alimentos que fornecem diversos nutrientes e compostos químicos que interagem entre si. Desde 1998, a Organização Mundial da Saúde sugere que o consumo alimentar seja avaliado com base em alimentos ao invés de nutrientes (WHO, 1998), o que permite medir com maior fidedignidade o padrão alimentar de uma população.

Em estudos sobre o consumo alimentar da população e recomendações dietéticas, o processamento industrial dos alimentos é praticamente ignorado ou minimizado (MONTEIRO *et al.*, 2010; MARTINS *et al.*, 2013). Neste contexto, um novo sistema de classificação de alimentos baseado na extensão, natureza e processamento dos produtos alimentares foi elaborada por Monteiro e colaboradores (MONTEIRO *et al.*, 2010), recentemente nomeada como “NOVA” (MOUBARAC *et al.*, 2014b; PAHO, 2015). O sistema NOVA considera os métodos e técnicas utilizados pela indústria para a transformação de alimentos *in natura* em produtos alimentícios.

A classificação divide os itens alimentares entre quatro grupos: 1) alimentos *in natura* ou minimamente processados; 2) ingredientes culinários processados; 3) alimentos processados e 4) alimentos ultraprocessados. Os exemplos dos alimentos que são incluídos em cada grupo estão no Anexo 1.

- *Alimentos in natura e minimamente processados.* Os alimentos *in natura* são aqueles de origem vegetal (folhas, caules, raízes, tubérculos, frutas, nozes, sementes) ou de origem animal (carnes, ovos, leite) logo após a colheita ou o abate. Alimentos minimamente processados são os alimentos *in natura* que foram submetidos a um processamento industrial mínimo antes de serem adquiridos e consumidos. Esse processamento não adiciona outros produtos ou substâncias. Envolve limpeza, remoção de partes não comestíveis, fracionamento, pasteurização, redução de conteúdo de gordura, refrigeração, congelamento, desidratação ou procedimentos similares, conservando grande parte das propriedades nutricionais do alimento original e aumentando sua

disponibilidade e segurança. Em combinações apropriadas, todos os alimentos desse grupo são a base para uma alimentação saudável.

- *Ingredientes culinários processados.* São as substâncias extraídas dos alimentos in natura ou minimamente processados, tais como óleos vegetais, farinhas e açúcar. O processamento inclui prensagem, moagem, pulverização, refinação, hidrogenação e outros métodos. Os ingredientes culinários não são consumidos isoladamente e são utilizados na preparação de outros alimentos, com refeições feitas à base de alimentos in natura ou minimamente processados.
- *Alimentos processados.* Os alimentos processados são fabricados através da adição de substâncias como o óleo, açúcar ou o sal nos alimentos in natura ou minimamente processados, bem como por processos que os tornam mais duráveis e palatáveis. Essas técnicas alteram substancialmente a sua natureza ou uso, apesar de manterem algumas características do alimento original. Para o processamento são utilizadas técnicas como a salga, salmoura, defumação, cura, acondicionamento dos alimentos em vidros ou latas.
- *Alimentos ultraprocessados.* Os alimentos ultraprocessados são produzidos de modo predominante ou unicamente a partir de ingredientes industriais, com pouco ou nenhum alimento integral em sua composição, com a proposta de serem produtos duráveis, acessíveis e convenientes, palatáveis, atraentes e rentáveis. São alimentos prontos ou quase prontos para serem consumidos por si só ou em combinação com outro produto ultraprocessado (por exemplo, biscoito recheado e refrigerante). Os componentes dos produtos ultraprocessados são, em grande maioria, aditivos como conservantes, estabilizantes, emulsionantes, solventes, agentes de ligação, adoçantes, além de realçadores sensoriais, de sabores e cores. O processamento inclui a hidrólise, a hidrogenação, a extrusão, a moldagem, a fritura e o cozimento prévios, além da adição de micronutrientes para fortificação do alimento.

Estudos populacionais conduzidos em diferentes países evidenciam a participação crescente na produção e consumo de produtos ultraprocessados. No Reino Unido, Moubarac e cols. (MOUBARAC *et al.*, 2013), em estudo conduzido a partir da Pesquisa Nacional de Orçamentos Familiares, mostraram que 58% da ingestão calórica da população veio a partir dos produtos prontos para consumo. Dados semelhantes foram encontrados no Canadá, onde os alimentos processados e ultraprocessados contribuíram com 55% da energia da dieta (MOUBARAC *et al.*, 2014a). No Brasil, MARTINS *et al.* (2013), com amostra representativa da população, evidenciaram o aumento na ingestão de produtos processados e ultraprocessados

nas últimas décadas em detrimento as dietas tradicionais compostas por alimentos in natura e minimamente processado e preparações com base nestes alimentos. Somando-se a todas estas evidências, recente relatório da Organização Pan Americana da Saúde (PAHO, 2015) revelou o aumento de 48% nas vendas de produtos ultraprocessados no período de 2000 a 2013 em 13 países latino-americanos. O volume de vendas ainda é maior em países de maior condição econômica, como Estados Unidos e Canadá, porém observou-se o crescimento exponencial destes produtos nos últimos anos em países de baixa renda, como Peru (107%), Bolívia (129,8%) e Uruguai (146,4%). Adicionalmente, os resultados evidenciaram que o aumento no consumo de alimentos ultraprocessados está fortemente associado ao aumento do peso corporal ($R^2 = 0.86$) na população dos países estudados.

2.4 Alimentos ultraprocessados: características e consequências

Os alimentos ultraprocessados possuem características peculiares em sua composição que favorecem o seu consumo excessivo. No que se refere a qualidade nutricional estes produtos são considerados inadequados, apresentam concentrações excessivas de açúcar, sal e gorduras, incluindo as saturadas e trans, e contém pouca ou nenhuma fibra alimentar e água em sua composição (MONTEIRO *et al.*, 2012; MOODIE *et al.*, 2013). Estas características propiciam alimentos com alta densidade energética, que facilitam o transporte e aumento a validade do produto. Em consonância com estas afirmações, um estudo realizado com escolares no Sul do Brasil mostrou que o consumo dos produtos ultraprocessados na alimentação das crianças foi associado a dietas ricas em energia, gorduras e sódio e menor teor de proteínas e fibras (BARCELOS *et al.*, 2014)

A combinação dos ingredientes e as técnicas de processamento industrial utilizadas aumentam a palatibilidade destes produtos, capaz de alterar os mecanismos de saciedade endógenos e assim promover o consumo excessivo de energia e, consequentemente, a obesidade (FORTUNA, 2012). A praticidade dos produtos ultraprocessados associados às estratégias de publicidade persuasivas e agressivas os tornam irresistíveis e preferíveis aos alimentos in natura e minimamente processados. Evidências recentes mostram que a publicidade de comidas e bebidas tem grande influência nas preferências alimentares das crianças, tornando esta população alvo da indústria alimentícia, utilizando como estratégias ofertas de brindes, personagens promocionais, diversão e humor (CAIRNS *et al.*, 2013; MALLARINO *et al.*, 2013). Além disso, sua acessibilidade e facilidade de transporte facilitam o hábito de substituir

e comer entre refeições. Em sua grande maioria podem ser consumidos em qualquer lugar, o que faz dos produtos ultraprocessados conhecidos como convenientes, pois estão prontos ou quase prontos para o consumo (MONTEIRO, 2010).

A classificação dos alimentos ultraprocessados tem sido utilizada para avaliar os possíveis impactos do consumo destes produtos à saúde humana. CANELLA *et al.* (2014), em estudo realizado com amostra representativa da população brasileira, demonstraram associação positiva e independente entre a disponibilidade domiciliar de produtos ultraprocessados e a obesidade. Um estudo transversal realizado com adolescentes em um município do Rio de Janeiro mostrou que o consumo de produtos processados e ultraprocessados teve associação com a síndrome metabólica (TAVARES *et al.*, 2012). Recentemente RAUBER *et al.* (2015), em estudo longitudinal com crianças de baixa condição socioeconômica no sul do país revelaram que o consumo de produtos ultraprocessados na idade pré-escolar é um preditor do aumento das concentrações de colesterol total e LDL-colesterol na idade escolar.

Recente revisão sistemática mostrou que os sistemas de classificação de alimentos que definem e distinguem diferentes tipos de processamento industrial de alimentos – como a classificação de alimentos proposta por Monteiro e cols. – podem auxiliar na compreensão de como prevenir e controlar o excesso de peso, a obesidade e as doenças crônicas relacionadas, além de auxiliar na avaliação e monitoramento dos padrões alimentares da população (MOUBARAC *et al.*, 2014b). Neste contexto, o Ministério da Saúde publicou em 2014 a nova edição do “Guia alimentar para a população brasileira” (BRASIL, 2014), que se constitui em uma das estratégias para implementação da diretriz de promoção da alimentação adequada e saudável. A nova publicação tem como princípios básicos a orientação para redução do consumo de alimentos processados e ultraprocessados, baseados de acordo com a classificação proposta, ressaltando a importância do processamento industrial dos alimentos e seu impacto na saúde. O novo guia brasileiro é um marco internacional, pois adota a classificação dos alimentos de acordo com o nível de processamento como base para as diretrizes de saúde pública e nutrição para a população do país.

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3 OBJETIVOS

3.1 Objetivo principal

Avaliar o impacto de um programa de atualização em alimentação infantil para profissionais de saúde no consumo de alimentos ultraprocessados em uma coorte de crianças aos 12 meses e 3 anos de idade.

3.2 Objetivos secundários

- Verificar a participação dos alimentos ultraprocessados no padrão alimentar das crianças.
- Avaliar a contribuição dos alimentos ultraprocessados na ingestão de energia, macronutrientes e micronutrientes durante a infância.

4 ARTIGO ORIGINAL

Será submetido ao periódico *Pediatrics*.

TITLE: Health workers training on children ultra-processed food consumption: A Cluster-randomized Trial

Short title: Health workers training on children consumption

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Conflict of Interest: The authors have no conflicts of interest to disclose.

Clinical Trial Registration: Registration number NCT00635453 - <https://clinicaltrials.gov/ct2/show/NCT00635453>

Abbreviations: CI – confidence interval; MD – mean difference; Multiple Source Method - MSM

What's Known on This Subject – Criteria have recently been established to classify foods according to degree of processing. Ultra-processed foods have been associated with unfavorable nutrition profiling, but we are not aware of intervention studies that have evaluated their effectiveness on ultra-processed consumption among children.

What This Study Adds – This first cluster-randomized field trial revealed that, in a low-income population, the update training among health workers in complementary feeding guidelines significantly reduced ultra-processed food intake at 3 years follow up.

Contributors' Statements:

Paula dos Santos Leffa: Ms. Leffa contributed to the data analyses, interpretation of the results, drafting, and critical revision of the article.

Caroline Nicola Sangalli: Ms. Sangalli contributed to the data analyses, drafting and critical revision of the article.

Fernanda Rauber: Dr. Rauber contributed to the data analyses and critical revision of the article.

Márcia Regina Vitolo: Dr. Vitolo contributed to the research proposal, data analyses, interpretation of the results, drafting of the manuscript, student supervision, and critical revision of the article.

All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

ABSTRACT

Objective: To assess the impact of a training program for health professionals about children's diets and the consumption of ultra-processed foods during the follow-up by a group of children at the ages of 12 months and 3 years. **Methods:** This was a cluster-randomized field trial conducted in Porto Alegre, Brazil. Public health centers were randomized into an intervention group (n=9) and a control group (n=11) and health workers in the intervention group were trained about the Brazilian Health Ministry's feeding guidelines for infants. The children's dietary data were assessed at 12 months and 3 years of age using 24-hour dietary recalls and the dietary items present were classified according to the NOVA system. **Results:** We evaluated 520 and 446 children at 12 months and 3 years of age, respectively. The absolute energy intake values from savoury and biscuits (MD -23.5 kcal 95% CI, - 42.2 – 4.8) were significantly lower in the intervention group compared to the control group, which decreased the energy intake values from ultra-processed foods (MD -50.3 kcal 95% CI, - 96.0 – 4.6), at 3 years of age. As a result, the children in the intervention group had smaller mean differences in daily energy intake (MD -77.6 kcal 95% CI, -147.1 -8.1). Ultra-processed food intake did not differ between groups at 12 months. The percentage of daily energy provided by ultra-processed foods was 36.1 ± 2.3 and 46.9 ± 12.0 at 12 months and 3 years, respectively. **Conclusion:** Training program for health professionals decreased energy intake from ultra-processed foods and improved dietary practices during childhood.

Keywords: Intervention studies. Children. Food consumption. Ultra-processed foods.

INTRODUCTION

The consumption of industrially processed foods by children has been investigated ¹⁻⁴ due to the changes in dietary patterns that have occurred over the last decades ⁵. In order to better analyze and understand dietary patterns, criteria have recently been established to classify foods according to their degree of industrial processing ^{6,7}. These studies have shown a dramatic expansion of the market for ultra-processed foods in developing countries and a resulting significant increase in the consumption of these foods in the last decade ⁸. A substantial body of literature demonstrates that this new dietary pattern among children is a predictive factor for low diet quality ⁹⁻¹¹ and negative health consequences. Studies have shown a relationship between ultra-processed food consumption and changes in the lipid profile at school age ¹² as well as metabolic syndrome in adolescence ¹³.

Because the first years of life are characterized by the formation of eating habits -which can continue throughout one's lifetime ¹⁴⁻¹⁸ - evidence suggests that intervention programs that target healthy dietary behaviors early in life (such as improving diet quality) are important and necessary to promoting healthy food choices throughout life ^{19,20}.

Previous studies have confirmed a positive impact from the implementation of the “Ten Steps to Healthy Feeding of Children Under Two” on both exclusive breastfeeding and complimentary feeding practices ^{21,22}. In light of these findings, the present study aimed to evaluate the impact of training health workers about the complementary feeding guidelines on the follow-up results for ultra-processed food intake in a group of children at the ages of 12 months and 3 years. Secondly, we also aimed to assess the contribution of these foods to dietary, nutrient and energy intake during childhood.

METHODS

This study is a cluster-randomized field trial conducted in the city of Porto Alegre, Brazil, in 2008. The randomization units were public health centers that provide primary medical services predominantly to low-income residents and the outcomes were assessed in mothers and children who were attended at these centers. Of 56 public health centers, 31 met the trial eligibility criteria. Exclusion criteria were ≤ 100 infant patient visits in 2006, staff-sharing among clinics, and participation in a concurrent community-based dietary program. Of the 31 eligible municipal health centers, 16 were initially selected via a witnessed drawing of labeled slips from an opaque container performed by the principal investigator, in which two health centers were chosen from each of the city's eight administrative districts. Following a stratified randomization process, the health centers were block-randomized by district, with one health center per district allocated to the intervention group and another to the control group. To increase statistical power, four additional health centers from the original 31, regardless of district, were randomly drawn. Health center size differed, and thus, to maintain a balanced number of births by group, these additional four health centers were block-randomized at a 1:3 ratio. This yielded nine intervention and 11 control group health centers. These 20 health centers were consented to participate in the study without disclosing their allocation status. Ethics approval was granted by the Federal University of Health Sciences of Porto Alegre (UFCSA, Brazil) and informed consent was obtained at study entry.

From April to December 2008, all women in the third trimester of pregnancy at the participating health centers were invited to sign up for outcome tracking by field workers, none of whom were involved in the health center recruitment process nor the training session and were blinded to the allocation status. The births occurred between May 2008 and February 2009. Of the 736 women, 715 (97%) consented to participate. Women who tested HIV-positive were excluded because of concerns about transmitting HIV through breastfeeding.

The sample size was calculated beforehand to estimate the intervention's impact on exclusive breastfeeding duration. A sample of 300 mother-infant pairs in each group was estimated, considering a 40% exclusive breastfeeding frequency until to four months of age in the intervention group²³ and a 25% frequency in the control group (90% power and α of 0.5) and a design effect of 1.5. Subsequently, 720 mother-infant pairs were recruited (accounting for a 20% loss rate).

Intervention

The principal investigator (an experienced nutritionist) delivered a standardized, one-hour training session to the health professionals (physicians, nurses, nutritionists and administrative staff) outlining the “Ten Steps for Healthy Feeding from Birth to Two Years of Age” program ²⁴ as well as strategies for incorporating the guidelines in the maternal consultations. This program is an initiative of the Ministry of Health that aims to support health professionals in promoting healthy eating habits for children under two years of age, prioritizing exclusive breastfeeding in the six first months of life and complementary feeding with sufficient quantity and quality to provide for the children's proper growth and development.

The health professionals in the intervention group received the program's technical handbook, which was developed by the Ministry of Health, as well as a pocket guide and educational materials to be given to the mothers of children under six months of age. In addition, the intervention health centers were given two posters to display: a) one providing information on the process for introducing complementary food, including the number of meals and composition of salty baby food; and b) one presenting colorful and easily visible pictures of foods that should not be offered to children under two years of age (including stuffed cookies, coffee, jelly, candy, soft drinks and *petit Suisse* cheese) and the message: “Remember that your child has his/her whole life to try these foods”.

In brief, the “Ten Steps” recommendations are: (1) exclusive breastfeeding until six months of age; (2) continued breastfeeding until two years of age, with the gradual introduction of complementary foods; (3) complementary feeding (grains, meat and fruits) starting at six months of age three times daily while continuing to breastfeed; (4) meal times at regular intervals, adjusted to a child’s internal hunger cues; (5) new foods should gradually get thicker until the child is able to eat a family meal, but foods should never be liquefied; (6) provision of a variety of healthy foods every day; (7) daily intake of different fruits and vegetables; (8) avoidance of sugar, sweets, soft drinks, salty snacks and processed and fried foods; (9) implementation of good hygiene practices when preparing and handling food; and (10) appropriate, responsible feeding when a child is ill.

The intervention was designed to mimic a low-cost program for large-scale implementation. The training was given once and the number of times mothers were provided dietary counseling was not monitored. The control group health centers continued their usual practices and their health care workers provided complementary feeding guidance as they saw fit.

Data collection

Trained field workers, masked to allocation status, contacted participants at baseline and approximately 6, 12, and 36 months after birth. Socio-demographic information was collected via a structured baseline questionnaire. Birth date, gender, birth weight/height and frequency of consultations at the health centers were obtained from the children’s vaccination records.

Data were authenticated by randomly calling 5% of the households and repeating several questions in the survey. Fieldworkers, undergraduate and postgraduate students in Nutrition, received theoretical and practical training on data collection, with an average duration of eight hours.

Dietary data

The children's dietary intakes were assessed at two points in time—at 12 months (between April 2009 and March 2010) and at 3 years of age (between August 2011 and May 2012) through two multiple-pass 24-hour dietary recalls for each child on two non-consecutive days. Undergraduate and graduate students who were not involved in the intervention program and were blinded to group allocation performed the dietary recalls during home visits. The mothers or other caregivers provided information about all of the foods their children consumed during the previous 24 hours. To quantify food portion size, pictures were used to illustrate standard household measurements, such as teaspoons, tablespoons and cups. A nutritional support program with a database of Brazilians foods (Dietwin® Professional, 2008 version, Porto Alegre, Brazil) was used to quantify the children's dietary, energy, macro- and micronutrient intake. Breastfeeding status at the time of the interview was recorded (24h recall) and 49.3% (n=256) of the children were still being breastfed at 12 months of age. However, the results presented here do not include energy and nutrient intake from breast milk.

Ultra-processed foods consumption was assessed using the NOVA classification system^{6,7}. The NOVA system gives primary importance to the nature, extent and purpose of food processing and is based on four groups: unprocessed and minimally processed foods (Group 1); processed culinary ingredients (Group 2); processed foods (Group 3) and ultra-processed foods (Group 4). For the purposes of this study, only the ultra-processed foods were analyzed. According to this classification, ultra-processed foods are industrial formulations manufactured from substances derived from foods or synthesized from other organic sources. They are typically composed of little or no whole food and are developed to create pre-prepared or ready-to-eat meals that are highly durable, convenient and palatable (e.g. bread, chips, cookies, candy, chocolate, soft drinks, breakfast cereal and processed meats). Their production processes generally use techniques such as hydrogenation, hydrolysis, extruding, molding,

reshaping and/or preprocessing by frying or baking and may also add artificial preservatives and colors as well as synthetic vitamins and minerals. Examples of ultra-processed foods include: ice-cream, soft drinks, potato chips, cookies, and sausages.

Usual dietary intake of nutrients and ultra-processed foods was estimated using the Multiple Source Method (MSM) ²⁵. The MSM calculates the dietary consumption of individuals through logistical regression and distributes the individual data (adjusted for the population). This method was used to correct dietary data for intra- and inter-personal variability for each of the ten ultra-processed food groups (bread, savoury/biscuits, sweets, soft drinks, processed meats, baby cereal, powdered chocolate, sugary milk beverages, mayonnaise, sauces/dressings and instant noodles/dehydrated soup). A probability value of 0.5 (50%) was used to assign the status of habitual consumer, assuming that there was a percentage (50%) of habitual consumers among the children who did not consume an ultra-processed food group in at least one of the dietary surveys. For energy, macro- and micronutrients, all participants were considered to be consumers. Intake estimates were calculated for those who were chosen in this manner. The presence of extreme values (outliers) was investigated using graphic analyses of ultra-processed food energy intake (Box-Plot graphs). No cases were excluded due to extreme over- or under-reported energy intake values.

Statistical analyses

Analyses were performed by intention to treat. The effect of the intervention on the absolute energy content from ultra-processed foods was evaluated by using the Generalized Estimation Equation and adjusting for cluster, monthly per capita income, maternal age and schooling. Data were expressed using mean differences (MD) and a 95% confidence interval (95% CI).

The ultra-processed foods' percent energy values adjusted in relation to total daily energy intake were used in the analyses of the secondary outcomes in regard to the contribution of these foods to dietary intake, as has been used in other studies ^{12,26,27}. To test for the differences in energy and nutrient intakes between the tertiles of ultra-processed food consumption, we used covariance analysis (ANCOVA) and Bonferroni correction in post-hoc, while adjusting for monthly per capita income, maternal age and schooling as covariates at both ages. Furthermore, breastfeeding status (yes or no) was used for adjustments at the age of 12 months due to the high prevalence of infants who were being breastfed at that age.

Baseline characteristics were compared between groups using the Student's t test for continuous variables and the chi-square test for categorical variables. All statistical analyses were performed using the SPSS 21.0 statistical program (SPSS Inc., Chicago, IL USA) and statistical significance was set at $p < 0.05$.

RESULTS

Of the 715 pregnant women recruited initially, 545 and 475 of their children were assessed at 12 month and at 3 years of age, respectively. Losses were principally due to withdrawal from the study or inability to locate and did not differ significantly by allocation status (**Figure 1**). No difference was found between children who were lost to follow-up and those who were assessed at 3 years of age in terms of birth weight (3274.0 ± 491.4 g vs. 3291.3 ± 511.6 g, $P = .71$), maternal education level (8.5 ± 2.6 years vs. 8.4 ± 2.6 years, $P = .73$), and monthly income per capita (R\$ 323.1 ± 307.8 vs. R\$ 318.9 ± 261.1 , $P = .85$). For the purpose of this study, children with genetic diseases and incomplete dietary data were excluded from the analyses. Therefore, dietary outcomes were available for 520 children (277 intervention vs. 243 control) at 12 month and 446 (233 intervention vs. 213 control) at 3 years, which represents

76.9% and 64.7%, respectively, of the initial sample. Dietary assessments occurred from April 2009 to March 2010 (12 months) and from August 2011 to May 2012 (3 years).

The intervention and control groups did not differ in any key socioeconomic or demographic characteristic at 12 months of age (**Table 1**). Overall, the mothers' ages varied from 12 to 44 years (25.6 ± 6.8) and 20.8% were adolescents when they gave birth. Family income was low for most families - 67.8% had a monthly income less than three times the national minimum wage (approximately US\$ 565.00 /month), and 29.8% of the mothers had eight years of schooling or less.

The intervention strategy had a positive impact on reducing absolute energy intake from ultra-processed foods (MD -50.3 kcal; 95% CI -96.0 to -4.6) due to a decrease in the consumption of savoury and biscuits (MD -23.5 kcal; 95% CI -42.2 to -4.8), compared with children in the control group at 3 years of age (**Table 2**). Consequently, the improvement in feeding practices significantly reduced total daily energy intake (MD -77.6 kcal 95% CI, -147.1 to -8.1), even in the multivariate analyses. On the other hand, no intervention impact was observed on dietary intake at 12 months of age.

No difference in percentage energy intake was observed between the intervention and control groups. Thus, we combined the data from the two groups in the analysis of the second objective. The results showed that the percentage of energy provided by consuming ultra-processed foods was 36.1 ± 2.3 (355.1 ± 169.5 kcal) and 46.9 ± 12.0 (704.1 ± 235.0 kcal) at 12 months and 3 years of age, respectively. Among the younger children, the largest contribution to total energy intake came from savoury and biscuits (8.4 ± 6.6), followed by baby cereal (6.9 ± 9.1), sweets (4.5 ± 4.7) and bread (4.4 ± 4.2). At 3 years of age, the most-consumed food products were savoury and biscuits (9.8 ± 6.7), soft drinks (8.0 ± 5.0), sweets (7.9 ± 5.1) and bread (6.8 ± 3.4) (**Figure 2**).

Participants were further classified based on their tertile of ultra-processed food consumption to evaluate its effect on energy, micro- and macronutrient intakes (Table 3). Protein, fiber and cholesterol intakes were significantly lower in the highest tertile of ultra-processed food consumption compared with those in the lowest tertile ($P = .05$) at both of the assessed ages. Significant differences were found between first and third tertiles for total fat (1st 32.3g vs. 3rd 28.1g) and saturated fat (1st 11.2g vs. 3rd 9.8g) intakes at 12 months of age. The children in the highest tertile of ultra-processed food intake consumed an average of 290µg of vitamin A, 8.9 mg of iron and 2.8 mg of zinc more than those in the lowest tertile at 12 months of age ($p < 0.05$). On the other hand, the opposite tendency was observed for vitamin A (-120.8 µg), calcium (-115.4mg), folate (-26.3µg) and zinc (-0.9mg) intakes at 3 years of age.

DISCUSSION

Our findings revealed that a low-dose intervention with the implementation of dietary guidelines by health professionals was effective in reducing total energy intake from savoury and biscuits in children who were in the intervention group at the public health clinics at 3 years of age. To our knowledge, this is the first randomized trial to examine the effects of health care center-based counseling on breastfeeding and complementary feeding using a new classification system according to children's consumption of processed foods.

There are two potential explanations for the results we obtained in regard to dietary quality at 3 years of age. First, the most important explanation for our results relates to the concept that providing dietary counseling to mothers can positively alter their child feeding practices without necessitating major socio-economic changes. The results of this study and particularly the application of Step 8 (avoidance of sugar, sweets, soft drinks, salty snacks and processed and fried foods) may be related to the reduction in energy intake from savoury and biscuits through two mechanisms. First, this step was reinforced among the health care

professionals during the training process about the premature introduction of these foods to children, as was observed in previous studies ²⁸. Second, the educational poster used in the intervention with the message to not introduce these foods was displayed in pediatric waiting rooms at the health clinics, where detailed analyses (not published) found that 77.3% of the mothers in the intervention group mentioned seeing these posters, which suggests that they may have had an effect on the mothers' behavior and contributed to the intervention group's results.

Second, promoting healthy dietary practices at the beginning of life can provide a basis for eating habits in childhood. The impacts found at 3 years of age follow from the results achieved during the first year of life. A previous study with this same sample of children demonstrated a positive impact on breast-feeding practices in the intervention group. In addition, the prevalence of children who had already consumed non-recommended foods (such as chocolate, soft drinks, petit suisse cheese and coffee) at 6 months of age was lower in the intervention group ²¹. These results reinforce the finding that dietary habits in childhood are strongly influenced by what mothers and other caregivers offer their children. Thus, early and continuous exposure to different foods can increase their acceptance ^{29,30}, although genetic factors determine preferences for flavors ³⁰, which underscores this period's importance to forming healthy eating practices.

Our dietary intake results show that the practice of reducing the consumption of savoury and biscuits was effective in reducing total energy intake from ultra-processed foods and thus daily energy intake, which is the main objective for preventing childhood obesity ³¹. Thus, an average excess consumption of 77 kcal per day implies more than 25.000 kcal per child per year in the control group. Decreasing excess energy intake could yield major public health benefits, as studies indicate such risk behavior is associated with overweight and related diseases ³²⁻³⁴.

The widespread use of baby cereal, which is widely advertised as being healthy for breastfeeding infants, may explain the lack of intervention effect on ultra-processed food consumption at 12 months of age. This kind of food was not included on the list of non-recommended foods in the training on child feeding given to the health professionals or in the educational materials prepared for the mothers participating in the study. This result can serve as a basis for future guidelines and dietary guides, which should emphasize that these products are not recommended for infant feeding due to their high energy density and sugar content.

This study makes an original contribution by showing that more than one-third of the energy consumed by children at 12 months and nearly one-half at 3 years of age came from ultra-processed foods. These results are much higher than the mean of 21.5% found in the Brazilian population as a whole ²⁶, which may be explained by the low socio-economic status of the study participants, who tend to choose low-cost foods of low nutritional value ^{35,36} and are consequently vulnerable to greater consumption of ultra-processed foods.

Furthermore, the children's consumption of these foods increased by an average of 130% at 3 years of age compared with their consumption at 12 months of age. This finding allows us to demonstrate the premature and prevalent participation of ultra-processed food in children's dietary intakes in the first years of life. From this perspective, a change can be observed in food group consumption trends, with a marked increase in soft drinks and sweets and a decrease in baby cereal. A study conducted with low-income children aged 7-8 showed that ultra-processed food consumption contributed an average of 47.2% of the children's daily energy intake ¹², corroborating the results found at 3 years of age and stressing that the consumption of these foods in the first years of life tends to continue throughout childhood.

There is evidence ultra-processed food consumption contributes significantly to vitamin and mineral intakes ^{37,38}, especially among children. Ultra-processed food consumption contributes to children's iron intake at 12 month of age, with values twice as high for this

nutrient in the highest tertile compared to the lowest. On the other hand, children in the lowest tertile of ultra-processed food consumption ate more fat and cholesterol, which was an unexpected result. However, this may be explained by the fact the mothers are often advised to offer meat and viscera to children as a good source of iron and zinc as soon as they start offering complementary food. In our study, total daily energy intake was not different between the consumption tertiles, as has been found in other studies ^{26,27}. However, this is not surprising due to the percentage of energy provided by ultra-processed foods even in the first tertile, which reflects a daily energy intake above the recommendation of 821 kcal at 12 months of age and 1165 kcal at 3 years of age ³⁹.

This study has some limitations. First, it is possible that the limited time given to each health center served as a limitation on the level of impact observed. However, the proposal was made according to actual conditions at the health centers as well as their activities, demands and routines. Secondly, a number of participants were lost to follow-up from birth to 2-3 years of age. These losses were mainly due to families moving to an unknown address and are similar to those of other long-term trials conducted in low-income settings. However, selection bias is unlikely to be a major problem, considering the similarity in baseline characteristics between the participants who were lost and those who were not lost. Third, the study included a sample of children of low socioeconomic status and this could limit the ability to generalize the results to other strata. Fourth, the average of the two dietary recalls may not represent the entire distribution of usual intake due to the intra-individual variance component. Therefore, the dietary intake data has been corrected for inter- and intra-individual variability using the MSM method. In addition, the 24-hour recall is the most appropriate method for collecting food processing information through food consumption surveys ⁴⁰. Despite these limitations, our study has strengths that warrant discussion: The randomized design was robust and many confounders were taken into account; The statistical analyses considered the cluster effect (GEE

model) to minimize the type I error and controlled for several confounding variables; In addition, the new food classification system was used, in which each food item was assessed according to its degree of industrial processing.

CONCLUSIONS

Considering this scenario, it is suggested that, in order to change those practices that are harmful to children's health, intervention strategies should not be limited to primary health care but also should include actions that involve different sectors of society. In Brazil, the new edition of the Dietary Guidelines for the Brazilian Population for adults ⁴¹ is an innovative proposal that deals with the development of public policies based on foods instead of only nutrients. A subsequent follow-up of this cohort will be relevant in evaluating whether the beneficial effects of the intervention persist at school age and assessing the impact of ultra-processed food consumption on health outcomes.

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Tables:

Table 1 – Baseline characteristics of children and family according to randomly assigned group

Characteristics	Intervention	Control
Boys, n (%)	151 (53.7)	129 (51.2)
Birth weight, mean (SD), (g)	3322.1 ± 504.6	3250.2 ± 515.2
Birth length, mean (SD), (cm)	49.1 ± 2.3	48.9 ± 2.6
Skin color (white), n (%)	184 (65.9)	154 (61.4)
Only child, n (%)	121 (43.1)	124 (49.2)
Maternal age at child's birth, mean (SD), (years)	26.1 ± 6.7	25.0 ± 6.8
Maternal schooling, mean (SD), (years)	8.6 ± 2.6	8.5 ± 2.7
Mother's unemployment, n (%)	182 (64.8)	179 (71.0)
Paternal schooling, mean (SD), (years)	8.7 ± 2.6	8.5 ± 2.8
Marital status (married/ living with partner), n (%)	224 (79.7)	186 (73.8)
Health consultations at first year of life ≥7, n (%)	180 (72.3)	168 (76.7)
Pre-gestational BMI mean (SD)	24.5 ± 4.8	24.2 ± 4.5
Monthly family income (R\$), mean (SD)	1145.0 ± 823.3	1045.0 ± 661.6

SD: standard deviation; g: grams; cm: centimeters; BMI: body mass index;

Table 2 – Intervention effect on absolute amounts of energy intake from ultra-processed foods and daily energy intake among children at 12 months and at 3 years.

	12 mo				3 y			
	Intervention	Control	MD (95% CI) ^b	P	Intervention	Control	MD (95% CI) ^b	P
	(n=277)	(n=243)			(n=233)	(n=213)		
	Mean (kcal) ^a	Mean (kcal) ^a			Mean (kcal) ^a	Mean (kcal) ^a		
Daily energy intake	1017.3	1029.0	- 11.7 (- 86.1 to 62.7)	.75	1461.6	1539.2	- 77.6 (- 147.1 to - 8.1)	.02
Ultra-processed foods	352.6	360.5	- 7.9 (- 36.8 to 21.0)	.59	679.0	729.4	- 50.3 (- 96.0 to - 4.6)	.03
Savoury and biscuits ^c	77.3	83.1	- 5.8 (- 21.6 to 9.9)	.46	138.7	162.2	- 23.5 (- 42.2 to - 4.8)	.01
Baby cereal	84.9	83.9	- 0.9 (- 24.8 to 22.8)	.93	29.9	22.9	7.0 (- 1.3 to 15.5)	.10
Soft drink ^d	28.1	28.2	- 0.1 (- 5.3 to 5.1)	.97	116.1	121.6	- 5.5 (- 18.1 to 7.0)	.39
Sweets ^e	42.6	38.9	3.6 (- 0.4 to 7.7)	.08	116.1	119.3	- 3.1 (- 17.4 to 11.0)	.66
Bread	39.6	41.6	- 2.0 (- 8.6 to 4.5)	.54	97.6	103.7	- 6.0 (- 18.3 to 6.2)	.33
Powdered chocolate	13.2	14.0	- 0.8 (- 8.3 to 6.7)	.83	59.8	69.3	- 9.4 (- 22.6 to 3.7)	.16
Sugary milk beverages	38.4	38.9	- 0.5 (- 8.0 to 7.0)	.89	57.5	63.2	- 5.7 (- 19.7 to 8.1)	.41
Processed meat	10.2	9.9	0.2 (- 1.9 to 2.4)	.80	45.0	46.6	- 1.5 (- 10.5 to 7.4)	.73
Mayonnaise, dressing and sauces	1.0	1.1	0.0 (- 0.9 to 0.9)	.96	3.5	3.8	- 0.2 (- 1.2 to 0.7)	.62
Instant noodle and dehydrated soup	17.8	19.4	- 1.5 (- 6.3 to 3.3)	.53	14.3	16.4	- 2.1 (- 5.6 to 1.4)	.24

MD, mean difference; CI, confidence interval; ^a Expressed as absolute energy; ^b Generalized estimating equations of absolute calories content from ultra-processed foods after adjustment for cluster, monthly income *per capita*, maternal age and schooling; ^c Crackers, chips, salty snacks, cookies; ^d Soda, sweetened juice; ^e Candy, chocolate and ice cream.

Table 3. Energy and nutrient intake according to tertiles of ultra-processed food (%) among children at 12 mo ($n=520$) and at 3 y ($n=446$).

Indicator	Tertiles of ultra-processed food consumption (% of total energy)		
	1 st (≤ 31.0)	2 nd (≥ 31.2 and ≤ 40.2)	3 rd (≥ 40.3)
<i>At 12 mo</i> ¹			
Daily energy (Kcal)	1041.4	1035.4	993.2
Carbohydrate (g)	145.6	150.7	149.2
Protein (g)	42.3	40.5	35.9 ^{a,b}
Total Fat (g)	32.3 ^c	30.4	28.1
Saturated Fat (g)	11.2	11.1	9.8 ^{a,b}
Cholesterol (mg)	109.1	109.2	89.1 ^{a,b}
Fiber (g)	10.2	9.8	8.0 ^{a,b}
Vitamin A (μg)	690.9 ^{b,c}	980.3	984.3
Folate (μg)	176.8	195.5	182.1
Calcium (mg)	793.1	778.4	711.8
Iron (mg)	6.0	12.2	14.9 ^{a, b}
Zinc (mg)	6.1 ^{b,c}	8.5	8.9
<i>At 3 y</i> ²			
	1 st (≤ 42.1)	2 nd (≥ 42.2 and ≤ 52.2)	3 rd (≥ 52.3)
Daily energy (Kcal)	1477.6	1512.6	1506.3
Carbohydrate (g)	204.1	211.2	208.3
Protein (g)	58.5	56.4	53.5 ^a
Total Fat (g)	47.7	49.4	50.1
Saturated Fat (g)	16.5	17.0	16.7
Cholesterol (mg)	174.8	168.6	154.1 ^a
Fiber (g)	14.3	13.4	12.2 ^a
Vitamin A (μg)	547.4	528.5	426.6 ^{a, b}
Folate (μg)	206.5	195.0	180.2 ^a
Calcium (mg)	955.2	935.7	839.8 ^a
Iron (mg)	9.3	9.6	9.4
Zinc (mg)	8.2	7.9	7.1 ^{a, b}

¹ Bonferroni-adjusted ANCOVA analysis for monthly income *per capita*, maternal age, schooling and breast milk.

² Bonferroni-adjusted ANCOVA analysis for monthly income *per capita*, maternal age and schooling

^a Significant difference than 1st tertile ($p < .05$);

^b Significant difference than 2nd tertile ($p < .05$);

^c Significant difference than 3rd tertile ($p < .05$);

Figure 1. Flow diagram of the health center clusters and individual participants from enrollment to 3 years of age

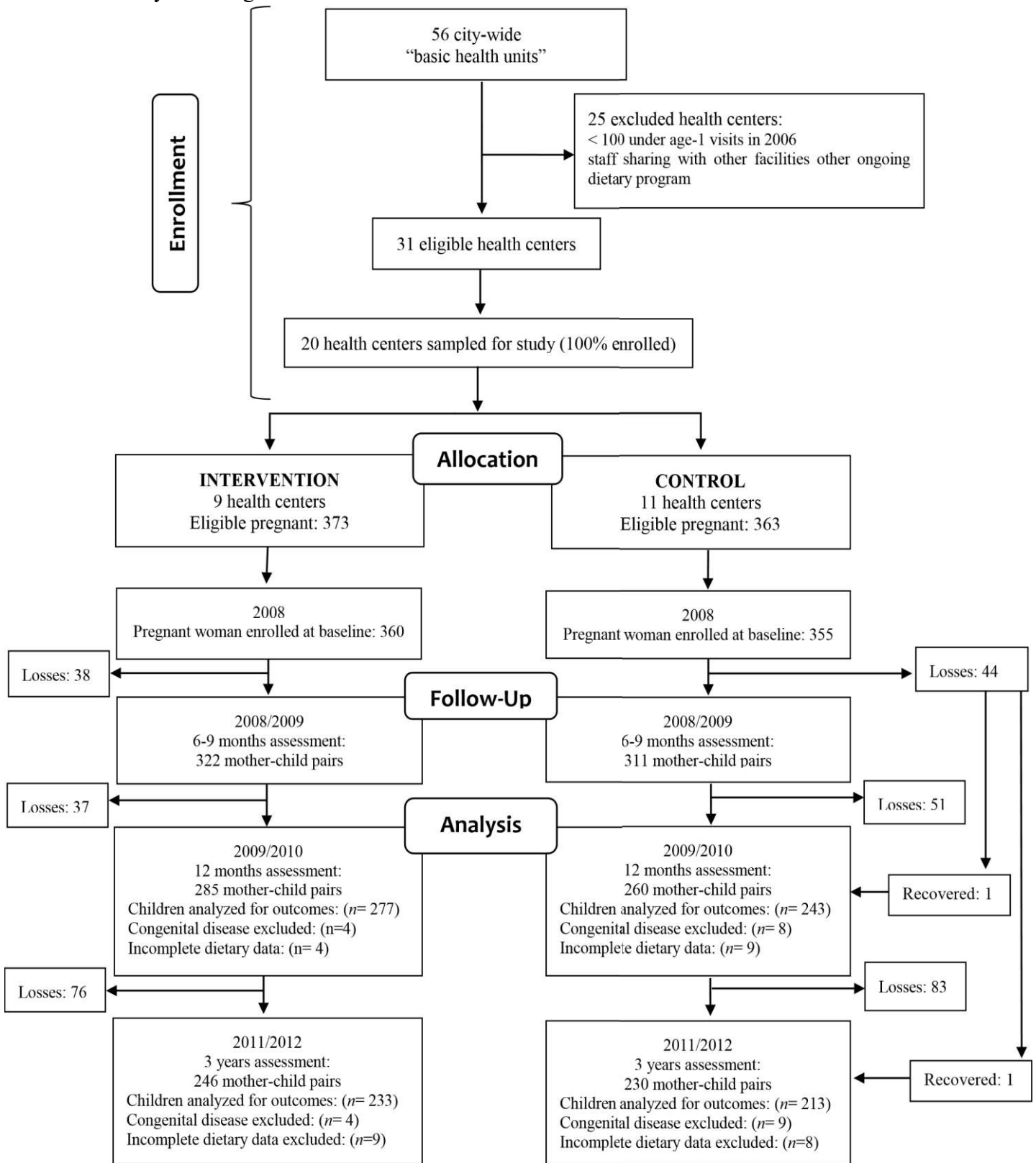
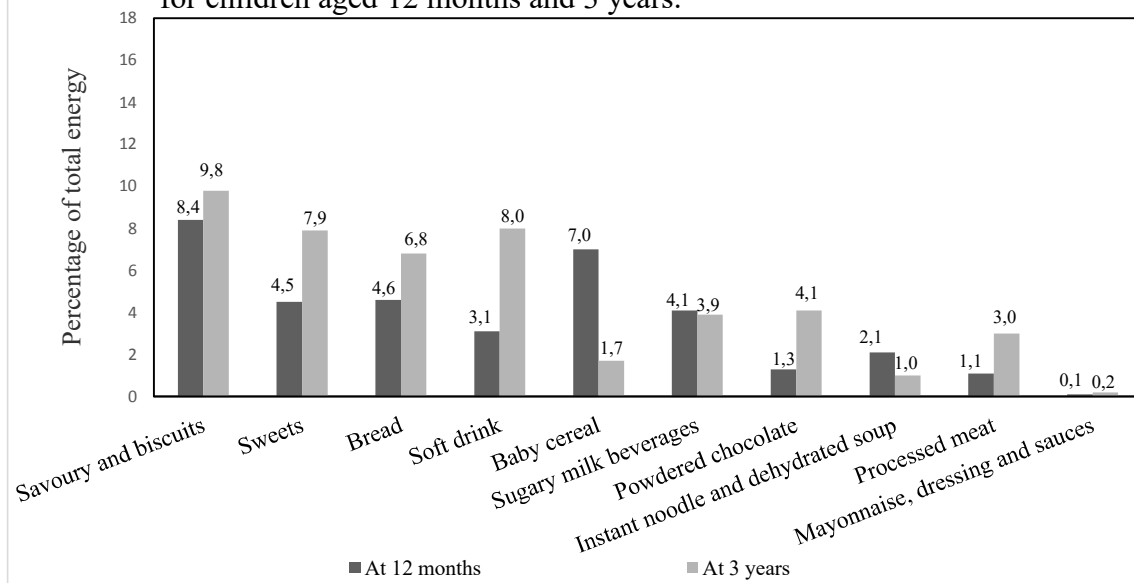


Figure 2. Contribution (%) of ultra-processed foods to dietary intake for children aged 12 months and 3 years.



5 CONCLUSÃO

Os resultados da presente dissertação permitem concluir que o programa de intervenção com a atualização dos profissionais de saúde apresentou impacto positivo nas práticas alimentares após três anos de seguimento, diminuindo o consumo energético de biscoitos e salgadinhos e como consequência, a redução de alimentos ultraprocessados. O presente estudo também elucidou a compreensão do padrão alimentar ao longo das idades avaliadas por meio da classificação de alimentos de acordo com o grau de processamento, evidenciando a participação prevalente de alimentos ultraprocessados desde os primeiros anos de vida.

Os resultados deste estudo sustentam à recomendação principal do Guia Alimentar para a População Brasileira do Ministério da Saúde “fazer de alimentos in natura ou minimamente processados a base da alimentação e evitar o consumo de alimentos ultraprocessados”. Por fim, sugere-se que as estratégias de intervenção, a fim de alterar estas práticas nocivas para a saúde das crianças, não estejam limitadas à assistência na atenção primária, mas que incluam ações que envolvam diferentes setores da sociedade

6 ANEXOS

6. 1 Tabela de classificação de alimentos de acordo com o grau de processamento

Tabela 1. Classificação de alimentos de acordo com o grau de processamento ^a	
Classificação	Exemplos
Grupo 1 – Alimentos in natura ou minimamente processados. Alimentos in natura incluem todos os alimentos na sua forma animal ou vegetal de origem. Os alimentos minimamente processados são aqueles que foram alterados, mas sem que nenhum ingrediente fosse adicionado.	Frutas, verduras, legumes e cereais frescos ou congelados; leguminosas, raízes e tubérculos frescos, congelados ou secos; castanhas, nozes, amendoim sem sal; carnes, aves e peixes frescos ou congelados; leite e iogurte natural; ovos; café, chás.
Grupo 2 - Ingredientes culinários processados São constituintes dos alimentos in natura. Os métodos de processamentos incluem: prensagem, moagem, refinação, pulverização, entre outros.	Óleos vegetais, gorduras animais, açúcar, sal, farinhas, amido.
Grupo 3 - Alimentos processados Formados pela adição de substâncias (sal, açúcar ou óleo) a alimentos in natura.	Verduras ou legumes preservados em água salgada; frutas em calda; peixe conservado em óleo; e queijos.
Grupo 4 - Alimentos ultraprocessados Formados a partir de ingredientes industriais, com pouco ou nenhum alimento in natura. São alimentos prontos ou quase prontos para consumo que imitam a aparência e qualidade sensorial dos alimentos. São duráveis, convenientes, hiperpalatáveis e rentáveis.	Cereais matinais, misturas para bolo, barras de cereais; sopas e massas instantâneas; pães e produtos panificados, como bolos, doces e sobremesas; salgadinhos “de pacote”, biscoitos, sorvetes, chocolates; achocolatados e bebidas lácteas, refresco em pó, refrigerantes e outras bebidas adoçadas; carnes processadas como embutidos, nuggets; preparações prontas ou pré-prontas para consumo; margarinas.
^a Adaptado de Pan American Health Organization. Ultra-processed food and drink products in Latin America: Trends, impact on obesity, policy implications. Washington, DC : PAHO, 2015.	

6.2 Aprovações do Comitê de Ética



MINISTÉRIO DA EDUCAÇÃO
FUNDAÇÃO FACULDADE FEDERAL DE CIÊNCIAS MÉDICAS DE PORTO ALEGRE
COMITÊ DE ÉTICA EM PESQUISA
APROVADO PELA CARTA Nº 880/2004-CONEP/CNS/MS
RUA SARMENTO LEITE, 245 – FONE: (51) 3224.8822
CEP 90050-170 – PORTO ALEGRE – RS - cep@fffcempa.edu.br

Of. 532/07-CEP

Porto Alegre, 06 de novembro de 2007.

Ilma. Sra.

Profa. Márcia Regina Vitolo

Nesta Faculdade

Senhora Professora

Informamos que seu projeto intitulado "Implementação dos Dez Passos da Alimentação Saudável para Crianças Menores de Dois Anos nas Unidades Básicas de Saúde.", Processo nº 226/07, foi aprovado por este Comitê, na reunião de 14 de junho 2007, conforme parecer consubstanciado nº 471-07.

Atenciosamente,

**COMISSÃO CIENTÍFICA E COMISSÃO DE PESQUISA E ÉTICA EM SAÚDE****COMITÊ DE ÉTICA EM PESQUISA - CEP
UFCSPA**

O Comitê de Ética em Pesquisa da UFCSPA, registrado na Comissão Nacional de Ética em Pesquisa (CONEP) sob o nº 075/05 em 23/07/04, analisou o Projeto:

Projeto: 11-748**Versão do Projeto:****Versão do TCLE:****Pesquisadores:**

MÁRCIA REGINA VITOLO

CARLOS ALBERTO FELDENS

Título: IMPACTO DE INTERVENÇÃO NA ATENÇÃO PRIMÁRIA À
SAÚDE NAS CONDIÇÕES NUTRICIONAIS DE CRIANÇAS EM IDADE
PRÉ-ESCOLAR: SEGUNDA FASE DE AVALIAÇÃO DE ENSAIO
DE CAMPO RANDOMIZADO POR CONGLOMERADOS

Esse projeto foi aprovado em seus aspectos éticos e metodológicos conforme as Resoluções 196/09 e demais Resoluções complementares. Toda e qualquer alteração do projeto, assim como eventos adversos graves, deverão ser comunicados a este CEP. Os TCLE, quando necessários, somente poderão ser utilizados após prévia e explícita aprovação (carimbo) de sua redação por este CEP".

Porto Alegre, 06 de maio de 2011.



José Gerslão Vernet Taborda
Coordenador do CEPI/UFCSA

6.3 Normas da revista: *Pediatrics*

Publication Ethics

Authorship. An “author” is someone who has made substantive intellectual contributions to a published study. Each author is required to meet ALL FOUR of the following criteria:

Substantial contribution(s) to conception and design, acquisition of data, or analysis and interpretation of data; and

Drafting the article or revising it critically for important intellectual content; and

Final approval of the version to be published, and

Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

NOTE: Acquisition of funding, collection of data, or general supervision of the research group alone does not constitute a sufficient basis for authorship.

All persons listed as authors must meet these criteria, and all persons who meet these criteria must be listed as authors. Although *Pediatrics* does not specifically limit the number of authors (except for Case Reports), articles submitted with an unusual number of authors invite scrutiny by editors and reviewers for clear justification for the presence of each person on the authorship list. *Pediatrics* does not permit more than one author to claim any particular position in the author list (e.g., two first authors, or two senior authors).

Decide authorship issues, including the order, before submission. Except in instances where the editorial office has determined that a person does not qualify for authorship, *Pediatrics* does not allow changes to the author order, including adding or removing authors from a paper or any subsequent revisions.

Conflict of Interest and Disclosure. After a paper is accepted by *Pediatrics* for publication, all authors must submit conflict of interest and disclosure forms. *Pediatrics* adheres to the policy and uses the standardized disclosure form of the International Committee of Medical Journal Editors (ICMJE). The collection of the forms is automated within the online system.

IRB Approval. All studies that involve human subjects must be approved or deemed exempt by an official institutional review board; this should be noted in the Methods section of the manuscript.

Industry Sponsorship. *Pediatrics* generally does not accept reports of studies in which all authors are employed by a commercial entity with a financial interest in the results of the study.

Registration of Clinical Trials. All clinical trials must be registered in a World Health organization-approved Clinical Trial registry prior to enrollment of the first subject. The

registry name and registration number should be included on the title page. Reports of unregistered trials will be returned to authors without review. Publication of the results of a trial that was initiated prior to the ICMJE requirement for trial registration will be considered by the editors on a case-by-case basis.

Journal Style

All aspects of the manuscript, including the formatting of tables, illustrations, and references and grammar, punctuation, usage, and scientific writing style, should be prepared according to the most current AMA Manual of Style (<http://www.amamanualofstyle.com>).

Author Listing. All authors' names should be listed in their entirety, and should include institutional/professional affiliations and degrees held.

Authoring Groups. If you choose to include an organization, committee, team, or any other group as part of your author list, you must include the names of the individuals as part of the Acknowledgments section of your manuscript. This section should appear after the main text prior to your References section. The terms “for” or “on behalf of” must also be used when referencing the authoring group in the by-line.

Titles. Pediatrics generally follows the guidelines of the AMA Manual of Style for titles. Titles should be concise and informative, containing the key topics of the work. Declarative sentences are discouraged as they tend to overemphasize a conclusion, as are questions, which are more appropriate for editorials and commentaries. Subtitles, if used, should expand on the title; however, the title should be able to stand on its own. It is appropriate to include the study design (“Randomized Controlled Trial”; “Prospective Cohort Study”, etc.) in subtitles. The location of a study should be included only when the results are unique to that location and not generalizable. Abbreviations and acronyms should be avoided. The full title will appear on the article, the inside table of contents, and in MEDLINE. Full titles are limited to 97 characters, including spaces. Short titles must be provided as well and are limited to 55 characters, including spaces. Short titles may appear on the cover of the journal as space permits in any given issue.

Abbreviations. List and define abbreviations on the Title Page. Unusual abbreviations should be avoided. All terms to be abbreviated in the text should also be spelled out at first mention, followed by the abbreviation in parentheses. The abbreviation may appear in the text thereafter. Abbreviations may be used in the abstract if they occur 3 or more times in the abstract. Abbreviations should be avoided in tables and figures; if used they should be redefined in footnotes.

Units of Measure. Like many US-based journals, Pediatrics uses a combination of Système International (SI)^{2,3} and conventional units. Please see the AMA Manual of Style for details.

Proprietary Products. Authors should use nonproprietary names of drugs or devices unless mention of a trade name is pertinent to the discussion. If a proprietary product is cited, the name and location of the manufacturer must also be included.

References. Authors are responsible for the accuracy of references. Citations should be numbered in the order in which they appear in the text. Reference style should follow that of the AMA Manual of Style, current edition. Abbreviated journal names should reflect the style of Index Medicus. Visit: <http://www.nlm.nih.gov/tsd/serials/lji.html>

References

Iverson C, Christiansen S, Flanagin A, et al. AMA Manual of Style. 10th ed. New York, NY: Oxford University Press; 2007.

Lundberg GD. SI unit implementation: the next step. JAMA. 1988;260:73-76.

Système International conversion factors for frequently used laboratory components. JAMA. 1991;266:45-47.

Clinical Trials

A study is considered a clinical trial if it prospectively assigns human subjects (whether randomized or not) to intervention or concurrent comparison or control groups to study the cause-and-effect relationship between a medical intervention and a health outcome. Medical interventions include drugs, surgical procedures, devices, behavioral treatments, process-of-care changes, and the like.

If authors report the results of a clinical trial, they must affirm that the study has been registered at www.clinicaltrials.gov or another WHO-approved national or international registry prior to the enrollment of the first subject. Information on requirements and appropriate registries is available at www.icmje.org. The trial registration number must be listed on the title page, and at the end of the abstract.

Authors are required to complete both pages of a CONSORT Form (flowchart and checklist) and submit these with their manuscript. In our submission system, these files appear under “Instructions and Forms”.

Reuse of Data Sets

If a manuscript uses the same or similar data contained in previously published articles, the authors must state this in the initial letter of submission and provide citations to the related or possibly duplicative materials.

Formatting Requirements

All submissions must adhere to the following format:

Times New Roman font, size 12, black

Title Page, Contributors' Statement Page, Abstract, Acknowledgments, and References should be single-spaced

Only the Main Body Text should be double-spaced

Main Submission Document as Microsoft Word or RTF file (no PDFs)

Do not include page headers, footers, or line numbers in new submissions.

Do not include footnotes within the manuscript body. Footnotes are allowed only in tables/figures.

Refer to the “Article Types” section for specific guidelines on preparing a manuscript in each category. Note in particular the requirements regarding abstracts for different categories of article.

Title Page

The “title page” should appear first in your manuscript document, and depending on the individual needs of a paper may encompass more than one page.

Title pages for all submissions must include the following items (as shown in the [sample Title Page](#)):

Title (97 characters [including spaces] or fewer)

Author listing. Full names for all authors, including degrees, and institutional/professional affiliations.

Corresponding Author. Contact information for the Corresponding Author (including: name, address, telephone, and e-mail).

Short title (55 characters [including spaces] or fewer). Please note: the short title may be used on the cover of the print edition.

Financial Disclosure Statement for all authors. Disclose any financial relationships that could be broadly relevant to the work. If none, say “Financial Disclosure: The authors have no financial relationships relevant to this article to disclose.”

Funding source. Research or project support, including internal funding, should be listed here; if the project was done with no specific support, please note that here. Technical and other

assistance should be identified in Acknowledgments. If your funding body has open access requirements, please contact the Editorial Office prior to submission. Pediatrics has a 12 month embargo on articles (followed by a 4 year open access period) and does not allow articles to be opened for Creative Commons or similar licenses.

Conflict of Interest Statement for all authors. If none, say “Potential Conflicts of Interest: The authors have no conflicts of interest relevant to this article to disclose.”

If applicable, Clinical Trial registry name and registration number. We adhere to ICMJE guidelines, which require that all trials must be registered with ClinicalTrials.gov or any other WHO Primary registry.

Abbreviations. List and define abbreviations used in the text. If none, say "Abbreviations: none".

For Regular Article submissions, include the “What’s Known on This Subject; What This Study Adds” (see below under article type for description). This is not needed for any other article type.

If a title page does not include all of the above items, the submission may be returned to the authors for completion.

Contributors' Statement Page

All submissions must contain a Contributors’ Statement Page, directly following the Title Page. Manuscripts lacking this page will be returned to the authors for correction.

All persons designated as authors should qualify for authorship ([see "Publication Ethics" above](#)), and all those who qualify should be listed. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content. The Contributors' Statement Page should list the authors in order, and for each, specify the contribution(s) made by that individual. Follow the required format shown in this example when creating your Contributors’ Statement Page:

Contributors' Statement:

Dr Smith conceptualized and designed the study, drafted the initial manuscript, and approved the final manuscript as submitted.

Drs Jones, Lee, and Weber carried out the initial analyses, reviewed and revised the manuscript, and approved the final manuscript as submitted.

Ms Green designed the data collection instruments, and coordinated and supervised data collection at two of the four sites, critically reviewed the manuscript, and approved the final manuscript as submitted.

Note: Contributors who do not meet the criteria for authorship (such as persons who helped recruit patients for the study, or professional editors) should be listed in an Acknowledgments section placed after the manuscript's conclusion and before the References section. Because readers may infer their endorsement of the data and conclusions, these persons must give written permission to be acknowledged. These permissions do not need to be submitted with the manuscript unless requested by the editors.

Word Count

To determine article length, count the body of the manuscript (from the start of the Introduction to the end of the Conclusion). The title page, contributors' statement page, abstract, acknowledgments, references, figures, tables, and multimedia are not included.

Figures, Tables, and Supplementary Material

Figures

Authors should number figures in the order in which they appear in the text. Figures include graphs, charts, photographs, and illustrations. Each figure should be accompanied by a legend that does not exceed 50 words. Abbreviations previously expanded in the text are acceptable. If a figure is reproduced from another source, authors are required to obtain permission from the copyright holder, and proof of permission must be uploaded at the time of submission.

Figure arrays should be clearly labeled, preassembled, and submitted to scale. Figure parts of an array (A, B, C, etc.) should be clearly marked in capital letters in the upper left-hand corner of each figure part.

Technical requirements for figures: The following file types are acceptable: TIFF, PDF, EPS, and PNG. Color files must be in CMYK (cyan, magenta, yellow, black) mode.

Style for figures: Readers should be able to understand figures without referring to the text. Avoid pie charts, 3-dimensional graphs, and excess ink in general. Make sure that the axes on graphs are labeled, including units of measurement, and that the font is large enough to read. Generally delete legends or other material from the graph if it makes the picture smaller. Color graphs should be interpretable if photocopied in black and white.

Please note: A charge will be billed for each color figure appearing in the print edition. You will have the opportunity to decline the use of color and have your figure converted to black and white during your review of page proofs.

Pediatrics cannot accept Excel or PowerPoint files for any part of your submission.

Tables

Tables should be numbered in the order in which they are cited in the text and include appropriate headers. Tables should not reiterate information presented in the Results section, but rather should provide clear and concise data that further illustrate the main point. Tabular data should directly relate to the hypothesis. Table formatting should follow the current edition of the AMA Manual of Style.

Style for tables: Tables should be self-explanatory. Avoid abbreviations; define any abbreviations in footnotes to the table. Avoid excess digits and excess ink in general. Where possible, rows should be in a meaningful order (e.g., descending order of frequency). Provide units of measurement for all numbers. In general, only one type of data should be in each column of the table.

Presentation of Numbers and Statistics

Results in the abstract and the paper generally should include estimates of effect size and 95% confidence intervals, not just P- values or statements that a difference was statistically significant.

Statistical methods for obtaining all P-values should be provided

Units of independent variables must be provided in tables and results sections if regression coefficients are provided

Authors should avoid expressing effect sizes in the form of highly derived statistics.

Equations should be typed exactly as they are to appear in the final manuscript. The following table, adapted from the guidelines for authors for the Annals of Internal Medicine by editors of Medical Decision Making, shows how to present certain percentages and some statistical measures:

Reporting:	Details:
Percentages	Report percentages to one decimal place (i.e., xx.x%) when sample size is greater than or equal to 200.
	To avoid the appearance of a level of precision that is not present with small samples, do not use decimal places (i.e., xx%, not xx.x%) when sample size is less than 200.
Error Measures	Report confidence intervals, rather than standard errors, when possible. Use "mean (error measures)" rather than "mean $\pm$ error measure" notation.

Except when one-sided tests are required by study design, such as in noninferiority trials, all reported P values should be two-sided. In general, P values larger than 0.01 should be reported to two decimal places, those between 0.01 and 0.001 to three decimal places; P values smaller than 0.001 should be reported as P [is less than sign]0.001. Notable exceptions to this policy include P values arising in the application of stopping rules to the analysis of clinical trials and genetic-screening studies.

P values

Use the word trend when describing a test for trend or dose-response.

Avoid the term "trend" when referring to p-values near but not below 0.05. In such instances, simply report a difference and the confidence interval of the

"Trend" difference (if appropriate) with or without the p-value.

Supplemental Information

Authors may wish to include additional information as part of their article for inclusion in the online edition of Pediatrics. References to any online supplemental information must appear in the main article. Such supplemental information can include but are not limited to additional tables, figures, videos, audio files, slide shows, data sets (including qualitative data), and online appendices. If your study is based on a survey, consider submitting your survey instrument or the key questions as a data supplement. Authors are responsible for clearly labeling supplemental information and are accountable for its accuracy. Supplemental information will be peer reviewed, but not professionally copyedited.

Videos

Pediatrics encourages the submission of videos to accompany articles where relevant. Links can be placed in the article for use when it is accessed electronically. All videos must adhere to the same general permission rules that apply to figures (i.e.: parental consent when a patient is identifiable).

All videos should be submitted at the desired reproduction size and length. To avoid excessive delays in downloading the files, videos should be no more than 6MB in size, and run between 30 and 60 seconds in length. In addition, cropping frames and image sizes can significantly reduce file sizes. Files submitted can be looped to play more than once, provided file size does not become excessive. Video format must be either .mov or .mp4.

Authors will be notified if problems exist with videos as submitted, and will be asked to modify them if needed. No editing will be done to the videos at the editorial office—all changes are the responsibility of the author.

Video files should be named clearly to correspond with the figure they represent (i.e., figure1.mov, figure2.mp4, etc.). Be sure all video files have filenames that are no more than 8 characters long and include the suffix “.mov” or “.mp4.” A caption for each video should be provided (preferably in a similarly named Word file submitted with the videos), stating clearly the content of the video presentation and its relevance to the materials submitted.

IMPORTANT: One to four traditional still images from the video must be provided. These still images may be published in the print edition of the article and will act as thumbnail images in the electronic edition that will link to the full video file. Please indicate clearly in your text whether a figure has a video associated with it, and be sure to indicate the name of the corresponding video file. A brief figure legend should also be provided.

Regular Article

Abstract length: 250 words or fewer (structured, as noted below)

Article length: 3,000 words or fewer

Regular Articles are original research contributions that aim to inform clinical practice or the understanding of a disease process. Regular Articles include but are not limited to clinical trials, interventional studies, cohort studies, case-control studies, epidemiologic assessments, and surveys. Components of a Regular Article include:

What’s Known on This Subject; What This Study Adds

These brief summaries are each limited to 40 words. Please use precise and accurate language in paragraph form (i.e., not bullet points). For manuscripts accepted as Regular Articles, these summaries will become a highly visible part of your published paper, with prominence on the first page. Moreover, these summaries will be highlighted and presented in other areas of the journal, namely *Pediatrics Digest*. It is therefore paramount that you use language of the same caliber as the rest of your paper.

Structured Abstract (four paragraphs with headings in boldface type; single-spaced)

The abstract should consist of: Background (or Objectives, or Background and Objectives), Methods, Results, and Conclusions. The Objective should clearly state the hypothesis; Methods, inclusion criteria and study design; Results, the outcome of the study; and Conclusions, the outcome in relation to the hypothesis and possible directions of future study.

Body of Article

For the body of your article, follow this general outline:

Introduction

A 1- to 2-paragraph introduction outlining the wider context that generated the study and the hypothesis.

Patients and Methods

This section should detail inclusion criteria and study design to ensure reproducibility of the research. All studies that involve human subjects must be approved or deemed exempt by an official institutional review board; this should be noted here.

Results

This section should give specific answers to the aims or questions stated in the introduction. The order of presentation of results should parallel the order of the methods section.

Discussion

The section should highlight antecedent literature on the topic and how the current study changes the understanding of a disease process or clinical situation, and should include a section on the limitations of the present study.

Conclusion

A brief concluding paragraph presenting the implications of the study results and possible new research directions on the subject.

General submission instructions (including cover letter, title page requirements, contributors' statement page, journal style guidance, and conflict of interest statements) apply to Regular Articles.