

## Effect of an educational intervention on pregnancy: a cluster-randomized clinical trial

Efeito de uma intervenção educativa na gravidez: ensaio clínico randomizado em cluster  
Efecto de una intervención educativa en el embarazo: ensayo clínico randomizado en clúster

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### Keywords

Feeding behavior; Health education; Pregnancy; Health knowledge, attitudes, practice; Clinical trial

### Descritores

Comportamento alimentar; Educação em saúde; Gravidez; Conhecimento, atitudes e práticas em saúde; Ensaio clínico

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### Abstract

**Objective:** To evaluate the effects of an educational intervention on the knowledge, attitudes, and practices of pregnant women regarding the use of regional foods.

**Methods:** Single-blind cluster-randomized clinical trial with two parallel groups. The study was carried out from January to September 2013. Cluster random allocation was defined by the simple random allocation process. A draw was performed with the clusters, followed by a random allocation to choose the health units. Cluster A was part of the intervention group and cluster B was included in the control group. The intervention group had 91 pregnant women, who were introduced to an educational booklet, and the control group had 94 pregnant women, who attended regular prenatal appointments.

**Results:** The effect of the educational booklet on the intervention group presented statistical significance ( $p < 0.001$ ) on the seventh and thirtieth days after the intervention when compared to the results of the control group, and there was an increase in the prevalence of adequacy of knowledge, attitudes, and practices regarding the use of regional foods.

**Conclusion:** The educational booklet was an effective intervention to improve the knowledge, attitudes, and practices of pregnant women regarding the use of regional foods.

### Resumo

**Objetivo:** Avaliar os efeitos de uma intervenção educativa no conhecimento, na atitude e na prática das gestantes sobre o uso dos alimentos regionais.

**Métodos:** Ensaio clínico controlado randomizado em cluster, unicoego, com dois grupos paralelos. O estudo foi realizado no período de janeiro a setembro de 2013. Alocação randômica dos conglomerados foi definida pelo processo de alocação aleatória simples. Na ocasião foi utilizado um sorteio entre os conglomerados/cluster e depois foi realizada uma alocação aleatória para escolha das USs. Desta maneira, o conglomerado A fez parte do GI e o conglomerado B do GC. Participaram 91 gestantes no GI (cartilha educativa) e 94 gestantes no GC (consulta pré-natal de risco habitual).

**Resultados:** O efeito da cartilha educativa no grupo de intervenção apresentou significância estatística ( $p < 0,001$ ) no sétimo e trigésimo dia pós-intervenção, quando comparados com o grupo controle e aumento da prevalência com adequabilidade do conhecimento, atitude e prática quanto ao uso dos alimentos regionais.

**Conclusão:** A cartilha educativa foi uma intervenção eficaz para melhorar o conhecimento, atitude e prática das gestantes quanto ao uso dos alimentos regionais.

### Resumen

**Objetivo:** Evaluar los efectos de intervención educativa en conocimiento, actitud y práctica de las embarazadas sobre uso de los alimentos regionales.

**Método:** Ensayo clínico controlado randomizado en clúster, simple ciego, con dos grupos paralelos. Estudio realizado de enero a setiembre de 2013. La asignación randomizada de los conglomerados fue definida por proceso de asignación aleatoria simple. Se aplicó un sorteo entre los conglomerados/clústeres, realizándose luego una asignación aleatoria para elección de las USs. De esta manera, el conglomerado A formó parte del GI y el conglomerado B del GC. Participaron 91 embarazadas en el GI (libreta educativa), y 94 en el GC (consulta prenatal de riesgo normal).

**Resultados:** El efecto de la libreta educativa en el grupo intervención presentó significatividad estadística ( $p < 0,001$ ) en el séptimo y trigésimo día postintervención al compararlo con el grupo control, hubo aumento de la prevalencia con idoneidad del conocimiento, actitud y práctica respecto del uso de alimentos regionales.

**Conclusión:** La libreta educativa demostró ser eficaz para mejorar el conocimiento, actitud y práctica de las embarazadas respecto al uso de los alimentos regionales.

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## Introduction

The guarantee of positive outcomes in the health of pregnant women and fetuses is a priority subject in the World Health Organization. Scientific evidence has been accumulated to ground food and nutrition policies and nutritional interventions to achieve a healthy diet during pregnancy. Nutritional guidance can provide an adequate weight gain from healthy dietary habits, thus preventing pregnant women from putting on excessive weight and consequently reducing the chances of maternal health problems and undesirable fetal outcomes.<sup>(1,2)</sup>

To promote a healthy diet in the Brazilian population, the Brazilian Ministry of Health developed a manual entitled Brazilian Regional Food. The objective of the publication is to disseminate the consumption of fruits, vegetables, tubers, and legumes and confirms the commitment to promote healthy dietary practices and prevent nutritional complications related to food and nutrition insecurity.<sup>(3)</sup>

International agencies recognize pregnancy as a phase with increased nutritional needs to support the maternal development and fetal growth<sup>(4)</sup> and recommend an increment in the ingestion of carbohydrates, fibers, proteins, and micronutrients, including vitamin A, complex B vitamins, folate, and iron.<sup>(5)</sup> However, an investigation carried out in Canada showed an inadequacy in the consumption of micronutrients from food sources with high prevalence for ingestion of iron (97%), vitamin D (96%), and folate (70%).<sup>(6)</sup> Authors pointed that in Brazil 90% of pregnant women present a high energy consumption, with an excessive ingestion of calories, and inadequacy of nutrients.<sup>(7)</sup> Consequently, it is recommended that primary healthcare professionals develop food and nutrition education strategies to promote a healthy diet based on the valorization of food culture.<sup>(2)</sup>

Food and nutrition education is a fundamental tool to promote health and aims to encourage the autonomy of individuals to value and respect cultural specificities and empower these people regarding their health care.<sup>(8)</sup> Authors consider that nurses, by developing health education actions, have the

objective to improve the health and life conditions of the population. Therefore, educational programs must be implemented constantly and effectively to achieve their goal of improving the health of the society.<sup>(9)</sup>

Studies show that educational strategies have been proved efficient for adapting knowledge, attitudes, and practices (KAP) of some populations.<sup>(10,11)</sup>

This scenario sets the need to know the behavior of the assisted population from the KAP diagnosis and offer healthcare professionals the basis to develop health education strategies.

Considering the relevance of this subject to promote healthy eating habits during pregnancy, the objective of the present study was to evaluate the effects of an educational intervention on the KAP of pregnant women regarding healthy dietary habits with the use of regional foods.

## Methods

The present investigation was a controlled single-blind cluster-randomized clinical trial, with two parallel groups, carried out with pregnant women submitted to the intervention of an educational booklet (intervention group or IG) and pregnant women who received nutritional guidance in regular prenatal appointments (control group or CG) according to the recommendation of the primary healthcare booklet of the Brazilian Ministry of Health.<sup>(2)</sup>

The study was blind when both pregnant women and nurses from health units did not have knowledge of the use of the educational booklet. Data collection occurred from January to September 2013, which allowed to reach the number of participants suggested by the sample size calculation. The confidence interval was 95% and the statistical power was 80%.

The political-administrative regions of Recife, state of Pernambuco, Brazil, were divided into clusters, with their respective health units. Cluster random allocation was defined by the simple random allocation process. A draw was performed with the clusters, followed by a random allocation to choose

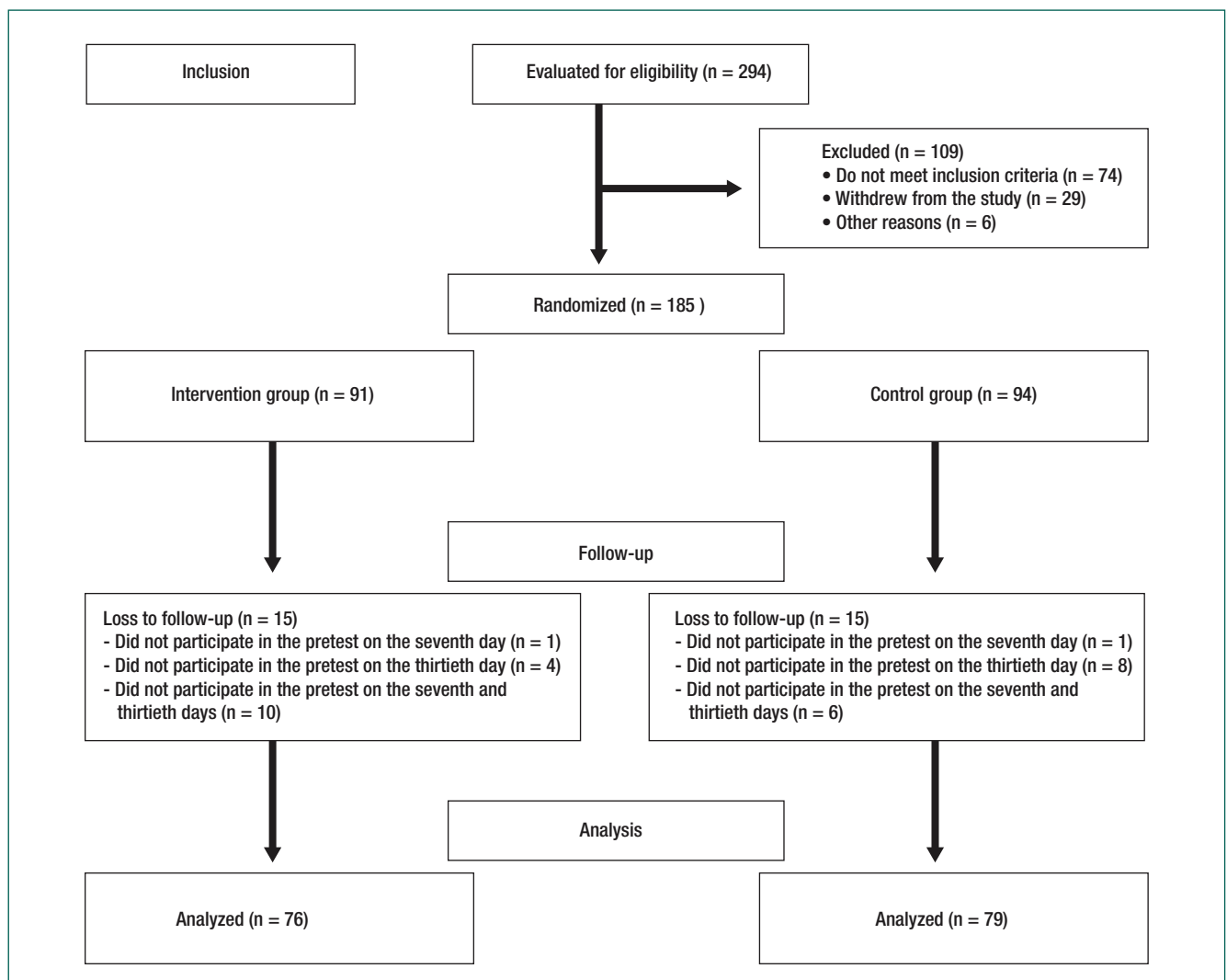
the health units. As a result, cluster A was part of the IG and cluster B was included in the CG.

It is noteworthy that the random assorting of the health units to make up the IG and the CG in the same conglomerate followed the Consolidated Standards of Reporting Trials 2010 guideline, this procedure implies a high contamination risk of pregnant women from health units from each branch, that is, pregnant women from the CG could be affected by the intervention and hence the experiment would have been contaminated.

The pregnant women included in the study where those 18 years old or older who received prenatal care in health units and had a landline or a cell phone. Exclusion criteria were pregnant women with a gestational age higher than 36 weeks,

or those who had difficulties to understand the questions of the questionnaire or the intervention, or had gestational or preexisting diabetes or gestational or chronic hypertension. Withdrawal or loss criteria were miscarriage or interrupted pregnancy or the impossibility to contact the patient by phone after ten attempts at different times and consecutive days. Initially, 294 pregnant women were eligible. The final analysis determined that the IG had 91 participants and the CG had 94. Figure 1 represents the sampling strategy to obtain the study sample.

Research assistants were trained before data collection to standardize collection procedures, addressed concepts, and execution of the pilot test, referring to tools and educational interven-



**Figure 1.** Sampling strategy to determine the study sample

tion. Collection took place in health units according to prenatal appointment days, analysis of inclusions, and active search of participants by phone contact.

A booklet entitled Healthy Diet during Pregnancy with Regional Foods (*Alimentação Saudável na Gravidez com os Alimentos Regionais*) was designed and validated to be applied in the intervention of the present study. The dimensions were 148 mm x 210 mm, and the publication had eight pages and was printed on both sides of the paper. The content is related to the concept of healthy nutrition, foods which are allowed and which should be avoided during pregnancy, the benefits of healthy dietary habits for mothers and babies, food hygiene, and recipes with regional foods.<sup>(12)</sup>

After a prenatal appointment, the women from the IG were invited to participate in the individual intervention in a private room, in a single session, with an average duration of 20 minutes. During this meeting, the booklet was introduced, read, and the patients kept a copy to take home.

The Brazilian Food Insecurity Scale (*Escala Brasileira de Insegurança Alimentar*) was used to assess the homogeneity of the sample and baseline of the IG and the CG in the pretest, before the prenatal appointment. This scale was developed and validated by researchers of the State University of Campinas, the Brazilian Ministry of Health, the Pan American Health Organization, and the São Paulo Research Foundation.<sup>(13)</sup>

The KAP survey was designed and validated for the present study to evaluate the primary outcome: analysis of the adequate and inadequate levels of knowledge, attitudes, and practices regarding regional foods. The instrument was applied on the seventh and thirtieth days to pregnant women from both groups. Follow-up was carried out by phone.

The authors created some definitions to analyze the KAP. The knowledge was considered adequate when used to prepare varied meals and/or juices, pregnant women referred to have heard of regional foods, knew three or more types of regional foods, and mentioned at least two types of meals prepared

with regional foods. The attitude was considered adequate when pregnant women referred to be necessary to use regional foods in their meals and mentioned the importance of these items. The practice was considered adequate when pregnant women referred to have used regional foods in their meals and to use these items at least twice a day. For all the axes, inadequacy meant that pregnant women had negative answers to each situation mentioned in this paragraph.

Data were analyzed by the SPSS version 20 program. Pearson's chi-square test was used to compare qualitative variables between the intervention and control groups. When the expected frequencies were lower than 5, the Fisher's test was applied, or the Fisher-Freeman-Halton test, if the comparison involved variables with more than two categories. The odds ratio and its confidence interval were calculated to check the magnitude of the effect. In the comparison between quantitative measurements and intervention and control groups, the Mann-Whitney test was used. A level of significance of 5% was applied in all analyses.

The proposal was submitted to evaluation by the Research Ethics Committee of the Federal University of Pernambuco and approved under protocol no. 123,140/2012.

## Results

There was no significant statistical difference between baselines in both IG and CG according to social and economic variables. The highest percentages referred to pregnant women with brown skin (IG = 68.4% and CG = 72.2%) who did not work (IG = 68.4% and CG = 64.6%) and had a family income of up to two minimum wages (IG = 73.7% and CG = 79.8%). Most pregnant women declared to have a partner and had complete elementary school and higher education (IG = 85.5% and CG = 86.1%). The age median was 24 years for the IG (CI = 23.90 – 26.31) and 25 years for the CG (CI = 24.27 – 26.75). The median gestational ages were 23 weeks and 5 days

(CI = 19.95 – 23.57) and 20 weeks (CI = 18.04 – 21.74) for the IG and CG, respectively. It is important to stress that the social and economic equivalence observed in the clusters minimized the so-called cluster effect.

The equilibrium between baselines of pregnant women from the IG and CG revealed the leveling of subjects in each branch of the experiment, thus decreasing the risk of bias. The evaluation of KAP showed no statistical difference ( $p > 0.05$ ). In terms of percentage, the number of women who had an inadequate level in the pre-appointment was higher in both IG and CG in comparison with the adequate level. The values were, respectively: inadequate knowledge (93.4% and 93.4%), inadequate attitudes (69.7% and 57.0%), and inadequate practices (88.2% and 91.13%) (Table 1).

**Table 1.** Results of the baseline of knowledge, attitudes, and practices of pregnant women from the intervention and control groups regarding regional foods

KAP survey**		Intervention group (n = 76) n (%)	Control group (n = 79) n (%)	p-value*
Pre-appointment knowledge	Adequate	5 (6.6)	5 (6.3)	0.950
	Inadequate	71 (93.4)	74 (93.4)	
Pre-appointment attitudes	Adequate	23 (30.3)	34 (43.0)	0.099
	Inadequate	53 (69.7)	45 (57.0)	
Pre-appointment practices	Adequate	09 (11.8)	07 (8.86)	0.542
	Inadequate	67 (88.2)	72 (91.13)	

\*The p-value was analyzed with Pearson's chi-square test; \*\*Knowledge, attitudes, and practices

Regarding the effect of the intervention caused by the use of the educational booklet, the results indicate an adequate KAP level on the IG in the seventh and thirtieth days after the intervention in comparison with the level shown in the CG. The IG had  $p < 0.001$ , with increased chances of adequate knowledge on the seventh (OR = 68.01 and CI = 24.48 – 188.97) and thirtieth days (OR = 83.57 and CI = 26.18 – 266.72). The results for adequate attitudes were OR = 13.16 and CI = 4.8 – 36.08 on the seventh day, and OR = 36.07 and CI = 8.27 – 157.23] on the thirtieth day for the IG. Analysis of adequate practices data revealed an OR = 6.61 and a CI = 3.13 – 13.98 on the seventh day, and an OR = 7.24 and a CI = 3.57 – 14.81 on the thirtieth day for the IG (Table 2).

**Table 2.** Effect of educational intervention on pregnant women according to the evaluation of knowledge, attitudes, and practices regarding regional foods

KAP survey		Intervention group (n = 76) n (%)	Control group (n = 79) n (%)	*Statistics
Knowledge Seventh day	Adequate	69 (90.8)	10 (12.7)	$p < 0.001$ OR = 68.01 CI (24.48 – 188.97)
	Inadequate	7 (9.2)	69 (87.3)	
Knowledge Thirtieth day	Adequate	72 (94.7)	14 (17.7)	$p < 0.001$ OR = 83.57 CI (26.18 – 266.72)
	Inadequate	4 (5.3)	65 (82.3)	
Attitudes Seventh day	Adequate	71 (93.4)	41 (51.9)	$p < 0.001$ OR = 13.16 CI (4.80 – 36.08)
	Inadequate	5 (6.6)	38 (48.1)	
Attitudes Thirtieth day	Adequate	74 (97.4)	40 (50.6)	$p < 0.001$ OR = 36.07 CI (8.27 – 157.23)
	Inadequate	2 (2.6)	39 (49.4)	
Practices Seventh day	Adequate	43 (56.6)	13 (16.5)	$p < 0.001$ OR = 6.61 CI (3.13 – 13.98)
	Inadequate	33 (43.4)	66 (83.5)	
Practices Thirtieth day	Adequate	53 (69.7)	19 (24.1)	$p < 0.001$ OR = 7.28 CI (3.57 – 14.81)
	Inadequate	23 (30.3)	60 (75.9)	

\*The p-value was analyzed with Pearson's chi-square test and the statistical significance was  $p < 0.05$ . OR: odds ratio. CI: confidence interval (95%)

## Discussion

The social and economic data collected in the present study revealed that most pregnant women in the sample were brown, did not work, and had a family income of up to two minimum wages. These results are compatible with the characteristics of the population that lives in the place where the investigation was carried out and the information from the State Plan for Food and Nutrition Security of Pernambuco, which pointed that the Brazilian regions with the lowest income are North and Northeast, with an average household income similar to that indicated by the present study.<sup>(14)</sup> Some authors declared that family income is a factor that directly interferes with the quality of the diet of the examined pregnant women, and that the higher the family income, the higher the adherence to a healthy eating plan.<sup>(15)</sup>

In this scenario, the consumption of regional foods is important to pregnant women because, in addition to their bioavailability and low cost, they are nutritious and enrich diet with fibers,

minerals, vitamins, and carbohydrates. The Northeast region of Brazil has a variety of regional foods, including fruits such as acerola, banana, and coconut, vegetables such as squash, watercress, and bur gherkin, roots such as yam and manioc, legumes such as green beans, in addition to tubers and cereals.<sup>(3)</sup>

Regarding the evaluation of inadequacy of knowledge, attitudes, and practices, most pregnant women in the CG had inadequate information regarding the use of regional foods, which may reinforce the limited access to the orientations about the consumption of these items, which are part of the eating culture of a region or community. These results also reveal the importance to emphasize the “regional foods” terminology during the guidance on healthy dietary habits. This would help pregnant women to develop adequate opinions about the importance of these foods. The women in the IG recognized this terminology with an adequate knowledge on the seventh (90.8%) and thirtieth (94.7%) days after the introduction of the educational booklet.

Similar findings were described in an investigation on the influence of an educational strategy on the promotion of the use of regional foods with preschool children. Most (96.8%) students began to recognize this terminology after the intervention. The authors of this study believed that the results should not be interpreted as if the examined population did not know nor consumed regional foods, but as an indication that it was not familiar with the used terminology.<sup>(16)</sup>

The findings of the present investigation reveal adequacy of knowledge, attitudes, and practices of pregnant women from the IG regarding the use of regional foods on the seventh and thirtieth days, with statistical significance, in comparison with the results obtained for the CG. It is valid to stress that the educational booklet presents illustrations of regional foods chosen by the pregnant women through a poll. Therefore, the publication respects local preferences and suggests recipes including regional foods with options for daily meals (mashed manioc, squash soup, tapioca, couscous, cooked banana, beans with squash, banana vitamin, etc.)

Authors consider that respecting regional eating habits is related to the recovery of a healthy dietary routine and has an important meaning for valuing the culture of the region. In addition, regional foods are commonly associated with a healthy diet and healthy people, which contributes to justifying their relevance in the promotion of healthy eating habits.<sup>(17)</sup>

Regarding the practice related to the use of regional foods, the IG obtained percentages of 56.6% on the seventh day and 16.5% on the thirtieth day in comparison with the CG ( $p < 0.001$ ). This result corroborates what is observed in the reality of prenatal care, when healthcare professionals notice the difficulties pregnant women have to follow a dietary plan.

A healthy eating plan advocates the consumption of six portions per day of cereals, roots, and tubers, three portions per day of fruits and vegetables, one portion per day of beans and seeds, and one portion per day of sugars and sweets, whose daily ingestion is recommended for pregnant women.<sup>(2,3)</sup> These food groups encompass a significant number of regional foods and are sources of fibers, vitamins, and minerals.

Results of a Brazilian study revealed that only 10% of the population eat fruits and vegetables in accordance with the nutritional recommendations.<sup>(18)</sup> Another investigation compared the food consumption of pregnant and nonpregnant women and showed that there was no significant difference between these groups. The first group presented inadequate consumption of the nutrients iron, folate, and calcium, according to the daily intake recommendation of the Institute of Medicine.<sup>(19)</sup>

Authors stress the importance of health education to achieve a healthy diet during pregnancy, because in this phase most women are motivated to receive guidance on healthy eating habits and declare that changes in the diet have low cost and represent a lower risk to develop problems.<sup>(20)</sup>

The intervention in the present study was the booklet, applied as an educational material designed to impact on KAP. The findings pointed to an influence on the adequacy of the use of regional foods. A study emphasized that the use of booklets is a means to carry out actions oriented toward promot-

ing nutritional improvement in medical offices and an important part of the verbal communication between professionals and clients.<sup>(21)</sup> An investigation described a clinical trial with pregnant women using an educational activity based on the use of leaflets designed to improve dietary habits, increase the level of physical activity, and reduce obesity during pregnancy. The IG showed a significant increase in the consumption of vegetables in comparison with the CG.<sup>(22)</sup>

The pregnant women who participated in the present study attended regular prenatal appointments with primary healthcare nurses. To include nutritional changes more effectively, the educational booklet *Healthy Diet during Pregnancy with Regional Foods (Alimentação Saudável na Gravidez com os Alimentos Regionais)* was developed and validated.<sup>(12)</sup> Its effect was assessed by applying a KAP survey, and the results confirmed its applicability to increase knowledge, attitudes, and practices of the women in the sample. After the clinical validation performed in the present investigation, the booklet may be indicated as a health educational material, adding to prenatal appointments.

Prenatal monitoring is an important healthcare strategy and includes the promotion of health, screening, diagnosis, and prevention of diseases.<sup>(2)</sup> A study designed to compare the KAP of women who attended prenatal appointments with the KAP of women who did not identified a significant effect on the level of awareness of the quantity of foods, the proper ingestion of proteins, vegetables, fruits, milk, greens, and meat, prevention of anemia with the consumption of iron, and vitamin supplementation.<sup>(23)</sup>

Studies aim to assess KAP in several populations and on different subjects, and there is the consensus that the KAP method is relevant to obtain diagnoses of examined populations, with the objective to improve the development of interventions oriented toward promoting adequate levels of knowledge, attitudes, and practices.<sup>(10,24)</sup> Researchers seek to assess the effects of interventions on the change of knowledge, attitudes, and practices using the KAP method.<sup>(10,16,23,24)</sup> Results similar to those described in the present paper have been reported.

Printed educational materials have been used to improve the knowledge, satisfaction, adherence to treatments, and self-care of patients. Educational publications written by healthcare professionals are a tool to reinforce the orientations discussed verbally and may positively impact on the education of patients and be able to help them answer questions which may emerge when the interaction with professionals is not possible.<sup>(25)</sup>

Therefore, the authors emphasize the importance of nutritional guidance on primary health care during prenatal monitoring as a dynamic and participative process involving professionals, pregnant women, and their families. Nurses must work with these women to obtain behavior changes toward healthy and adequate eating habits during this phase. Nurses commonly have experience on strategies to promote health and are an important part of the primary healthcare team.<sup>(26)</sup>

The present study was carried out in a specific area of the metropolitan region of Recife, state of Pernambuco, Brazil. Consequently, the sample size may not be large enough to generalize the findings and be representative of Brazilian pregnant women.

## Conclusion

The intervention design, based on the educational booklet, made possible the access of pregnant women to guidance on healthy eating habits. It was observed that pregnant women from the IG presented more adequate knowledge, attitudes, and practices regarding the use of regional foods in comparison with the women from the CG, with an increase in the prevalence of the level of adequacy on the seventh and thirtieth days after the intervention. The educational booklet was an efficient intervention to improve knowledge, attitudes, and practices of pregnant women regarding the use of regional foods.

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## Contributions

Oliveira SC, Fernandes AFC, Vasconcelos EMR, Ximenes LB, Leal LP, Cavalcanti AMTS, and Lopes MVO declare to have contributed to the project conception, data analysis and interpretation, manuscript writing, relevant critical review of the intellectual content, and final approval of the version to be published.

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