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Effectiveness of mobile applications in pregnant women's adherence to prenatal consultations: randomized clinical trial

Eficácia de aplicativo móvel na adesão de gestantes às consultas de pré-natal: ensaio clínico randomizado

Eficacia de una aplicación de telefonía móvil para la adhesión de gestantes a las consultas prenatales: ensayo clínico aletaorizado

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ABSTRACT

Objective: to evaluate the effectiveness of a mobile application for cell phones in the adherence of pregnant women to prenatal consultations. **Method:** a randomized controlled clinical trial, simple-blind with two parallel groups, conducted from January to December 2018. Data collection was carried out through a structured interview at the end of the third trimester of pregnancy. For analysis, Chi-Square and Mann-Whitney tests were used. The sample consisted of 88 pregnant women from 2 Family Health Strategies in Northeast Brazil. Participants were randomized into two groups: intervention (IG), who used the application, and control (CG), who attended prenatal consultations. **Results:** pregnant women who used the application (IG) attended a greater number of consultations when compared to participants in the CG, identifying a statistical difference between the groups ($p<0.05$). **Conclusion:** the application showed to be an effective health technology to improve adherence to prenatal care. Brazilian Registry of Clinical Trials: RBR-74SNST.
Descriptors: Women's Health; Prenatal Care; Mobile Applications; Clinical Trial; Nursing.

RESUMO

Objetivo: avaliar a eficácia de um aplicativo móvel para celular na adesão de mulheres grávidas às consultas de pré-natal. Método: ensaio clínico controlado randomizado, simples-cego, com dois grupos paralelos, realizado de janeiro a dezembro de 2018. Os dados foram coletados por meio de entrevista estruturada ao final do terceiro trimestre de gestação. Para análise, utilizaram-se os testes de Qui-Quadrado e Mann-Whitney. A amostra consistiu em 88 gestantes de 2 Estratégias Saúde da Família, do Nordeste do Brasil. As participantes foram randomizadas em dois grupos: intervenção (GI), que fizeram uso do aplicativo; e controle (GC), que frequentaram as consultas de pré-natal. **Resultados:** as grávidas que fizeram uso do aplicativo (GI) compareceram a um maior número de consultas, quando comparadas às participantes do GC, identificando-se diferença estatística entre os grupos ($p<0,05$). **Conclusão:** o aplicativo apresentou-se como uma tecnologia em saúde eficaz para melhorar a adesão ao pré-natal. Registro Brasileiro de Ensaios Clínicos: RBR-74SNST
Descritores: Saúde da Mulher; Cuidado Pré-Natal; Aplicativos Móveis; Ensaio Clínico; Enfermagem.

RESUMEN

Objetivo: evaluar la eficacia de una aplicación de telefonía móvil para la adhesión de gestantes a las consultas prenatales. Método: se trata de un ensayo clínico controlado aleatorizado y a ciegas realizado con dos grupos paralelos entre enero y diciembre de 2018. Los datos se recogieron mediante entrevista estructurada al final del tercer trimestre de gestación. Para el análisis se utilizaron las pruebas de Chi-cuadrado y Mann-Whitney. La muestra estaba compuesta por 88 mujeres embarazadas de 2 Estrategias de Salud Familiar del Noreste de Brasil. Las participantes fueron asignadas aleatoriamente a dos grupos: intervención (IG), que hacía uso de la aplicación, y control (CG), que asistía a las consultas prenatales. **Resultados:** las gestantes que usaron la aplicación (GI) asistieron a un número mayor de consultas, comparadas a las participantes del GC, identificándose una diferencia estadística entre los grupos ($p<0,05$). **Conclusión:** la aplicación se mostró como una teconología sanitaria eficaz para mejorar la adhesión al prenatal. Registro Brasileño de Ensayos Clínicos: RBR-74SNST.
Descriptores: Salud de la Mujer; Atención Prenatal; Aplicaciones M**óviles**; Ensayo Clínico; Enfermería.

INTRODUCTION

The perinatal period remains among the priorities of global public policies, because despite its important advancement and the improvement in the organization of health systems, there is a perpetuation of high rates of maternal mortality from preventable causes[1-2]. In this sense, aiming to promote the quality of care during pregnancy, childbirth and the postnatal period and to reduce maternal morbidity and mortality, the World Health Organization (WHO) recommended increasing the number of prenatal consultations to accomplish at least eight consultations of the pregnant woman with the health team[3-5].

Prenatal consultations help in the management and identification of clinical conditions, as well as risky behavioral signs for the pregnant woman, through welcoming, qualified listening, clinical and laboratory exams, allowing the professional to intervene early in order to avoid outcomes unfavorable in childbirth and birth[6-7]. However, the effectiveness of prenatal care is closely related to the attendance of pregnant women to consultations, adherence to educational actions and, above all, to the training of professionals responsible for the care of pregnant women[8].

Studies indicate that the failure to perform prenatal care occurs mainly due to socioeconomic factors (low family income and education), maternal age (adolescence and older age), not living with a partner, use of alcohol or other drugs during pregnancy, multiparity, non-acceptance of pregnancy, access to consultations (place of residence far from the service and cost for commuting), quality of health care, lack of family support, adverse social context, negative experiences of care and conceptions of discredit about the prenatal[9-10]. It is worth noting that the low adherence to prenatal care implies obstetric complications and an increase in maternal and neonatal deaths, which are due to the lack of diagnoses and treatment of pregnancy complications[10-11].

Although Brazil has a public health system that provides universal prenatal care, the low adherence of pregnant women has been evidenced in several studies[3-4,12-13]. In 2018, in Brazil, 49,083 pregnant women did not have any prenatal consultations, with the lowest frequency in the North (12.090) and Northeast (17.730) regions of the country[14], which can result in damage to maternal and child health due to the absence the identification of conditions such as syphilis, urinary tract infection and changes in blood pressure, thus causing fetal growth restriction, a higher prevalence of premature births, a high rate of cesarean section, preeclampsia, abortions and higher rates of neonatal and maternal mortality[13].

Therefore, it is necessary to develop care strategies/technologies that promote the pregnant woman's adherence to prenatal care, aiming at the tracking and monitoring of risk factors that may be potentiated during the pregnancy cycle.

Thus, mobile health technology is promising in expanding care coverage, treatment adherence, enabling decision-making, health promotion, prevention and improvement in disease management. It is important that this new technology also includes specific groups such as pregnant women[8-13].

Thus, in the search for technological tools that promote greater and better adherence of pregnant women to prenatal care, more dynamically and efficiently, we sought to test a mobile application that favors and enables the ideal reach of eight or more meetings with the health professional, aimed at greater autonomy in the self-care of pregnant women and care for the newborn and therefore better outcomes in delivery and birth.

OBJECTIVE

To evaluate the effectiveness of a mobile application for cell phones in the adherence of pregnant women to prenatal consultations.

METHODS

Ethical aspects

The study was approved by the Research Ethics Committee with human beings. The research was registered at the Brazilian Clinical Trials Registry Platform under the Universal Trial identification[15] number: RBR-74SNST, U1111-1219-7069.

Study design, location and period

This is a randomized controlled clinical trial (RCT), simple-blind, with two groups: intervention group (IG) - pregnant women who received the intervention from the mobile application, besides prenatal consultations[15] and monthly meetings; and the control group (CG) - pregnant women who received guidance in group meetings and prenatal consultations of usual risk, according to the recommendations of the primary care notebook of the Ministry of Health (MS), and did not have access to the application.

In the preparation and execution of the study, the recommendations of the Consolidated Standardsof Reporting Trials (CONSORT) were used, which translate into the use of a checklist and a flow chart, essential to assess the relevance and reliability of the results.

The intervention was carried out from January to December 2018, in two *Unidades de Saúde da Família* – USFs (Family Health Units), each with four teams, located in two municipalities in Northeast Brazil[15].

Study participants

To outline the sample size, a survey was initially carried out of the number of women registered in the pregnancy monitoring system (SisPreNatal) of the chosen USFs. Thus, we used the sample calculation for finite populations with a 95% confidence level, a sampling error of 5% and a population of 393, which estimated a sample of 98 pregnant women.

The inclusion criteria were pregnant women aged 18 years or older, registered in the two USFs of choice for the study; have cognitive ability to participate in the research; know how to read; having a supported smartphone to receive the application; and have access to the internet. The exclusion groups were pregnant women who did not start prenatal care in the first trimester, hypertensive and diabetic. The exclusion of pregnant women with these comorbidities was justified by the fact that they are followed up in high-risk prenatal care, and the screen research is applied to those at usual risk, attended in the two selected USFs.

Data collection

In the data collection, the structured interview technique was used. To this end, a roadmap composed of two parts was developed. The first consists of questions about social data, daily life and health history, namely: characterization of the pregnant woman (age; marital or civil status; work; profession; family income; parity; planned pregnancy; living with the father of the fetus; existence of comorbidity; alcoholism; smoking; opinion on the importance of prenatal care; difficulties in making appointments for prenatal care; scheduled appointments; if you use any other type of application; how do you evaluate the use of applications). The second, addressed questions about the evaluation of the use of the application "Healthy pregnancy" by pregnant women in the third trimester of pregnancy (opinion regarding the use of the application; ease of access; satisfaction with the use of the application; if the application brought any guidance that contributed positively in the period of pregnancy; if the application facilitated adherence to prenatal care).

The data collection was entirely performed by the researcher responsible for the study. The assessment of the application was carried out at the end of participants' third trimester of pregnancy (38th week).

Randomization and allocation

Respecting the inclusion criteria described above, the participants were randomized into two groups, respecting the following control variables, namely: age, number of pregnancies, living with the partner, planned or unplanned pregnancy, if works or not and education. The randomization process must constitute very similar groups, with comparable characteristics, with the exception of the interventions to be evaluated[16]. Therefore, the variables were considered because it is understood that the disparate characteristics existing among the selected pregnant women could tend the results and therefore, randomization allowed the formulation of intervention and control groups in a more homogeneous way. For this purpose, a drawing was carried out using a thick envelope containing cards with the identification IG or CG, thus defining the allocation. The drawing of pregnant women took place at the USFs through meetings previously scheduled by community health agents in agreement with the researcher. Three recruitment meetings were held.

Blinding

The RCT was considered blind, because pregnant women did not know about the research hypothesis. The statistical team was also blinded, since, before the data were made available, the groups, CG and GI, were coded in G1 and G2 to prevent statisticians from distinguishing the group that received the intervention[17].

Interventions

After the drawing, the pregnant women of the IG and CG were sent to two private rooms to start data collection. Before collection, pregnant women signed the informed consent form and answered the interview script. At the time, the pregnant women selected for the IG after randomization were invited to install the application on their respective cell phones and received information and instructions for use with an average duration of 30 minutes. The moment was used to guide the way of use, explain the purposes of each screen contained in the application, clarify doubts about the handling, as well as about the "contact us" menu. The CG pregnant women were instructed on the importance of participating in consultations and educational activities in the USFs. It is noteworthy that the pregnant women were monitored throughout the pregnancy by the researcher, those of the IG through the application using the menu "contact us" and evaluation of the medical records to confirm the presence in the prenatal consultation, and the CG only by the medical records .

For the intervention of this study, an application for mobile device entitled "Healthy Gestation" was developed and validated, a step prior to this research. The application contains 111 screens in all, in which questions and answers about prenatal care, childbirth, the puerperium, breastfeeding, the virtual pregnant woman's booklet, the alarm clock to remember the date and time of the prenatal consultation and an menu contact us. Figure 1 shows examples of some screens.

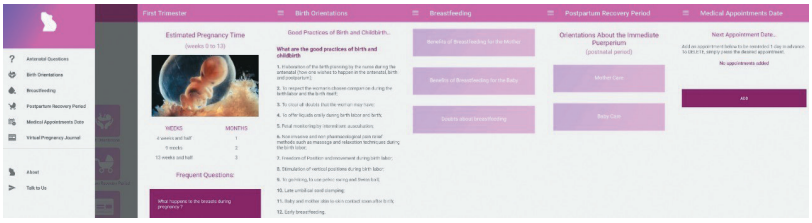

Figure 1 - Main screens of the Healthy Gestation application[15]

The guide instrument designed to compose the application was made from an integrative literature review and subsequently validated the content by obstetric nurses. The usability and applicability of the application have been validated by experts in the field of information and communication technology. The data related to the development and validation of the application "Gestação Saudável" refer to a previous study, entitled: Application for mobile device as a tool for the adhesion of pregnant women to prenatal care[15].

Outcomes

Prenatal adherence was defined as the primary outcome, assessed by the number of consultations. Adherence was considered as ≥ 8 consultations, with the evaluation at the end of the study.

Data analysis

The data analysis was carried out using the Statistical Package for the Social Sciences (SPSS), version 2.0. The statistical method used to compare the groups (IG and CG) for the primary outcome was inferential statistics, in which Pearson's Chi-Square, Fisher's

Exact and Mann-Whitney tests were applied. For all analyzes, the significance level of 5% was used.

RESULTS

A total of 88 pregnant women were included in the investigation. The final analysis was 36 for the intervention group (IG) and 39 for the control group (CG). The recruitment of pregnant women was not expanded to the full range of the pre-settled sample (n=98), because in the three months defined by the researcher for the selection and monitoring of participants, there were no new cases of pregnancies within the estimated period.

Figure 2 represents the sampling strategy to determine the study sample according to CONSORT standards.

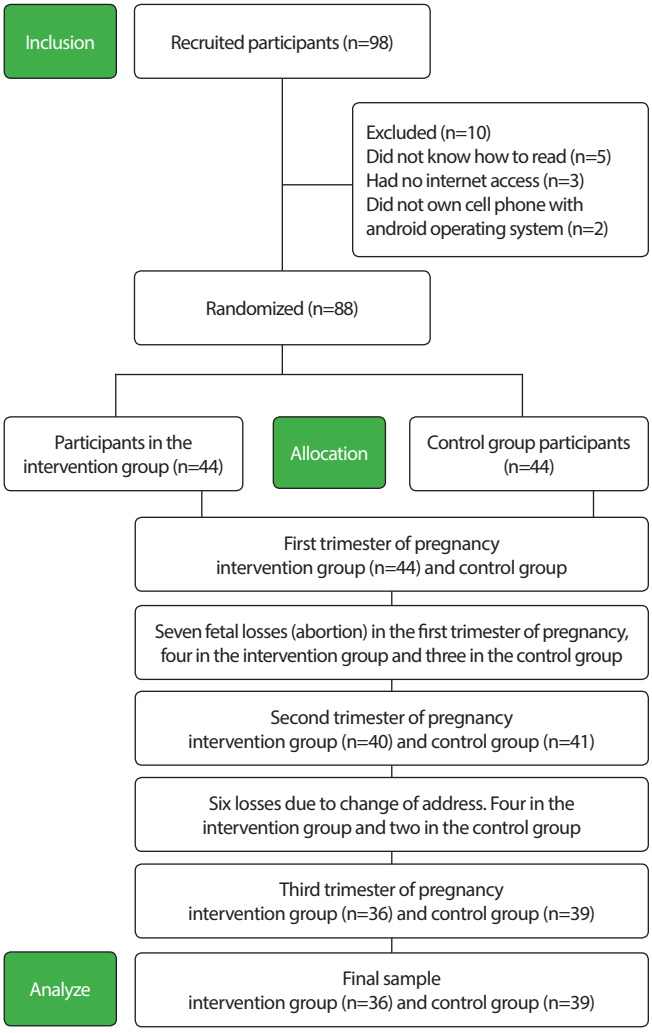

Figure 2 - CONSORT diagram for inclusion, allocation, follow-up and analysis, Northeast, Brazil, 2018

In the IG and CG, according to the sociodemographic variables, no statistically significant differences were detected in a previous pregnancy and prenatal absences in the previous pregnancy. Regarding parity, the CG (46.2%) and the IG (47.2%) had previous pregnancies, did not attend all prenatal consultations in the previous pregnancy (CG= 84.6% and IG= 88 , 9%), did not have a paid occupation (CG= 81.3% and IG= 85.6%), with a family income of up to one minimum wage (CG= 86.4% and IG= 82.7%), were alcoholics (CG= 12.8% and IG= 8.3%) and smokers (CG= 11.2% and IG= 5.2%). The IG's average age was 24 years and 25 years for the CG.

Table 1 represents the frequencies and percentages referring to prenatal information between the groups.

Table 1 - Information regarding prenatal care for pregnant women in the intervention and control groups, Northeast, Brazil, 2018

Variables/Category	Group				*p* value
	Intervention		Control		
	n	%	n	%	
Is prenatal care important?					
Yes	36	100	39	100	
Do you have difficulty making an appointment for prenatal care?					0.026*
Yes	05	13.9	24	61.5	
Not	31	86.1	15	38.5	
Is the time for the scheduled prenatal consultation better?					
Yes	36	100	39	100	
Did you use any type of application before this study?					0.001*
Yes	11	30.5	05	12.8	
Not	25	69.5	34	87.2	
Did you attend all the prenatal appointments scheduled in the last pregnancy?					0.014**
Yes	04	11.1	6	15.4	
Not	32	88.9	33	84.6	

*Note: * Pearson's Chi-square test ** Fisher's exact test.*

Pregnant women who used the application during pregnancy (IG) attended a larger number of prenatal consultations when compared to participants in the control group, identifying a statistical difference between the groups (p <0.05), as Table 2.

Table 2 - Frequency of prenatal consultations for pregnant women in the intervention and control groups, Northeast, Brazil, 2018

Variables/Category	Group				*p* value
	Intervention		Control		
	n	%	n	%	
Number of prenatal consultations					0.018*
≤ 5 consultations	0	00.0	20	51.3	
From 6 to 7 consultations	06	16.7	16	41.0	
≥ 8 consultations	30	83.3	3	7.7	

*Note: *Fisher's exact test.*

With regard to the use of the application by the intervention group, we sought to assess the satisfaction of pregnant women in relation to the use of this technology, using the following guiding question: in general, did you feel satisfied with the use of the application? Satisfaction was understood as the performance perceived in relation to the expectations created, measured through the choice between one of the options, yes or no.

An assessment was also made regarding ease of access, quality of information, guidance provided and facilitator of adherence to prenatal care, all nominal qualitative variables with dichotomous responses (yes or no). An association between satisfaction with the use of the application and the variable ease of access was identified, being statistically significant (p <0.05), as shown in Table 3.

Table 3 - Association between variables for evaluating the use of the application and satisfaction by pregnant women in the intervention group, Northeast, Brazil, 2018

Variables/Category	Satisfaction with using the application		*p* value
	n	%	
Was the application easy to access?			
Yes	31	86.1	
Does the application's content answer any questions and have quality information?			
Yes	36	100	
Did the application's guidelines contribute during the gestational period?			0.001*
Yes	36	100	
Did the application facilitate adherence to prenatal care?			
Yes	36	100	

*Note: *Pearson's Chi-square test.*

Finally, the overall quality of the application was assessed using a 5-point Likert scale, with the following gradations: very bad, bad, regular, good and excellent, where 30 (83.3%) pregnant women rated it excellent and 6 (16.7%) as good.

DISCUSSION

In this study, there was a majority of young women with an average age of 24 years, complete elementary school, family income of up to 1 minimum wage, primiparous women, with an unplanned pregnancy. This profile corroborates with that found in other studies on the non-attendance of prenatal care, which reveals an association between low income and education, being primiparous, young maternal age, unplanned pregnancy and not seeking attendance[9-10,12-13].

These aspects must be considered when planning actions for the inclusion of women in prenatal care, both by the head management and by the nursing professionals of the Family Health Strategy. The restructuring of actions to identify women with these risk factors in the community can be considered the starting point for improving adherence. It is also necessary to incorporate activities between local programs on the mother-child group for the constant search of pregnant women without care.

In the study of the screen, it was proved that the application "Healthy Gestation" enabled greater participation of pregnant women in the IG in prenatal consultations when compared with those of the CG, with statistically significant results. Furthermore, there was the possibility of clarifying doubts for the IG concerning the pregnancy-puerperal period, during the whole pregnancy, through the "*fale conosco*" (talk to us) menu, enhancing the knowledge of the women about the pregnancy.

Educational applications have supported improvements in the accessibility of users to information, with greater speed and accuracy. These can also be provided with functions that bring patients closer to caregivers, contributing to adherence to self-care and therapy[18].

Thus, information and communication technologies have changed the relationship between health professionals and patients/users, broadening access and sharing of information related to health/disease/care[18]. Therefore, once applied to risk and vulnerability groups, such as pregnant women, applications present themselves as a viable alternative for improving adherence to health care and expanding knowledge about specific subjects when used in a complementary way to pre-natal consultation[18-19].

In this context, besides the aforementioned benefits, the application tested in this study proved to be effective in supporting nurses and pregnant women, allowing IG pregnant women to have opportunities for clarification from the team about their pregnancy at any time through the application, similarly to consultations, in this way, there is room for dialogical construction of knowledge among the participants.

Based on the experiences of using the "*Gestação Saudável*"[15] (Healthy Gestation) application, the evaluations of the pregnant women showed an excellent degree of satisfaction in all the points covered, showing that it is an important tool in providing information, encouraging self-care during pregnancy and in health promotion.

An RCT developed in the United States of America that aimed to compare the effectiveness of a mobile application and guide book throughout the prenatal period showed that the IG that used the application was more motivated to attend pre-natal consultations and better adopted the conducts and recommendations during the gestational period, thus demonstrating the effectiveness of the application when compared to the printed booklet[20].

One other randomized clinical trial conducted with pregnant women in Singapore, that aimed to determine the viability of a smartphone application in assisting gestational weight control and nutrient intake, found that more participants achieved the ideal gestational weight gain per week in the intervention group when compared to the control group. In addition, there was a high rate of satisfaction with this technology[21]. In Israel, an RCT was performed with newly diagnosed patients with gestational diabetes mellitus, which aimed to assess the impact of using an application, in which it was demonstrated that the IG showed greater adherence to prenatal consultations and better control glycemic when compared to CG, thus showing its effectiveness[22].

Thus, mobile applications for cell phones are useful tools capable of promoting adherence to prenatal care, in addition to a closer monitoring of pregnant women by nurses, in different contexts, such as hypertension, risk of premature birth and in encouraging breastfeeding[23-24]. Thus, they are presented as a potential instrument in health promotion and disease prevention, with a complementary characteristic in health care, which is demonstrated through scientific evidence[25].

In the present study, all pregnant women in the intervention group stated that the application's content clarified doubts and had quality information, and that the guidelines of this tool contributed during the gestational period, being associated with satisfaction regarding the use of this technology.

The information offered by the nurse in the prenatal period allows women to detect the non-physiological signs and symptoms of pregnancy, contributing to its diagnosis and early management, which prevents complications and reduces morbidity and mortality[20]. These, when made available through information and communication technologies, can be a powerful and useful tool for pregnant women[20], which corroborates with the purpose of the application "Healthy pregnancy".

Study developed in Germany with pregnant women of habitual risk, which sought to know the perceptions and expectations

of the use of applications during pregnancy; evidenced positive attitudes of users towards their usability and importance. Furthermore, there was a favorable influence on adherence to prenatal care and self-care during pregnancy[26].

The "Healthy Gestation"[15] app provided clear questions and answers about pregnancy, childbirth, the puerperium and breastfeeding. The use of simple vocabulary through short texts to avoid ambiguity and facilitate understanding, being assessed as satisfactory in the present study. This data corroborates the findings of a study about the validation of an educational manual for companions during pregnancy, which obtained a satisfactory assessment of the language's clarity, objectivity and attractiveness, making it more favorable to use[27].

The use of applications with accessible language for pregnant women with low level of education showed a positive result as a strategy to develop care and self-care for monitoring and controlling events in various situations. A survey carried out in maternity hospitals in South Korea, through a cross-sectional study, applied to pregnant women with a low level of education, which aimed to assess satisfaction with the use of mobile apps on pregnancy, childbirth and child care among pregnant women , showed a high degree of satisfaction as a result[28].

The application developed under discussion was rated as excellent by the IG and was associated with satisfaction regarding its use. This fact can be explained by the fact that it is accessible for clarification of existing doubts during pregnancy through the information offered. In addition, it provides an alarm function to remind them of the date and time of scheduled appointments, with the purpose of ensuring that the pregnant woman attends prenatal care.

Evidence demonstrates that the use of applications aimed at women during the pregnancy period improves the quality of care and generates positive impacts on maternal and child health, improving health indicators, reducing the number of maternal deaths[23-24], helping the practice of Nurse in Primary Health Care, and reduced costs for the Health System[29-30].

Finally, the deficiency of national and international scientific articles with RCT in prenatal care was observed, especially with regard to adherence to consultations, which demonstrates the importance of the research on screen.

Limitations of the Study

The small number of Family Health Units used to carry out the research, as well as the long duration of the intervention are considered as study limitations, with an opening for eventualities throughout the data collection process, causing losses in the sample.

Contributions to the field of Nursing, women's health and public policies

The application has 111 screens with instructive information, besides the contact us menu for pregnant women and women who have recently given birth to promote health and contribute to the prevention of maternal deaths from preventable causes, such as hypertension, hemorrhages, and infections.

The technological tool, in addition to providing information, explores and favors the construction of knowledge, which translates into an enormous potential for education. The digital learning environment, when adding multiple media and being available in mobile technology, in the case of cell phones, becomes a privileged space, as it favors mobility and provides pregnant women with access anywhere. In favor of this perspective is the expressive use of mobile devices in our society, as well as the familiarity of their use in various activities, and not only as communication devices[31].

Thus, this study is relevant to the area of nursing, women's health and public policies, since it will contribute to greater adherence of pregnant women to prenatal consultations, as well as improving health indicators, delivery outcomes and birth, and reduced spending in public coffers.

CONCLUSION

The research enabled to identify that pregnant women in the intervention group when compared with those in the control group had a higher frequency in prenatal consultations, observing a statistical difference between the groups. Therefore, it is accepted the alternative hypothesis that the application "*Gestação Saudável*" (Healthy Gestation) was effective in adhering to prenatal care, offering major contributions to the care of women during pregnancy.

The use of this technology as a strong ally in health promotion is emphasized. In addition, it can also be used by health professionals as an educational tool to improve maternal health indicators in Primary Health Care. Finally, it is intended to expand the research in the future, by conducting a multicenter study in different regions of the country. country, in order to better assess the effect of women's adherence to prenatal consultations.

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