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A communication and information strategy in health and preparation for childbirth: a randomized cluster trial (PRENACEL)

Estratégia de comunicação e informação em saúde e a percepção de sentir-se preparada para o parto: ensaio aleatorizado por conglomerados (PRENACEL)

Estrategia de comunicación e información en salud y la percepción de sentirse preparada para el parto: ensayo aleatorizado por conglomerados (PRENACEL)

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Abstract

PRENACEL is a study that incorporates two innovative approaches to maternal and perinatal health: the need to improve women's level of satisfaction with the birthing experience and an assessment of the impacts of information and communication technologies in health. The approaches involve a communication program via short cellphone text messages, developed for Brazilian pregnant women in prenatal care in the Brazilian Unified National Health System. The analysis aims to determine whether the program contributes positively to women's perceived preparedness for childbirth. A randomized cluster trial was performed in 20 primary care units in Ribeirão Preto, São Paulo State, in 2015 and 2016. Data were collected for 1,210 women from interviews and patient charts. The data were submitted to two analytical models, per protocol and intention-to-treat. Women that had received information from the PRENACEL program during pregnancy were more likely to feel prepared for labor and delivery and to feel that prenatal care had helped them feel more prepared. There were also positive impacts on bonding with the newborn and breastfeeding in the delivery room and on knowledge of obstetric interventions. No differences were seen in the other maternal and perinatal outcomes, including women's satisfaction with the birthing care. PRENACEL can help expand women's access to strategic information for them to feel better prepared for the birthing experience.

Health Communication; Prenatal Education; Randomized Controlled Trial; Text Messaging; Maternal Health

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Introduction

Although the reduction of maternal mortality remains a global target in the sustainable development goal related to women's health [1], the international community has focused increasing attention on issues beyond surviving the pregnancy [2,3]. Growing importance has been assigned to developing solutions that help women achieve their full life potential [4,5]. A new milestone in 2018 emphasizes the need to promote and value models of care that ensure more positive birthing experiences. Such models should be based on adequate use of evidence-based interventions and respect for women decisions and emotional and psychological needs [6,7,8].

In Brazil, access to institutional care during the pregnancy and postpartum cycle is considered practically universal, with 99% of births assisted in hospitals [9]. Brazil adopted a model of care for pregnancy, childbirth, and postpartum with a medical obstetrician as the principal provider of obstetric care. The model of care has been described as highly interventionist and medicalized [10,11,12], and recent analyses have focused on strengthening the debate on care centered on the women's needs and preferencees [13]. Current population-based data indicate low or varied prevalence of good practices during care for labor (for example, eating and hydration, walking, use of non-pharmacological pain relief methods, completion of the partograph, and presence of an companion of choice) and high prevalence of obstetric interventions during labor and delivery (for example, venous catheter, Oxytocin induction, amniotomy, analgesia, lithotomy position, Kristeller maneuver, episiotomy, and cesarean section). Fewer than 5% of Brazilian women have had the experience of intervention-free birthing [11]. Some studies have also suggested that many women are dissatisfied with the quality of care, including complaints of disrespect, abuse, and mistreatment in health services [7,13]. On the other hand, health professionals assisting labor and delivery highlight the relevance of women's preparation for the birthing process [14,15,16,17].

The use of mobile phones to disseminate health information (Mobile Health or mHealth) during the pregnancy and postpartum cycle has been tested in various countries [18,19,20,21]. The results of these assessments suggest that communication programs via mobile phones can provide benefits and prevent health problems, especially important for increasing women's adherence to professional care and essential interventions in the prenatal and postpartum periods [22]. Considering such results and the experience of this article's authors in assessing the effects of text messages on pregnancy and care [23], we formulated the hypothesis that short text messages can help increase women's knowledge on the pregnancy's evolution and care during labor and delivery, thereby improving self-confidence in their birthing capacity.

The PRENACEL intervention presented in this article was developed to simulate a public policy in the Brazilian Unified National Health System (SUS), as a complementary resource to the free institutional care during pregnancy, childbirth, and postpartum used by 60% of all Brazilian women. PRENACEL is a health education and information program developed with the aim of improving maternal and perinatal health. Details on the program's development are provided in a specific article, currently in the peer review process.

The results of the impacts of PRENACEL on prenatal indicators have been published elsewhere [23], demonstrating their usefulness for increasing the coverage in the number of consultations and repetition of serological tests for HIV and syphilis. The aim of the current analysis was to determine whether the program contributes positively to women's feeling of preparedness for the experience of vaginal or cesarean delivery, a process we refer to here as "perception of birthing capacity".

Methods

Study design

To assess the effect of the PRENACEL intervention, a randomized parallel cluster trial was performed in health units that provide prenatal and childbirth care in the public healthcare system in the municipality of Ribeirão Preto, São Paulo State, Brazil.

Selection of participating clusters involved the identification of 20 basic health units (UBS in Portuguese) with the highest numbers of pregnant women in prenatal care according to consolidated data from the Municipal Health Department for the year 2013. The health units were randomized to form the intervention versus control groups (10 UBS in each group).

Selection aimed to optimize the study's cost-benefit ratio in order to reach the number of pregnant women calculated for the sample, without the need to encompass the city's entire territory.

In addition to participation by UBS and individuals, the study also included the municipality's four maternity hospitals, which provide childbirth care for the entire study population.

Participants

The study population consisted of all pregnant women 18 years or older with gestational age less than 20 weeks during the recruitment period for the intervention (April to June 2015), as long as they were in prenatal care in the health units selected to participate in the study.

Randomization of clusters involved two stages. First, two balanced groups of clusters were formed, considering the coverage population's size and situation of vulnerability (assessed as the number of beneficiaries in the Bolsa Família or conditional cash transfer program). A series of random selections were performed, dividing the clusters into two groups. The clusters' random allocation was considered balanced when the two groups differed by less than 15%. The selections were performed with the randomization function in Microsoft Excel 2013 (https://products.office.com/) – computer-generated number sequences.

The second stage consisted of allocation of the two groups to intervention versus control, using the same software.

Random selection of clusters was chosen to maximize the applicability of evidence to the health unit and minimize contamination due to the research subject's or health professional's preference for a given cluster. The balancing was done to optimize the groups' comparability.

Intervention

At the cluster level, PRENACEL was implemented in 10 health units allocated to the intervention group. In each site, health professionals that provide care during the pregnancy and postpartum cycle participated in a training meeting with the researchers, during which the study's objectives and hypotheses were presented and the processes were organized for participants' recruitment. The health professionals were identified to act as the study's focal points in the respective health service, reporting difficulties and distributing the recruitment materials to the women. These professionals also displayed posters in the health units and delivered book markers to the women with information on PRENACEL before and after the medical consultation.

At the individual level, the intervention consisted of participation in the PRENACEL program, receiving four text messages per week during pregnancy and until the immediate postpartum. Pregnant women interested in participating requested their registration in the study by sending a text messages with the keyword PRENACEL to the project's contact number. Next, they received a VoIP call (Voice Over Internet Protocol, on Skype: http://www.skype.com/pt-br/) to attend the registration interview (with obstetric data, childbearing history, and sociodemographic data). The registration interviews were audio-recorded (with the Callnote software: https://callnote.net/) and included the moment of agreement to the free and informed consent and activation of their participation. The women then began to receive text messages according to their reported gestational age. Throughout the intervention period, participants could send their doubts and complaints to the research team. All interaction with the pregnant women was via the online information system SISPRENACEL, developed specifically for the project [23].

During the hospital admission for childbirth, all the eligible women were informed about the research project and could consent to participate in the study, even if they had already agreed to participate during their prenatal care. Data from the patient charts and prenatal cards were collected for all the eligible women. Women who agreed to participate in the project were interviewed using a structured script, and data were collected from the medical charts and prenatal cards.

Data collection

Before the beginning of data collection at the maternity hospitals, the interviewers were trained, and for a month they applied a semifinal version in the field with the instrument prepared for the study. From August 2015 to February 2016, data were collected for all the women who had undergone prenatal care in the 20 health units participating in the study, as long as they met the other inclusion criteria, namely: age 18 years or older and gestational age 20 weeks or less from April to June 2015. Field interviewers conducted daily visits to the maternity hospitals to screen all the postpartum women in the hospital and select those eligible to participate in the study.

The eligible women were invited to participate in a structured individual interview, and their prenatal cards and hospital records were reviewed to obtain the pertinent data.

Control group

In health units allocated to the control group, the women received standard prenatal care. Only when they were admitted for labor and delivery, the "control" women were contacted by the research group and learned of the project. The same protocols were followed as for the intervention group to collect consent and review the medical data.

Assessment of the outcome measures

The principal outcome measure in the analysis was women's reported perception of having reached the end of pregnancy feeling "*very prepared for the delivery or cesarean*"; "*more or less prepared*"; or "*totally unprepared*". The secondary outcomes in this analysis are listed below.

(i) Maternal and perinatal results: Beginning of labor (spontaneous, induced, or scheduled cesarean); Presence of a companion of choice; Offer and consumption of diet or liquids during labor; Permission to walk and move around; Offer and use of non-pharmacological pain relief methods; Use of corticoids (during the prenatal period and/or at the maternity hospital); Use of venous catheter during labor; Use of oxytocin during labor; Amniotomy; Epidural analgesia; Episiotomy; Kristeller maneuver; Delivery in lithotomy position; Delivery route (vaginal, forceps/vacuum, cesarean); Breastfeeding and skin-to-skin contact in the first hour of life.

(ii) Knowledge of interventions, decisions on delivery, and satisfaction with care: Participation in educational activity during prenatal care (yes or no); Assessment of the relevance of prenatal care in preparedness for birthing (helped or did not help); Knowledge of Kristeller maneuver (whether previous or during this admission); Knowledge of oxytocin for inducing/conducting labor (whether previous or during this admission); Preference for vaginal delivery, at the beginning of pregnancy; Preference for vaginal delivery, at admission; Final decision on delivery route (whether jointly between the woman and the team, or not); Timing of indication for cesarean (whether in labor or not); Quality of obstetric care (very good, good, satisfactory, bad, very bad); Quality of neonatal care (very good, good, satisfactory, bad, very bad); Comfort and privacy (very good, good, satisfactory, bad, very bad); Continuity of care and support received (all of the time, most of the time, only part of the time, or only during examination); Sufficiency of information received (yes or no); Reported prevalence of disrespect, abuse, and mistreatment (yes or no).

Study period

Health units allocated to the intervention group recruited pregnant women for three months (April to June 2015). Women included in the PRENACEL intervention were followed up until hospital discharge, after outcome of the pregnancy. The data collection stage in the maternity hospitals for the entire study population lasted from August 2015 to February 2016. There were a total of 13 months of participants' follow-up, with daily data collection in the maternity hospitals for seven months.

Sample size

The primary study's sample size was determined so as to assess the effects of PRENACEL on prenatal care practices. Details of this calculation have been published elsewhere [23]. Briefly, 581 women were needed in the sample (145 pregnant women receiving the intervention and 436 in the control group), with the participation of 10 health units in each group.

Statistical analysis

Assessment of the PRENACEL intervention used two analytical approaches: (i) per protocol analysis (PPA), comparing the pregnant women that received the text messages from PRENACEL versus pregnant women from the control health units and (ii) intention-to-treat analysis (ITT), comparing all the women from the health units in the intervention group versus women from the health units in the control group.

The analyses were performed by comparison of the relative risks (RR), with 95% confidence intervals (95%CI). Significance was set at 5% for all the tests. The data were analyzed with the R software, version 3.3.1 (http://www.r-project.org), with calculation of RR and 95%CI by an Excel table with the formula developed by Rob Herbert [24].

Ethical aspects

The study was conducted in compliance with the recommendations in *Resolution n. 466/2012* of the Brazilian National Health Council, after administrative approval by the institutions involved and the Institutional Review Board of the Academic Health Center, Ribeirão Preto School of Medicine, University of São Paulo. The trial is registered in the Brazilian Clinical Trials Registry (REBEC code RBR-54zf73).

Results

The study's complete flowchart and the health units' characteristics by study group have been reported elsewhere [23]. In relation to balancing of the clusters, no differences were observed between the groups as to healthcare coverage, covered population, and proportion of families enrolled in the conditional cash transfer program. However, the health units in the intervention group had a 30% higher proportion of favela residents (80% vs. 50% in the control group), and 90% of the health units in the control group belonged to universities (vs. 50% in the intervention group).

During recruitment of participants, 350 women expressed interest in receiving PRENACEL messages, and 157 women met the eligibility criteria and received the intervention. After giving birth, during the individual interview stage in the maternity hospitals, 1,210 women were included in the analyses of the principal outcomes: 770 in the intervention group and 440 in the control group. Among the women in the intervention group that expressed interest and were enrolled in PRENACEL (157/770; 20.4%), 41 were excluded after reporting that they had not read the messages, resulting in 116 participants analyzed in the PRENACEL group (116/157; 73.9%).

During the follow-up period for eligible pregnant women registered to receive text messages, the computerized program SISPRENACEL sent 21,703 messages programmed for each gestational age. Importantly, during the same period, 1,087 spontaneous messages were received with participants' doubts and comments. In response to messages, the research team sent 1,230 personalized text messages, most of which with content focused on institutional prenatal care to answer individual clinical questions.

Per protocol analysis

In the comparison of sociodemographic data between women in the PRENACEL group and the control group (n = 116 vs. n = 440), a difference was found in the number of women with marital status "married or living with companion": 88.8% in the PRENACEL group versus 80% in the control group (p = 0.04). There was a lower proportion of women in the PRENACEL group from higher social classes (5.6% vs. 14.7%, p = 0.02) and that reported illicit substance use during pregnancy (0% vs. 4.3%, p = 0.02). Details on the study participants' sociodemographic data have been published in table format elsewhere [23].

In the comparison of the principal outcome measures between the groups, having received the program with messages showed a protective effect in perception of preparedness for childbirth (Table 1). Among the PRENACEL women, 59.5% reported feeling very prepared for childbirth, versus 47.1% of the controls (RR = 1.26; 95%CI: 1.05-1.52). The proportions that reported the relevance of prenatal care for this perception were 81.9% among the PRENACEL women versus 66.2% of the controls (RR = 1.24; 95%CI: 1.11-1.38).

The intervention was also associated with greater prior knowledge on the three main obstetric interventions during labor and delivery. Among the PRENACEL women, 90.5% reported having knowledge of episiotomy, versus 79.5% of controls (RR = 1.14; 95%CI: 1.05-1.23). Knowledge of the Kristeller maneuver showed a RR = 1.19 (95%CI: 1.01-1.41), and knowledge of oxytocin for inducing/conducting labor showed an RR = 1.14 (95%CI: 1.02-1.29).

There was no difference in the obstetric, maternal, and perinatal characteristics and results (Table 2). Among the process indicators in childbirth care (Table 3), there was a protective effect from the intervention for breastfeeding and skin-to-skin contact in the first hour of life (RR = 1.21; 95%CI: 1.01-1.45) and a negative effect on the reported offer and consumption of diet during labor (RR = 0.79; 95%CI: 0.64-0.98).

No differences were observed between the groups in the assessment of satisfaction with obstetric care in the maternity hospitals (Table 4).

Intention-to-treat analysis

In the comparison of the sociodemographic data between women in the intervention and control groups (n = 770 vs. n = 440), the intervention group showed a lower proportion of women from more affluent social classes (10.1% vs. 14.7% in the control group; p = 0.0002) and a lower proportion of women that reported illicit substance use during pregnancy (2% vs. 4.3% in the control group; p = 0.03). The complete table has been reported in a previous publication on this study [23].

In the approach to the principal outcome measures (Table 1), no difference was found for the variable "feeling very prepared for childbirth", while the assessment of the relevance of prenatal care for preparedness for childbirth resulted in a RR = 1.13; (95%CI: 1.04-1.38). In the selected triad of obstetric interventions during labor and delivery, PRENACEL produced a protective effect in terms of prior knowledge on the fundal pressure maneuver (RR = 1.16; 95%CI: 1.04-1.30). No differences were found in the other variables concerning knowledge of interventions and perception of preparedness for birthing, or in women's satisfaction with care in the maternity hospitals (Table 4).

No effects from the intervention were observed on the obstetric, maternal, and perinatal characteristics and outcomes (Table 2). For the process indicators in childbirth care (Table 3), comparison of the intervention and control groups showed a protective effect for breastfeeding and skin-to-skin contact in the first hour of life (RR = 1.17; 95%CI: 1.04-1.32) and a negative effect on the reported offer/consumption of diet during labor (RR = 0.85; 95%CI: 0.76-0.96).

Table 1

Knowledge of interventions, woman's preference and decision on delivery route, perception of preparedness for childbirth.

	Intervention		Control	ITT	PPA
	Total (n = 770) n (%)	PRENACEL (n = 116) n (%)	(n = 440) n (%)	RR (95%CI)	RR (95%CI)
Knowledge on interventions					
Available data	708	116	391		
Episiotomy				1.01 (0.95-1.08)	1.14 (1.05-1.23)
Yes	571 (80.6)	105(90.5)	311 (79.5)		
No	137 (19.4)	11 (9.5)	80 (20.5)		
Kristeller				1.16 (1.04- 1.30)	1.19 (1.01-1.41)
Yes	433 (61.2)	73 (62.9)	206 (52.7)		
No	275 (38.8)	43 (37.1)	185 (47.3)		
Oxytocin				1.06 (0.98-1.15)	1.14 (1.02-1.29)
Yes	509 (71.9)	90 (77.6)	265 (67.8)		
No	199 (28.1)	26 (22.4)	126 (32.2)		
Initial preference for vaginal delivery				0.99 (0.94-1.04)	0.94 (0.85-1.04)
Available data	681	115	380		
Yes	576 (81.7)	93 (80.2)	326 (83.4)		
No	105 (18.3)	22 (19.8)	54 (16.6)		
Preference for vaginal delivery, at admission				1.00 (0.95-1.06)	1.01 (0.92-1.11)
Available data	674	112	377		
Yes	562 (79.8)	94 (81.7)	314 (80.7)		
No	112 (20.2)	18 (18.3)	63 (19.3)		
Joitn decision on delivery route				0.95 (0.82-1.11)	1.05 (0.82-1.34)
Available data	704	116	389		
Yes	271 (38.3)	49 (42.2)	157 (40.4)		
No	433 (61.7)	67 (57.8)	232 (59.6)		
Women's decision	131 (18.5)	21 (18.1)	79 (20.3)		
Attending team	302 (42.7)	46 (39.7)	153 (39.3)		
Indication of cesarean in labor *				1.01 (0.76-1.35)	1.17 (0.74-1.85)
Available data	219	34	142		
Yes	78 (35.6)	14 (41.2)	50 (35.2)		
No	141 (64.4)	20 (58.8)	92 (64.8)		
Prenatal	95 (43.4)	15 (44.1)	74 (52.1)		
Admission	32 (14.6)	4 (11.8)	10 (7.0)		
Delivery room	14 (6.4)	1 (2.9)	8 (5.6)		
Perception of preparedness for childbirth				1.01 (0.89-1.16)	1.26 (1.05-1.52)
Available data	708	116	391		
Yes, very prepared	338 (47.7)	69 (59.5)	184 (47.1)		
No	370 (52.3)	47 (40.5)	207 (52.9)		
Fairly prepared	224 (31.6)	26 (22.4)	116 (29.7)		
Unprepared	146 (20.6)	21 (18.1)	91 (23.3)		
Prenatal helped prepare for labor and delivery				1.13 (1.04-1.23)	1.24 (1.11-1.38)
Available data	705	116	390		
Yes	528 (74.9)	95 (81.9)	258 (66.2)		
No	177 (25.1)	21 (18.1)	132 (33.8)		
Very little	107 (15.2)	10 (8.6)	74 (19.0)		
No	70 (9.9)	11 (9.5)	58 (14.9)		

95%CI: 95% confidence interval; ITT: intention-to-treat analysis; PPA: per protocol analysis; RR: relative risk.

* Only women that underwent cesareans (n = 391). Although the indication for cesarean is more frequent during prenatal care, the analysis was done with reference to the indication for cesarean during labor, based on the study's technical and conceptual parameters.

Table 2

Obstetric, maternal, and perinatal characteristics and results.

	Intervention		Control	ITT	PPA
	Total (n = 770) n (%)	PRENACEL (n = 116) n (%)	(n = 440) n (%)	p-value	p-value
Type of pregnancy					
Singleton	762 (99.1)	116 (100.0)	434 (98.6)	0.56	0.35
Multiple	7 (0.9)	0 (0.0)	6 (1.4)		
Information not available	1	0	0		
Gestational age (complete weeks)					
Early premature: < 34	26 (3.4)	3 (2.6)	15 (3.4)	0.67	0.34
Late premature: 34 < 37	57 (7.4)	2 (1.7)	27 (6.1)		
Early term: 37 < 39	179 (23.2)	30 (25.9)	109 (24.8)		
Term: 39 < 41	392 (50.9)	66 (56.9)	216 (49.1)		
Late term: 41 < 42	103 (13.4)	13 (11.2)	60 (13.6)		
Post-term: 42 < 45	13 (1.7)	2 (1.7)	13 (3.0)		
Fetal presentation at delivery					
Cephalic	724 (96.0)	110 (96.5)	411 (95.2)	0.45	0.39
Breech	26 (3.5)	3 (2.6)	20 (4.6)		
Other	4 (0.5)	1 (0.9)	1 (0.2)		
Information not available	16	2	8		
Beginning of labor					
Spontaneous	494 (65.3)	75 (65.8)	281 (65.2)	0.43	0.93
Induced	154 (20.3)	19 (16.7)	78 (18.1)		
Without labor	109 (14.4)	20 (17.5)	72 (16.7)		
Information not available	13	2	9		
Birthweight (g)					
≥ 2,500	693 (90.7)	110 (94.8)	398 (91.3)	0.78 *	0.49 *
1,500-2,499	62 (8.1)	6 (5.2)	35 (8.0)		
< 1,500	9 (1.2)	0 (0.0)	3 (0.7)		
Information not available	6	0	4		
5-minute Apgar score					
≥ 7	744 (98.8)	114 (99.1)	422 (97.7)	0.22	0.54
< 7	9 (1.2)	1 (0.9)	10 (2.3)		
Information not available	17	1	8		
Admission to neonatal UCI					
Yes	111 (14.5)	11 (9.6)	65 (14.8)	0.96	0.19
No	652 (85.5)	104 (90.4)	373 (85.2)		
Information not available	7	1	2		
Severe maternal complications					
Yes	58 (7.5)	3 (2.6)	35 (8.0)	0.88	0.07
No	712 (92.5)	113 (97.4)	405 (92.0)		
Newborn's status at mother's discharge					
Alive	719 (94.2)	112 (97.4)	410 (93.6)	0.94 *	0.43 *
Transferred	9 (1.2)	1 (0.9)	5 (1.1)		
Hospitalized	33 (4.3)	2 (1.7)	22 (5.0)		
Deceased	2 (0.3)	0 (0.0)	1 (0.2)		
Information not available	7	1	2		

(continues)

Table 2 (continued)

	Intervention		Control	ITT	PPA
	Total (n = 770) n (%)	PRENACEL (n = 116) n (%)	(n = 440) n (%)	p-value	p-value
Mother's status at discharge					
Alive	767 (99.7)	115 (100.0)	439 (100.0)	0.54	1.00
Transferred	2 (0.3)	0 (0.0)	0 (0.0)		
Deceased	0 (0.0)	0 (0.0)	0 (0.0)		
Information not available	1	1	1		
Mean maternal lenght-of-stay (days)	2.8 (2.04)	2.53 (1.71)	2.93 (2.66)	0.7747	0.8521
Delivery route					
Vaginal	522 (67.8)	79 (68.1)	281 (63.9)	0.03	0.21
Forceps/Vacuum	14 (1.8)	2 (1.7)	2 (0.5)		
Cesarean	234 (30.4)	35 (30.2)	157 (35.7)		

ITT: intention-to-treat analysis; PPA: per protocol analysis.

* Fisher's exact test.

Table 3

Process indicators for care during labor and delivery.

	Intervention		Control	ITT	PPA
	Total (n = 770) n (%)	PRENACEL (n = 116) n (%)	(n = 440) n (%)	RR (95%CI)	RR (95%CI)
Partograph completed *,**				1.01 (0.97-1.04)	1.00 (0.94-1.07)
Available data	681	100	379		
Yes	635 (93.2)	93 (93.0)	351 (92.6)		
No	46 (6.8)	7 (7.0)	28 (7.4)		
Breastfeeding/skin-to-skin contact				1.17 (1.04-1.32)	1.21 (1.01-1.45)
Available data	700	116	381		
Yes	402 (57.4)	69 (59.5)	187 (49.1)		
No	298 (42.6)	47 (40.5)	194 (50.9)		
Dilatation at admission in early active phase (4-8cm)				1.01 (0.87-1.16)	1.02 (0.80-1.31)
Available data	715	107	416		
Yes	303 (42.3)	46 (43.0)	174 (41.8)		
No	412 (57.7)	61 (57.0)	242 (58.2)		
< 4cm	339 (47.4)	45 (42.0)	206 (49.5)		
≥ 8cm	73 (10.3)	16 (15.0)	36 (8.7)		
Presence of a companion of choice					
Prepartum/Delivery/Postpartum				0.98 (0.90-1.08)	1.05 (0.91-1.21)
Available data	661	110	353		
Yes	438 (66.3)	78 (70.9)	238 (67.4)		
No	223 (33.7)	32 (29.1)	115 (32.6)		
Prepartum				0.99 (0.94-1.04)	0.96 (0.88-1.05)
Available data	663	110	353		
Yes	572 (86.3)	92 (83.6)	307 (87.0)		
No	91 (13.7)	18 (16.4)	46 (13.0)		

(continues)

Table 3 (continued)

	Intervention		Control	ITT	PPA
	Total (n = 770) n (%)	PRENACEL (n = 116) n (%)	(n = 440) n (%)	RR (95%CI)	RR (95%CI)
Presence of a companion of choice					
Delivery				0.98 (0.92-1.04)	1.00 (0.91-1.11)
Available data	665	111	356		
Yes	532 (80.0)	91 (82.0)	291 (81.7)		
No	133 (20.0)	20 (18.0)	65 (18.3)		
Postpartum				1.01 (0.94-1.08)	1.00 (0.89-1.12)
Available data	665	111	355		
Yes	520 (78.2)	86 (77.5)	276 (77.7)		
No	145 (21.8)	25 (22.5)	79 (22.3)		
Good practics during labor					
Eating				0.85 (0.76-0.96)	0.79 (0.64-0.98)
Available data	552	92	292		
Yes	305 (55.3)	47 (51.1)	189 (64.7)		
No	247 (44.7)	45 (48.9)	103 (35.3)		
Movement *				0.99 (0.91-1.07)	1.04 (0.92-1.18)
Available data	529	87	275		
Yes	400 (75.6)	69 (79.3)	210 (76.4)		
No	129 (24.4)	18 (20.7)	65 (23.6)		
Non-pharmacological pain relief *				1.03 (0.95-1.11)	1.02 (0.89-1.16)
Available data	648	94	359		
Yes	484 (63.1)	77 (67.0)	261 (59.6)		
No	164 (21.4)	17 (14.8)	98 (22.4)		
Interventions during labor and delivery *					
Corticoids				0.85 (0.67-1.09)	0.70 (0.44-1.13)
Available data	682	108	378		
Yes	131 (19.2)	17 (15.7)	85 (22.5)		
No	551 (80.8)	91 (84.3)	293 (77.5)		
Peripheral venous catheter				1.04 (0.92-1.18)	1.00 (0.81-1.23)
Available data	563	93	305		
Yes	324 (57.5)	51 (54.8)	168 (55.1)		
No	239 (42.5)	42 (45.2)	137 (44.9)		
Oxytocin				0.98 (0.84-1.14)	1.02 (0.81-1.30)
Available data	316	54	161		
Yes	191 (60.4)	34 (63.0)	99 (61.5)		
No	125 (39.6)	20 (37.0)	62 (38.5)		
Amniotomy				1.00 (0.83-1.22)	1.04 (0.76-1.43)
Available data	552	90	302		
Yes	189 (34.2)	32 (35.5)	103 (34.1)		
No	363 (65.8)	58 (64.5)	199 (65.9)		
Epidural analgesia				0.97 (0.86-1.09)	1.09 (0.91-1.30)
Available data	523	87	276		
Yes	304 (58.1)	57 (65.5)	166 (60.1)		
No	219 (41.9)	30 (34.5)	110 (39.9)		
Episiotomy				1.21 (0.82-1.77)	1.36 (0.75-2.47)
Available data	534	83	287		
Yes	74 (13.9)	13 (15.7)	33 (11.5)		
No	460 (86.1)	70 (84.3)	254 (88.5)		

(continues)

Table 3 (continued)

	Intervention		Control	ITT	PPA
	Total (n = 770) n (%)	PRENACEL (n = 116) n (%)	(n = 440) n (%)	RR (95%CI)	RR (95%CI)
Interventions during labor and delivery *					
Kristeller maneuver				1.38 (0.89-2.15)	1.49 (0.78-2.85)
Available data	486	83	248		
Yes	65 (13.4)	12 (14.5)	24 (9.7)		
No	421 (86.6)	71 (85.5)	224 (90.3)		
Lithotomy position				1.01 (0.93-1.10)	0.99 (0.87-1.14)
Available data	489	84	249		
Yes	380 (77.7)	64 (76.2)	191 (76.7)		
No	109 (22.3)	20 (23.8)	58 (23.3)		

95%CI: 95% confidence interval; ITT: intention-to-treat analysis; PPA: per protocol analysis; RR: relative risk.

* Only women that entered labor, early active phase;

** Information on patient chart.

Table 4

Satisfaction with care received at the maternity hospital.

	Intervention		Control	ITT	PPA
	Total (n = 770) n (%)	PRENACEL (n = 116) n (%)	(n = 440) n (%)	RR (95%CI)	RR (95%CI)
Obstetric care very good or good				0.99 (0.95-1.03)	0.98 (0.91-1.06)
Available data	707	116	390		
Yes	628 (88.8)	102 (88.0)	350 (89.8)		
No	79 (11.2)	14 (12.0)	40 (10.2)		
Very good	381(53.9)	64 (55.2)	219 (56.2)		
Good	247 (34.9)	38 (32.8)	131 (33.6)		
Satisfactory	59 (8.3)	11 (9.5)	34 (8.7)		
Bad	13 (1.8)	1 (0.9)	4 (1.0)		
Terrible	7 (1.0)	2 (1.7)	2 (0.5)		
Neonatal care very good or goodm				1.01 (0.98-1.04)	1.02 (0.98-1.06)
Available data	704	116	390		
Yes	676 (96.0)	112 (96.6)	370 (94.8)		
No	28 (4.0)	4 (3.4)	20 (5.2)		
Very good	435 (61.8)	75 (64.7)	256 (65.6)		
Good	241 (34.2)	37 (31.9)	114 (29.2)		
Satisfactory	24 (3.4)	4 (3.4)	18 (4.6)		
Bad	3 (0.4)	0 (0.0)	1 (0.3)		
Terrible	1 (0.1)	0 (0.0)	1 (0.3)		

(continues)

Table 4 (continued)

	Intervention		Control	ITT	PPA
	Total (n = 770) n (%)	PRENACEL (n = 116) n (%)	(n = 440) n (%)	RR (95%CI)	RR (95%CI)
Comfort and privacy very good or good				0.98 (0.95-1.01)	0.95 (0.88-1.01)
Available data	708	116	390		
Yes	651 (92.0)	103 (88.8)	366 (93.1)		
No	57 (8.0)	13 (11.2)	24 (6.9)		
Very good	312 (44.1)	55 (47.4)	198 (50.8)		
Good	339 (47.9)	48 (41.4)	168 (43.1)		
Satisfactory	46 (6.5)	12 (10.3)	20 (5.1)		
Bad	9 (1.3)	1 (0.9)	3 (0.8)		
Terrible	2 (0.3)	0 (0.0)	1 (0.3)		
Continuos care and support				0.96 (0.86-1.08)	0.91 (0.74-1.11)
Available data	706	116	390		
Yes	375 (53.2)	58 (50.0)	215 (55.1)		
No	331 (46.8)	58 (50.0)	175 (44.9)		
Most of the time	253 (35.8)	41 (35.3)	134 (34.4)		
Little	44 (6.2)	11 (9.5)	16 (4.1)		
No	34 (4.8)	6 (5.2)	25 (6.4)		
Information received was sufficient				1.02 (0.98-1.06)	0.99 (0.92-1.07)
Available data	707	116	391		
Yes	643 (90.9)	103 (88.8)	349 (89.3)		
No	64 (9.1)	13 (11.2)	42 (10.7)		
Insufficient	49 (6.9)	12 (10.3)	33 (8.4)		
No	15 (2.1)	1 (0.9)	9 (2.3)		
Disrespect, abuse, and mistreatment				0.95 (0.54-1.68)	0.94 (0.36-2.47)
Available data	707	116	391		
Yes	31 (4.4)	5 (4.3)	18 (4.6)		
No	676 (95.6)	11 (95.7)	372 (95.1)		
Does not know	0 (0.0)	0 (0.0)	1 (0.3)		

95%CI: 95% confidence interval; ITT: intention-to-treat analysis; PPA: per protocol analysis; RR: relative risk.

Discussion

The study's findings suggest that the use of text messages with information on pregnancy, labor, delivery, and their management help improve women's perception of their birthing capacity. The study also found that receiving text messages contributed to the perception that prenatal care increases the participants' birthing capacity. Other associations were found with the supply of information to the women: greater knowledge (prior to childbirth) on the use of interventions such as episiotomy, fundal pressure, and oxytocin induction, in addition to better results with early skin-to-skin contact and breastfeeding.

No differences were observed between the groups in the use of obstetric interventions in labor and childbirth, medical outcomes of the pregnancy and birth, or women's satisfaction with the care.

Although most studies on the effectiveness of mHealth interventions have focused on assessing prenatal and postnatal indicators, the absence of impact on maternal and perinatal outcomes had already been observed in some situations [22], described next. According to a recent systematic review of 27 intervention studies employing communication via mobile technologies, only one study provided information on severe maternal morbidity or maternal mortality. Conducted in Nigeria, the study concluded that the communication technology did not produce differences in the determinants

of deaths in the analysis [25]. The evaluation of an incentive to consume iron supplements in pregnancy via *mHealth* showed women's improved adherence to the protocol, but without resulting in differences in maternal anemia or hemoglobin, hematocrit, and ferritin levels [26]. Another study, in Thailand, managed to show better levels of satisfaction, confidence, and anxiety in women that received text messages during prenatal care, but no differences were found in gestational age at delivery or delivery route [27].

Importantly, most of the evidence to date in this area has been produced in settings in which coverage and access to clinical interventions may be insufficient, and thus where "delays" in managing care are common. Such interventions have achieved their objectives by delivering educational information and reminders that stimulate women's demand for inputs and/or interventions, and in the final analysis they include practices that depend on women active adherence and engagement. Meanwhile, in the context of the PRENACEL study, the health situation of women receiving care in the SUS is characterized by high coverage of essential interventions in prenatal care and childbirth [11,28] and the high human development index in the city where the study was performed [29]. Nevertheless, this scenario is quite timely for the proposed test of effectiveness, since PRENACEL confirmed its usefulness for further expanding the coverage of some recommended practices in prenatal care [23] and childbirth, such as early breastfeeding and skin-to-skin contact, besides having promoted the women's access to relevant information on practices in maternity hospitals.

Another strength in the study was the communications model implemented by PRENACEL. Besides the messages' educational function, including reminders, the intervention guaranteed the women's opportunity for two-way communication; that is, during follow-up, the online communication system allowed automatically sending the scheduled text messages and spontaneously receiving the women's questions and comments (at zero cost to participants), which were answered by the researchers. Active engagement in the spontaneous and individual communication with the study by nearly 40% of the participants may be relevant to the women's satisfaction and their perception of being included in the decisions on their care. These are important results for our research questions and potential analyses for future publications.

The study's limitations include a potential selection bias of women interested in receiving text messages as a complement to their regular prenatal care. In addition to the study population's sociodemographic characteristics, the community in Ribeirão Preto is in constant and varied contact with the university and its research centers. Such factors may have contributed to the absence of impact on most of the target indicators.

Another significant limitation to the study was the demarcation of the PRENACEL target public: since this was a test of effectiveness of a program targeted to healthy pregnant women, it excluded women with a diagnosis of high-risk pregnancy. In addition, the study did not include adolescents under 18 years of age. This decision was based on the age of majority in Brazil. The country's prevailing legislation would not allow women under 18 to participate spontaneously in the individual intervention or to consent to having their data collected in the maternity hospitals. This suggests an avenue for future studies, which could focus on customizing the information to orient the women. Participants in the current study presented privileged social indicators in terms of social vulnerabilities: most of the women included in the analysis were white or brown, had at least nine years of schooling, were white, and were married or living with a companion.

Considering the high rates of obstetric interventions in childbirth care in Brazil, the study showed the strength of raising women's awareness concerning good practices for a positive birthing experience. Providing women with knowledge on female physiology and healthcare practices had already been associated with lower rates of early admission in labor, increased use of good practices in care during labor, and reduction of unnecessary cesareans among primiparous women assisted by the SUS [30].

In addition to encouraging compliance with recommendations associated with better outcomes and satisfaction, such as presence of a companion of choice, consumption of diet during labor, and freedom of movement, PRENACEL sought to promote the informed refusal of some interventions such as episiotomy and the lithotomy position during fetal expulsion [6,31]. In the context of this study, despite acknowledging women's limited control over the interventions performed during the process of care, especially in the hospital setting [13,32], we highlight the relevance (for health policies) of the association between receiving educational information and women's improved perception of their

birthing capacity in general, and specifically the finding that prenatal care helps them feel better prepared for childbirth. Health education to prepare for labor and delivery has been highlighted as an effective strategy for including women's preferences during the decisions. In addition, the literature emphasizes that a positive birthing experience is associated with women's participation in decisions on their care [7,17]. The literature review suggests that this is the first result of cellphone text messages as an intervention to improve perceived birthing capacity.

Conclusion

The improvement of women's confidence in their birthing capacity and valuing the limited and adequate use of interventions during labor and delivery is a challenge in the cultural context of obstetric care in Brazil. PRENACEL can contribute to the expansion of women's access to strategic information for them to feel better prepared for the birthing experience.

Contributors

A. C. A. Franzon developed the PRENACEL messages, led the expert panel in the assessment and tests with users, elaborated the analytical plan and first draft of the article, and contributed to the study's implementation, analysis, and/or interpretation. L. Oliveira-Ciabati developed the computerized system for sending and receiving the messages, contributed to the study's implementation, analysis, and/or interpretation, and revised the article and approved the final version for publication. L. P. Bonifácio, M. S. Andrade, J. A. C. Sanchez, G. C. Braga, V. Nogueira-Pileggi, and M. Fernandes contributed to the study's implementation, analysis, and/or interpretation and revised the article and approved the final version for publication. E. M. Vieira was responsible for the project's technical coordination, participated in the study design, fieldwork planning, and development of the instruments. contributed to the study's implementation, analysis, and/or interpretation, and revised the article and approved the final version for publication. J. P. Souza conceived the research project, elaborated the analytical plan and first draft of the article, contributed to the study's implementation, analysis, and/or interpretation, and revised the article and approved the final version for publication.

Additional informations

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Resumo

O PRENACEL é uma pesquisa que incorpora duas abordagens inovadoras para a saúde materna e perinatal: a necessidade de melhorar os níveis de satisfação das mulheres com a experiência do parto; e, a avaliação de impactos do uso de tecnologias de informação e comunicação em saúde. Trata-se de um programa de comunicação via mensagens curtas de textos no celular desenvolvido para gestantes brasileiras atendidas no pré-natal do Sistema Único de Saúde. Nesta análise, pretende-se determinar se o programa contribui positivamente para a percepção das mulheres de sentirem-se melhor preparadas para o parto. Um ensaio aleatorizado por conglomerados foi realizado em 20 unidades de saúde da atenção primária de Ribeirão Preto, São Paulo, entre 2015 e 2016. Dados de entrevista e revisão de prontuários foram coletados de 1210 mulheres. Eles foram submetidos a dois modelos de análise, por protocolo e intenção de tratamento. Receber informações do programa PRENACEL durante a gestação foi associado a um aumento na percepção das mulheres de se sentirem melhor preparadas para o parto, e na percepção de que o pré-natal colabora para que se sintam mais preparadas. Também foram observados impactos positivos no estabelecimento do contato pele a pele e aleitamento materno em sala de parto e no conhecimento sobre intervenções obstétricas. Não foram encontradas diferenças nos demais desfechos maternos e perinatais avaliados, incluindo a satisfação das mulheres com o atendimento ao parto. O PRENACEL pode contribuir com a ampliação do acesso das mulheres a informações que lhes sejam estratégicas para que se sintam mais bem preparadas para a experiência do parto.

Comunicação em Saúde; Educação Pré-natal; Ensaio Clínico Controlado Aleatório; Mensagem de Texto; Saúde Materna

Resumen

PRENACEL es una investigación que incorpora dos abordajes innovadores para la salud materna y perinatal: la necesidad de mejorar los niveles de satisfacción de las mujeres que han vivido la experiencia de un parto; además de la evaluación de los impactos del uso de tecnologías de la información y comunicación en salud. Se trata de un programa de comunicación vía mensajes cortos de texto en el móvil, desarrollado para gestantes brasileñas atendidas en el servicio prenatal del Sistema Único de Salud. En este análisis se pretende determinar si el programa contribuye positivamente a la percepción de las mujeres respecto a sentirse mejor preparadas para el parto. Se realizó un ensayo aleatorizado por conglomerados en 20 unidades de salud de atención primaria en Ribeirão Preto, São Paulo, entre 2015 y 2016. Los datos de entrevista y revisión de registros médicos se recogieron con 1.210 mujeres. Estos se sometieron a dos modelos de análisis, por protocolo e intención de tratamiento. Recibir información del programa PRENACEL durante la gestación se asoció a un aumento de la percepción de las mujeres en cuanto a sentirse mejor preparadas para el parto, y desde la percepción de que el periodo prenatal presta apoyo para que se sientan más preparadas. También se observaron impactos positivos en el establecimiento del contacto piel con piel, lactancia materna en sala de parto, y en el conocimiento sobre intervenciones obstétricas. No se observaron diferencias en los demás desenlaces maternos y perinatales evaluados, incluyendo la satisfacción de las mujeres con la atención durante el parto. PRENACEL puede contribuir a la ampliación del acceso de las mujeres a información que les resulte estratégica para que se sientan mejor preparadas durante la experiencia del parto.

Comunicación en Salud; Educación Prenatal; Ensayo Clínico Controlado Aleatorio; Mensaje de Texto; Salud Materna

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