Contemporary Clinical Trials 81 (2019) 40–43

Contents lists available at ScienceDirect

Contemporary Clinical Trials

journal homepage: www.elsevier.com/locate/conclintrial

Short Communication

Effectiveness of shortened time interval to postpartum visit in improving postpartum attendance: Design and rationale for a randomized controlled trial

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ARTICLE INFO

Keywords:
Randomized controlled trial
Postpartum visit attendance
Shortened time interval
Study design and rationale
Completion and adherence rates

ABSTRACT

Background/Aims: Recent evidence suggests that there are numerous benefits to scheduling postpartum visits as early as 3 weeks post-delivery. However, findings are not conclusive due to methodological limitations. This report discusses the unique aspects of a randomized controlled trial's (RCT) design, intervention, and strategies to maintain participant retention.

Methods: This study was a four-year, prospective, open-label RCT conducted at the Virginia Commonwealth University Medical Center. Women who recently delivered a healthy, full-term baby vaginally, were randomized to receive a 3–4 or 6–8 weeks postpartum appointment and were followed for 18 months.

Results: A total of 364 women participated in this study. A large proportion of women were retained in the study as demonstrated by the high completion rates at the 18-month follow-up interview (Total sample: 87.6%; 3–4 weeks group: 88.0%; 6–8 weeks group: 87.3%). Similarly, high adherence to the protocol-directed postpartum visit schedule was reported in the overall study sample (79.7%), as well as in the 3–4 (70.5%) and 6–8 (90.0%) week postpartum groups.

Conclusion: The study design offered unique features which ensured excellent participant completion and adherence rates, despite the presence of hard-to-track women who typically do not return for their postpartum visits.

1. Introduction

The postpartum visit is critical to maintaining a continuum of care for women after child birth. The American College of Obstetricians and Gynecologists (ACOG) recommends that women attend a postpartum visit within 6 weeks of an uncomplicated delivery [1]. To improve attendance rates and achieve national targets [2], prior research studies have investigated the potential benefits of implementing earlier postpartum visits [3,4]. However, the ambiguity of study findings on health services use and maternal health behaviors yields insufficient evidence to promote policy change. Moreover, the lack of randomized controlled trials (RCT) and low participation rates among women during the perinatal period has posed many research challenges for practitioners [5,6]. To improve the quality of available evidence that can inform future practice recommendations [7] and increase study participation rates [5,6], it is necessary to explore effective methodological approaches in the field.

This paper highlights the unique design and intervention of a RCT conducted to compare the effectiveness of a shortened postpartum visit interval on improving our primary outcome variable, postpartum visit

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https://doi.org/10.1016/j.cct.2019.04.012
Received 16 March 2018; Received in revised form 2 April 2019; Accepted 17 April 2019
Available online 18 April 2019

attendance. Additionally, this paper describes strategies employed to maintain participant retention for an 18-month follow-up period.

2. Methods

2.1. Design and study setting

This study was a prospective, open label RCT. Women were randomized to receive 3–4 and 6–8 weeks postpartum appointments and were followed for 18 months. The trial was conducted at the Virginia Commonwealth University Medical Center (VCUMC), a tertiary medical center located in Richmond, Virginia, that provides care to inner city, underserved pregnant women. The study was approved by the Virginia Commonwealth University Institutional Review Board and registered on ClinicalTrials.gov (registration number NCT03165838).

2.2. Eligibility criteria

Women were included in the study if they were at least 18 years of age, delivered a healthy, full-term (at least 37 weeks gestation) baby vaginally, received prenatal care at the VCUMC obstetric clinic, spoke English, and provided informed consent for study participation. Women with cognitive impairment, psychiatric instability, or language barriers that limited their ability to provide informed consent were excluded. Women were also excluded if they had surgical sterilization or complicated deliveries that required extended hospital stays or early follow-up to monitor their conditions. Additionally, women who had problems with their infants such as preterm birth, admission to the Neonatal Intensive Care Unit, congenital malformations or respiratory problems were excluded.

2.3. Recruitment, enrollment, and informed consent

Study participants were recruited from the VCUMC in-patient postpartum unit by using Electronic Health Records (EHR) to monitor deliveries. Eligible women were contacted within 48 h of delivery and informed about the study. Women who agreed to participate were asked to sign the informed consent form, which authorized research staff to access participants' EHR to enhance tracking of postpartum visit attendance.

2.4. Randomization

Eligible women were randomly assigned in a 1:1 ratio to attend a postpartum visit at either 3–4 weeks or 6–8 weeks post-delivery. Allocation sequence was randomly generated using the Research Electronic Data Capture (REDCap) software, and to maintain concealment of the allocation sequence, the allocation list was generated by a statistician who did not maintain direct participant contact. To ensure adequate balance between the intervention groups, randomization was stratified by race and parity, two factors that have been found to influence postpartum visit attendance [8–10].

2.5. Follow-up assessments and retention strategies

Study participants were interviewed in person at baseline (within 48 h of delivery) and at the postpartum visit. Participants were compensated $25 for completing the baseline interviews and $30 for completing the postpartum interviews. Follow-up assessments were administered via telephone at 3, 6, 9, 12, and 18-months post-delivery to evaluate secondary outcomes including contraceptive use, infant feeding practices, pregnancy status, stress and social support, and sociodemographic and medical information. Each of the follow-up assessments lasted approximately 10–15 min, and participants were compensated $10 per follow-up assessment.

To reduce loss to follow-up, participants' contact information, as well as contact information for at least three persons who would know the participants' whereabouts and could get messages to them, were collected from the patients. To compensate study subjects for their participation and encourage follow-up assessment compliance, thank you letters along with appointment reminders and additional $10 checks were mailed to each participant monthly. This was especially important for hard-to-track women who did not have working phone numbers and did not return for postpartum visits. Additionally, per study protocol, participants received appointment reminder SMS text messages and/or emails 1 day before their scheduled follow-up phone interviews. If participants could not be reached, up to four attempts were made to contact the participant on different days and times of the day, in an effort to schedule the interviews. If the participant was unreachable within 1 week after the scheduled follow-up appointments, a letter was sent to the listed address asking the participant to call the study staff. If the participant was still unreachable, the back-up contacts listed on the patient tracking forms were used to contact the participant.

2.6. Outcomes

The primary outcome, postpartum visit attendance, was measured using documentation in the EHR.

2.7. Statistical power and sample size requirements

Sample size estimates were based on expected differences in postpartum visit attendance. Based on a previous study [11], we assumed that the intervention group whose postpartum visit is scheduled at 3–4 weeks post-delivery would have 16% less women miss their visits compared to the 6–8 week postpartum group. Using the Fisher's exact method, 174 subjects in each group were deemed sufficient to detect the difference of 16% between the two groups with power of 85% and a two-sided alpha of 5%.

2.8. Statistical analysis

All baseline characteristics were summarized and compared across the two study groups using the Chi-square test (Fisher's exact test for small samples) for categorical variables, and Wilcoxon rank-sum test for continuous variables. Logistic regression was used to assess the difference between the groups for postpartum visit attendance.

3. Results

A total of 364 participants were enrolled in the study; of which 183 and 181 women were randomly assigned to 3–4 and 6–8 week postpartum groups, respectively (Fig. 1). Overall, the study participants were largely Caucasian (48%) or African-American (43%). Their median age was 28 years (range 18–43 years), 57% were employed, and 40% were primiparous. No statistically significant differences in baseline maternal characteristics were observed between the two groups.

Table 1 shows study completion rates at each visit and follow-up interview and adherence rates for the treatment groups. Completion rates, measured as the number of women who completed a scheduled or re-scheduled study interview at each time point, were high at each follow-up interview. The overall completion rate was 82% at the postpartum interview and 88% at the 18-month interview. Completion rates for the 3–4 weeks and 6–8 weeks postpartum groups were similar at each follow-up interview, with no statistically significant difference observed (p-values > .05). The study adherence rate, women attending their postpartum visits within the protocol-prescribed timeframe, was 80% overall, 71% in the 3–4 weeks group, and 90% in the 6–8 weeks group (p-value < .0001).

For the 3, 6, 9, and 12-month follow-up interviews, women generally completed the assessments (92%, 85%, 81%, and 82%,

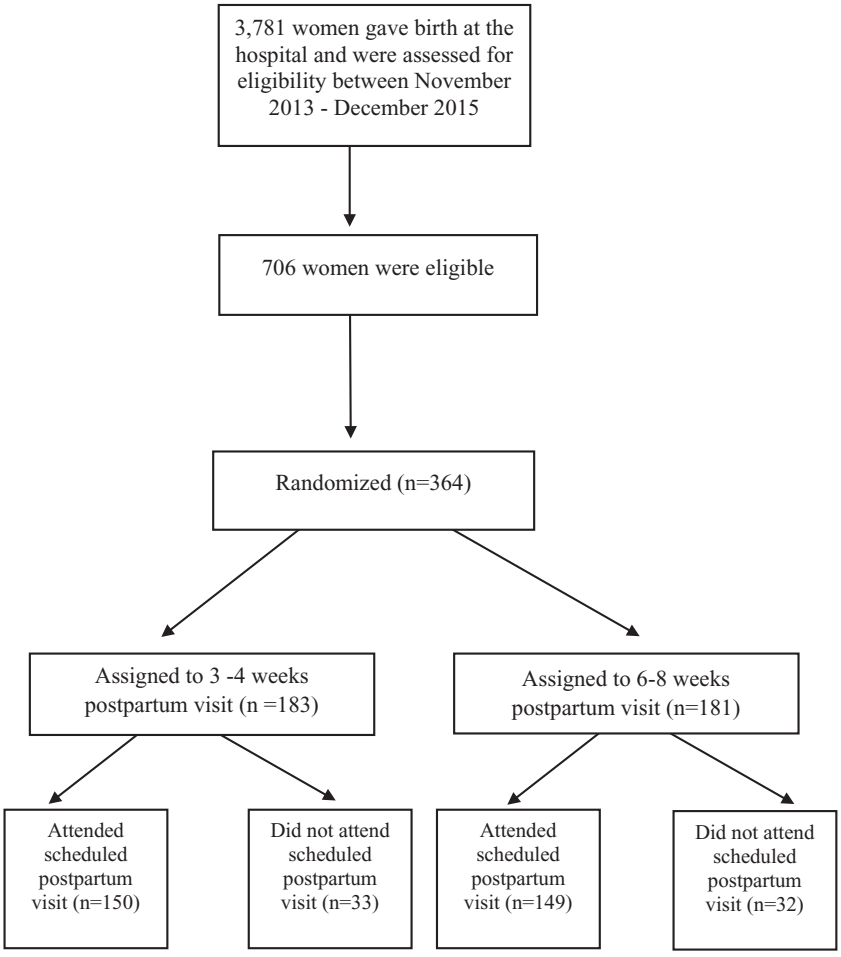

Fig. 1. Flow diagram of study participants.

respectively). For the 18-month follow-up interviews, 216 (59%) women completed the assessments as scheduled; another 103 women completed the interview after additional reminders from study staff; overall, 88% of women competed the 18-month assessment. There was no difference in the number of women who attended the follow-up interviews as scheduled between intervention groups.

4. Discussion

To our knowledge, this is the first RCT to examine the effectiveness of a shortened time interval to postpartum visit in improving visit attendance. In this trial, we successfully maintained high completion rates throughout the course of the study. This is important given that the study population included hard-to-track women who typically do not return for postpartum visits [12]. Due to economic challenges, underserved women may not have permanent addresses or phone

Table 1
Participant completion and adherence rates for study.

	N = 364							
	Completion rate [a]							Adherence rate [b]
	Baseline n (%)	Postpartum n (%)	3 months n (%)	6 months n (%)	9 months n (%)	12 months n (%)	18 months n (%)	n (%)
Completed interview 3–4 weeks group	183 (100)	150 (82.0)	170 (92.9)	159 (86.9)	150 (82.0)	154 (84.2)	161 (88.0)	129 (70.5)[c]
Completed interview 6–8 weeks group	181 (100)	149 (82.3)	164 (90.6)	152 (84.0)	146 (80.7)	144 (79.6)	158 (87.3)	161 (90.0)
Total completed interviews	364 (100)	299 (82.1)	334 (91.8)	311 (85.4)	296 (81.3)	298 (81.9)	319 (87.6)	290 (79.7)
Rescheduled interviews [d]	–	–	21 (11/10)	74 (30/44)	53 (31/22)	62 (33/29)	103 (46/57)	

[a] Completed follow-up interview call with study staff.
[b] Fidelity to assigned postpartum attendance group.
[c] Significant difference [(χ [2]) $p < .0001$] in adherence rate between 3 and 4 and 6–8 weeks postpartum groups.
[d] Out of the total completed interviews, participants who rescheduled a follow-up interview call outside of the 3 day window from their original appointment. Presented as total and (3–4 week group/6–8 week group).

numbers. By utilizing a participant tracking form, we obtained contact information from at least three persons who generally knew the participants' whereabouts and could contact them. This provided multiple avenues for reaching participants and enhanced retention. Additionally, monthly communication and incentives provided the opportunity to maintain participant engagement.

Another unique aspect of this trial was the linkage of participants' EHR to the study database. Even when women were lost to follow-up, we were able to access data on their postpartum visit attendance. Additionally, we were able to obtain reasons for not attending (e.g., illness) and know if the visit was rescheduled.

The overall postpartum visit adherence rate was generally high in the study. However, the adherence rate was observed to be relatively lower in the 3–4 weeks group (71%) compared to the 6–8 weeks group (90%). One reason that may explain this finding is that participants may have been more familiar with the traditional 6–8 weeks postpartum visit and thus, may have had some inertia or difficulty in attending a 3–4 week postpartum visit.

Although this study used rigorous approaches to understand an understudied area in perinatal care, one main limitation must be noted. Women necessarily had additional interaction with health system personnel (i.e., the research team) as a result of study participation, and this may have positively influenced their postpartum visit attendance relative to historic attendance rates. However, the study was intentionally designed to preclude any additional reminders about the postpartum visit from the research team to enhance the translatability of the results. Nonetheless, this trial offers unique features that ensured excellent participant completion and adherence rates. The participant follow-up methods used in this study are promising and could be considered for similar future studies.

Conflict of interest

The authors report no conflict of interest.

Funding source

This study was funded by the Agency for Healthcare Research and Quality, grant number 1R01HS021504. ClinicalTrial.gov Registration Number: NCT03165838

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