Effectiveness of a Mobile Prenatal Care App to Reduce In-Person Visits: A Prospective Trial

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Mobile App for Prenatal Care to Reduce In-Person Visits V.1.0

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Abstract

Background:

Risk appropriate prenatal care has been asserted as a way for cost effective delivery of prenatal care. A virtual care model for prenatal care has the potential to provide patient-tailored, risk-appropriate prenatal educational content and may facilitate vital sign and weight monitoring between visits. Previous studies have demonstrated safe reduction of frequency of in person prenatal care visits in low risk patients, but have noted a reduction of patient satisfaction.

Objective:

The primary objective of this study is to test the effectiveness of a mobile prenatal care app to facilitate a reduced in-person visit schedule, for low risk pregnancies, while maintaining patient and provider satisfaction.

Methods:

This controlled trial compared a control group receiving usual care to an experimental group receiving usual prenatal care plus a mobile prenatal care app. The experimental group had a planned reduction in the frequency of in-person office visits while the control group had the usual number of visits. The trial was conducted at two diverse outpatient obstetric practices that are part of a single academic center in Washington, DC, USA. Women were eligible for enrollment if they presented to care in the first trimester, were between the ages of 18 and 40, had a confirmed desired pregnancy, were not considered “high-risk,” and had an iOS or Android smartphone that they used regularly. We measured the effectiveness Marko, et. al
of a virtual care platform for prenatal care via the following measured outcomes: (1) the number of in-person Obstetric (OB) visits during pregnancy; (2) patient satisfaction with prenatal care; (3) and provider satisfaction.

Results:

88 patients were enrolled in the study, 47 in the experimental group and 41 in the control group. For patients in the experimental group, the average number of in-person OB visits during pregnancy was 7.8 and the average number in the control group was 10.2 ($P=0.01204$). There was no statistical difference in patient satisfaction or provider satisfaction in either group.

Conclusion:

The use of a mobile prenatal care app was associated with reduced in-person visits and without a reduction in patient or provider satisfaction.

Trial registration: ClinicalTrials.gov NCT02914301.

Keywords: prenatal care, mobile technology, remote patient monitoring, health apps, patient safety, patient satisfaction, innovative practice, controlled trial, mobile health, digital health.

Introduction

Background

In the United States, there are nearly four million live births each year. This makes prenatal care one of the most widely utilized preventative care health services [1,2]. Despite its

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widespread use, the effectiveness and organization of standard prenatal care has been debated. Rigorous scientific evidence of the effectiveness of standard prenatal care, including effects on maternal and infant outcomes, healthy-related behaviors, and health care costs is limited [2]. In the early mid-1980s, an expert panel recommended stratifying women into high and low-risk categories, with high-risk women receiving more intensive prenatal care and low-risk women following a reduced visit frequency schedule [6]. The rationale for this recommendation was that unnecessary visits for low-risk patients consume health care resources that could be applied more judiciously to women with higher risk pregnancies. However, despite these recommendations, the standard model of prenatal care with high-frequency visits has persisted. Almost a third of low-risk women receive more visits than recommended by the American College of Obstetricians and Gynecologists (ACOG) [7]. The barriers cited by providers for not reducing visits for low-risk pregnancies include: (1) concern about decreased patient satisfaction; (2) need for frequent weight and blood pressure monitoring; and (3) concern about reduced transmission of educational information regarding health and lifestyle choices during pregnancy.

Goal of This Study

The primary objective of this study was to determine if a mobile prenatal care app facilitates a reduced in-person prenatal care visit schedule while maintaining patient and provider satisfaction. Mobile health apps have the potential to address many of the perceived barriers to reducing in-person visits [8]. The application of smartphone technology has been shown to improve disease management for diabetes self-care activities, HIV infection medication adherence and sickle cell anemia medication adherence [9-11]. We hypothesize that a similar approach using a mobile app and connected monitoring devices may also be beneficial to manage prenatal care. A pilot trial with eight patients was performed prior to this trial and feedback from that trial guided this investigation [12].

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Methods

Study Design

This pragmatic controlled trial compared an experimental group that received a mobile app for prenatal care and an integrated Wi-Fi connected blood pressure and weight scale to a control group that received usual care. Institutional Review Board (IRB) approval has been obtained from the George Washington University IRB (IRB#: 015422).

Study Setting

The educational components and clinical triggers were developed and refined at the George Washington University (GWU) in Washington, DC (United States) working in conjunction with local mobile health technology firm 1EQ and their product Babyscripts™ [13]. The clinical trial occurred in two obstetric offices in the United States: one in downtown DC and one in suburban Maryland. For both offices, deliveries take place at the GWU Hospital in Washington, DC. Enrollment occurred between July 2015 and March 2016.

Inclusion and Exclusion Criteria

Eligible participants were women between 18 and 40-years-old, visiting the OB for a first-trimester verification of pregnancy visit or new OB visit, and who were low-risk per treating provider. Participants were also required to regularly use a smartphone and be fluent in English. Exclusion criteria included the following: multiple gestation, significant maternal comorbidities, gestational diabetes, pregnancy induced hypertension, maternal substance abuse, fetal abnormalities or by physician discretion.

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Allocation

Allocation into experimental group versus control group was based on the operating system of the patient’s smartphone. Patients with iOS-based smartphones (i.e. iPhones) were allocated to the experimental group; patients with Android or Windows operating systems were allocated to the control group. This allocation system was chosen as a practical solution to the challenges of randomization and blinding. Allocation was concealed until after consent was obtained.

Study arms

Participants who were assigned to the experimental group were instructed to download the mobile app and set up the connected monitoring devices at the time of enrollment. Participants incurred no additional costs for app or connected devices. Participants allocated to the control arm, were not given access to the mobile app. The experimental group was also placed on an alternative prenatal care schedule of 8 expected visits as compared to the typical 12-14 expected visits in the control group. The experimental visit schedule was based on Department of Defense/Veterans Affairs Uncomplicated Pregnancy Guidelines [14]. For all participants, prenatal care met established guidelines for management of uncomplicated pregnancies.

Data Collection

To capture satisfaction outcomes, we administered patient surveys via an online survey tool at weeks 16, 20, 25, 30, 35, and two weeks postpartum. Participants who completed all six surveys and responded to all related questionnaires were compensated with a $20 gift card to Amazon™ at completion of the study. To capture patient clinical outcomes, we reviewed the electronic medical record, analyzed hospital billing records and conducted in-depth

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interviews with a representative subset of patients after delivery. Patient demographics, including the highest level of education and household income, were also obtained by self-report at the time of enrollment. Detailed patient characteristics were also collected at the time of enrollment, including age, race, insurance status and ethnicity.

Outcome Measurements

The primary outcome of the study was the number of in-person prenatal care visits as assessed by patient chart review. In addition, all patients were evaluated for satisfaction with their prenatal care experience and pregnancy outcomes. Patient satisfaction surveys were administered to participants at gestational weeks 16, 20, 25, 30, 35 and two weeks postpartum. We defined serious combined adverse events as we did in the pilot study: preeclampsia / eclampsia, non-optimal weight gain, NICU admissions, stillbirth, neonatal mortality and other serious outcomes per expert review. Cesarean delivery rate was analyzed separately. All chart reviews were completed using trained abstractors with defined data collection sheets.

Statistical Analysis

We compared outcomes between study arms using t-tests for continuous outcomes and $\chi^2$ tests for dichotomous outcomes. For differences in baseline characteristics between the two study groups, we used a hierarchical generalized logistic or linear regression model that includes an indicator for the study arm. We conducted descriptive heterogeneity of treatment effect analyses by age, gender, race/ethnicity, and highest attained parental education level.
Description of Mobile App

The Babyscripts™ app was designed with two major goals: to deliver educational content via a mobile app and to remotely monitor blood pressure and weight. The educational content was based upon American College of Obstetrician and Gynecologists (ACOG) standards and refined by a committee of four board-certified obstetricians at the George Washington University (GWU) School of Medicine. Input from a variety of other stakeholders including patients, midwives and administrators was also obtained. The mobile app sends educational content to the expectant mother at gestation-appropriate times throughout pregnancy. This information encompasses material covering pregnancy progression, pre-existing risk hazards such as alcohol intake, smoking or drug abuse, advice to address these risk hazards, dietary and nutritional content, breastfeeding information, guidelines for appropriate weight gain and warning signs for pregnancy complications. In addition, the app integrates with a Wi-Fi-connected scale and blood pressure cuff to provide both feedback and alerts depending on the readings. The alerts were created to provide early warnings to patients and providers about aberrant data points with the hope of providing early detection of high-risk features.

Results

User Statistics

181 women met inclusion criteria and were screened for enrollment. Of those, 118 met screening criteria and agreed to participate. 60 patients were allocated to the experimental group and 58 patients were allocated to control group (Figure 1.) Of those, 13 patients dropped out of experimental group and 17 dropped out of control group. Patients discontinued involvement in the study because they transferred care, developed high-risk features.
characteristics, experienced a miscarriage or requested to no longer participate. Ultimately, 47 patients in the experimental group and 41 in the control group were retained in the study until completion and were analyzed. There was no significant difference in baseline characteristics (Table 1.)

Evaluation Outcomes

The experimental group had significantly fewer prenatal care visits than patients in control group (7.9 visits versus 10.2 visits). (Table 2, Figure 3) Patient satisfaction measured over several intervals demonstrated no difference in satisfaction between the experimental and control group. (Figure 4) Provider surveys demonstrated aggregate scores demonstrating high perceived quality and satisfaction with the virtual care platform. (Figure 5)

Although maternal and fetal outcomes were tracked, the study was not powered to demonstrate the effect of the virtual care platform on maternal or fetal outcomes. Regarding gestational weight gain, we noted trends toward better weight management in the experimental group, specifically in women who were identified as obese or underweight. (Figure 6A, 6B.) We identified one adverse fetal event of stillbirth at 38 weeks gestation. Investigation of the case revealed patient had an uncomplicated pregnancy and was compliant with prenatal care schedule of experimental group. She was seen in person by her obstetrician within three days of the fetal demise at which time no abnormalities were noted normal fetal movement and fetal heart tones were identified. Workup revealed a likely fetal-maternal hemorrhage unrelated to study protocol.

Discussion

Principal Results

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Pregnant women represent a promising target for digital health applications. Unlike digital health apps that target chronically ill or elderly populations, pregnant women are a young and healthy population. A mobile health app that targets pregnant women may facilitate integration of prenatal care into other aspects of their family and professional life. In addition, pregnancy is a unique period of life when healthy behaviors including exercise, diet and sleep take on greater importance. As such, women are highly engaged with their health care decisions during pregnancy and may be more receptive to educational programs that can be delivered through a mobile health app. Finally, the majority of prenatal care visits are scheduled to exchange educational information to the patient or weight and blood pressure data to the provider. Both of these exchanges are that are especially amenable to communication via mobile technology or remote monitors. Ultimately, the app does not replace in-person visits but may replace some of the current activities that occur at each visit. If the app is effective, the in-person visits may become more focused on high-level discussions, individual patient questions and personalized care.

As part of this study, several important elements emerged as critical to the success of a mobile prenatal care app. First, the initial assessment is critical to identifying high-risk versus normal-risk on initial assessment; second, accurate communication of patient data to the provider is necessary to assess for early signs of pregnancy complications; third, educational information must be provided at the appropriate time-period during pregnancy; fourth, educational information should be targeted to individual patient (e.g., not all women need regular reminders about the importance of smoking cessation); and fifth, a clear explanation that the role of the mobile app is to augment and not replace the obstetrician or midwife.

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Limitations

There are several limitations to our study. First, the use of a quasi-randomization scheme where participants were allocated by type of phone creates a risk of confounders. The second risk concerns the possibility of contamination across groups. It is possible that by reducing visits in the experimental group, physicians were more likely to reduce the visits in all patients. Third, the mobile prenatal care app was prescribed as part of the reduced care schedule and it is unknown if a reduced care schedule might have been effective without the mobile care app or with a different solution.

Conclusions

In conclusion, satisfaction was unchanged and visits were reduced through the use of prenatal mobile care app, Babyscripts™. Future studies will look for predictors of adverse clinical outcomes in a variety of populations in hopes of mitigating risk of adverse events.

Acknowledgements

Authors’ contributions

Substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data KIM, JMK, NG, NDG, JAB, JO, LMR, ACM,

Involved in drafting the manuscript or revising it critically for important intellectual content KIM, JMK, NG, NDG, JAB, JO, LMR, ACM

Provided final approval of the version to be published. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content KIM, JMK, NG, NDG, JAB, JO, LMR, and ACM

Agreed to be accountable for all aspects of the work in ensuring that questions related to the
accuracy or integrity of any part of the work are appropriately investigated and resolved
KIM, JMK, NG, NDG, JAB, JO, LMR, ACM

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Conflicts of Interest
Authors declares that they have no competing interests, JMK, NG, JAB, LMR

Authors that declare a competing interest and hold a position in Babyscripts, JO, ACM

Authors that are unpaid consultants, KIM, NDG

Abbreviations
ACOG: American College of Obstetricians and Gynecologists
BMI: Body Mass Index
GDM: Gestational Diabetes Mellitus
GWU: George Washington University
HELLP: Hemolysis, Elevated Liver Enzymes, Low Platelet Count
HIV: Human Immunodeficiency Virus
IRB: Institutional Review Board
IUGR: Intrauterine growth restriction
IVF: In Vitro Fertilization
MFA: Medical Faculty Associates
NICU: Neonatal Intensive Care Unit
OB: Obstetric

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Table 1 – Patient Characteristics (see eligibility assessment case report form)

<table>
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<th>Babyscripts (N=47)</th>
<th>Standard Care (N=41)</th>
</tr>
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<tr>
<td>Mean age at Screening (yr.)</td>
<td>33.0±3.3</td>
<td>32.2±3.2</td>
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<tr>
<td>Mean BMI at Screening*</td>
<td>22.9±3.2</td>
<td>24.9±4.0</td>
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<tr>
<td>Non-white race</td>
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<tr>
<td>Gravidity per Patient</td>
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<tr>
<td>Greater than one</td>
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<td>19</td>
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<tr>
<td>Parity per Patient</td>
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<tr>
<td>Greater than one</td>
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* P = 0.01204
## Table 2 – Primary Results

<table>
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<th>Babyscripts (N=45)</th>
<th>Standard Care (N=51)</th>
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<tr>
<td><strong>Number of Visits</strong></td>
<td>7.9 ±1.8</td>
<td>10.2 ±1.8</td>
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<td><strong>Gestational Weight Gain</strong></td>
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<tr>
<td>Underweight (BMI&lt;18.5)</td>
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<td>20.9 ±4.8</td>
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<tr>
<td>Normal (18.5&lt;BMI&lt;25)</td>
<td>34.0 ±8.4</td>
<td>30.5 ±7.7</td>
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<tr>
<td>Overweight (25&lt;BMI&lt;30)</td>
<td>35.0 ±10.8</td>
<td>24.2 ±11.2</td>
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<tr>
<td>Obese (BMI&gt;30)</td>
<td>13.0 ±0</td>
<td>9.4 ±9.6</td>
</tr>
</tbody>
</table>

* *P* < 0.001
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A

Overall weight gain vs BMI class

Data Type
- Brx
- Controls

B

% of patients within IOM guidelines

- Greater
- Inrange
- Under

Underweight
Normal
Overweight
Obese

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