A Pharmacist Intervention to Improve Mother and Child Health

Study Protocol

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Protocol Version and Amendment Tracking

Study Title: A Pharmacist Intervention to Improve Mother and Child Health

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Protocol Synopsis

Protocol Title	A Pharmacist Intervention to Improve Mother and Child Health
Main Criteria for Inclusion	Biological mother of a baby attending 1-week to 6-month well-child visit.
Study Objective	To learn if a research pharmacist can improve the health of new mothers and their babies.
Research Questions	1) Will postpartum women who had elevated blood pressure during pregnancy be willing to participate in the study, talk to the pharmacist about their health and the health of their child, and text us their blood pressure measurements? 2) Will contact with the pharmacist improve the health of the mother and/or child?

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1. Introduction

1.1 Background

After delivery, women are frequently lost to follow-up, and 48% do not transition to primary care.[1] In contrast, women are more likely to attend well-child visits for their children. Accordingly, well-child visits are used to screen mothers for postpartum depression.[2-4] Indeed, many pediatricians, in addition to caring for children, are ideally suited to assess the health and behavior of other family members as well.[5] Members of our group have pioneered the use of remote pharmacy teams to improve hypertension treatment. First, in 32 primary care offices throughout the U.S. we tested whether an on-site pharmacist intervention for hypertension could be implemented.[13,14] Following the success of this study, we performed two additional studies using centralized, off-site pharmacists: one was implemented in 12 small, rural clinics throughout Iowa,[15] and another was implemented in 20 large, university-based clinics.[16] In addition, we showed that our bi-directional texting approach is superior to asking subjects to use an electronic medical record (EMR) web portal[17] and that it is more effective for collecting home BP measurements than usual care.[18] Currently, we are combining our remote pharmacist intervention with bi-directional texting to improve BP control among rural populations.[19]

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2. Objective and Aim

2.1 Objective

The goal of this clinical trial is to learn if a research pharmacist can improve the health of new mothers and their babies.

2.2 Specific Aims

1) Will postpartum women who had elevated blood pressure during pregnancy be willing to participate in the study, talk to a pharmacist about their health and the health of their child, and text us their blood pressure measurements?

2) Will contact with the pharmacist improve the health of the mother and/or the child?

3. Subject Inclusion/Exclusion Criteria

3.1 Inclusion Criteria

- Age 18 – 55 years
- biological mother of a baby attending a 1-week to 6-month well-child visit,
- received prenatal care at University of Iowa Hospitals and Clinics,
- had at least 2 elevated blood pressures (>= 130 mmHg systolic or >= 80 mmHg diastolic) during pregnancy,
- owns a smartphone

3.3 Exclusion Criteria

- arm circumference > 17 inches,
- prisoner status
- unable to provide own written informed consent

4. Study Design

4.1 Overview

We propose an intervention in collaboration with a virtual pharmacist. Specifically, we will enroll new mothers in UIHC Pediatric Clinics who had two high blood pressure readings during pregnancy. We will give them a home blood pressure cuff and text them to send us their measurements for 7 days initially, and 3 days the following month. The pharmacist will determine if the mother has health insurance and a primary care provider for herself. If not, the pharmacist will work with the patient to establish care. The pharmacist will address the mother's health concerns and monitor her blood pressure. The pharmacist will also answer questions about infant health and stress the importance of well child-visits, child immunizations, and breastfeeding. The pharmacist will work closely and collaboratively with the child's pediatrician.

4.2 Recruitment/Screening Procedures

A member of the research team will screen the schedule of the participating clinic each day for infants attending their 1-2-week to 6-month well-child visits. Alternatively, clinic staff who are not on the research team, but are aware of the study may notify the research team of a potentially eligible family visiting the clinic. If an infant in the correct age range is identified by either method, the research team member will see if the infant's biological mother has an Epic medical record, received her prenatal care at UIHC, and had at least 2 elevated blood pressures (≥ 130 mmHg systolic or ≥ 80 mmHg diastolic) during her pregnancy. If all of these are confirmed, the research team member will inform the medical team that the mother is eligible for the study and ask when the best time will be to approach the mother about the study. When the medical team approves, the research team member will approach the mother and ask if she has a smartphone. If she does, they will tell her about the study. If she is interested in participating, they will present her with the informed consent, answer any questions she may have, and get her written informed consent.

If the mother is not interested in participating at that time and she is not attending the 6-month well-child visit, we will ask her if we can approach her again at a later date. If she answers "no", we will not approach her again. If she answers, "yes", we will attempt to approach her at the next well-child visit.

4.3 Visit Procedures

After consent, participants will complete a baseline demographic survey interview-style with the research team member. Then, they will be provided with a blood pressure cuff and taught how

to use it. They will be scheduled in Boomerang (the research team's bi-directional text messaging system) to complete baseline blood pressure measurements 2 times per day for 7 days and to return them to the research team via text message. This enrollment visit is expected to last 20-30 minutes. After this visit, the research team will collect the mother's co-morbidities from her medical record.

After the 7 days of baseline blood pressure values have been obtained, the participants will be contacted by the research pharmacist. The pharmacist will help the mother find a primary care physician if she doesn't have one, obtain health insurance if she doesn't have any, and discuss any health-related information about herself or her child, as needed. These pharmacist interactions will occur 7 days after baseline and again 1 month later (the participant will be asked to measure and text their blood pressure again 1 time per day for 3 days during the follow-up month). If the participant's blood pressures become elevated, the pharmacist will provide behavioral and lifestyle interventions to attempt to lower the blood pressure. They may also recommend medications to the participant's physician. The pharmacist will have access to the participant's electronic medical record to obtain any blood pressure-related medications that the mother is prescribed as well as throughout the follow up to ensure any health-related conditions can be discussed, as necessary. Each monthly call is expected to last 5 to 20 minutes.

At the end of the study, we will send the participants a link to an exit survey where they can provide their feedback about the study. We expect this exit survey to take less than 10 minutes to complete.

4.4 Statistical Analysis Plan

We will compute descriptive statistics related to the number of eligible participants, the number of participants approached, the number of women who agree to participate, the number of participants who talk to the pharmacist, the number of participants who visit a primary care physician, the mother's BP, the number of well-child visits attended, and the number of vaccinations received by the child.

We will stratify these outcomes by time of enrollment: before the 2-month well-child visit versus during the 2-month well-child visit or later.

This is a pilot project, so no power analysis was performed. The results from this study will be used to inform future power analyses. We have chosen 25 participants as this is a reasonable number to enroll during the funding window and will provide enough data to inform future studies.