Brief Report

Lessons Learned by Novice Nursing Investigators When Developing and Implementing a Research Protocol

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Abstract

Introduction: This lessons learned paper provides recommendations for novice investigators to consider when writing a research protocol; specifically when it involves clinical staff with varying levels of research experience, multiple departments, and is conducted at a non-academic medical center. It further explores each specific lesson with generalizability to help future novice investigators successfully develop and implement their own research study.

Methods: There were several lessons learned during the development and implementation of the research teams' original study. These lessons include: (1) Conduct feasibility assessments; (2) Assess external factors; (3) Partner with stakeholder(s); (4) Develop tools that promote transparency; (5) Coordinate with Information Technology personnel; and (6) Engage and educate stakeholders.

Conclusion: The aim of this study was to determine if unrestricted oral intake of low fat, low residue foods during labor impacts maternal and neonatal outcomes, with the goal of contributing an adequately powered study to the current literature. Due to the challenges experienced in executing this study, the findings were not able to be generalized. However, the challenges encountered are not specific to the original focus of the researchers' study. Each of the lessons are generalizable and can be applied to nursing research. As nurses begin to develop clinical research protocols, utilizing the lessons learned in this paper may help ensure successful implementation and completion of their research.

Keywords

nursing research, feasibility studies, research design, protocol development, research personnel

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Introduction

Nurses are trained to advocate for patients and provide evidence-based care supported by research. However, many nurses are not routinely active in nursing research as part of their responsibilities (Siedlecki & Albert, 2017). Often this is a result of the increasing demands of nursing practice, organizational setting, and lack of time and knowledge (Al-Yateem et al., 2019). These challenges, along with the shortage of both clinical nurses and nurse scholars, contribute to the need for leaders to address extrinsic barriers and promote development of clinical nurse researchers through collaboration and mentorship (Johnston et al., 2021).

Direct care nurses are in a unique position to identify clinical questions and pursue answers through nursing research (Siedlecki & Albert, 2017). Linking these nurses with nursing research support can be effective in fostering nurse-led clinical research (Cato et al., 2019; Johnston et al., 2021). In addition to research support, sharing lessons learned throughout the development and execution

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of a research protocol is important to advance nurses' knowledge of the research process.

This paper provides an example of an interventional research study conducted by novice nurse investigators. The aim of the study was to develop a protocol to evaluate the impact of unrestricted low fat, low residue oral intake during labor on maternal and neonatal outcomes as well as maternal satisfaction. Challenges in development and execution of the protocol prevented investigators from obtaining measurable outcomes to draw a conclusion. During implementation of an interventional clinical trial, Landon et al. (2019), identified barriers related to logistics (i.e. time constraints, administrative support) and difficulties in maintaining expertise with the intervention. To overcome this, they advised ongoing collaboration between stake holders and the investigative team to ensure study activities are meaningful and relevant to nursing practice. The focus of this article is to provide insight into what the team learned during the development and implementation of a protocol and how that can foster future nursing research.

Description of Referenced Study

Design

A Perinatal Clinical Nurse Specialist and two bedside obstetric nurses performed a review of the current literature on allowing women to ingest food during labor. A gap was identified, so they developed a randomized controlled trial (RCT) to capture and analyze both quantitative and qualitative data, respectively.

Eligible participants were assigned to groups on a rolling basis, then reassessed to ensure they did not develop any conditions that would exclude them from continued study participation. Data collection and documentation occurred until after delivery.

Outcomes

Quantitative data were compared between the two groups and analyzed using Chi-square and/or repeated measures ANOVA tests. A descriptive analysis between groups was performed on demographic information. Qualitative responses from the open-ended questions were analyzed using constant comparative analysis.

Sample Size

The proposed sample size was 200, with 100 participants to be enrolled into each group. The initial study duration was two years; however, it was extended an additional year to allow for further enrollment to meet the proposed sample size. Despite this, only 126 participants were enrolled into the study.

Lessons Learned

The lessons learned during the development and implementation of the protocol included: (1) Conduct feasibility assessments; (2) Assess external factors; (3) Partner with stakeholder(s); (4) Develop tools that promote transparency; (5) Coordinate with Information Technology personnel; and (6) Engage and educate stakeholders.

Conduct Feasibility Assessments

Feasibility is the first step of protocol development. If the sample size is unrealistic or unavailable, then there is no point in going any further without modifications. Ensure the population under study is large enough, despite the attrition rate, to provide an adequate sample size that will allow findings to be generalized. Consider partnering with another site with similar demographics, widening inclusion criteria, or conducting the study at a larger institution to enable access to a greater pool of eligible participants. Determine the best time to screen for eligibility. If there is a condition of exclusion that would preclude participation, ensure testing to identify this has been completed prior to screening for enrollment to avoid a screen fail or later withdrawal. For example, the population for this study was low risk pregnant women; a diagnosis of gestational diabetes would exclude participation. This condition is diagnosed with a glucose tolerance test at 24–28 weeks gestation. The appropriate time to screen for study eligibility is after 28 weeks, when the condition has been ruled out.

Assess External Factors

Forecast and timing are important aspects to consider when planning to implement a study. External factors may interfere with the investigator's ability to complete the study and yield meaningful results. Though timelines are established when the initial proposal is submitted for IRB approval, it is not an exact science. Studies may require an extension because investigators are not able to meet target enrollment. Awareness of events that may impact the study allows investigators an opportunity to develop plans to troubleshoot potential road blocks. For example, a new electronic medical record (EMR) system was implemented during the course of the study. This affected data collection due to the learning curve associated in identifying where to document information, as well as, the time associated with developing a report generated from the new EMR. Since some data points could be documented in multiple areas of the EMR, research staff had to review all possible locations, until a new report could be generated, to determine if the data were captured. Additionally, for safety reasons, bed capacity was limited on the unit after implementation. 48% (10 out of 21) of the participants were withdrawn, who were otherwise eligible, due to transferred care to a nearby hospital. Modify timelines to minimize the potential impact of external factors.

Partner with Stakeholder(s)

Interdepartmental studies can be challenging because each section has an interest, or stake, in achieving the research objective. Depending on the level of support invested, this can result in the study's success or failure. The stakeholders for this study included enrolled participants, the research team, and staff from various disciplines (medicine, nursing, and dietary) who worked on the inpatient Labor & Delivery (L&D) unit, in clinics (Women's Health, Family Medicine, Nutrition), and the anesthesia department. Partnership between the research staff and other stakeholders can positively affect outcomes through a sense of inclusion and by encouraging buy-in. Solicit support from managers/leaders in the early phases of the research proposal to secure support. Ongoing communication is imperative to ensure everyone has a basic understanding of the purpose, department and role-specific study procedures (and any modifications that occur throughout the duration of the study), objectives, and expectations of all parties involved. Research staff need to be aware of current practice standards that may impact the study and the department's operations, specifically, if a change to an established process or procedure occurs. Since this study involved offering patients a meal option that was not the standard of care, the research team initially collaborated with Nutrition Clinic leadership to solicit ideas on how to ensure participants would have access to the study diet. This collaboration established a connection with the research team, created an environment that was more receptive to change, assured buy-in through a sense of ownership, and provided feasible options for meal delivery. As previously stated, ongoing communication is necessary throughout the duration of the study. For this protocol, the intervention diet needed to be available 24 hours a day, but this was not possible due to the Nutrition Clinic's operating hours (7:00 am–5:00 pm). The availability of food items outside this time was restricted (i.e. limited selection of items from the intervention diet on the unit after hours), resulting in decreased or no intake for those in the intervention group. Collaboration and buy-in are critical to study success!

Develop Tools That Promote Transparency

Develop printed materials (i.e. diagram, guide with illustrations) that are easy to follow and provide clarity on a procedure that could otherwise be misinterpreted. In this particular protocol, it was not clear to investigators if the percent of food intake documented was based on all items consumed or only the solid food on the tray, since the intervention diet (i.e. gastric/soft bland) consisted of a combination of food and liquids, some of which were also available on the clear liquid diet (i.e. gelatin). For example, a participant may have received turkey, mashed potatoes, gelatin, and tea, however the gelatin and tea were also available on the clear liquid diet, and therefore, should not have been included in the overall percentage of food intake. Using a printed menu to identify food options, then circling those consumed for study records, would have eliminated any ambiguity.

Coordinate with Information Technology (IT)

Create a plan for data collection. If data points will be extracted from a secondary source, such as an EMR, then imported into downloadable reports, prepare them in advance. Establish a realistic timeline to complete the report and trial it at least 60 days prior to the study's tentative start date. This will allow the research team the opportunity to identify any missing data points, determine if additional information is needed to generate a variable, or if erroneous calculations are present. Meet with IT administrators to identify study variables, discuss expectations for the output report, and feasibility of completion within the specified timeline. Ensure regular follow up to assess progression, and periodically test draft versions to ensure the reports meet the intent. Additionally, confirm research staff that will be accessing it have the appropriate credentials to do so. Issues related to accessing reports may delay identifying trends that may affect study outcomes. The EMR report was not functional for this protocol for approximately four months after enrolling the first participant. This prevented earlier identification of trends related to omission of data points.

Engage and Educate Stakeholders

Knowledge is powerful. Education is essential when study interventions involve non-research staff or personnel from various departments. Education ensures all parties are equipped with the knowledge to fulfill study requirements. If staff in a particular area are unaware of the study and their role in it, they won't know what to do for enrolled participants. In this study, depending on the outcome of randomization, participants were given a clear liquid (control group) or gastric/soft bland (intervention) diet tray during active labor. Because there were gaps in nursing education, several participants received the wrong tray, resulting in protocol deviations.

In order for education to be effective, it must include the following elements: educators with subject matter expertise (SME) in the research topic, receptive learners, organized and standardized content-appropriate for the end user (specific to what they need to know), timely, and presented in a way that is easily understood. Research staff in coordination with SMEs are in the best position to present the information. They are knowledgeable of the protocol, work in the departments where the study will be conducted, and are able to address questions and concerns presented to them in real-time because of their expertise. A team approach was taken by investigators (L&D and anesthesia SMEs) and the

research coordinator to provide staff education. Learners are receptive when the information presented is beneficial (i.e. will increase efficiency), they are able to voice their concerns—negative and positive, and ask questions in order to gain a better understanding of what is being asked of them. The goal is to ensure staff are knowledgeable of and proficient in their study role.

Determine what information is most appropriate to present–this will vary by department and the staff's research experience. If data collection is required, include what data will be collected, steps on how this is to be done (if this is not standard practice), and where to document. Clinical staff must be aware that the standard practice of charting by exception is not used in research. All variables (data points) must be captured. For example, in this study nausea was a data point. This required staff to assess for nausea at regular intervals, and document it based on the patient's response (answer). In clinical practice nausea is typically documented if the patient requests an intervention for management, otherwise, no documentation is recorded. Therefore, no documentation of nausea could either indicate it was assessed by staff and the patient/participant reported none, or that no nausea was reported nor assessed by the patient or staff. Though education and training were provided to clinical staff prior to and throughout the duration of this study, data points were not consistently captured in documentation.

After the educational needs have been identified, organize them, then present in a standardized format to ensure everyone receives the same information. Use layman's terminology, to avoid misunderstanding and confusion with research language, for those with little or no research background. Develop a checklist to guide instruction, and include each item to be addressed, names of trainees and the trainer, and the date completed. In the first year of the study, staff turnover from various departments and trends in protocol deviations, such as failing to provide or collect the questionnaire, occurred. The root cause was related to staff knowledge deficit. A majority of the staff either had no awareness of the study, or awareness but a poor understanding of their role in the study. The research team addressed this by developing a standardized protocol orientation checklist that included the study purpose, objectives, and tasks specific to the role/department (e.g. provide the questionnaire to participants after delivery but prior to hospital discharge). All L&D staff completed either one-to-one or small group training provided by the research coordinator, on a designated work day during "quiet times" on the unit. L&D management modified their unit orientation checklist to include protocol orientation to ensure education of new staff. The research coordinator briefed clinic and anesthesia staff as a group during regularly scheduled recurring meetings. Additionally, algorithms of the process were placed into participant study packets (envelope placed into the outpatient obstetrical record containing the signed consent, laminated door sign indicating study diet, study procedures documentation form, and questionnaire) to reinforce study procedures. When changes in study procedures occurred, ad hoc sessions and briefings were coordinated to disseminate the information.

Next, select the optimal time to educate staff by coordinating with the department managers/leaders, and using the study timeline as a guide. The optimal time is after the protocol is approved by the Institutional Review Board (IRB) but prior to enrollment of the first participant, since the information will be fresh and ready to apply. If education is completed too early, staff are likely to forget. Alternatively, if provided too close to the study start date, there may not be sufficient time to complete training for all staff; or those who were able to complete training may not have reached a level of confidence to correctly perform study procedures. Offer sessions over a period of time, with more than one time slot to accommodate differing work schedules. This flexibility offers ample opportunity for staff to attend training before implementation, and ensures maximum attendance. Provide education on a recurring basis, and at specified time points throughout the study, to account for new personnel and modifications to study procedures. Additionally, incorporate hands-on training into the education plan. Everyone learns in a different way, some are visual, while other are auditory or tactile learners. Application of knowledge with scenarios where staff are asked to perform mock procedures and document on sample study forms will identify gaps in knowledge and practice. Conduct dry runs until staff are competent to perform required tasks. Because of the educational requirements, this study would have benefited from implementation at a research-based site, or one very familiar with research practices.

Conclusion

The aim of the referenced study was to determine if unrestricted oral intake of low fat, low residue foods during labor impacts maternal and neonatal outcomes, with the goal of contributing an adequately powered study to the current literature. Due to the challenges experienced in executing this study, the findings were not able to be generalized. However, the challenges encountered are not specific to the original focus of the researcher's study. Each of the lessons is generalizable and can be applied to other nursing research studies. As nurses begin to develop clinical research protocols, utilizing the lessons learned in this paper may help ensure successful implementation and completion of their research.

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Conflicting Interests

The views expressed in this material are those of the authors, and do not reflect the official policy or position of the U.S. Government, the

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Contributorship

All three authors listed meet the full criteria for authorship.

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