

STUDY PROTOCOL NCR191281

OFFICIAL TITLE:

How Will an Educational Video About the Induction of Labor Process Impact Patient's Knowledge of and Satisfaction With the Induction Process

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Recruitment and Data Collection:

Patients were screened for study enrollment during routine prenatal visits at the George Washington University Hospital. A trained research team member met with and spoke to eligible patients about the randomized study at the time of their scheduled induction of labor visit. There was an induction of labor schedule that is created monthly, which the research team members had access to and determined when eligible participants had their induction of labor visit scheduled.

Informed consent was obtained from the patient if interested in participating. Privacy and confidentiality were assured as approved team members were the only individuals with access to patient records and maintained strict confidentiality. All consent forms were kept in a locked cabinet and survey responses were de-identified. Patients were able to ask questions and/or opt out of the study at any time.

The research team member assessed patient's understanding of the information and participation by asking them to describe in their own words what they were consenting to. Signed informed consent were obtained prior to study enrollment.

Once a patient was enrolled, participants were randomized to the control group (no intervention) or the intervention group (3-minute educational video intervention). The randomization schedule was predetermined. The enrolled participant was given a pre-randomized study envelope that contained a unique Study ID number, randomization group, and paper surveys.

The control group took the knowledge-based survey. Twenty-four to forty-eight hours after delivery, at a time convenient to the participant during the postpartum stay at GW, a research team member asked the participant to fill out a second survey, focused on satisfaction with the labor and delivery process.

The intervention group had the opportunity to watch the 3-minute educational video. The video shown to these participants is linked here: <https://youtu.be/Pc9tclV4Dm8>. After watching the video, the participant was asked to take the knowledge-based survey. Twenty-four to forty-eight hours after delivery, at a time convenient to the participant during the postpartum stay at GW, a research team member asked the participant to fill out a second survey, focused on satisfaction.

If the patient ultimately chose not to participate in the study following the signing of informed consent, all their data was destroyed. All of the surveys were stored in a locked cabinet, secured. No one but the research team members had access to the collected data and none of the stored paper copies had any identifying information. The basic demographic information, as well as the outcome of the induction of labor process, was collected using the hospital's electronic medical record. Some of the information (race and ethnicity) was collected by self-report.

Recruitment goal:

At minimum, the goal was an n= of 106 total, 53 per arm. This was powered based on an alpha of 0.05, 80% power, 10% attrition rate to accurately detect a 20% difference given 96% correct in the intervention group.

Data entry:

After enrollment and completion of study surveys, a member of the research team entered in all of the information collected into a de-identified Redcap database using the unique Study ID numbers. The research team also collected data from the patient's electronic medical record about the enrolled participant's induction of labor process, including gravity, parity, pregnancy complications, induction agents utilized, and delivery method (vaginal vs cesarean delivery). All of this data was entered into the de-identified Redcap database. Access to the participant's medical record was only available to the research team through the MFA's HIPAA compliant, password protected, firewalled electronic medical record (Allscripts) and GW hospitals' EMR (Cerner).

After the data was entered into Redcap, a second and different member of the research team re-checked the entry to ensure the answers were correctly captured into the system.