

Study Summary

Title	A Randomized Trial Assessing the Impact of Educational Podcasts on Personal Control and Satisfaction During Childbirth
Short Title	LaPPS
NCT	NCT04933708
Date of Document	7/16/2021
Methodology	Randomized Clinical Trial
Study duration	1 year
Study Center (s)	Single-center
Objective	To assess the effect of listening to physician-created podcasts of common labor topics on patient satisfaction and perception of their birth experience
Number of Subjects	63 subjects per arm
Diagnosis and Main Inclusion Criteria	Age between 16-50; singleton gestation
Study Procedures	Enrolled at 19w0d-28w0d. Randomized at 28w0d to one of two arms: <ul style="list-style-type: none">• Labor podcasts – Six labor podcasts that can be downloaded for any podcast app• Usual care
Primary Outcome	Patient satisfaction as measured by LAS + 2 satisfaction questions
Statistical methodology	Intention to treat analysis Non-parametric tests for LAS-10 scores, birth satisfaction surveys, and EDPS scores Logistic regression for multivariate analysis

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Abstract:

Objective:

To assess the effect of listening to physician-created podcasts of common labor topics on patient satisfaction and perception of their birth experience

Methods:

This is a randomized-controlled trial to assess the effect of listening to podcasts vs. usual patient education on patient birth experience satisfaction. Patients who will be eligible for the study will be nulliparous, low-risk women who have reached at least 36 weeks of gestation. Women will be recruited through the Hospital of the University of Pennsylvania, through Penn Ob/Gyn Associates, Maternal Fetal Medicine, and the Helen O. Dickens Clinic. At time of enrollment, redcap will be used to randomize women to either receive access to the Labor Podcast Application on their smartphones or usual teaching methods by their respective clinics. Method of contact by text or email will also be collected. Patients can use the application as much or as little as they desire. Demographics, labor, and birth data from each patient enrolled will be included. After delivery, the patients will receive surveys assessing use of podcast, labor agency, labor satisfaction, and the Edinburgh Depression Scale.

Expected Results:

We hypothesize that patients randomized to receiving the labor podcast will score higher on surveys assessing labor agency, satisfaction, and lower on the Edinburgh Depression Scale.

Implications:

This study may help Ob/Gyn providers to better care for their patients through technology and spend more time during clinic hours discussing other portions of care. Also, by receiving the same message via podcast, patients are more likely to receive equitable care. Finally, by answering common questions, the podcast may increase patient's health access and understanding, allowing for better care.

1 Background and Rational

Recently, podcasts have been used for both undergraduate and graduate medical education, with studies showing that they are feasible, acceptable, and effective (1-6). Learners appear to enjoy podcast learning because they increased efficiency by allowing listeners to multitask, made listeners keep up to date with medical literature, and increased overall knowledge (4). However, podcast learning has not been as widespread for patient education. There have been some studies that showed that podcast patient education is feasible, and one small study showed increased knowledge scores after listening to podcasts (7,8).

To our knowledge, podcast learning has never been studied in the obstetric population. Labor and delivery is usually a time that is fraught with questions from first time mothers, and more education may increase these women's perception of control and satisfaction overall with birth and the postpartum period. The Labor Agency Scale (LAS)-10 is a validated instrument measuring expectancies and experiences of personal control during childbirth (9). The Edinburgh Postnatal Depression Scale (EPDS) is also a validated scale that measures levels of postpartum depression that is commonly used at our institution both immediately postpartum and at the postpartum visit 4-6 weeks after delivery (10).

2 Study Aims

2.1 Aim:

The aim of our study is to assess the effect of listening to physician-created podcasts of common labor topics on patient satisfaction and perception of their birth experience through the LAS-10 and a birth satisfaction survey created by HUP, as well as how this affects postpartum depression as assessed by the EPDS.

2.2 Endpoints

Primary Endpoint

Score on the LAS-10 and HUP based birth satisfaction survey

Secondary Endpoint

Score on EPDS

3 Patient Eligibility

Subjects must meet all of the inclusion and exclusion criteria to be enrolled to the study. Study treatment may not begin until a subject is consented and randomized.

3.1 Inclusion criteria

- Nulliparous
- Singleton pregnancy
- English-speaking
- Age 18-50
- Own a smart phone or device capable of downloading podcasts
- Reached at least 36w0d of gestation
- Willing and able to sign consent form

3.2 Exclusion criteria

- Planned cesarean delivery
- Complication in pregnancy including:
 - Placenta accrete spectrum
 - Vasa previa
 - Intrauterine fetal demise

- Known major fetal anomaly
- Delivery planned at location other than HUP and PAH

Women included in the analysis included those that met the inclusion criteria and had a liveborn singleton fetus between 36w0d and 42w0d either by vaginal delivery or cesarean section.

3.3 Vulnerable patient population

Pregnant women are considered a vulnerable population. As the condition of interest is a pregnancy-related and specific condition, it is unavoidable to exclude pregnant women from this research study. As the research study involves listening to podcasts and no other clinical intervention, we anticipate no increased risks from that experienced in routine clinical care.

3.4 Ensuring Necessary Medical Interventions

Enrollment in this study will not alter postpartum women's access to needed medical services. All women will have the opportunity to ask their obstetricians regarding labor expectations and usual labor and delivery care.

3.5 Potential Benefit to Participants

Women randomized to the labor podcast group may have increased satisfaction toward their labor experience.

4 Study Arms

4.1 Study Arms

- Labor Podcast Group – Women randomized to this arm will receive access to a link to download six HUP physician created labor podcasts in addition to usual care during labor, delivery, and postpartum
 - Podcast topics:
 - Labor Anesthesia, Induction of Labor, Second Stage of Labor, Reasons for Cesarean Section, Postpartum Recovery, Complications of Labor and Birth
 - LAS-10 and Birth Satisfaction survey – Women will be sent these surveys on postpartum day 2 via method they indicated they desire (either email or text message)
 - EDPS – Women will receive this survey on postpartum day 7 via method they desire
- Usual care – Women randomized to this arm will receive usual care during labor, delivery, and postpartum with the following exceptions:
 - LAS-10 and Birth Satisfaction survey – Women will be sent these surveys on postpartum day 2 via method they indicated they desire (either email or text message)
 - EDPS – Women will receive this survey on postpartum day 7 via method they desire

4.2 Duration of Therapy

Women will be followed from time of consent until 7 days postpartum

4.3 Duration of Follow Up

Women will be followed from time of consent until 7 days postpartum. No information will be collected on women in either group after that time.

4.4 Blinding

Due to the nature of the treatment arm, neither providers nor participants will be blinded to their treatment arm.

5 Procedures

5.1 Screening for Recruitment and Recruitment Process

Women meeting the criteria listed in section 3.1 will be invited to participate in the study. Consent via Redcap, with signature (see HIPPA form), will be obtained from those who choose to participate. Invitation to participate will be done during inpatient visits after 19 week gestation either at prenatal visits or at ultrasound appointments.

Patients that decline enrollment will be asked to participate in a de-identified demographics survey for further comparison with enrolled group. Written or digital consent will also be done via Redcap.

5.2 Enrollment Period

Upon enrollment, patients will provide a method of contact, either email or text, which will be stored on an encrypted drive that is only associated with their study number. A survey regarding demographics data will be sent upon enrollment.

5.3 Randomization

Subjects who agree to enrollment will be immediately randomized by Redcap to receive the intervention (an application that they can download on their smartphones with the podcasts available) or usual care (standard patient education regarding labor by their physicians).

5.4 Procedures During Treatment

After randomization, women will be given a link or a QR code pending preference to the podcast. Patients can download the podcasts and listen to them as many times as they desire. After delivery, on schedule reviewed in 4.1, women will receive above surveys on the above schedule via text or email, depending on their preference collected during enrollment.

5.5 Protection Against Physical Risk

There is minimal physical risk incurred by participants as part of this study.

5.6 Protection against Loss of Privacy/Breach of Confidentiality

All information collected from subjects will be protected in the following manner. Patients will only be approached in a private setting. Upon recruitment and randomization, all subjects will be identified by a number key, which will be kept on a password protected Redcap account. This will hold information as to whether the subject was randomized to podcast intervention or usual care (ie. Subject 1: Randomized to usual care), demographics information, and birth outcomes.

A separate spreadsheet will be used to track subject medical record number and contact information by key (ie. Subject 1: MRN, Email, phone number) and whether the subject desires to be contacted via email or text. This list will be kept behind the hospital firewall in a password-protected file. This list will also be used to follow-up with the LAS-10, birth satisfaction survey, and EPDS and track if these emails or texts have been sent and if the subject has completed them.

No PHI will be shared with anyone outside the institution.

6 Study Design/Study Endpoints

This will be a prospective, randomized, single-center study on the utility of labor podcasts support on patient labor satisfaction compared to usual care.

6.1 Sample size

Based on previous studies using the LAS-10, average score ranged between 45-53/70, with standard deviations ranging from 6-12. Therefore, we would estimate that the LAS score in the usual care group to be approximately 50. To be able to detect an effect size of 4, with a standard deviation of 9, and to achieve a power of 0.8 and alpha of 0.05, we would need a sample size of approximately 79 subjects per group. Calculating for a 20% loss to follow-up rate, we would anticipate recruiting 95 subjects per group.

Our city has an average of 16% preterm birth rate. Our hospital averages 1400 nulliparous deliveries/year. We would conservatively estimate approaching 50% of these women in the prenatal period for enrollment. If we assume a 75% consent rate for the RCT, which is standard for our center, we anticipate enrolling 30-36 women per month in our study. We would therefore anticipate it taking 6 months before we reach our target sample size.

6.2 Data analysis plan

Demographics data and birth outcomes will be described. Comparison between groups will be performed using appropriate non-parametric tests for LAS-10 scores, birth satisfaction surveys, and EDPS scores. P values of <.05 will be considered statistically significant. Secondary analysis will be performed looking at the effect of podcast use (how many episodes listened to and time spent listening to podcasts) with regards to LAS-10 score, birth satisfaction scores, and EPDS. Logistic regressions will be calculated to see if there relationship between time spent with the podcast and overall LAS-10 score as well as number of podcasts used and overall LAS-10 score.

Intention-to-treat analyses will be conducted such that all patients with available follow-up measures be included in the analysis.

7 Additional Information

Podcast creation and distribution

A small group of nulliparous women were asked about their labor experience and asked to provide areas of improvement in their labor experiences. All patients were asked while postpartum or postoperative day 1-4 while in the hospital. Questions asked included:

- 1) Tell me about your experience with labor and birth
- 2) What are some things that you wished you had known prior to coming in for delivery?
- 3) What were some things that were different from your expectations regarding your birth experience?
- 4) How could we have better prepared you for labor and delivery?
- 5) During pregnancy, would you have been open/willing to listen to podcasts with more information about the labor process?

From these questions, answers aggregated from these nulliparous women were used to create the following podcast topics:

- 1) Labor Anesthesia
- 2) Induction of Labor
- 3) Second Stage of Labor
- 4) Reasons for Cesarean Section
- 5) Postpartum Recovery
- 6) Complications of Labor and Birth
- 7) Normal Labor

Podcast topics were then given to two focus groups composed of 8 antepartum and 8 postpartum women for review. Once the topics were discussed and refined with the focus groups, the podcasts were created by obstetrics providers at HUP, including maternal fetal medicine and general obstetrics and gynecologic faculty. The conversations were led by one of the study personnel, FC.

References

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Shell Tables

Table 1: Demographics

Characteristic	Podcast Intervention	Usual Care
Maternal age, years		
BMI, kg/m ²		
Race		
Non-Hispanic White		
Hispanic White		
Non-Hispanic Black		
Asian/Pacific Islander		
Native American		
Other		
Private Insurance		
Gestational Age at Delivery (weeks)		
Received Antenatal Steroids		
Diabetes		
Gestational		
Pregestational		
Hypertensive Disease of Pregnancy		
Gestational Hypertension/ Preeclampsia w/o SF		
PEC w/ SF		
HELLP/Eclampsia		
Fetal growth restriction		

Childbirth Classes

Table 2: Labor and Delivery Outcomes

Outcome	Podcast Intervention	Usual Care
Method of Delivery		
Vaginal		
Unscheduled cesarean delivery		
Operative vaginal delivery		
Induction of Labor		
Augmentation of Labor		
Time to Delivery		
Admission to Delivery		
Second Stage to Delivery (vaginal delivery only)		
Regional Anesthesia		
Perineal Laceration		
First		
Second		
Third		
Fourth		
Complications during postpartum stay		
NICU stay		
Composite neonatal complications (ARRIVE)		
Chorioamnionitis /endometritis		
Hemorrhage >1 L (collapse with transfusion and OR		

Takeback)		
Transfusion		
OR Takeback		
Postpartum LOS		
Consider doing “Prolonged LOS” - >2 days for VD, >4 d for CS		

Table 3: LAS, Birth Satisfaction, and EPDS

Outcome	Podcast Intervention	Usual Care	P-Value
LAS-10			
HUP Birth Satisfaction Survey			
EPDS ≥ 9			
Overall EPDS			
Self-harm question +			

Table 4: Analysis of Podcast Use in Podcast Intervention Group

Outcome	Percent of Podcast Intervention
# of podcasts used	
0	
1-2	
3-4	
5-6	
Time spent listening to podcast	
0 - 10 min	
11 - 20 min	
21 - 30 min	
31 min - 60 min	

>1 hr	
How many times each podcast was listened to	
Labor Anesthesia	
Induction of Labor	
Second Stage of Labor	
Reason for Cesarean Section	
Postpartum Recovery	
Complications of Labor and Birth	
Normal Labor	
Rating of Podcast Material (1-10)	
Would you recommend to your friends and family?	

Subanalysis of people who actually listened vs. intention to treat (primary analysis)

Things to put into multivariable analysis:

Age, race, insurance type, method of delivery, maternal complication (composite), neonatal complications (composite), childbirth classes? (but may be a lot of people)

Consider: amount of time listening to podcast?

Vs which podcasts were listened to most?