

Participation in Perinatal Interventional Research: Which Characteristics Matter?

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Participation in Perinatal Interventional Research: Which Characteristics Matter?

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Objectives

Identify characteristics of pregnant women that are associated with the decision to participate in perinatal interventional research.

Methods

- A retrospective cohort study of two interventional trials conducted on Labor and Delivery
 - Study 1: patient-blinded, randomized trial of an adhesion barrier at the time of cesarean delivery
 - Study 2: non-blinded, randomized trial of discontinuation of oxytocin during induction of labor once in active labor
- Demographic, medical, and obstetric data were collected from medical records and compared based on participation.
- Stepwise logistic regression was performed to identify independent predictors of study participation controlling for the specific study.

Results

- 605 subjects screened eligible to participate
 - 363 (60%) agreed to participate
 - 242 (40%) declined participation
 - Participation rates were similar for both studies (~60%)
- Stepwise logistic regression (R²=0.18)
 - Prior obstetrical complications (aOR: 0.6 (95% CI: 0.4, 0.8))
 - History of hypertension (aOR: 3.8 (95% CI: 1.0, 13.4))
 - History of mental health condition (aOR: 1.5 (95% CI: 1.0, 2.3))

Table 1. Demographic characteristics of participants and non-participants for two perinatal interventional trials.

Screen Eligible Subjects			
	Accepted n=361	Declined n=342	P
Age	27.8 ± 5.6	28.5 ± 6.0	0.15
Gravidity	2 (1-10)	2 (1-11)	0.04
Parity	1 (0.6)	1 (0.6)	0.002
Gestational Age (wks)	39.2 ± 1.9	39.0 ± 1.8	0.07
Race			0.21
Caucasian	71.2%	65.3%	
Hispanic	19.1%	19.4%	
African American	4.4%	6.6%	
Other	5.3%	8.7%	
Married	55.1%	63.2%	0.11
Education ≥ College	65%	67.5%	0.53
Insurance			0.27
Private	63.5%	69.8%	
Public	27.6%	22.3%	
None	8.9%	7.9%	
Private provider	63.3%	73.1%	0.01
Employed	63.3%	73.1%	0.01
BMI (kg/m ²)	33.2 ± 7.3	32.0 ± 5.8	0.03
BMI >30kg/m2	67.6%	63.2%	0.27
Tobacco Use	18.8%	19%	0.96
Drug use	2.5%	2.1%	0.73
Alcohol Use	4.4%	3.3%	0.48

Data presented as mean ± SD or median (range); *n=335

Table 2. Maternal medical co-morbidities, current and previous obstetrical complications based on decision to participate in two perinatal interventional trials.

Screen Eligible Subjects			
	Accepted n=361	Declined n=342	P
Composite medical conditions	27.7%	23.6%	0.26
cHTN	3.9%	1.2%	0.08
Pregestational DM	2.5%	2.1%	0.73
Other comorbidities	23.8%	22.3%	0.67
Mental health history	20.8%	15.7%	0.12
Composite obstetric conditions	35.7%	40.1%	0.28
Gestational DM	11.9%	12.4%	0.86
Gestational	13.6%	12.4%	0.67
HTN/preeclampsia			
other	14.4%	19.4%	0.10
Previous obstetrical complications	16.4%	24.9%	0.01
Maternal complications	35.2%	34.3%	0.82
Fetal complications	11.4%	14.9%	0.20

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Conclusions

- Small differences exist between pregnant women who agreed and declined to participate in perinatal interventional trials.
- The most important predictors of participation were prior obstetrical complications (less likely to participate) and history of hypertension and mental health condition (more likely to participate).
- These data may help when developing strategies to improve recruitment for clinical research on Labor and Delivery.