Original Article

Characteristics that influence the acceptance of pregnant women to participate in observational studies

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Abstract

This work aims to investigate whether there are reports in the literature about the role of the recruiter's characteristics on participation in research projects focused on gestational women.

A bibliographic search was performed in SCIELO, Redalyc, Latindex, MEDLINE (through PubMed), SCOPUS and Web of Knowledge of articles published in English or Spanish with the search terms: Participation in research, informed consent, motivation and influence, reasons to participate in clinical research, recruitment characteristics.

We conclude that sociodemographic characteristics and perception of risk are important in the decision-making process of pregnant women to decide a positive answer when being asked to participate in a clinical trial.

INTRODUCTION

Scientific knowledge is directly related to the research and the ethical aspects of it having grown along with such knowledge. Among the basic principles, we can mention respect for life, autonomy, beneficence-not maleficence and justice[1]. In this field, informed consent is a crucial tool to mediate between the interest of the participants, researchers and sponsors of the study[2].

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The informed consent procedure involves explaining to an attentive and mentally competent person about the characteristics of the study, as well as about the balance of the possible risks and benefits that their participation implies, in such a way that the participant decides that he/she consider best for oneself[3]. In Mexico, the characteristics that the written document must comply with, for informed consent are established in the Regulation of the General Law on Health in the Field of Research[4]. Both in the document and in the verbal explanation, researchers must meet three conditions or golden rules which are: providing sufficient and quality information, adapting information to the level of the receiver and seeking voluntary participation without coercion[2].

The success of research studies depends on a large extent of adequate enrollment of subjects, attachment and the possibility of completing all study procedures[5]. For the first case, it is crucial to have recruiters with adequate characteristics and capacities to get the subjects to understand the relevance of participation in research projects. These characteristics go beyond the knowledge of the study protocol; it is essential to know if other aspects, such as demographic can affect the participation of subjects.

Pregnant women are a vulnerable group that may be subjected to the stressful condition that

Key words: *gestational women, perception of risk, sociodemographic characteristics.*

compromises a decision about participating in a trial[6]. This work aims to investigate whether there are reports in the literature about the role of the recruiter's characteristics on participation in research projects focused on gestational women.

METHODS

A bibliographic search was performed in the scientific databases including: SCIELO, Redalyc, Latindex, MEDLINE (through PubMed), SCOPUS and Web of Knowledge of articles published in English or Spanish with the search terms: Participation in research, informed consent, motivation and influence, reasons to participate in clinical research, recruitment characteristics, pregnancy and women.

The titles and abstracts of articles obtained in the search were reviewed to ensure that they meet the inclusion criteria that the informed consent procedure was to participate in a research study and that it explored the role of the recruiter's characteristics on successful recruitment. Reference lists of the retrieved papers were also searched for documents that were of interest for this review. Samples of manuscripts with different types of recruitment analysis were selected. The following types of papers were excluded: journal papers without peer review, conference summaries, opinion statements, commentaries, content articles that reported results on clinical research or uncontested trials of recruitment problems.

RESULTS

The results of the literature review are shown in Table 1, describing the type of study that was performed.

Table 1. *Analysis of consent form use in studies with pregnant women*

Author	Type of study / Method of data collection	Population	Main results	Observations
Mohanna and Tuna[7].	A qualitative, cross-sectional, retrospective study using semi - structured interviews with thematic content analysis.	Eighteen women who had been invited previously to participate in a clinical trial in pregnancy, but who had declined.	The invitation to participate in a clinical trial when pregnant has different implications for different women, and the meanings they ascribe to the invitation to participate will affect the likelihood of them participating. A pregnant woman may feel the pressure of conflicting duties: a protective duty to the fetus and to be a 'good citizen' when asked to participate in research. The sharing of information during the recruitment phase has a crucial bearing on how the invitation will be received. The design of the trial, the type and style of information available, the way it is conveyed, the timing and process of the invitation and by whom it is made all affect the likelihood of a woman agreeing to take part.	A state of data saturation, in which the authors could predict what the interviewer would say in response to the questions, began to emerge after 12 interviews.

Dorantes et al[8].	Quantitative. Cross sectional / Questionnaire	106 pregnant women who agreed to participate in a study to assess the effect of epidural analgesia by the Minimum Local Analgesia Concentration Model and 109 who did not.	There were no demographic differences between women who agreed to partic ipate and those who did not. The most important factors for accepting participation were related to the study's understanding and potential benefits for other women. More than 40% of the women who refused to participate strongly considered the pain or discomfort for that decision. Patients who read full consent form had participated in previous studies and those who had lower anxiety levels were more likely to agree to participate.	The questionnaire sought to know the reasons that motivated the decision to participate or not in the study.
Nechuta et al[9].	Cross sectional. Interviews.	Women were approached in clinic waiting rooms at the time of their first prenatal visit and 311 (91.0%) participated.	Percentages for willingness to participate were highest for telephone interview (83%), followed by in-person interview (60%), infant examination (57%), and maternal (56%) and infant medical records (54%). About 34 –48% of women reported that no compensation would be required for participation by data procedure. Education greater than high school was associated with increased odds of refusal for infant physical examination. Resistance to these research procedures was especially noted among more highly educated women.	Women were asked about their willingness to participate, and the smallest amount of compensation required for participation in a 45-min in -person interview, a 15 -min telephone interview, maternal and infant medical record abstraction, and an infant physical examination.
Gatny and Axinn[10].	Cross secti onal. Interviews.	90 pregnant women in a matched control - comparison study of patients receiving prenatal care in private practice and clinic settings.	Women experiencing prenatal care at a clinic reported less willingness to participate in research than wo men experiencing prenatal care at a private practice. Women who deemed “contributing to science”, “learning about pregnancy health”, and “helping future patients” as important motivations for participating in research were more likely to express willingness to participate in a study.	African American women reported less willingness to answer questions in a survey compared to white women.
Smyth et al[11].	Qualitative. Semi-structured interviews.	Women recruited to the Magpie Trial (prophylactic anticonvulsants for women with severe pre-eclampsia).	Several major but related themes emerged regarding influences on the women’s decision - making: unpredictability of pre - eclampsia; quality of information received; role of others in the decision -making process; percei ved personal benefit from trial participation; and perception of voluntariness of joining.	

Oude et al[12].	Qualitative case control study Face-to-face interviews	21 women who had been asked in 2010 to participate in one of eight clinical trials during preg nancy or shortly after giving birth.	12 women were participants and 9 non-participants. For 5 of the 12 participants, contribution to scientific research was their main motive, while 5 had participated because the intervention seemed favorable and was no t available outside the trial. Key motives for non -participation (n = 9) were a negative association or a dislike of the intervention, either because it might do harm (n = 6) or for practical reasons (n = 3).	28 women were invited for the interview.
Palmer et al[13].	Quantitative, cross-sectional. A 32-item questionnaire.	110 consenting women over a four-week period in the waiting room of an ambulatory obstetrics and gynecology clinic.	The final response rate was 74.8%, with most participants agreeing with statements about the importance of obtaining safety data about products in pregnancy and the importance of a woman having the ability to choose whether to participate in such research. Of all participants, 16.3% indicated they would consider participating in vaccine research during pregnancy and 20.0% would consider participating in medication research during pregnancy.	Factors relating to maternal or fetal/child health were the most frequently cited factors influencing willingness to participate, with lack of trust in researchers and pharmaceutical companies as factors that would discourage participation.
Meshaka et al[14].	Cross sectional.	30 research participants from the PRiDE study (an observational trial investigating the role of micronutrients in gestational diabetes).	There were two overarching motivators that emerged: a willingness to help medical research and improve our knowledge of medical science, and having a personal connection to the disease, therefore a potential fear of being affected by it. A third, less significant viewpoint, was that of a lack of inconvenience being a motivating factor.	The authors developed a set of 40 statements that encompassed the reasons why pregnant women might want to take part in research. The participants were asked to rank them in order of agreement.

DISCUSSION

The reasons some women accept, and some decline an invitation to enroll themselves in clinical research has been underexplored, although the perception of risk and how recruitment is conducted might be necessary.

To have a point of comparison, adults consider several variables to be recruited, such as: 1) feeling ill prior to participation in a study, 2) perception of having a condition that had to be treated as soon as possible, 3) confidence in the ability of the physicians to control and reduce the likelihood of adverse effects, 4) patient assessment of having greater personal comfort within the study than did before or 5) patient evaluation of the risks of undergoing new and previously unproven procedures and 6) patient evaluation of the imposed burden (time) for their participation in the study, 7) perception of threat to their health condition; 8) patient evaluation of obtaining a better treatment within the study that previously or not participating in it, and 9) patient evaluation of the risks of undergoing new and previously untested procedures[15].

In order to have a framework of what happens in other age groups, we can mention that older adults

are more likely to consent if they took five or more medicine but decline to participate depending on the nature of the letter of invitation, confusion or lack of understanding, discomfort, non-availability, impact on the relationship with the doctor, distrust of the objectives of the study[16]. When talking about the consent of parents to have their children participate in clinical research, the primary motivation for participation in pediatric research is the direct benefit to the health of the child. The other factors differ significantly depending on the severity of the child's illness. The least essential motivational factor was the understanding and regulation of the study[17].

The involvement of family members is another issue to be analyzed[18]. If the mother lives alone, she will make decisions that may differ from those who are taken care by their mothers who live as a couple or with their direct relatives. In the case of Mexico, with a high rate of teenage pregnancies, with emotional fragility and tendency to be influenced by the mother, the father, partner or siblings, the principle of self-determination is reduced[19,20].

In a study of cardiological patients, the main reasons for participating were grouped into four categories: intellectual, altruistic, health-related and financial. There was a negative correlation of intellectual motivation with the severity scale of cardiac symptoms, indicating that participants with a lower burden of symptoms supported this point with higher intensity. Participants with greater gratitude, less pessimism and greater spirituality were more likely to support an altruistic motivation compared to other participants. Not being married, lower levels of spirituality and greater medical comorbidities were related to health-related motivation. The financial motivation was to which the participants gave less importance. Other motivations reported by the participants were: gratitude to the health team and the hospital, which the investigator or team member would like and an interest in learning from the study[21].

We cannot discard the fact that mothers' understanding of information given during the consent process may be crucial to the acceptance rate in a clinical trial. Probably, beyond the education level, the extension and technicisms used in a consent form might confuse the patients.

This exploratory survey takes a different focus and considers the reasons that pregnant women accept or decline an invitation to enroll themselves in clinical research. Non-response bias (self-selection or voluntary effect) occurs when the degree of motivation of a subject who participates voluntarily in an investigation can vary significantly among other subjects; either over or under reporting[22]. Perhaps we would be observing in projects that record little response of pregnant women this bias for lack of empathy or similarity with the interviewer if it is a man. On contrary, when considering that many parents are overwhelmed by the risks that ill health poses to their child's life, they tend to view the innovation of research positively, raising the rate of acceptance to participate in a clinical study[23].

Surveys on the rate of acceptance have stated that perhaps, living in countries without publically funded healthcare could be a reason to participate in clinical trials[24]. In the particular situation of Mexico, with a fragmented health system, this could apply for Private Hospitals but not to the governmental institutions: Instituto Mexicano del Seguro Social (IMSS), Instituto de Seguridad Social al Servicio de los Trabajadores del Estado (ISSSTE), Secretaría de Salud, Seguro Popular, Instituto de Seguridad Social del Estado de México y Municipios (ISSEMYM).

In some countries, patients might take an economical benefit while participating in clinical trials, but generally speaking, in Mexico, monetary retribution to the participant in research protocols are forbidden.

Methods to obtain informed consent digitally or electronically may increase the participation of geographically diverse pregnant women[25]. It must be analyzed for each Country if this strategy is affordable and reliable.

The role of the type of study might also influence the decision. For example, when talking about merely

descriptive studies, the rejection could be lower as there is no evidence of danger possibilities; by contrast, in case of an intervention study, concerns about the safety of the therapy could represent an impassable barrier.

Until now there are no quantitative studies that explore differences between the gestational mother and father decisions who agree to participate in research and those who refuse. Probably, socio-demographic characteristics and perception of risk are essential.

A limitation of this study is the exclusion of papers written in languages different to Spanish and English. Notwithstanding, the information of this work shows the general view of some valid concerns when asking a pregnant woman to sign an informed consent to participate in a clinical research.

A matter to be clarified is the role of ethnic and racial implications when developing clinical projects with the pregnant women. For example, speaking a native language of a particular ethnic group is a natural barrier to understand an informed consent.

From this explorative first approach, it is clear that more studies are still required to explore the reasons that lead pregnant women to participate in research studies and, in the same way, the reasons that make them decline participation.

Conflict of Interest

The authors have no conflict of interest in relation to the subject matter in this manuscript.

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