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Reasons for and Reservations about Research Participation in Acutely Injured Adults

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CLINICAL RELEVANCE: Understanding perceptions of participants' experiences of being in a research study after acute injury can guide researchers to improve future study protocols and recruitment strategies in order to optimize participants' experiences. Recruitment and retention into clinical research studies is essential to build nursing science to enhance the recovery of injured individuals.

Keywords
Acute Disease, Adult, Aged, Altruism, Biomedical Research, Confidentiality, Emergency Service, Hospital, Emotions, Female, Humans, Longitudinal Studies, Male, Middle Aged, Motivation, Patient Participation, Perception, Research Subjects, Wounds and Injuries

Disciplines
Medicine and Health Sciences | Nursing

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Reasons for and Reservations about Research Participation in Acutely Injured Adults

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**Keywords**

injury; research participation; reservation; research ethics

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Research is essential in order to systematically build nursing knowledge, especially for health conditions that have high prevalence, affect vulnerable populations, and have the potential for lasting health and functional consequences. Traumatic injury is one such condition. It is a major public health concern and is the fifth leading cause of death in the...
United States (Centers for Disease Control & Prevention, 2013a). One in ten people in the U.S. are treated for injuries in emergency departments (ED) every year; approximately 31.7 million people in 2012 alone (Centers for Disease Control & Prevention, 2013b). Despite the global prevalence and impact of injury and the unique perspectives brought by nurse scientists, relatively little nursing research has focused on this population (Sommers, 2006). Nurse scientists often confront challenges while enrolling and retaining acutely injured patients in research studies. Therefore, we sought to answer the following research questions: 1) Why do injured patients choose to participate in clinical research? and 2) What reservations do injured patients have prior to or during their participation in a clinical research study?

**Recruitment in Clinical Research**

Participant recruitment and retention in clinical research is challenging and carries with it a wide range of ethical challenges. Emanuel, Wendler, and Grady (2000) developed a set of principles that guide researchers in forming a strong ethical foundation for clinical studies. The seven principles are: value and scientific validity of the research, fair subject selection, favorable risk-benefit ratio to the subjects and society, independent review of the study plan by external individuals, informed consent, and respect for potential and enrolled subjects. These seven principles are not mutually exclusive; all are essential for the ethical conduct of research.

Nurse researchers strive to develop the safest and most efficient plan to conduct research studies. They carefully consider sampling criteria, participant safeguards, timing of enrollment, and retention strategies. Researchers expect that patients weigh their willingness to participate and remain in research studies by evaluating their potential risks and benefits, especially when they are approached soon after an acute event, such as a traumatic injury. Yet little is known about how injured patients decide to engage in clinical studies and their perceptions of research participation. Therefore, it is essential to explore the reasons injured patients participate in a research study in order to more sensitively design research studies and incorporate perspectives of this population.

**Reasons for Research Participation**

Factors that influence patients’ decisions to participate in research can only be understood by asking the participants themselves. Several empirical studies have examined the reasons patients participate in clinical research and their reactions to participation upon study completion. Patients reported feeling a duty to participate and “give back” to their providers, and expressed how their trust in their providers had a major role in their agreement to be part of a research study and their understanding of the possible risks (Canvin & Jacoby, 2006; Lowton, 2005).

Similarly, Ulrich et al. (2012) found that research participants wanted to “give something back” and identified a broad array of reasons for participation in research, including physical, psychological, economic, familial, and social benefits. Most research participants indicated that they want to help other individuals with the same condition or assist the institution providing care. Helping others focuses on altruism, which is characterized by
voluntary actions to enhance the welfare of others in the absence of external rewards (Steinberg, 2010). Besides altruism, there is also a belief in the value of the potential benefits they may receive as study participants (Canvin & Jacoby, 2006; McCann, Campbell, & Entwistle, 2010; Nakash, Hutton, Lamb, Gates, & Fisher, 2008; Willis, Robinson, Wood-Baker, Turner, & Walters, 2011). In fact, when involved in a clinical study, participants realize they are monitored, receive professional care and have access to specialists.

**Reservations to Participation**

Reservations to research participation are related to multiple dimensions, including physical, psychological, economic, familial, and social factors (Ulrich et al., 2012), and can be shaped by the patient’s understanding of the study. Potential reservations can be affected by the quality of communication between the research team and patients regarding the research requirements and expected participant commitment. Lack of time is one of the most commonly stated reasons for not participating in a research study, along with a disinterest in the research objectives and the presence of other life priorities (Barratt, Levickis, Naughton, Gerner, & Gibbons, 2013; de Wijkerslooth et al., 2012). The level of trust and ability to communicate with providers and researchers can also greatly impact the person’s perception of the risks of participating (Lowton, 2005), which can contribute to reservations about study participation. de Wijkerslooth et al. (2012) explored such perspectives of risk and discomforts in a study that compared colorectal cancer screening by colonoscopy and computed tomographic colonography, where individuals who declined participation stated the burden and unpleasantness of the procedure as a major reason.

**Participation in Injury Research**

Research conducted with injured patients is held to the same ethical principles that guide clinical research with any other population. Research with injured patients and trauma survivors is often regarded by the research community and Institutional Review Boards (IRB) to have a potentially greater risk to participants, in part because of the potential for emotional distress (Newman, Risch, & Kassam-Adams, 2006). Moreover, patients who are severely injured or have any associated brain injury may have altered decisional capacity and might mistakenly consider research studies an opportunity to receive clinical services (Collogan, Tuma, Dolan-Sewell, Borja, & Fleischman, 2004).

Nevertheless, there is no evidence to indicate that participants in injury research regret their decision to be part of research studies. In fact, several studies have examined the impact of injury research on patients approached after an event, including acutely injured adults (Ruzek & Zatzick, 2000; Theadom, Fadyl, Hollands, Foster, & McPherson, 2014), acutely injured children and their parents (Kassam-Adams & Newman, 2005), and assault victims (Campbell, Adams, Wasco, Ahrens, & Sefl, 2010; Griffin, Resick, Waldrop, & Mechanic, 2003). These studies indicate that most injured participants felt satisfied after participating in a research study. They wanted to help other survivors, receive support, have access to resources, and help advance the science. In the majority of these studies however,
investigators enrolled patients during their hospitalization or after the acute event rather than patients being treated acutely in the ED and released to home.

**Purpose**

The purpose of this study was to explore the reasons adult patients seeking ED care for minor injuries agree to participate in clinical research and to identify their reservations about participating in a research study.

**Method**

**Design**

This study is a secondary analysis of a longitudinal cohort study in which 275 adults who presented to the ED of a university hospital with minor injuries were randomly selected to be followed over 12 months. The primary aim of the parent study was to examine the development of depression and post-traumatic stress disorder during the first year after injury and to evaluate the impact of these psychological disorders on the return to pre-injury function (Richmond et al., 2009). In this study, we obtained cross-sectional data from the 12 month interviews where participants were asked open-ended short-response questions about their perceptions of participation in the study. We also secured relevant variables from the parent study, specifically income, injury severity, and social support to add more insight to participant responses. Approval was granted by the IRB prior to recruitment of participants into the parent study and additional approval was obtained for this secondary analysis.

**Instruments**

Standard demographics, injury characteristics (mechanism, type, severity), and social support were collected at intake. Anatomic injury severity was measured by the widely used Injury Severity Scale (ISS), derived from injury severity across six body systems with a range of scores of 1 (least severe) to 75 (most severe) (Baker, O'Neill, Haddon Jr, & Long, 1974; Baker & O'Neill, 1976). Physiologic injury severity was measured by the triage Revised Trauma Score (rRTS) which incorporates mental status, systolic blood pressure and respiratory rate (Champion et al., 1989). Minor injury was operationally defined as an anatomical injury with an ISS of 2-8 and a normal rRTS of 12. The Brief Social Support Questionnaire, a well-established valid and reliable measure, was used to solicit social network size (Sarason, Sarason, Shearin, & Pierce, 1987). Social network scores could range from 0 to 54, with higher scores indicating larger social networks. Although social support was not central to this study on research participation, the level of social support participants had could illuminate some of the reasons identified for research participation.

Reasons and reservations about research participation were elicited using a short-response open-ended interview at the final 12-month follow-up interview. Specifically, “What were your reasons for participating in this study?”; “What reservations did you have about participating or continuing to participate in this study?”, and “Even though you agreed to participate other people decided not to. Do you have any ideas about what might encourage more people to participate in this or future studies?” The intent was to elicit short responses that the interviewer recorded in writing. The interviewer summarized the response, using the
words of the participant and then verified his documentation of the response with the participant.

Procedure

All adult patients presenting to the ED for acute minor injury were approached once medically stable and asked for verbal permission to release their contact information to the research team. From the pool of those providing verbal consent, patients were randomly selected for study participation using a stratified random number chart based on the time of entry to the ED treatment cubicle. Patients randomly selected were contacted by a member of the research team within approximately 48 hours to describe the study, answer all questions and obtain consent for study participation. An appointment was then made for the first of four data collection meetings over the following year. At the first interview, the study was once again explained, questions answered and written consent obtained. Subsequent interviews at three, six and 12 months post-injury were held either in a private room in the participant’s home or in a private office at the hospital, depending on the participant’s preference. Relevant to this secondary analysis, the research participation questions were collected at the final 12-month interview. The 12-month interview lasted approximately one hour and consisted of psychiatric, functional status, and quality of life assessments, followed by short-response questions about perceptions of study participation. All interviews were conducted by a master’s prepared social worker with extensive training and experience in conducting research interviews.

Analysis

Conventional content analysis was the primary analytic approach; free text responses were analyzed by the first author for major and most recurrent themes without using any existing coding scheme. The themes and supporting narrative data were organized in one Microsoft Office word document. To maintain scientific rigor, the second author independently reviewed all participants’ responses and validated the themes that initially emerged. The two authors used discussion to reach consensus on the labels for the six major themes. Subthemes were jointly determined by revisiting the narrative responses within each thematic category. Subsequently, the major themes were coded and entered into SPSS statistics software to explore and inquire about any possible relationship between the themes and demographic and social support variables collected at intake.

Results

Sample Characteristics

Two hundred and forty-eight participants were retained at 12 months and responses to questions about research participation relevant to this analysis were available for a subset of 214 participants. Our sample consisted of 214 participants, equally males and females, on average 41 years old (±17, range 18-93 years). Participants reported 14 (±2.6) years of education and most were employed (71%). Half of the sample was Black (54%), slightly less than the half was White (42%), and the remainder was Asian or multi-racial (4%). Half of the sample had a household income of less than $40,000. The main causes of injury were slip or fall (44%), followed by motor vehicle/pedestrian/bike crash (30%), sports (10%) and

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Other mechanisms of injury were machinery/household accidents, gunshot, and dog bites. At baseline, the average ISS was 4 (±1) and the average social network score was 23 (±12.6).

**Reasons for participation**

Six major themes about why injured patients participated in the research study emerged (see table 1). The majority of participants specified one reason for their participation in the study whereas others reported different combinations of reasons. We present illustrative quotations that are broadly representative of each theme.

**Being asked**—Being asked was the most common theme. Close to half of the participants stated that they participated in the study simply because they were asked to do so and had nothing to lose. “They asked me. It seemed like a good idea at the time, there was no reason not to.” Some participants mentioned the importance of the recruiter’s approach: “You seemed sincere and enjoyed what you were doing.” Moreover, the data collectors’ interaction with the participants during the follow up interviews influenced continued participation: “Your interest in how others and me would recover,” or “You were [the reason I participated in the study]. You kept tracking me down.” Although participants did not use the word trust, their responses suggest trust in the study team as a reason for participation.

Patients were approached in the ED for verbal consent solely for permission to release their contact information to the research team, not to obtain full consent. Consequently, one subtheme that emerged focused on the setting and approach when patients were asked to release their information to the research team. Some participants stated that this initial approach was not under optimal circumstances “I wasn’t paying attention in the ED since I was worried about what had just happened.” Despite this, patients did provide verbal consent.

**Altruism**—Altruism was the second most common reason for participating in this research study. Some participants had general responses and reported that they wanted to “help out”, while others specified the intentions underlying their altruism. Some decided to participate in the study to help other injured individuals “I think this will help other people see what emotions do to healing,” or “To help someone else who can set a positive attitude to move on; regardless of your injury, you can still move on and be motivated.” Other participants reported that they wanted to contribute to science and help improve health care: “I think in general that healthcare gets better the more people know” and “to make a difference or add to the study.”

**Potential for personal benefit**—Nearly one in five participants indicated they participated in the study for the potential resources and benefits they believed they would receive. Three subthemes were identified: sharing concerns, practicing self-reflection, and being regularly monitored. First, some participants wanted to share their concerns with someone, and they felt that it was safe for them to ventilate during the meetings with the data collector whom they perceived as interested in their recovery, “At that time I knew I was going to get depressed and I needed someone to talk to and you came right on time,”
and “It gave me time to express myself to someone other than my family.” Second, some participants indicated that the follow up sessions helped them self-reflect on their progress and evaluate their statuses, “I thought it would be a way to monitor myself to see how I was doing.” The discussions they had during the interview sessions with research staff enlightened them and made them more aware of the issues that they were experiencing. For example, as one person said, “I felt it would be interesting to see how the injury would affect me”. Third, other participants were interested in the regular follow-up that was provided through the preset data collection sessions. They wanted to make sure that someone else knew how they were progressing and whether or not they were adequately recovering from their injury “It’s good that someone calls on me to check on me and see how things are working with me.”

We considered the possibility that patients who participated in this longitudinal study and indicated that they wanted to be followed by a specialist or have someone with whom they could share concerns were possibly lacking a support system (lower social network score) and/or have a more severe injury (higher ISS) when compared to those who reported other reasons for participation. However, no such trend was found.

**Financial gain**—Fifteen percent of the participants stated that money served as the initial motivator to enter the study. Each participant was given a total of $150 over the course of the study ($30 at intake, 3 and 6 months and $60 at the final 12 month visit). “I didn’t have anything better to do and the money was nice.” Some participants provided one word responses saying “money”. However, other participants indicated incentives were not the sole reason. For example, “First it was the money, but also just in case I felt different, I had someone following me.” We considered the possibility that lower income participants are more likely to state financial gain as their motive to participate in the study. However, by examining the household income of these respondents, there is not enough evidence to suggest that lower income patients were more likely to participate in this research study for financial reasons.

**Curiosity**—Some participants agreed to take part of the study because the study description piqued their interest, “I thought it was interesting,” and “I said yes because it seemed interesting.” Others were interested in the unknown, “I just wanted to experience what a study was,” or had an innate interest; for example “Curiosity. I wanted to see what it was about.”

**Valuing and/or knowledge of research**—The importance of research was a clear theme, but the least frequently mentioned motivator. Only six percent of the participants stated “research” as being the reason for their participation. “I’m a believer in research.” Several responders stated that they value research for what it brings to people. “I’m all for any kind of research especially for those people who have recently undergone trauma of some sort.” “Because I think all research helps others.” The minority reflected on their personal experience either as previous participants in a research study or by being part of a research team.
Reservations to initial or continuing participation

Most participants did not have any reservations about deciding to participate in this study. Among those who reported reservations, time commitment was the most prevalent theme with approximately half of the participants identifying this as a concern. Participants indicated “time constraints,” “scheduling,” and concerns of “not being able to complete [the study].” The focal concerns were about time constraints and scheduling difficulties that might arise around the follow-up meetings. Nevertheless, the research team was very flexible and provided several options for the time and location of follow-up meetings. Issues of confidentiality and privacy were the second most common reservation identified by more than one-quarter of participants who reported reservations. For example, one participant expressed the following: “Worried it was just going to be about me.” Another would not have enrolled “If it had been funded by a pharm company.” The rest were concerned that they might not be a good candidate for the study and might negatively affect its findings; for example “Worried about my data screwing up the numbers.” Some of them felt that their injuries were too minor and that they would recover very quickly, while others stated that they might become too depressed and would not be able to communicate with the research staff as needed.

Discussion

In this study, we explored the reasons that adults with minor injury seeking ED care chose to participate and remain in a research study conducted over the course of one year. The most common reasons for study entry were that patients participated simply because they were asked to do so, they wanted to help other people with similar injuries, and they were interested in staying in contact with professionals to be monitored and discuss their concerns. Most of the participants reported no reservations. The reservations that were identified were related to time constraints, confidentiality and whether patients approached for consent believed they were well suited to fulfill the study objectives.

The results of this study are consistent with the existing literature. Campbell and Adams (2009) found that rape survivors decided to participate in community-based, face-to-face interviews intending to help other survivors and themselves during the recovery process and some expressed a general interest in supporting research or receiving monetary compensation. In a randomized controlled trial comparing two antidepressant drugs, patients with depression stated that the research was compelling and important, the team was very supportive, and they were motivated by altruism and the potential for personal benefit (Tallon et al., 2011). Patients with cystic fibrosis or epilepsy were aware of the voluntariness of their participation in clinical research, but at the same time, felt a duty to participate to give back to their providers while receiving practical and emotional support (Canvin & Jacoby, 2006; Lawton, Fox, Fox, & Kinmonth, 2003; Lowton, 2005). However, patients with cystic fibrosis and epilepsy differ in two important ways from the injured population. First, they have a chronic disease and likely have had ongoing experiences with providers and the health care system. They already have long-term or established relationships with providers who are often the gateway into research studies. On the other hand, injured patients presenting to an ED may have had little experience with this clinical setting and are
typically meeting providers for the first time. Second, patients with chronic diseases have a longer period of time to adjust to their condition whereas injured patients are experiencing an acute event and might have a higher potential for emotional burden and inability to focus on anything other than their injury.

There are challenges to enroll research participants in acute care settings that can affect decisions to participate (Willis et al., 2011). For instance there is a concern about enrolling acutely injured patients in research studies because they are vulnerable to additional stress (Newman et al., 2006) and their decision-making capacities can be impaired due to their injury. This is a significant concern even in minor injury since there is clear evidence of the limited association between severity of physical injury and psychological distress (Alarcon et al., 2012), indicating that patients can have significant distress even after minor injury. Yet our findings show that injured patients can be recruited into research studies in acute settings and that their participation is commonly associated with positive experiences.

The majority of patients indicated they enrolled because they were ‘asked’; hence researchers should not rule out emergent settings for identifying potential research participants. Nevertheless, researchers planning to recruit injured adults should consider the timing and approach of when to ‘ask’. In our study, we successfully enrolled injured patients in the ED because we waited until medical stability was established and we used a sequenced approach to enrollment: first asking only for verbal permission for release of information to the research team and second by contacting patients (either in hospital or at home) for a full informed consent. Indeed, the participant who verbally consented to have his contact information released to the research team but indicated he was not “paying attention” confirms the value of not obtaining full consent in the ED setting and reinforces the importance of ongoing and meaningful consent to ensure participants are fully informed and freely consenting (Richmond & Ulrich, 2013).

Participants indicate the importance of a supportive research team that is willing to accommodate their meeting preferences. Several studies have indicated that offering flexible and convenient options to meet with the research team enhances the participants’ experience and retention (Luschin, Habersack, & Gerlich, 2012; Mein et al., 2012; Tallon et al., 2011; Theadom et al., 2014). One participant indicated he participated and remained in the study because study staff was so effective in “tracking me down.” Although this response could be interpreted negatively as ‘pestering’ research participants, longitudinal studies require tenacity in reaching out to participants to maximize retention. This response highlights a fine ethical line to which researchers must attend; our study staff were counseled to be respectful but tenacious in follow-up contacts unless participants indicated their intent to withdraw from the study. This is particularly important when working with urban, injured participants who may have unstable housing and frequent geographic moves. In the parent study, several participants were homeless and moved from shelter to shelter over the course of the year.

Retention is critical in conducting longitudinal studies. Our findings indicate that a substantial subset (18%) stated that they gained personal benefits from participating in the research study, despite the fact that the parent study was not an intervention study. This is consistent with the extant literature showing that participants remaining in longitudinal
studies indicated that their commitment gave them the right to ask for professional guidance and gave them access to experts and regular medical examinations (Lawton et al., 2003; Mein et al., 2012). Ethically, nurse scientists need to be exquisitely mindful of the tendency of patients to mistakenly perceive research as clinical care, even in the face of a fully informed consent.

Findings should be interpreted within the context of study limitations. It is possible that patients who declined to have their contact information released to the research team or those who subsequently refused consent to enter the study would provide differing views about research participation after an acute injury. Despite the high retention rate (90%), results might have differed from participants lost to follow-up. The interview was conducted at the final data collection point and does not reflect potential temporal variations in perceptions of research participation. Whereas there is a continuum of severity of physical injury, findings may differ in more severely injured patients. The parent study included in-depth data collection involving psychiatric, functional status and quality of life assessments and because of participant burden concerns, we chose to use only a few questions requiring short responses. Also, we did not have permission to tape the interviews in the initial study protocol so there might have been missing details in some of the answers. Nonetheless, these findings provide insight into the perspectives of acutely injured research participants and serve as an important foundation for future studies.

Conclusion

Patients seeking ED care for minor injuries agree to participate in clinical research for diverse reasons, including the fact that they were approached to participate, their desire to help others and help advance the science, the potential for personal benefit, financial reasons, curiosity, and their value of research. Our study confirms that acutely injured patients can be successfully recruited in acute care settings and retained in clinical research studies, and their participation is commonly associated with good experiences. Our findings illuminate patient-identified priorities for this participation that need to be considered when designing study protocols. By incorporating the perspectives of our research participants, nurse scientists can more sensitively design research studies to recruit a diverse patient population, retain participants in longitudinal research studies, and optimize their experiences. Effective and sensitive recruitment and retention strategies are essential in building nursing knowledge to improve the care of injured patients.

Acknowledgement

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**Clinical Relevance**

Understanding perceptions of participants’ experiences of being in a research study after acute injury can guide researchers to improve future study protocols and recruitment strategies in order to optimize participants’ experiences. Recruitment and retention into clinical research studies is essential to build nursing science to enhance the recovery of injured individuals.
Clinical Resources

Table 1
Reasons for Participation in Clinical Research after Minor Physical Injury

<table>
<thead>
<tr>
<th>Themes</th>
<th>Subthemes</th>
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<tbody>
<tr>
<td>1. Being Asked</td>
<td>– Recruiter’s approach</td>
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<td></td>
<td>– Setting and circumstances</td>
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<tr>
<td>2. Altruism</td>
<td>– Helping other injured individuals</td>
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<td></td>
<td>– Contributing to knowledge development</td>
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<tr>
<td>3. Potential for Personal Benefit</td>
<td>– Sharing concerns</td>
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<td>– Practicing self-reflection</td>
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<td>– Being regularly monitored</td>
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<td>4. Financial Gain</td>
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<td>5. Curiosity</td>
<td>– Interest in the study</td>
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<tr>
<td>6. Valuing and/or knowledge of Research</td>
<td>– Personal experience with being part of a research study/team</td>
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