



Published in final edited form as:

J Racial Ethn Health Disparities. 2016 December ; 3(4): 724–730. doi:10.1007/s40615-015-0191-y.

Seriously injured urban black men’s perceptions of clinical research participation

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Abstract

Purpose—Black men are uniquely vulnerable in American society and our health care system: they bear a disproportionate burden of injury, yet are underrepresented in clinical research. This study aimed to explore the reasons why urban Black men with serious injuries chose to participate in clinical research and their concerns about research participation.

Methods—This qualitative study was conducted within the context of a larger study focused on psychological effects of serious injury in urban Black men. 83 Black men with serious injuries were recruited while hospitalized in an urban trauma center. Informed consent was obtained. Semi-structured interviews were conducted in participants’ homes three months after discharge from the hospital, and were audiotaped, transcribed, and de-identified. Thematic content analysis was used to identify themes about perceptions of participating in clinical research.

Results—The mean age of our sample was 38.2 years, and the mean injury severity score was 10.7 (SD 9.6). The majority (53.2%) of injuries was due to interpersonal violence and 46.8% were due to unintentional mechanisms. Eight reasons for research participation emerged from the data: human connection, altruism/community, self-improvement, compensation, gaining knowledge, curiosity/interest, low risk, and reciprocity.

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Ethical Approval, Statement on Human Rights and the Welfare of Animals All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards

Compliance with Ethical Standards:

This article does not contain any studies with animals performed by any of the authors. Informed consent was obtained from all individual participants included in the study.

Conflict of Interest: Author Bruce, Author Ulrich, Author Kassam-Adams, and Author Richmond declare that they have no conflict of interest

Contributors All authors contributed substantially to the article, including the conception and design of the study, analysis and interpretation of the data, drafting and revision of the article, and providing final approval for it to be published.

Compliance with Ethical Standards and Ethics approval Informed Consent obtained for all participants. Study has been approved by approved by institutional review boards of the Hospital of the University of Pennsylvania and have been performed in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

Competing interests: None.

Provenance and peer review Not commissioned; externally peer reviewed.

Conclusions—A major finding was that injured urban Black men participated in clinical research for the opportunity for human and therapeutic connection. Despite some expressions of mistrust, participants were willing to participate for altruistic reasons rooted in community priorities, and as part of their recovery process post-injury.

Keywords

Trauma; Injuries; Qualitative research; Research participation; Vulnerable populations

MeSH

Psychological; Crime Victims; Domestic Violence; Emergency Service; Hospital; Humans; Male; Mental Healing; Psychological; Patient Care Team; Psychotherapy; Group; Recurrence; Social Work; Psychiatric; Stress Disorders; Post-Traumatic; Urban Population; Violence; Wounds and Injuries; Young Adult

INTRODUCTION

Health problems are unequally distributed across race and class [1]. This is especially evident with the burden of injury in the United States. Injured urban Black men from predominately low-income neighborhoods, for example, epitomize ongoing health care disparities; unfortunately, they bear a disproportionate burden of traumatic injury in terms of mortality [1, 2], years of life-expectancy loss [3–5], and psychological sequelae that are often unrecognized and untreated [6]. Although injury is an acute event, it can be an entrée into chronic health problems and disability that are endemic in urban America. Indeed, the risk of sustaining a recurrent traumatic injury is 40% and being Black is an independent risk factor for injury recidivism [7,8]. The risk of violence-related arrest in patients hospitalized for a firearm-related injury is significantly higher compared to a non-injury-related index hospitalization [9]. Injury and its sequelae also impact the families and communities of these injured men. Developing a sound knowledge base on prevention of injury and strategies to improve outcomes and reduce recidivism from injury requires participation of vulnerable populations in clinical research.

Clinical research is essential for developing new knowledge that will benefit the care and treatment of all people, contributing to the generalizability of information as well as equity in health care delivery. Despite twenty years since the NIH Revitalization Act that passed in 1993, and a series of initiatives urging representation of women and minority patients in NIH-sponsored research, minority populations (particularly Black men), remain underrepresented in clinical research. Evelyn et al. found that while racial and ethnic minority groups represent around 30% of the total population, they made up less than 18% of FDA clinical trial participants over a 5-year period [10]. The Agency for Healthcare Research and Quality in 2011 indicated that health-care quality is suboptimal for minority and low-income groups and that urgent attention is needed in particular for residents of inner-city areas [11]. An important way to improve quality of care for all groups is to ensure all are fully represented in research studies that are so central to the improvement of prevention, treatment, and recovery from illness and injury.

Barriers to the participation of people of ethnic and racial minorities in research studies are significant. Elements of study design [12], lack of culturally or linguistically competent research staff, low health literacy, and logistical issues such as obtaining childcare, transportation, and competing demands of work schedules have all been cited [13, 12, 14]. But mistrust of the health care system and health research in general seems to be the most considerable factor of concern. In addition, racism, both at the institutional and interpersonal level, has been identified as a factor alienating people from the health care system and from health research. While the extent to which incidents of research misconduct such as the Tuskegee Syphilis Public Health Study influence recent generations' underrepresentation in health research is debated [15, 16], it has been well established that ongoing health disparities, lack of access to health care, and negative interactions with health care providers affect participation rates [13]. This study builds on the theoretical work of Ulrich and colleagues to suggest that research participation can be perceived as beneficial or burdensome based on several domains: psychological, physical, societal, economic, and familial [17]. The purpose of this study was to capitalize on an ongoing cohort follow-up study of seriously-injured urban Black men to better understand the reasons they chose to participate in a clinical research study and to ascertain their concerns about participation.

METHODS

This study was embedded in a larger primary study focused on the psychological effects of injuries among urban Black men. The parent study included both quantitative and qualitative data (i.e. demographics and injury characteristics, questionnaires about risk and protective factors contributing to injury outcomes, collection of geographical data, and psychological symptom severity interviews). Our sample was drawn from this larger study, which consecutively recruited hospitalized Black men with serious injuries in an urban trauma center in the northeastern U.S. Entry criteria for the larger study (and thus for this study) were: Black men admitted to urban trauma center with a diagnosis of injury (ICD-9-CM codes 800–995), who were 18 years old, English-speaking, oriented (Glasgow Coma Scale of 15) at time of study entry, provided informed consent and resided in the greater Philadelphia metropolitan area. Men were excluded if they had pre-existing mental status dysfunction or CNS injury prohibiting consent and ability to participate in interviews, had an active psychotic disorder, or were currently receiving treatment for depression or PTSD.

In the IRB-approved study protocol, all participants provided written informed consent. Standard demographic and injury-related data were collected during the intake interview, which took place in the hospital. Injury mechanism and injury severity scores were obtained from the hospital's trauma registry. Mechanisms were determined using standardized definitions (e.g. motor vehicle crash, fall, assault, pedestrian, bicycle) [18]. The Injury Severity Score (ISS) ranges from 1 (least severe) to 75 (most severe), providing one numerical score that compares multiple injuries across body systems [19, 20].

Participants were interviewed in their homes three months post-discharge as part of a follow-up visit for the larger study. In this interview, participants were asked to reflect on previous experiences with research, why they chose to enter the study, their perceptions about participation and their willingness to participate in future studies. Consistent with the

qualitative paradigm, questions were broad to allow exploration of issues raised by participants in more depth. The interview guide (presented in Table 1) was modified over the course of the study, based on concurrent data analysis, in order to most fully discover and uncover factors that affect willingness to participate in research studies. At the completion of the interview, participants received a gift card valued at \$50. Data were collected between December 2013 and December 2014.

We summarized sample characteristics using descriptive statistics that include means (with SD) for continuous variables and frequencies for discrete variables. Semi-structured interviews were audiotaped and transcribed verbatim with names and other identifying information removed. Content analysis was used to identify the major and recurrent themes about participants' perceptions of research participation. To maintain scientific rigor, co-authors reviewed participants' responses, validated the themes that emerged and reached consensus on the thematic labels. Data were sorted and managed using NVivo, a data integration and analysis software program for qualitative data. A text search query was used to identify frequently occurring words (presented in Table 2), and interview transcripts were read and reread, until recurring patterns were identified from the data. Data were coded in NVivo with initial descriptive codes. The process involved determining what words meant within the context of the question/response as well as the broader consideration of the entire interview for the participant. After all interviews were coded, patterns were re-examined. This process of developing themes followed the qualitative approach outlined by Streubert and Carpenter [21].

We subsequently examined the way men talked about their reasons for participating in research using the attributes of intentionality (intentional vs. unintentional injury) and age. In our sample of 83 men, the majority (62%) of intentional injuries occurred to men 30 years of age and the majority (62%) of unintentional injuries occurred to men >30 years of age. Thus we decided to examine the way in which men talked about their reasons for research participation according to the both attributes.

RESULTS

The sample consisted of 83 seriously injured Black men with a mean age of 38.2 years. The mean Injury Severity Score was 10.7. The most common mechanism of injury was gunshot wounds (32.5%), followed by falls (14.5%) and other types of trauma (see Table 3). Overall, more than half (53.2%) of the injuries were due to interpersonal violence.

Eight themes emerged as to why men chose to participate in the study: human connection, altruism/community values, self-improvement, compensation, gaining knowledge, curiosity/interest, low risk, and reciprocity. The eight themes are presented in Table 4 and ranked by the number of sources (participants who contributed to each theme) and number of references (frequency of responses falling within each theme). Representative quotes are presented to illuminate each theme.

We focus the narrative below to highlight the dominant and most novel theme of human connection that emerged in this study. Human connection was a noteworthy theme in this

study, and an important component of the post-injury recovery process. Several participants stated that being in the study allowed them to talk about the experience of being injured and how it affected them, with someone who would listen. It afforded them an opportunity to express the emotions that they ‘held inside’. When asked why he chose to participate in the study, one patient-participant responded in this way:

“For somebody to talk to. Express my feelings. I usually keep everything bottled in. Actually I needed somebody to talk to, somebody I can trust...”

Processing the injury, with an opportunity for human connection with health care staff, was identified as very important, but lacking for patient-participants. The interviews gave patient-participants an opportunity to express the importance of their physical and emotional needs following a serious trauma. As noted in the three quotes below, patient-participants perceived that participation in the study provided means for processing their injury in ways they hadn’t been able to with the health care staff prior.

“Because you ask me real questions that I never had asked before. So I could tell you something. I never talked to nobody about my problems...like I wouldn’t tell nobody none of this stuff here... I need to talk to someone and get it out. And that really helps it out. Thank you. Thank you.”

“Y’all gave me an opportunity to actually have somebody to talk to...when y’all came in it was kind of great, I wasn’t able to talk to the nurses ‘cause they always wanna go help other people, so when y’all came in it was great for me to have someone to talk to.”

“It was a...good experience for somebody to ask you like how you feel, so they like, *know* [emphasis participant’s] what’s going on, instead of everybody guessing and saying oh maybe he’s ok, he’s alright, and he’s not, it’s good that they find out, ask questions, to see everything, to see where you at, mentally, physically...”

The study participants consistently expressed appreciation just for being acknowledged and listened to. Experiencing someone’s concern for their holistic health and well-being was a key incentive to participating in this study.

The data were explored to examine in a more nuanced manner to see if patient attributes affected the way in which men discussed their perspectives of participating in research. All men expressed a need to discuss and process their injury experiences across mechanism of injury, which related a need for human connection. However, by age, we found that the younger cohort (< 30 years) spoke more about self-improvement as a facilitator than the older cohort. The younger participants discussed wanting to heal and grow following these serious traumatic injuries, and “get stronger”, “become better”, and “grow from the experience”. Key to this group was “healing, both mentally and physically.”

DISCUSSION

To our knowledge, this is the first study to examine perceptions of research participation by urban Black men with serious injuries, a uniquely vulnerable population in our health care system and society. Our study highlights several key considerations that warrant discussion.

First, urban Black men with serious injuries participated in our research for human connection; second, to help other injured Black men or help their community was also particularly important; and third, the role of financial compensation in research requires continuing evaluation with respect to vulnerable populations.

We found that Black men are willing to participate in clinical research despite some expressions of mistrust. Our findings support those of Wendler and colleagues, in that Black men do express interest in participating in clinical research once invited and given appropriate remuneration and provisions for logistical issues [16]. Our participants shared several other common facilitators for research participation consistent with the literature [17], including low-risk, altruism [12], reciprocity, self-improvement, and gaining knowledge. Our findings suggest that participants want knowledge about their injury and recovery process, which has implications for patient education during hospitalization and discharge.

Generally, all patients want human connection and caring attitudes when they are ill, injured, and in a precarious state. In fact, in a recent study by Auriemma et al., the importance of caring was identified as a significant qualitative theme for patients and their family members who spent time in the medical intensive care unit [22]. There is a distinction, however, between clinical care and clinical research. Empirical bioethics research suggests that many patient-participants suffer from a therapeutic misconception believing they will personally benefit from their research participation [23]. The importance of receiving therapeutic care and a human connection for urban Black men by participating in our study opens a broader dialogue on the intersection between clinical care and clinical research and the emotional or psychological benefit that research participation provides. Patient-participants reported limited opportunities for psychosocial support networks in the health care system and in their daily experiences. These findings possibly indicate that urban Black men experience dehumanization in the health care systems based on injury cause (e.g. violence vs. accident), or on the race or cultural background of the patient (or health care staff). These findings may also reflect limited opportunities for humanistic interactions with health care staff due to the fast pace of busy acute care environments. Whatever the cause(s) for limited personal interaction, this is of concern given the significant consequences of dehumanization [24]. Further research is needed to explore this finding in more depth, particularly the underlying reasons for patient-participants' perceived lack of human connection and to determine the degree to which emotional and psychological needs of this patient population are not being met by the health care system, and strategies to improve holistic care.

Benefit is an important element of research participation, whether it is physical, psychological, financial, familial, or social [17]. Our findings are consistent with studies in diverse populations that have found that the majority of participants view research as personally beneficial [25, 26, 27]. Studies examining research participation among adult survivors of traumatic injuries also reinforce our findings [25, 26, 28]. Trauma survivors may perceive research as personally beneficial; it may offer an opportunity to share their story [29] gain new insights about their experiences [28], access resources and scientific knowledge, and help others [26]. Participation in research may provide a unique setting for injured patients to discuss their experiences with the option of referrals.

Finally, several patient-participants spoke to the value of compensation for research participation because it provided for their basic necessities of life, such as food. Research compensation is a measure of respect for participants' time and effort but it also needs to be balanced with protection of those who are vulnerable. Patient-participants in our study received an initial intake amount of \$30 followed by \$50 for a follow-up interview. While this amount is nominal and follows the wage-payment model of research compensation [30], more research is needed to better understand from vulnerable patient-participants themselves how they might rank or weigh compensation compared to other factors in a larger study.

This study demonstrates that continued work is needed to create patient-centered care environments where patients feel that their physical as well as their psychological and emotional needs can be met, especially following serious traumatic injury. An important concern of injured urban Black men is to have an opportunity to discuss their experiences with someone who will listen. This preliminary finding may imply an unmet emotional need of patients who have sustained violent injuries. The extent to which the cause of injury factors into participants' health care experiences and emotional and psychological needs during recovery deserves greater study. Findings, however, should be considered within the context of limitations of this study. Because only men who agreed to participate in this study were interviewed, the concerns of non-participants are not reflected in our data. Nevertheless, this concern is mitigated to some extent by the very high participation rate: nearly three quarters (72%) of eligible injured men consented to enroll in the study.

Identification of the perceived risks and benefits to research participation may be used by researchers to design future studies that overcome commonly cited barriers such as lack of exposure, information, or access to trials [31] for injured urban Black men in their home communities. Based on prior experiences of time constraints and scheduling issues in a previous sample that included men and women of different races and ethnicities with minor injuries as research participants [32], in this study research staff met with patient-participants initially at their hospital bedside and then in their homes for follow up assessment. Building trust with research participants within communities where research is often feared—through their personal experiences of injury—is a way to bridge the challenging issues that urban Black men encounter in our society on a daily basis.

Acknowledgments

Research reported in this publication was supported by the National Institute of Nursing Research of the National Institutes of Health under Award Number R01NR013503 to Dr. Richmond and the National Institute of Nursing Research under award number R01NR013503-02S1 for Ms. Bruce. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health. We thank the Hillman Scholars Program in Nursing Innovation for funding support, and thank Jessica Webster and Andrew Robinson for assistance with data collection and analysis.

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What is already known on the subject

- Participation of people of color in health research is low.
- Black men have lower rates of participation in health research due to multiple factors, including mistrust of health research, perceived systemic and interpersonal racism, lack of access to and information about health research, logistical issues, and lack of culturally sensitive research methods.

What this study adds

- Despite some expressions of mistrust of research and the health system, Black men chose to participate in clinical research for reasons rooted in altruism and community priorities, and for opportunities for human connection.
- Given invitation and opportunity, and provisions for logistics, Black men were willing to participate in health research.
- Participating in this study was perceived as an opportunity for human connection and a means to address emotional and psychological responses to severe traumatic injury.

Table 1

Semi-Structured Interview Guide

Initial Interview Guide	
1	Why did you decide to join the study?
2	Why did you stay in the study?
3	Do you have any concerns about participating in research?
4	Is there anything else you want to tell us about being in this study?

Modified Interview Guide based on concurrent data analysis	
1	Why did you decide to join this study?
2	Have you ever participated in a research study before?
3	What do you think your family/friends think about you participating in research studies?
4	This study only involves talking about your experiences since being injured. Have you ever participated in a study that drew your blood, tested medicines, or some other type of medical research? Would you consider participating in a study like that?
5	Would you be willing to participate in a future research study like this one?
6	What did you like most about doing this study?

Table 2

Words used to generate themes in NVivo.

Human Connection	bottled up, let it out, talk to someone, tell my story, share my story, share my experiences, express myself, good to tell someone about it, let you know how I felt
Altruism/Community	to help, my community [family, other victims, other people, others in this situation, other crime victims, others who have been through this], pass it forward, for future research
Self-improvement	heal, recovery, improve myself, get better, change, grow
Gaining knowledge	understand [learn, discover] about injuries [wounds, brains], how do wounds heal, how do brains recover, learn about research studies
Compensation	gift card, groceries, money, assistance, financial
Reciprocity	because you were nice [kind, pleasant] to me, because you [the study, the research] helped me
Low risk	no harm in it, couldn't hurt, I wouldn't do [needles, medicines, drugs, procedures, tests, experiments] but I would do this again [answer questions, talk to researcher, participate in a study]

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Table 3

Sample demographics (n=83)

Variable	Mean(SD)	% (n)
Age	38.2(16.2)	
30 years		50.6% (42)
>30 years		49.4% (41)
Injury Severity Score	10.7(9.6)	
Mechanism of Injury		
-Gunshot wound		32.5% (27)
-Fall		14.5% (12)
-Blunt Assault		13.2% (11)
-Motor vehicle crash		10.8% (9)
-Not reported		10.8% (9)
-Stabbing		8.4% (7)
-Motorcycle crash		4.8% (4)
-Pedestrian		4.8% (4)
Intent		
-Unintentional		46.8%(38)
-Intentional		53.2%(45)

Table 4

Themes with representative quotes.

Data Themes	# of Sources (# of References)	Representative Quotes
Human Connection	27(30)	<p>“Actually have somebody care about me, is, you know, it’s good.”</p> <p>“That y’all listened to me...Y’all like helped me, a lot. Because instead of me keeping how I feel inside, I’m actually venting right now, so it’s helping me.”</p> <p>“Because I believe that there are a lot of nurses that treat the patients unfairly... it’s their job to cater to the patients, you know, and if they didn’t want to cater to the patients, they shouldn’t have never been nurses in the first place....”</p> <p>“It was very satisfying with just some of the questions being asked. So I really enjoyed the study...it was soothing to be ask—being asked some of the things that, you know, being asked.”</p>
Altruism/Community Values	26(28)	<p>“I figured that the study could help other victims of crimes if I put my thoughts into it. And I just want to help other people out, make sure they know that they ain’t the only ones going through it.”</p> <p>“Being able to help people. So if I can do that, I guess, through my little situation, I guess, I’m doing some kind of justice for somebody somewhere.”</p> <p>“Any bit of information that can help the next person would be good...It would be beneficial for me, and for medicine, you know, I’m all for that.”</p>
Self-improvement	14(13)	<p>“Because I figured it would help me release some of my stress and energy if I talk to you about it...So I thought this was gonna help me. I wanted therapy, and help me know, help me figure out, like, what can I do after I got stabbed.”</p> <p>“Um, I think it was good for me, because, you know, it’s...sometimes you get better answers when the questions are being asked by someone else...”</p> <p>“Because, um, it relieve a little strain, a little anger.”</p>
Compensation	9(8)	<p>“I guess I needed the finances and knew I was gonna need some type of help. You know, and every little bit counts.”</p> <p>“Partly, no lie, because I wasn’t going to be working [laughs] and this is just, money, so that’s, that’s awesome, it’s not a lot but I’ll go get groceries.”</p> <p>“they came and helped me out with a gift card, it made me feel even better! I was so broke, I needed that, I needed that, it got me some food in the house, and everything! I said oh, thank you! That was a blessing.”</p>
Gaining knowledge	7(6)	<p>“Because it would help me gain some knowledge about my injury...”</p> <p>“Um, decide to join to get a better uh, understanding as far as like with accidents so they know like how...how the person feels after...like how does he get better.”</p> <p>“Just to see if I could get some help on learning about head injuries and stuff like that”</p>
Curiosity/Interest	7(6)	<p>“When you asked me, it seemed like an interesting study to participate in. So why not.”</p> <p>“I was bored [laid up, nothing to do, nothing else to keep my mind occupied, I was just curious [about studies, research], it was interesting [fascinating, cool]”</p>
Low Risk	6(5)	<p>“No. I mean, well, certain studies, you know, I’m kinda scared of them myself. You know, it’s like, the ones where they stick and poke you, and flip you over and turn you upside down, and swing you around, you know, that kind of study. Oh no, uh uh. I can’t do that. That’s not me.”</p> <p>“No um, I would be willing to participate in any type of research study that prob—most likely did not involve me having to take medications or something.”</p> <p>“Well, I knew you, and...I felt safe with you.”</p>
Reciprocity	5(4)	<p>“Because you helped me so much the first time. It was very thoughtful.”</p> <p>“And you were nice [laughs]. You was uh, pleasant.”</p>