Journal of Psychiatric Research 56 (2014) 90–97

Contents lists available at ScienceDirect

Journal of Psychiatric Research

journal homepage: www.elsevier.com/locate/psychires

Giving voice to study volunteers: Comparing views of mentally ill, physically ill, and healthy protocol participants on ethical aspects of clinical research

Laura Weiss Roberts*, Jane Paik Kim

Department of Psychiatry and Behavioral Sciences, Stanford University School of Medicine, USA

ARTICLE INFO

Article history:
Received 20 January 2014
Received in revised form
6 May 2014
Accepted 9 May 2014

Keywords:
Ethics in psychiatric research
Clinical research participation
Vulnerable populations
Burden of disease

ABSTRACT

Motivation: Ethical controversy surrounds clinical research involving seriously ill participants. While many stakeholders have opinions, the extent to which protocol volunteers themselves see human research as ethically acceptable has not been documented. To address this gap of knowledge, authors sought to assess views of healthy and ill clinical research volunteers regarding the ethical acceptability of human studies involving individuals who are ill or are potentially vulnerable.

Methods: Surveys and semi-structured interviews were used to query clinical research protocol participants and a comparison group of healthy individuals. A total of 179 respondents participated in this study: 150 in protocols (60 mentally ill, 43 physically ill, and 47 healthy clinical research protocol participants) and 29 healthy individuals not enrolled in protocols. Main outcome measures included responses regarding ethical acceptability of clinical research when it presents significant burdens and risks, involves people with serious mental and physical illness, or enrolls people with other potential vulnerabilities in the research situation.

Results: Respondents expressed decreasing levels of acceptance of participation in research that posed burdens of increasing severity. Participation in protocols with possibly life-threatening consequences was perceived as least acceptable (mean = 1.82, sd = 1.29). Research on serious illnesses, including HIV, cancer, schizophrenia, depression, and post-traumatic stress disorder, was seen as ethically acceptable across respondent groups (range of means = [4.0, 4.7]). Mentally ill volunteers expressed levels of ethical acceptability for physical illness research and mental illness research as acceptable and similar, while physically ill volunteers expressed greater ethical acceptability for physical illness research than for mental illness research. Mentally ill, physically ill, and healthy participants expressed neutral to favorable perspectives regarding the ethical acceptability of clinical research participation by potentially vulnerable subpopulations (difference in acceptability perceived by mentally ill - healthy = −0.04, CI [−0.46, 0.39]; physically ill − healthy = −0.13, CI [−0.62, −.36]).

Conclusions: Clinical research volunteers and healthy clinical research-"naïve" individuals view studies involving ill people as ethically acceptable, and their responses reflect concern regarding research that poses considerable burdens and risks and research involving vulnerable subpopulations. Physically ill research volunteers may be more willing to see burdensome and risky research as acceptable. Mentally ill research volunteers and healthy individuals expressed similar perspectives in this study, helping to dispel a misconception that those with mental illness should be presumed to hold disparate views.

1. Introduction

Clinical research seeks to develop new knowledge to better understand and to formulate better treatments for serious illnesses that give rise to great personal suffering and represent a burden to the public health. Many thousands of clinical research protocols are underway throughout the world (U.S. National Institutes of Health, 2011). These protocols may produce valuable data regarding new treatments and inspire hope for a better future, and yet their conduct is ethically sensitive because they necessarily involve people who live with significant symptoms or deficits, who may feel desperate, and who may have few options for adequate care

* Corresponding author.
E-mail address: RobertsL@stanford.edu (L.W. Roberts).

http://dx.doi.org/10.1016/j.jpsychires.2014.05.007
0022-3956/

Table 1
Study population characteristics.

	Mentally ill In protocol	Physically ill In protocol	Healthy In protocol	Healthy Not in protocol	*P*-value
	$N = 60$	$N = 43$	$N = 47$	$N = 29$	
Age (yrs)[a]					
18–35	20% (12)	23% (10)	36% (17)	59% (17)	<0.001
36–50	62% (37)	35% (15)	19% (9)	28% (8)	
51–60	13% (8)	28% (12)	19% (9)	3% (1)	
61+	2% (1)	14% (6)	26% (12)	10% (3)	
Sex					
Women	67% (40)	56% (24)	45% (19)	55% (16)	0.16
Men	33% (20)	44% (19)	55% (26)	45% (13)	
Marital Status[b]					
Married (or living w/partner)	38% (23)	44% (19)	68% (32)	45% (13)	0.07
Single	60% (36)	56% (24)	32% (15)	55% (16)	
Race[b]					
Hispanic	25% (15)	47% (20)	19% (9)	31% (9)	0.05
Other	23% (14)	9% (4)	9% (4)	17% (5)	
White	50% (30)	44% (19)	72% (34)	52% (15)	
Education level[b]					
Less than HS	15% (9)	12% (5)	0% (0)	0% (0)	0.01
HS	25% (15)	23% (10)	13% (6)	10% (3)	
Some college/vocational training	27% (16)	40% (17)	26% (12)	48% (14)	
College degree	22% (13)	19% (8)	43% (20)	31% (9)	
Graduate degree	10% (6)	7% (3)	19% (9)	10% (3)	
Missing	2% (1)	0% (0)	0% (0)	0% (0)	
Disease type					
Cancer	–	28% (12)	–	–	[c]
Diabetes	–	33% (14)	–	–	
HIV	–	40% (17)	–	–	
Anxiety mood disorder	42% (25)	–	–	–	
Schizophrenia	58% (35)	–	–	–	
BSI global[c]	1.14 (0.86)	0.64 (0.70)	0.28 (0.29)	0.38[α] (0.38)	<0.001
Social Support overall	63.15[a] (23.04)	77.98 (15.41)	82.27[α] (15.69)	76.36 (21.91)	<0.001
SF-36: Current health subscale[c]	53.12 (22.11)	49.64 (25.65)	76.81 (19.26)	72.5 (26.59)	<0.001
MHLOC					
Internal Health Locus[c]	25.57 (5.97)	26.36 (5.51)	25.84[α] (4.34)	25.89 (5.55)	0.78
Powerful Other Locus[c]	20.86 (7.11)	20.45 (6.62)	16.98[α] (5.05)	15.93 (6.12)	<0.001
Chance Locus[c]	19.43[b] (5.85)	17.38[γ] (6.47)	15.41[γ](4.16)	16.29[α] (4.83)	<0.01

[a] Missing observations (m) were excluded from analysis: Mentally ill in protocol $m = 2$.
[b] Mentally ill in protocol: $m = 1$.
[c] Mentally ill in protocol, Physically ill in protocol: $m = 4$ with exceptions $^{a}m = 7$ and $^{b}m = 6$; Healthy not in protocol: $m = 1$ with exceptions $^{α}m = 2^{γ}$ $m = 3$.

(Chen et al., 2003; Candilis et al., 2008; Coletti et al., 2003; Roberts, 2000; Brody et al., 2005). Moreover, many worry that people with certain illnesses such as schizophrenia or HIV may never be able to participate fully in the clinical research process without the potential for exploitation, due to stigma and the nature of these diseases (Shamoo, 1997). Indeed, concerns have persisted for decades regarding the ethical acceptability of including people with different illnesses or have characteristics that may make them especially vulnerable in the context of human studies (Dunn and Misra, 2009; Grisso and Appelbaum, 1995; Jeste et al., 2009).

Amidst the controversy and concerns surrounding clinical research, very little is known about the perspectives held by the very individuals who are personally affected with illness and whose participation is essential to the conduct of clinical research – namely, people living with serious illness and healthy people who are willing to volunteer for human studies. Learning the distinct perspectives of ill individuals who may be recruited into research protocols is vital to fulfilling the fundamental ethical principles of respect for persons, beneficence, and justice, upon which human research is predicated (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979, Buchanan et al., 2007; Wallerstein and Duran, 2010; Cargo and Mercer, 2008; Roberts et al., 2006a, 2006b, 2004; Roberts, 2006) Understanding these perspectives is important for investigators who are entrusted with the conduct of human studies as well as for policy makers who establish the overarching societal framework of safeguards for scientific experimentation. Nevertheless, few data exist to help guide stakeholders in the research process regarding attitudes of seriously ill people who volunteer to participate in clinical research protocols.

To address this gap, the lead author with colleagues undertook a study to determine the attitudes of clinical research participants and to compare the perspectives expressed by participants with physical illness, with mental illness, and in good health. In this paper we sought to assess the ethical acceptability for human research as endorsed by clinical research participants, and to examine the degree to which perspectives expressed by seriously ill individuals differ from those of healthy individuals. Furthermore, we sought to explore the degree to which ill individuals express attitudes that were sensitive to the potential vulnerabilities of certain subpopulations that may emerge in the research situation (e.g., conditions and attributes) and their acceptance of participation in the context of protocol-related burdens ranging from mild severity to life-threatening danger. As a secondary exploratory aim, we explored whether and how the experience of being in a protocol may shape perspectives on clinical research.

2. Methods

2.1. Study population

Eligible study participants included volunteers in clinical protocols at the University of New Mexico School of Medicine with a concurrent primary diagnosis of schizophrenia, depression or