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Do Research Intermediaries Reduce Perceived Coercion to Enter Research Trials Among Criminally Involved Substance Abusers?

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Abstract

We examined the efficacy of including a research intermediary (RI) during the consent process in reducing participants' perceptions of coercion to enroll in a research study. Eighty-four drug court clients being recruited into an ongoing study were randomized to receive a standard informed consent process alone (standard condition) or with an RI (intermediary condition). Before obtaining consent, RIs met with clients individually to discuss remaining concerns. Findings provided preliminary evidence that RIs reduced client perceptions that their participation might influence how clinical and judicial staff view them. This suggests that using RIs may improve participant autonomy in clinical studies.

Keywords

Coercion; Autonomy; Research Ethics; Consent

Introduction

Numerous studies have documented unacceptably poor comprehension and recall of consent information among research volunteers. In fact, many research participants, including drug abusers, lack awareness of being in a study, fail to recall potential risks of the research, do not realize they have a right to withdraw from the study, and are unaware of what to do if they are harmed by participation. These deficiencies are likely to be magnified among drug abusers involved with the criminal justice system. Limited educational opportunities, prior head trauma, and co-morbid health problems are common in drug abusers and may reduce concentration and limit understanding during the informed consent process (Anderson & DuBois, 2007; Munro, Saxton, & Butters., 2000; Saxton, Munro, Butters, Schramke, & McNeil, 2000; Tapert & Brown, 2000; Victor, Adams, & Collins, 1989). Moreover, drug abusers involved in the criminal justice system may experience additional vulnerabilities including the potential for implicit or explicit coercion. These individuals may believe that their future liberty, livelihood, or reputation depend on cooperating with authorities.

The issue of whether consent is voluntary takes on particular significance for individuals involved with the criminal justice system. As criminal justice clients may be exposed to implicit and explicit threats of coercion, duress, deceit, and other kinds of overreaching that

may jeopardize the element of voluntariness. In particular, there is a substantial risk that, as a result of their current situation, they may become convinced, rightly or wrongly, that their future depends on cooperating with authorities. This source of vulnerability is very different from knowingness or competence, because even the most informed and capable individual may not be able to make a truly autonomous decision if he or she is exposed to a potentially coercive or compromising situation.

Despite the obvious importance of this central element of informed consent, relatively few studies have examined potential methods for decreasing coercion in research. McCrady and Bux (1999) surveyed investigators who were currently recruiting participants from settings designated as implicitly “coercible” (e.g., inpatient units, detoxification facilities, prisons). Investigators from over 90 studies were surveyed about the types of procedures they used to ensure that participants were free from coercion. The most commonly reported protections involved (1) contacting the participant’s primary clinician, (2) not recruiting the potential participant if the researcher was not convinced that he or she understood the research, (3) re-emphasizing the participant’s rights, (4) accentuating the language in the consent form regarding participants’ right to decline or withdraw from the study, and (5) not telling the individual about research payment incentives until after he or she had already consented to the study (McCrady & Bux, 1999). While most of these responses certainly seem practical and reasonable, it is clear from this list that, despite the recommendations of several federal agencies and Presidential Commissions, there are few strategies in use to reduce the influence of coercion or to promote the autonomy of human research subjects.

Several commentators have suggested that a third party -- variously described in the literature as a “neutral educator” (Benson, Roth, Appelbaum, Lidz, & Winslade, 1988), a “research intermediary” (Reiser & Knudson, 1993), a “consent auditor” (DeRenzo, 1994), or a “third-party facilitator” (Stiles, Poythress, Hall, Falkenbauch, & Williams, 2001) -- be involved in the consent process as a means of facilitating potential research participants’ *understanding* of consent information. Although these studies have generally examined the influence of a third-party intermediary in improving understanding, they have not specifically examined their effect on perceived coercion. While it is certainly possible that an intermediary might better assist in explaining relevant consent information to participants, no convincing rationale has been put forth to explain why such an intermediary would be expected to do a better job of explaining consent information than a trained research technician. On the other hand, these intermediaries might very well advocate on the behalf of participants, monitor research technicians’ behavior, and report transgressions and adverse events to the IRB or DSMB.

Several federally commissioned advisory panels recently issued formal recommendations in favor of including third-party intermediaries in the consent process. For instance, the Bioethics Interest Group (1998) issued an Expert Panel Report to NIH making the following recommendations regarding the consent process:

Depending on the complexity of information to present, this [informed consent] process may need repetition and discussion over several days. Involvement of the participants’ family, clinician, or a patient advocate may be useful to enhance comprehension and confidence that an informed decision is being made . . . The primary goal should not be simply to determine whether a subject is (or is not) to be labeled as “decisionally impaired,” but to help potential participants better understand the risks, benefits, purposes, and alternatives to proposed research. Family, friends, surrogates, and peers may all help in that function, as can patient advocates and certain other third parties at the IRB’s discretion [Bioethics Interest Group, 1997, p. 2, emphases added]

Similarly, the National Bioethics Advisory Committee (1998) concluded that it may be desirable for an independent party to meet with participants prior to their giving consent to discuss their reasons for participating in a study. Finally, the Declaration of Helsinki (World Medical Association, 1964) includes a provision stating that when treating physicians are conducting research studies, informed consent should be obtained by another physician who is completely independent of this relationship.

To our knowledge, only *two* studies have experimentally examined the effects of third-party intermediaries on the consent process. Benson et al. (1988) examined the use of a neutral educator in research involving patients with schizophrenia. In that study, a standard oral consent condition was compared to an enhanced videotape condition and to a neutral educator condition. The results indicated that both of the novel enhanced procedures improved patients' understanding of consent information over the standard condition; however, there were no differences between the two enhanced consent procedures. Stiles et al. (2001) assigned groups of individuals with depression, individuals with schizophrenia, and healthy control subjects to an informed consent process in which two factors were manipulated: (1) the use of a textual vs. a graphically enhanced consent form, and (2) the presence or absence of a third-party facilitator. Results indicated that *neither* the graphically enhanced consent form nor the presence of a third-party facilitator was associated with improved understanding or memory of consent information. As noted earlier, however, this study did not evaluate participants' perceptions of *coercion*, which may have been influenced by the presence of the third-party facilitator. To our knowledge, *no* study has evaluated the effects of third-party intermediaries on perceptions of voluntariness or coercion.

Methods

Participants and Procedures

Eighty-four participants being consented for an NIH funded study of adult drug court clients (host study) were randomly assigned to one of two conditions: (1) consent process as usual (control condition, $N = 45$), or (2) a consent process with a third-party research intermediary ($N = 39$). Rather than developing a "sham" study to test these interventions, we added the informed consent protocol into an on-going NIDA-funded study in which we were experimentally "matching" the frequency of participants' status hearings before the judge in drug court based on prior treatment and criminal involvement. The study received full approval by two institutional review boards, and all participants went through a detailed informed consent procedure and were given a copy of the signed informed consent document.

Approximately half of the individuals approached to participate in the parent study agreed to go through the informed consent procedure. All of these individuals subsequently consented to participate in the study, completed the baseline assessment, and returned for the two day post follow-up. Participants were 24 years old on average ($SD = 7.0$), predominantly male (75%), and Caucasian (63%) or African American (31%). Participants in the two groups did not differ significantly on any baseline demographic or status variables.

All study participants, regardless of the group to which they were assigned, received the research group's manualized, standard informed consent procedure. This standard procedure begins with the interviewer explaining the overall consent process to the client. The research technician then asks the client to read the consent form silently to him or herself as the interviewer reads it aloud (this avoids clients' experiencing embarrassment by having to admit difficulties with reading). The research technician also informs the client that he or she may stop them at any time to ask for clarification, and that they will also have time at

the end of the process to discuss the form and ask additional questions. The technician then proceeds to read and then paraphrase, according to a standard script, each section of the informed consent document. When the technician is finished, the client is given yet another opportunity to ask additional questions. Subsequently, the client is asked to paraphrase each section of the consent form him or herself. Errors are immediately corrected by the technician and this process continues until the client can correctly paraphrase each of the main sections of the consent document.

Conditions

Standard Consent Procedure – As Usual—Participants in the standard condition completed the informed consent procedure as usual with only our research interviewer present and completed all assessments (see Assessment Section below).

Research Intermediary – Experimental—Individuals assigned to the research intermediary condition also received the standard informed consent procedure and completed all assessments. Importantly, for clients assigned to this group the informed consent procedure was conducted in the presence of a third-party intermediary. At the start of the consent procedure, the research intermediary introduced him or herself to potential participants as an “independent observer,” explaining that he or she was *not an employee of the research team, the treatment program or the court*, and that their sole purpose for being present was to monitor the consent process and to ensure that the client understood his or her rights and the voluntariness of research participation, including the right to withdraw from the project at anytime without negative consequences.

Following the consent process, but before clients provided written informed consent, the intermediary met with them *individually* to discuss any additional issues or concerns that the clients might have. The intermediary provided the clients with a handout explaining the intermediary’s role and a business card listing his or her phone number and a schedule of times he or she would be available to speak further with the clients to answer questions and to receive reports about adverse events. Clients were told that if they wished to drop out of the study in the future, and they felt uncomfortable discussing this directly with research staff, the intermediary would communicate their desire to drop out of the study and would continue to monitor study procedures to ensure there was no retaliation against them.

The research intermediaries consisted of Psy.D. students at a local university. Importantly, the hiring and supervision of the research intermediaries was carried out by the university faculty, and not the investigator group. This ensured that they were *independent* of the research team and were not in a subordinate relationship to the PI or our research organization. The intermediaries were therefore paid employees of the university rather than of the investigator group. Personnel costs and materials related to their work were subcontracted to the university.

Assessments

Coercion Assessment Scale (CAS): After clients provided written consent, they completed a 7-item coercion assessment scale (CAS; Dugosh, Festinger, Croft, & Marlowe, 2010) immediately following the consent process. The items that comprise the CAS are presented in Table 1. Clients rate their level of agreement with item, and scale scores are calculated by summing individual responses for each item.

Consent Quiz: Because we routinely go through a form of corrected feedback for *all* clients prior to obtaining consent, a second baseline assessment for both the experimental and treatment as usual participants was conducted two-days later to examine recall of consent

information. At this assessment, *all* participants completed a comprehensive consent quiz, based on the Understanding Scale of the MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR, 2001).

The scale was tailored to assess 16 principal aspects of the host study's consent form including the purpose of the study, the procedures and assessments, remuneration, and human rights protections (e.g., confidentiality, recourse in the event of being harmed, whom to contact with additional questions or concerns). It was developed by translating each of the main elements of the consent form into a scorable question format. This modified version of the scale has been used in a number of previous studies as a measure of consent recall (e.g., Festinger, Ratanadilok, Marlowe, Dugosh, et al., 2007; Festinger, Marlowe, Croft, Dugosh, Arabia, & Benasutti, 2009). Consent quiz scores were calculated by summing the number of correct responses, and could range from 0 to 16. The 16-item questionnaire took an average of 12.5 minutes (SD = 2.6) to complete.

Data analyses—Chi square analyses were used to compare participants in the standard and intermediary groups on the rate of agreement with each coercion item. Independent sample t-tests were used to compare participants in the two groups on the total coercion scores and consent quiz scores.

Results

Consistent with our hypothesis (see Table 1) a significantly higher proportion of clients in the standard vs. the intermediary condition agreed that “it would look bad to their case manager if they did not participate” (16% vs. 3%, $p = .04$; $w = .22$). There was a similar trend for agreement on “the judge would like it if they participated” (58% vs. 38%, $p = .08$, $w = .19$). These findings provided preliminary support for the utility of research intermediaries in reducing participants' unfounded beliefs that their research participation will influence the way that clinical and judicial staff view them. Analysis of total scale scores revealed a trend ($t(76) = 1.83$, $p = .07$; $d = .42$) in which participants in the intermediary condition reported lower levels of coercion than participants in the standard condition. Finally, consistent with prior research findings (Stiles et al., 2001), the presence of the intermediary had no effect on consent recall.

Discussion

Findings demonstrated that the use of a third party intermediary moderately reduced levels of perceived coercion among a criminally involved substance using population. The presence of an RI resulted in reduced perceptions that their research participation would influence how they were viewed by clinical and judicial staff. Importantly, these perceptions are unfounded in this study as the court and counseling staff were kept naïve as to which clients accepted or refused study participation. The procedure's effectiveness within this population may suggest its utility in other vulnerable research populations who may experience perceptions of coercion to participate. For example, this procedure may be beneficial with hospitalized populations who may believe that the quality of their care is contingent upon their agreement to participate in proposed research protocols. Similarly, incarcerated individuals may believe that their future liberty, livelihood, or reputation depend on cooperating with requests to participate in research. The use of a neutral intermediary may significantly improve the autonomy of such individuals.

A number of theories have been offered to explain why third-party intermediaries might be expected to reduce perceptions of coercion. One such theory is that of “procedural justice.” In studies of involuntarily committed psychiatric patients, for instance, perceptions of

coercion have been found to be substantially reduced when patients believed they were being treated fairly, that caregivers were acting out of genuine concern for them, when they were treated respectfully and in good faith, and when they were afforded a chance to tell their side of the story (Lidz, Hoge, Gardner, Bennett, Monahan, Lulvey, et al., 1995; Monahan, Lidz, Hoge, Mulvey, Eisenberg, Roth, et al., 1999). This was true regardless of patients' demographic characteristics and how strongly opposed they were to entering the hospital in the first place. One of the principal components of procedural justice is having a "voice" in the decision; i.e., an opportunity to be heard and to have one's point of view considered. As applied to the consent process in research, this could suggest that the more a client perceives the process as being fair and just, and the more he or she is able to voice possible concerns about participation, the less likely they are to feel coerced. This could be a strong argument for including an independent intermediary in the informed consent process. Potential research participants may feel more open to talking with an independent advocate who is not directly involved in the research protocol and whose role it is to ensure fairness and openness in the consent process.

The presence of a third-party intermediary may also have an effect on the behavior of research technicians. Although research technicians are typically trained to obtain consent in a professional, standardized, and objective manner, they are not immune from, or necessarily aware of, subtle influences on their own behavior or on the behavior of participants. For instance, a desire to gain the approval of the Principal Investigator through higher consent rates could lead a technician, intentionally or unintentionally, to manipulate or place greater pressure on potential participants. The presence of a third party could serve to reduce these behavioral influences, or at least to monitor their occurrence.

This study has several limitations. First, clients met with the research intermediary *after* they had already received the informed consent information from the RA but prior to providing written consent. As a consequence, the effectiveness of the intermediary in reducing perceptions of coercion could not be evaluated among those people who had not already actively begun the consent process. Future studies should evaluate the effects of introducing the intermediary prior to meeting with research staff. Second, the intermediary in the study was rather passive in that clients were informed that they could call the intermediary with any questions or concerns that they may have. The use of a more active intermediary who contacted clients periodically to "check in" with them about their questions or concerns may have resulted in larger intermediary effects on perceptions of coercion and satisfaction. Third, we developed the coercion assessment scale for use in this study as, to our knowledge, there is no reliable and valid measure of the construct of coercion to participate in research. Further research is needed to validate the scale. Fourth, the findings only support the use of research intermediaries in a single population involved in a single study involving moderate risk. Future research should examine the utility of these interventions in other, potentially more vulnerable populations and in studies involving higher levels of risk. Finally, we did not evaluate the extent to which clients actually perceived the intermediary to be independent from the research staff. Future studies should evaluate whether such independence is perceived and how this perception may moderate the effects of the intervention.

The current study demonstrated moderate effects of the use of a research intermediary in reducing substance abusing criminal justice client's perceptions of coercion to participate in a research study. Future studies are needed to more clearly define the role of research intermediaries in clinical research involving various vulnerable populations and posing variable levels of risk.

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References

- Anderson EE, DuBois JM. The need for evidence-based research ethics: a review of the substance abuse literature. *Drug and Alcohol Dependence*. 2007; 86(2–3):95–105. [PubMed: 16930856]
- Appelbaum, PS.; Grisso, T. *MacAuthor Competence Assessment Tool for Clinical Research (MacCAT-CR)*. Sarasota, FL: Professional Resource Press; 2001.
- Benson PR, Roth LH, Appelbaum PS, Lidz CW, Winslade WJ. Information disclosure, subject understanding, and informed consent in psychiatric research. *Law and Human Behavior*. 1988; 12:455–475. [PubMed: 11659248]
- Bioethics Interest Group, National Institute of Health. Research involving individuals with questionable capacity to consent: Ethical issues and practical considerations for Institutional Review Boards (IRBs). 1998. Retrieved August 29, 2010 from http://www.nih.gov/sigs/bioethics/reports/exec_sum.htm
- DeRenzo EG. The ethics of involving psychiatrically impaired persons in research. *IRB: A Review of Human Subjects Research*. 1994; 16:7–9. 11.
- Dugosh KL, Festinger DS, Croft JR, Marlowe DB. Measuring coercion to participate in research within a double vulnerable population: Initial development of the Coercion Assessment Scale. *Journal of Empirical Research on Human Research Ethics*. 2010; 5(1):93–102. [PubMed: 20235867]
- Lidz C, Hoge S, Gardner W, Bennett N, Monahan J, Mulvey E, et al. Perceived coercion in mental hospital admission: Pressures and process. *Archives of General Psychiatry*. 1995; 52:1034–1039. [PubMed: 7492255]
- McCrary BS, Bux DA Jr. Ethical issues in informed consent with substance abusers. *Journal of Counseling & Clinical Psychology*. 1999; 67:186–193.
- Monahan, J.; Lidz, C.; Hoge, S.; Mulvey, E.; Eisenberg, M.; Roth, L., et al. Coercion in the provision of mental health services: The MacAurther studies. In: Morrissey, J.; Monahan, J., editors. *Research in community and mental health*, Vol. 10: Coercion in mental health services – International Perspectives. Stamford, CT: JAI Press; 1999.
- Munro CA, Saxton J, Butters MA. The neuropsychological consequences of abstinence among older alcoholics: a cross-sectional study. *Alcoholism: Clinical & Experimental Research*. 2000; 24:1510–1516.
- National Bioethics Advisory Commission. Report and recommendations of the National Bioethics Advisory Commission. Vol. 1. Rockville, MD: NBAC; 1998. Research involving persons with mental disorders that may affect their decision making capacity.
- Reiser SJ, Knudson P. Protecting research subjects after consent: The case for the “research intermediary”. *IRB: A review of Human Subjects Research*. 1993; 15(2):10–11.
- Saxton J, Munro CA, Butters MA, Schramke C, McNeil MA. Alcohol, dementia, and Alzheimer’s disease: Comparison of neuropsychological profiles. *Journal of Geriatric Psychiatry & Neurology*. 2000; 13:141–149. [PubMed: 11001137]
- Stiles PG, Poythress NG, Hall A, Falkenbauch D, Williams R. Improving understanding of research consent disclosures among persons with mental illness. *Psychiatric Services*. 2001; 52:780–785. [PubMed: 11376225]

- Tapert SF, Brown SA. Substance dependence, family history of alcohol dependence and neuropsychological functioning in adolescence. *Addiction*. 2000; 95:1043–1053. [PubMed: 10962769]
- Victor, M.; Adams, R.; Collins, G. *The Wernicke-Korsakoff Syndrome and Related Neurologic Disorders Due to Alcoholism and Malnutrition*. 2. Philadelphia: FA Davis; 1989.
- World Medical Association. Declaration of Helsinki: Ethical principles for medical research involving human subjects. 1964. Retrieved September 20, 2010 from <http://www.wma.net>

Table 1**Coercion Assessment Scale**

1	I felt like I was talked into entering the study.
2	It was entirely my choice to enter the study.
3	I thought that it would look bad to my counselor or case manager if I did not enter the study.*
4	I felt that the judge would like it if I entered the study.**
5	I entered the study even though I did not want to.
6	I felt that I could not say “no” to entering the study.
7	I felt that entering the study would help my court case.

*
p < .05;

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p < .10