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Personal Control Over Decisions to Participate in Research by Persons With Histories of Both Substance Use Disorders and Criminal Justice Supervision

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Abstract

Individuals must feel free to exert personal control over decisions regarding research participation. We present an examination of participants' perceived personal control over, as well as reported pressures and threats from others, influencing their decision to join a study assessing the effectiveness of extended-release naltrexone in preventing opioid dependence relapse. Most participants endorsed a strong sense of control over the decision; few reported pressures or threats. Although few in number, participants' brief narrative descriptions of the pressures and threats are illuminating and provide context for their perceptions of personal control. Based on this work, we propose a useful set of tools to help ascertain participants' sense of personal control in joining research.

Keywords

decision making; perceived personal control; research ethics; substance use disorder; criminal justice supervision

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Authors' Note

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Introduction

Respect for persons ethically obligates the research enterprise to allow autonomous individuals to make their own decisions about research participation and to protect participants with limited autonomy. These requirements are found in all major ethical guidelines and the U.S. federal regulations governing research (Basic HHS Policy for Protection of Human Research Subjects, 2017; Emanuel, Wendler, & Grady, 2000; Protection of Human Subjects, 2017). To exercise autonomy, individuals must feel free to exert meaningful personal control over decisions about whether and when to participate in research. It is possible to exert meaningful personal control in the midst of influence from other people; in fact, decisions commonly are influenced by others. Nevertheless, some attempts to influence one's decisions are ethically unacceptable. For example, influences can become coercive when a person perceives available options to be narrowed unfavorably by someone "trying to get her to do something she would not otherwise do" (Hawkins & Emanuel, 2005). One's decisions also are no longer considered voluntary if they are subject to "a particular type of influence that is external, intentional, illegitimate, and causally linked to the choice of the research subject" (Appelbaum, Lidz, & Klitzman, 2009a, p. 33).

Some populations are considered more vulnerable to ethically problematic influences than others. For example, the U.S. research regulations provide extra protections to prisoners due in part to concerns that they might experience or perceive pressure to enroll in studies in which they would not otherwise choose to participate (Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects, 2017; Institute of Medicine [IOM], 2007). For instance, some have worried about individuals being pressured or threatened by other prisoners to join a study to attain access to material rewards or incentives (e.g., cigarettes or canteen coupons) which they are then forced to share. Others express concern regarding situations that may lead to more subtle forms of pressure. For example, they worry prisoners might feel unable to decline if offered an opportunity to participate in research by someone in authority, perceiving pressure even when none is intended, given the inherent difficulties associated with keeping this decision private in the prison setting. Thus, the federal regulations provide for heightened scrutiny and set stricter limits on research protocols when seeking to enroll prisoners.

Concern that individuals under community criminal justice supervision (e.g., probation or parole) are similarly vulnerable led the IOM to recommend in their 2007 report *Ethical Considerations for Research Involving Prisoners* that regulatory protections covering research with prisoners be extended to individuals under community supervision (Gostin, 2007; IOM, 2007). Although this recommendation was not adopted, concerns remain that individuals under community criminal justice supervision are vulnerable to real or perceived coercive pressures (Edens, Epstein, Stiles, & Poythress, 2011; Festinger, Dugosh, Croft, Arabia, & Marlowe, 2011). These concerns are particularly salient for individuals with substance use disorders, who are considered by some to be doubly vulnerable due to ways in which both criminal justice involvement and addiction contribute to circumstances that restrict one's autonomy (Dugosh, Festinger, Croft, & Marlowe, 2010; DuVal & Salmon, 2004). One worry is that these individuals will perceive coercive pressures from authorities

associated with the criminal justice system (CJS), including affiliated clinicians or researchers, to enroll in research about substance use in which they otherwise would not choose to participate (Dugosh, Festinger, Lynch, & Marlowe, 2014a; Hawkins & Emanuel, 2005).

These issues were given serious consideration during the design of a five-site randomized-controlled effectiveness trial assessing extended-release naltrexone (XR-NTX; Vivitrol) compared with treatment-as-usual (TAU) in preventing relapse to opioid dependence among community-dwelling adults with CJS involvement (Lee et al., 2015). When the study was designed, XR-NTX was Food and Drug Administration (FDA)-approved to treat alcohol dependence but not yet for use to prevent relapse to opioid dependence and, thus, was difficult to access for this purpose. Although a daily oral version was available, the extended-release formulation was anticipated to be more effective by avoiding the need to take a pill everyday and lessening the vulnerability to relapse after missing just a few days. Furthermore, as an opioid-receptor antagonist with no known diversion or abuse potential and a noncontrolled substance, naltrexone did not carry the stigma associated with evidence-based FDA-approved opioid agonist maintenance therapies (i.e., methadone and buprenorphine) of being one addictive substance treating dependence on another addictive substance (Bonnie, 2005; Friedmann et al., 2012). For these reasons, there was cause to believe this study might hold particular interest to criminal justice authorities.

As an effectiveness study, the design aimed to be as consistent with anticipated real-life use of XR-NTX as possible. One important question was whether to recruit participants directly from probation or parole officers (POs) in addition to utilizing more general recruitment strategies (e.g., newspaper ads, word of mouth, etc.). On one hand, it was anticipated that in the future, POs and other criminal justice authorities might refer their clients to receive this treatment if it were shown to be effective at decreasing relapse, rearrest, and reincarceration. On the other hand, recruiting subjects directly through POs raised the possibility of real or perceived coercion and was ultimately abandoned in favor of focusing recruitment efforts on standard sources outside the CJS. In addition, to avoid more subtle pressures, some limits were placed on communication between the researchers and personnel from the CJS to allow participants to make decisions about study participation away from the watchful eye of that system.

During these deliberations, it was recognized that real and/or perceived pressures can also come from people other than personnel affiliated with the CJS. For example, people with substance use disorders frequently experience or perceive pressure to enter treatment programs from families and significant others (Dugosh, Festinger, Lynch, & Marlowe, 2014b; Fry & Dwyer, 2001; Marlowe et al., 1996; Polcin & Beattie, 2007; Wild, Newton-Taylor, & Alletto, 1998), so it is possible they might experience or perceive similar pressures to participate in research as a way to manage their addiction or contribute to family income. At the same time, real or perceived pressure from family, friends, employers, or the CJS can also serve a powerful, beneficial role in getting individuals needed treatment. For example, many individuals with substance use disorders would not engage in treatment without nudging, encouragement, and supportive pressure, and some of the most effective treatment

modalities incorporate these types of pressures (Rash, Stitzer, & Weinstock, 2017; Sullivan et al., 2008; Weisner et al., 2009).

With all of these concerns in mind, this study provided an excellent opportunity to learn about participants' perceptions of personal control over their decisions to join this study, and whether they perceived pressures or threats from other people related to this decision. Although perceived pressures or threats are not the same as actual pressures and threats, determining the validity of these perceptions is difficult to accomplish reliably and perceptions exert significant influence over decisions (Lidz et al., 1997); thus, we focused on participants' perceptions as described in detail below.

Method

The XR-NTX Relapse-Prevention Effectiveness Study and Participants

The primary study consisted of a five-site open-label randomized-controlled trial of approaches to combating relapse to opioid dependence among community-dwelling CJS-involved adults, comparing XR-NTX, a sustained-release full mu-opioid-receptor antagonist, with TAU consisting of brief counseling and referrals to community treatment programs (Lee et al., 2015; Lee et al., 2016). For both arms, study visits were scheduled every 2 weeks for 6 months with follow-up visits at 12 and 18 months.

A common protocol was implemented across the five independent National Institute on Drug Abuse (NIDA)-funded sites: University of Pennsylvania in Philadelphia, New York University School of Medicine/Bellevue Hospital Center and Columbia University Medical Center—both in New York City, Rhode Island Hospital/Brown University in Providence, and Friends Research Institute in Baltimore. Participants were compensated for each visit they completed, receiving up to US\$385 to US\$820 (based on site/ local standards) in cash or vouchers for full trial participation, including follow-up visits. All sites obtained local Institutional Review Board and Office of Human Research Protection approval with provisions to allow participants to be interviewed for research follow-up if they became incarcerated.

Eligible participants were adults between the ages of 18 and 60 years who had a *Diagnostic and Statistical Manual of Mental Disorders* (4th ed.; *DSM-IV*; American Psychiatric Association, 1994) diagnosis of current or prior opioid dependence, were serving an adjudicated sentence that included community supervision (e.g., parole, probation, outpatient drug court programs, or other court-mandated treatment) or in the past year had been arrested or incarcerated, had a stated goal of opioid-free treatment rather than opioid agonist/partial agonist maintenance therapy, were opioid-free (confirmed with a urine analysis), and did not have a condition that would interfere with the XR-NTX or render its use unsafe under the research conditions.

Participant recruitment began in February 2009 and concluded in November 2013. Direct referrals from POs and drug courts were not accepted. Of the 308 participants randomized, 85% were male, and 50% identified as African American, 20% as Caucasian, 27% as Hispanic, and 3% as another race or ethnic group. All had a lifetime history of opioid

dependence with 89% reporting heroin use. Regarding use within 30 days prior to screening, 34% of participants reported any opioid use (9% required opioid detoxification to enter the study), 19% reported cocaine use, 12% reported heavy alcohol use, and 19% reported marijuana use; 57% reported none of these within 30 days of the baseline visit. At the start of the study, 80% of participants reported current CJS supervision; 38% were on probation, 36% were on parole, and 6% were under some other type of CJS supervision. The remaining 20% of participants were not under current CJS supervision, but had recent criminal involvement (i.e., arrest, incarceration, conviction, or plea bargain within 12 months prior to baseline).

After a standard informed consent process, individuals were required to score 100% on a consent quiz to demonstrate knowledge of important features, including the voluntary nature of participation, alternatives to participation, confidentiality safeguards, and risks and potential benefits of the study following a procedure used at the University of Pennsylvania since the 1970s (Grabowski, O'Brien, & Mintz, 1979). Participants scoring less than 100% were provided feedback, given an opportunity to ask questions, and allowed to retake the consent quiz until they answered all questions correctly (up to five attempts). Overall, 96% passed the test in one or two tries, seven after three tries, one on the fourth try, and one on the fifth. With an average score of 89% on their first attempt, they performed on par with or better than other populations with published results for a basic consent quiz across multiple content domains (Allen et al., 2017).

This study found XR-NTX to be effective in preventing relapse to opioid dependence: The frequency of relapse events decreased and the time to relapse event increased under this arm. Details on study methods and outcomes have been published elsewhere (Lee et al., 2015; Lee et al., 2016).

Perceived Personal Control Over Decision Making About Research: An Empirical Ethics Substudy

Data for this substudy were collected from all enrolled participants at baseline, prior to randomization ($n = 308$).

Instruments

Perceived Personal Control scale (PPC): To assess participants' sense of personal control over their decision to enroll, we adapted the MacArthur Perceived Coercion Scale (PCS), a validated scale measuring a person's perceptions of coercion (Gardner et al., 1993). Initially developed to measure perceived coercion during admission to a psychiatric treatment unit, the PCS has been adapted for a variety of settings (Cusack, Steadman, & Herring, 2010; Rain, Steadman, & Robbins, 2003a; Rain et al., 2003b; Steadman et al., 2001), including the decision to participate in research (Appelbaum et al., 2009a; Appelbaum, Lidz, & Klitzman, 2009b; Edens et al., 2011; Festinger et al., 2011; Moser et al., 2004).

We adapted the five items from the PCS to address enrollment in the relapse-prevention study (e.g., "I chose to sign up for this study") and utilized a 5-point Likert-type response scale (*strongly agree, somewhat agree, neutral/mixed, somewhat disagree, strongly disagree*;

for adapted items, see Table 1). Following scoring procedures similar to the PCS, we generated a summary score from these items. However, we reversed the scoring from the PCS so that higher scores represent a respondent's perception of more personal control over the decision to participate in the study (i.e., no perceived coercion) and lower scores represent a sense of less personal control (i.e., higher perceived coercion) over this decision. We did this to be more faithful, conceptually speaking, to the normative baseline for individuals participating in a voluntary clinical trial for which participants attend clinic-based research visits every other week as opposed to the experience of psychiatric hospitalization, a process that sometimes occurs over the person's objection. Within this context, we found the items matched more closely to concepts of personal control over decisions, rather than coercion, per se. We named our reverse-scored instrument the Perceived Personal Control scale (PPC) to avoid confusion with results from studies that used the PCS.

To generate a PPC score, we assigned one point to responses indicating agreement to each item (i.e., a response of *strongly agree* or *somewhat agree*) and zero points to responses that did not indicate agreement (i.e., *neutral/mixed*, *somewhat disagree*, or *strongly disagree*). Summing up the points for the five items produces the PPC score, such that a score of 5 represents agreement to all five items and the highest measured perceived personal control over a decision (akin to a PCS score of 0 = *lowest perceived coercion*); a PPC score of 0 represents lack of agreement to any statement and the lowest perceived control over the decision (akin to a PCS score of 5 = *highest perceived coercion*).

As the participants responded to the five items using a Likert-type scale, but the final score is calculated by dichotomizing the Likert-type scale questions, we tested the PPC's internal consistency with Cronbach's alpha for the full Likert-type scale (α coefficient = .812) and the Kuder–Richardson 20 for our dichotomized scale ($KR-20 = 0.797$). Both results support acceptable reliability of the scale.

Perceived pressures and threats: We also collected information from participants regarding their perceptions of pressures and threats using a written questionnaire adapted from a semistructured interview developed by Appelbaum et al. (2009b). The stem query for perceived pressures was “Sometimes people feel pressured or pushed to do things. Do you feel that any of the following people *pressured or pushed* you to be in or stay out of the study?” and the following list of people was provided for participants to respond “yes” or “no”: (a) spouse/girlfriend/boyfriend/partner, (b) other family member, (c) psychiatrist/psychologist/therapist (i.e., mental health clinician), (d) case manager, (e) probation or parole officer (PO), (f) judge, (g) researcher, or (h) anyone else: _____. The questionnaire then asked “What did [this person] say or do?” with a comment box for a free text response along with the questions: “How important was this pressure or push in your decision to participate?” and “How fair do you think this pressure or push was?” Both the “importance” and “fairness” questions used a 4-point Likert-type scale for participants to indicate their responses (*not at all*, *somewhat*, *moderately*, *extremely*). The same format was used to ask about any perceived threats, with the lead-in query being, “Sometimes people do things because they are threatened into doing it. Do you feel that any of the following people *threatened you in any way* to be in or stay out of this study?”

Data Analysis

We report summary statistics on responses to individual PPC items, PPC scores, and perceived pressures and threats, including the sources of pressures and threats. Qualitative theme analysis of the open-ended descriptions of the reported pressures and threats, including ratings of perceived importance and fairness, was conducted by five investigators at the University of Virginia, who constituted the empirical ethics research subteam (A.A., R.B., D.C., T.K., C.S.).

Fisher's exact test was used to test for an association between the presence of a perceived pressure or threat and perception of personal control over the decision to sign up for the research study. For this analysis, we compared individuals with PPC scores of 5 with those scoring less than 5. Similarly, we divided participants into those reporting a pressure and/or threat and those who did not.

Results

Perceived Personal Control Over Decision to Participate in Research Study (PPC)

For each of the five PPC statements, the vast majority of participants responded in agreement (range = 89%-97%, see Table 1). Overall, 259 individuals (84% of participants) responded in agreement to all five statements for a total PPC score of 5, representing the highest measure of personal control over the decision to participate in the primary study. Four participants (1.3%) did not agree to any of them (e.g., responded *neutral/mixed* or *disagree*) for a PPC score of 0, representing the lowest measure of personal control over this decision (see Figure 1).

Perceived Pressures or Threats

Few participants reported pressures or threats (see Tables 2 and 3). Of the 308 enrolled study participants, 290 (94%) reported no pressures or threats. Eighteen individuals reported a total of 29 pressures and/or threats with brief narrative descriptions provided for 20 (see Table 3). Although the questionnaire asked participants to report pressures and threats separately, our qualitative analysis of the narrative descriptions revealed substantial similarities between reported pressures and threats; when these descriptions were combined into an intermixed unlabeled list, five investigators (A.A., R.B., D.C., T.K., C.S.) were unable to recategorize them. Thus, we discuss them as a single group of pressures and threats.

Of the 18 individuals reporting a pressure or threat, 10 reported one pressure or threat, seven reported two, and one person reported five. Among these 18 individuals, most (11 of 18) had PPC scores of 5 denoting the highest measured level of perceived personal control; seven scored less than 5 (see Table 3). None of the four participants in the trial with a PPC score of 0 reported a pressure or threat.

The 29 reported pressures and threats came from a variety of sources: partners (five), other family members (nine), mental health clinicians (three), a case manager (one), a PO (one), researchers (two), and other persons (eight). The perceived fairness of these 29 reported

pressures and threats, as well as perceived importance to the decision to participate in the study, ranged from “extremely” to “not at all” with no clear pattern discernible across participants (see Table 3).

Analysis of the narrative descriptions given by participants revealed several themes. Some statements revealed disappointment about the failure of past treatment and a hope that the opportunity to try naltrexone would mark a turning point: “They think it is a good idea. Up till now no other treatment has worked” and “get your life together, something has to change” are sample responses suggesting the research study might have been the latest effort at managing opiate addiction. Positive encouragement was apparent in some descriptions such as “please get help”; “that I needed the help, to go ahead”; and “asked me to just try it.” Access to housing was mentioned twice, once as a pressure (“really wanted me to do this program and it would mean a lot to them and I can live at their house”) and once as a threat (“said I have to move out”); both came from family members and were associated with PPC scores of 1, the two lowest PPC scores among the individuals reporting specific pressures or threats.

Three participants reported attempts by others to *dissuade* them from joining the study. For example, one participant described an extremely fair and extremely important pressure from a house manager as, “He wants me to do rather something else than be here. He thinks I am wasting my time. But he is not me. I will do what I want to do. I do it for myself and not for anybody else.” Another participant reported that his mother “pressured me not to do the study,” and yet another noted, “my counselor asked me why I signed up to be a guinea pig.” These participants perceived these pressures to be unfair though of moderate to no importance to their decision, and all three of these individuals had the highest PPC scores of 5.

Relationship Between PPC and Perceived Pressures and Threats

We detected a statistically significant but weak association between the presence of a reported pressure or threat and participants’ perceptions of personal control as measured by the PPC: Reporting at least one pressure or threat is associated with a PPC < 5 (Fisher’s Exact Test: $p < .05$; $\phi = -0.157$, $p < .05$).

Discussion

The vast majority of participants who signed up for this study reported a strong sense of personal control over their decision. Both the PPC scores and responses to individual items suggest that few participants perceived a weak sense of control. Similarly, very few participants reported pressures or threats, even when asked directly. Appelbaum et al.’s (2009b) empirical study of voluntariness in research settings also found very little evidence that research participants’ decisions to join a research study were constrained by others, as measured by the MacArthur PCS. In addition, of the 88 clinical trial participants from multiple disease groups, very few reported pressures or threats. This suggests that this relapse-prevention study’s population is more similar to than different from other research subjects, at least in this regard. Of the reported pressures and threats, some appear more

along the lines of encouragement or support rather than either a true pressure or a threat, and a few were aimed at convincing the person to stay *out* of the study.

Nonetheless, some participants did perceive a weak sense of personal control over their decision to join the study, though most did not provide sufficient details to give a comprehensive picture. For example, of the four participants with a PPC score of 0, none reported a pressure or threat when given the opportunity through direct query. It is possible that they did not feel comfortable providing these details in part *due to* their weak sense of control. Alternatively, they may perceive a lack of control for reasons other than pressures or threats from other people; for instance, they may feel that their involvement in the CJS or their lack of easily accessible or affordable treatment for their addiction deprives them of personal control over their lives more generally. Regardless, a weak association was found between reporting a pressure or threat and perceptions of weaker personal control over the decision to enroll in the study.

Although there were relatively few reported pressures or threats overall, our findings generally follow the patterns described in previous studies. Of the 18 individuals reporting a pressure or threat, most (11 of 18) had PPC scores of 5 denoting the highest measured level of perceived personal control even though some rated the pressure or threat to be “not at all fair” and “extremely important” to their decision. This suggests that even in the face of unfair pressures and threats perceived to exert an important influence over a decision, individuals can retain a sense of strong personal control over that decision.

The sources and types of pressures reported in our study also align with those revealed in other studies. For example, we find that important pressures and threats can come from family members and be related to personal issues, such as housing (Appelbaum et al., 2009b; Dugosh et al., 2014b). Indeed, of participants reporting pressures or threats, the two with the lowest PPC scores reported pressures or threats from a family member related to housing and one reported pressure from an additional family member who “asked me to just try it.” This reinforces the notion that some contributors to a weak sense of personal control are less ethically problematic than others. As Appelbaum et al. (2009a, p. 33) explain, attempts to influence are illegitimate when “the person exerting the influence does not have the right to act in this way according to generally accepted moral norms.” Accordingly, attempts by family members and significant others to influence decisions over participation in a relapse-prevention study, even when these attempts are unwanted, are frequently considered more ethically legitimate than those coming from outside the family.

Along these lines, a few participants reported pressures or threats from sources outside the family that potentially raise greater concern, including from researchers, POs, case managers, and mental health clinicians. However, most participants reporting pressures or threats from these groups retained a strong perception of control, and among those who did perceive a diminished sense of control, just a couple reported any further detail on the pressure or threat at hand. Although not many were provided, the descriptions given by participants related to pressures or threats from the aforementioned groups suggest that many of these reported pressures or threats could have been intended as support or encouragement. This inference would align with studies suggesting that support or

encouragement from authority figures can be felt as a source of unwanted pressure vis-à-vis a perceived need to appease authority figures (Dugosh et al., 2014b; Edens et al., 2011; Stiles, Epstein, Poythress, & Edens, 2012), even though one still feels an overall sense of personal control. The potential for self-imposed pressure stemming from the desire to appease these authority figures muddies the waters when considering whether and to what extent authority figures ought to play a role in referrals to or decisions about research participation.

On the other hand, two of the three reported pressures to stay *out* of the study came from nonfamily members, including a clinician and a house manager; the third came from a family member. For these individuals who actually enrolled in the study, it is unclear how these reported pressures or threats influenced their decision. Although it is not particularly surprising that these individuals also reported high personal control regarding the decision to sign up for the study—after all, they did enroll in the study—it is encouraging that individuals are able to assert their agency to participate in research despite perceiving pressure to do otherwise. Indeed, these reports of other people telling individuals not to participate help direct our attention to what may have motivated these individuals to actually choose to enroll. The pressures and threats questionnaire only addresses external influences exerted by other people whereas the PPC score is a broader measure which likely reflects influence from a broader array of both external and internal forces. By suggesting that, in some cases, the types of influences ascertained here played very little role in keeping individuals out of study participation, the potential importance of other motivating factors, both external and internal, are emphasized. For example, the desire for a chance to overcome addiction, the desire to earn money by participating, or the altruistic desire to help others through research participation may have played a greater role in a participant's decision (Appelbaum et al., 2009b; Fry & Dwyer, 2001; Hanson et al., 2015). Most studies find that individuals participating in research have many different reasons for doing so (Appelbaum et al., 2009b; Bell & Salmon, 2011; Fry & Dwyer, 2001; Hanson et al., 2015; McCann, Campbell, & Entwistle, 2010). Thus, perceived pressures or threats from others may play just a small role in their decision and exert a small, though measurable, effect on their sense of control.

Our study has limitations. We ascertained only self-reported perceptions of pressures and threats and personal control over decisions to participate from individuals who enrolled; thus, we have no information on individuals for whom perceived pressure or threats might have prevented participation. We also have no information on whether there were actual pressures or threats, only participants' perceptions. Unfortunately, trying to determine the validity of perceived pressures and threats requires substantial resources and is difficult to accomplish reliably (Lidz et al., 1997). In addition, as mentioned previously, participants may have been reluctant to report pressures and threats and/or a sense of diminished personal control. Nevertheless, as in Appelbaum et al.'s (2009b) original study, the small number of individuals who provided information help to illuminate these important concepts. Regrettably, our study is unable to address whether referrals to research from members of the CJS (e.g., judges, POs, etc.) weaken a person's sense of personal control as the parent study did not allow such referrals. Studies on these types of referrals are critically important to help inform best practices in these areas.

Best Practices

The voluntary decision to participate in research reflects an important ethical value, and worry persists that some individuals—including individuals under criminal justice supervision and those with histories of substance use—may perceive or experience ethically inappropriate pressures and threats to participate. In this study of individuals under community criminal justice supervision and with history of substance use disorders, very few reported any pressures or threats, and the vast majority of participants perceived a strong sense of personal control over their decision to participate, including many of those who reported a pressure or threat.

The few pressures and threats that individuals did report provide a small window into these ethically important concepts and suggest that external influences can come from a variety of sources, including family members and significant others. In studies for which there is concern that participants might perceive or experience ethically inappropriate pressures to participate, researchers could directly inquire about these during the informed consent process and engage in conversation to clarify concerning responses. In these conversations, it would be important to reiterate to the participant that his or her participation is indeed voluntary, and to probe whether the participant's decision to participate in the study was based primarily on a perceived or actual pressure or threat, giving special attention to the source of the pressure or threat as some are considered more problematic than others. In cases where a pressure or threat comes from a potentially problematic source such as a researcher, PO, or clinician, *and* the pressure or threat is the primary stated reason for the individual's decision to enroll, Appelbaum et al. (2009a, 2009b) recommend considering administrative intervention. This could entail excluding the individual from study participation. However, this is unlikely to be a common occurrence because participants' motivations for joining research studies are multifactorial, and past studies show that even people who experience pressures and threats from others often report a degree of self-motivation in choosing to participate.

An instrument like the PPC, adapted from a well-validated scale and found to have acceptable internal reliability (Cronbach's $\alpha = .80$), could provide a quick, systematic way to assess an individual's perceived control over the decision to join the study and provide some assurance that participants did not feel unfairly pressured or threatened to do so. That said, we do not suggest using the PPC to make enrollment decisions; rather, we recommend the PPC as a screening mechanism to identify individuals who might benefit from a more robust discussion to ascertain whether they perceive pressure to seek study enrollment intended to override their wishes.

Although we did not study ways to manage situations in which individuals perceive ethically inappropriate pressures or threats, a process akin to that which occurs when potential organ donors feel pressure to donate against their wishes might serve as a suitable way to protect these individuals. For example, it might be possible to provide a document stating simply that the individual did not qualify for the study without providing the reasoning behind the conclusion (Ross, 2010; Thiessen, Kim, Formica, Bia, & Kulkarni, 2015). Such a document could help individuals who really do not wish to participate in the study and provide

additional assurance to the research team that participants are choosing to enroll. Stiles et al. (2012) suggest a similar option for prisoners declining participation in research.

Research Agenda

Given the screening potential for an instrument like the PPC, we encourage further research designed to determine the most useful scoring algorithms and cutoff points for requiring further discussion in different populations. Different scoring schemes for the PPC should be explored, such as a more stringent one categorizing only “strongly agree” as indicating a sense of personal control, as opposed to what was done in the present study, where it was combined with “somewhat agree” as an indicator of participants’ perceived control over their decision. Similarly, implications of responses more clearly noting disagreement could be explored by grouping “neutral/mixed” responses together with those registering agreement. More robust research designed to guide investigators who wish to implement the PPC as a screening tool would be enormously helpful.

For researchers interested in further understanding the extent to which participants perceive pressures or threats in trial enrollment, we note that most participants in the present study did not appear to distinguish between these two concepts: some reported pressures better fit the definition for threats, and vice versa. In addition, participants reported influences that seemed a degree weaker than pressures or threats, which might have been more appropriately categorized as expressions of encouragement or support. Although there are important ethical differences between encouragement and support on one hand and pressures and threats on the other, if these influences are unwanted, they may still be perceived as negative. We believe that there are two approaches to handling future studies of such influences: The first is to simply inquire about unwanted external influences as a single more general group, or else one could provide exact definitions of each term in the questionnaire prompt. Alternatively, some researchers might opt to forego these general screening questions and move to inquiring directly about specific influences (Dugosh et al., 2014b).

We regret our inability to ascertain from individuals who declined enrollment their sense of personal control over this decision, and whether they perceived any pressures or threats from others related to it. We suggest further research to help understand these decisions. It would also be interesting to study whether people receiving traditional treatment (or no treatment) had considered participating in research, and whether others’ opinions influenced their decision to pursue clinical trials or not.

We encourage further studies to help understand what types of factors affect one’s sense of control over decisions to sign up for research studies, with the inclusion of additional parameters that would more closely resemble practical applications in this and other research communities. For example, the XR-NTX relapse-prevention study did not accept direct referrals from POs; therefore, we are unable to comment on whether such referrals would introduce ethically inappropriate pressure on decisions related to research participation, and if so, how such pressures might be managed. Studies of these important issues should be conducted in conjunction with clinical trials enrolling individuals under community criminal justice supervision, who are referred to research by officials connected

to this system. Only after such examination can best practices be established that would allow criminal justice officials to inform participants about, and refer them to, research studies while respecting potential participants' autonomous choices. As it is unlikely that randomized-controlled trials of these practices will be conducted, this study provides a useful baseline measure of perceived control and reported pressures in a context without referrals to research by criminal justice personnel and could serve as a historical comparison group for further studies.

Educational Implications

Voluntariness of research participation remains a fundamental value of ethical research; researchers and institutional review boards should be somewhat reassured that a large majority of individuals with histories of substance use disorders and criminal justice involvement perceive strong personal control over their decision to enroll in a study of a relapse-prevention treatment that is otherwise hard to access. For researchers and those charged with ethical oversight of research, the PPC can serve as a brief and easy tool to screen for potential participants' sense of personal control over the decision to enroll in a research study and identify individuals for whom further discussion over this decision might be warranted.

Summary and Conclusion

Worry persists that individuals with histories of substance use and criminal justice supervision are at high risk of experiencing real or perceived pressures and threats that undermine their sense of personal control over the decision to participate in research. However, this sample of individuals with such histories reported a strong sense of personal control over the decision to participate, with very few participants overall reporting any pressures or threats. Nevertheless, the few instances that were reported give us a glimpse into these ethically important concepts. In part, this study provides a baseline measure of perceived control and reported pressures in a context without referrals to research by criminal justice personnel. Against this baseline, perceptions of control and pressures should be studied in a population of individuals under community criminal justice supervision referred to research by officials connected to the CJS. Only after such examination can best practices be established that would allow criminal justice officials to inform participants about, and potentially refer them to, research studies while respecting their autonomy.

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Declaration of Conflicting Interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Dr. Lee has received investigator-initiated study funding and study drug in-kind from Alkermes and Reckitt-Benckiser for additional studies. Dr. Friedmann was paid an honorarium and received reimbursement for travel for attendance at an Indivior Advisory Board Meeting, and served as a roundtable leader for Orexo. Dr. Gordon received investigator-initiated study funding and study drug in-kind from Alkermes for an additional study. Dr. Nunes received study drug in-kind from Alkermes/Cephalon, Inc., Reckitt-Benckiser, and Duramed Pharmaceuticals for additional studies; web-based behavioral intervention for a research study from HealthSim, LLC; and devices under investigation and reimbursement for travel for investigators' meeting from Brainsway. Dr. Nunes was paid an honorarium and received reimbursement for travel for attendance at a Lilly Advisory Board Meeting in January 2012, and received educational materials from Otsuka America Pharmaceutical, Inc. in 2013. He serves on an Advisory Board for Alkermes. Dr. O'Brien has served as a consultant to Alkermes. The authors have no additional conflicts of interest to report regarding the ethics substudy.

Biography

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Figure 1.

The distribution of PPC scores among the participants is displayed. PPC scores were calculated by dichotomizing the responses for each item (1= strongly agree or somewhat agree, 0 = neutral/mixed, somewhat disagree, or strongly disagree), and summing the value for the five items. Thus, a PPC score of 5 represents a perception of more personal control and a score of 0 represents a perception of less personal control. The number of individuals with each PPC score is listed above the bar.

Note. PPC = Perceived Personal Control Scale.

Table 1.

The distribution of categorized responses for the five items on the Perceived Personal Control scale (PPC) is displayed. PPC items were adapted from the MacArthur Perceived Coercion Scale (PCS) (Gardner et al., 1993).

Perceived personal control: Individual questions	Agree		Neutral/mixed		Disagree	
	Strongly agree	Somewhat agree	Neutral/mixed	Somewhat disagree	Strongly disagree	
I felt free to do what I wanted about signing up for this study	270	20	8	4	6	
I chose to sign up for this study	289	8	3	2	6	
It was my idea to sign up for this study	265	20	8	6	9	
I had a lot of control over whether I signed up for this study	284	14	3	1	6	
I had more influence than anyone else on whether I signed up for this study	253	23	9	10	13	

Table 2.

The number of perceived pressures and threats reported by participants.

Number of pressures or threats reported by a participant	Frequency	Percentage
0	290	94
1	10	3.2
2	7	2.2
3	0	0
4	0	0
5	1	0.03
>5	0	0

Table 3.

This table displays information about perceived pressures and threats from the 18 individuals reporting them, including source, ratings of importance and fairness, and narrative comments when given. The individuals are ranked by PPC score.

Code	Source	Perceived pressures: Source, importance, fairness			Perceived threats: Source, importance, fairness			PPC score
		Importance	Fairness	Comments	Source	Importance	Fairness	
1	Family Member	Somewhat	Extremely	They think it is a good idea. Up till now no other treatment has worked				5
2					Case manager Researcher	Moderately	Moderately	5
3	Other (unspecified)	Not at all	Not at all	Into doing something positive				5
4	Spouse/partner Parole officer	Extremely Somewhat	Somewhat Extremely	Clean up or there [they're] gone Wants me to get help before I end up back in prison				5
5	Spouse/partner	Extremely	Extremely	Please get help				5
6	Spouse/partner Family Member	Extremely Extremely	Extremely Extremely	Get your life together Something has to change				5
7	Other (unspecified)	Not at all	Not at all		Other (unspecified)	Somewhat	Somewhat	5
8	Other (unspecified)	Moderately	Not at all		Other (unspecified)	Not at all	Not at all	5
9	Family Member	Moderately	Not at all	Mother pressured me not to do the study				5
10	Mental health clinician	Not at all	Not at all	My counselor asked why I signed up to be a "guinea pig"				5
11	Other (House manager)	Extremely	Extremely	He wants me to do rather something else than be here. He thinks I am wasting my time. But he is not me I will do what I want to do. I do it for myself and not for anybody else.				5
12	Researcher	Moderately	Moderately	They offer help for my addiction				4
13	Family Member	Moderately	Extremely	Offered ad from newspaper				4
14	Spouse/partner	Somewhat	Somewhat	Nothing				4
15	Spouse/partner Family Member	Moderately Somewhat	Moderately Moderately	That I needed the help To go ahead				4
16	Mental health clinician Other (unspecified)	Moderately >Moderately	Not at all Somewhat		Family Member Mental health clinician Other (unspecified)	Not at all Somewhat Moderately	Not at all Somewhat Moderately	2

Code	Perceived pressures: Source, importance, fairness			Perceived threats: Source, importance, fairness			ppC score		
	Source	Importance	Fairness	Comments	Source	Importance		Fairness	Comments
17	Family Member	Extremely	Moderately	Asked me to just try it	Family Member	Extremely	Not at all	Said I have to move out	1
18	Family Member	Moderately	Moderately	That they really wanted me to do this program and it would mean a lot to them and I can live at their house					1

Note. PPC = Perceived Personal Control Scale.