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The effect of depression on the decision to join a clinical trial

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Abstract

Objective—Clinical trials are necessary for evaluation of novel treatments. However, concerns have been raised about the vulnerability of depressed individuals when joining clinical trials, that is, about their abilities to make good decisions about clinical trial participation. The purpose of this study was to determine whether depression compromises decisions to join clinical trials, by comparing the decisions of three groups: depressed individuals, individuals suffering from chronic pain, and individuals with comorbid depression and chronic pain.

Methods—Participants (depressed: n=61; chronic pain: n=60; comorbid: n=58) completed, via a clinical interview, common decision-making tasks from the field of judgment and decision-making (time trade-off and standard gamble). The rationality of decisions was defined as the concordance between the evaluations of their health and the amount of risk participants would accept to improve health.

Results—Depressed individuals made less rational decisions than individuals with chronic pain (partial eta^2=.075, 90%CI:.009–.180), however, the discrepancy was in the direction of risk aversion, suggesting that depressed individuals were overly cautious about clinical trial participation. Further, this risk aversion was not limited to clinical trials for depression, but also extended to clinical trials for chronic pain (partial eta^2=.041, 90%CI:.002–.117), suggesting that depressed individuals may be overly cautious in their health choices more broadly.

Conclusions—Our findings suggest that concerns about depressed individuals making overly risky “desperate” decisions is likely unfounded, and it is more likely that depressed individuals may forgo valuable care options in an attempt to avoid risk.

Keywords

vulnerability; research participation; mental health; decision-making

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INTRODUCTION

Major depressive disorder (MDD) affects over 350 million people worldwide. A number of treatments for MDD have been developed, however, over one third of depressed individuals fail to respond to treatments (DeRubeis et al., 2005). It is imperative that new treatments be developed and that existing treatments be improved. Clinical trials recruiting depressed individuals will continue to play an essential role in the evaluation of treatments for depression.

Clinicaltrials.gov lists over 3000 open clinical trials related to depression. Joining a clinical trial involves making an informed decision, however, decision-making may present a difficulty for depressed individuals (First, Spitzer, Miriam, & Williams, 2001). Given the experimental nature of treatments evaluated in clinical trials, it is imperative for participants to have appropriate and consistent ethical protection. This is especially true for trials of procedures that may have significant adverse effects, such as deep brain stimulation, and some have argued that depression may adversely affect decisional capacity to consent to such procedures (Glannon, 2010). Indeed, some commentators have tended to presume that mental disorders, including depression, compromise the decisional capacity of individuals, by making depressed individuals, for instance, less concerned about their well-being (Elliott, 1997). However, the guidance regarding determining decisional capacity for people with psychiatric conditions is vague (National Institutes of Health Office of Extramural Research, 2009). That vagueness may be partially responsible for the considerable variability of additional safeguards required by institutional review boards (IRBs) for clinical research (Abbott & Grady, 2011), which can increase research costs (Humphreys, Trafton, & Wagner, 2003), and, in turn, hinder progress in research for the individuals such research is intended to help.

Nonetheless, much of the research on decisional capacity in patients with serious mental illness has shown that the majority of these individuals are able to make informed, capable decisions about research participation (Dunn, Candilis, & Roberts, 2006), and though considerable variability may exist, the designation of psychiatric patients as “vulnerable” population, by virtue of diagnosis alone, is controversial (Dunn, 2006). Importantly, even if differences in medical decisions or difficulties with decision-making are present, they do not necessarily indicate vulnerability.

The standard method of determining vulnerability is to assess the capacity to consent to research or treatment (Grisso & Appelbaum, 1998). However, while capacity assessment instruments can provide useful information about components of decision-making abilities, they may not be able to evaluate whether the involved decisions are rational. In this context, we can define “rational” as internally consistent with one’s health-related preferences. For instance, the decision to enroll in a higher-risk clinical trial (e.g., an invasive, experimental protocol) may be rational for a patient who is very dissatisfied with her own health state, and whose preference for improvement is considerable (i.e., that choice is consistent with her health-related preferences). In contrast, the same decision would be arguably inappropriate for a patient who is only mildly dissatisfied with her own health state and whose preference for improvement is slight. Thus, the level of risk a patient is willing to take should be

commensurate with the patient's own preferences regarding health and improvement of health (Baron, 2006).

Tools from decision-making and health economics that measure "utility" may help in evaluating the rationality of health decisions by measuring the consistency of decisions with one's preferences. In health sciences, "utility" refers to the degree of preference, or value, a person has for a health outcome or a health state. The most common ways to measure expected utility in health applications are the Standard Gamble (SG) and the Time Trade-Off (TTO), both of which have an established history in health research (Morimoto & Fukui, 2002). To measure a utility of a health state using the SG, participants are asked to indicate their preference for one of two options: a certain option (health state), and an option with an x% probability of a good outcome (e.g., perfect health) and a 100-x% probability of a bad outcome (e.g., death). The value of x% at which a person is indifferent between the two options is the utility value of that health state. With TTO, a person is asked to estimate the number of years in perfect health which would make them indifferent in a choice between that time and 10 years of their current health. The utility value is the proportion of years retained (number of years in a better state) over 10 years.

Although both SG and TTO measure utilities of health states by presenting a choice, they do not usually produce the same utility estimates (Buchholz et al., 2006), likely due to differences in which the competing alternatives are presented. The competing alternatives of SG are certain state (e.g., staying with one's depression) and a risky uncertain state (e.g., a clinical trial with some likelihood of recovery and some likelihood of death). The competing alternatives in TTO are lengths of times in two health states, with no risk in either option. SG can be conceptualized as a model for decisions to join a clinical trial, as they also involve a choice between a reasonably certain state (not joining the trial and likely continuing to experience the poor health state) and an uncertain state (joining, and risking a negative outcome while hoping for a better outcome). This discrepancy can be used to model rationality (i.e., consistency with preferences). Accepting more or less risk (via SG) than would be reasonable given their utility estimates of their health (via TTO) would suggest that participants are deciding irrationally.

The present study aimed to compare the decisions of depressed individuals with the decisions of individuals with chronic pain, a non-mental health condition that is similar to depression in several ways (see Footnote [1]), and to determine whether depressed individuals make more irrational decisions than those with chronic pain. Given the concern about decision-making of individuals with depression (Elliott, 1997), we hypothesized that depressed individuals would be willing to accept more risks. If this outcome is observed, it would point to the need for additional safeguards for depressed individuals when joining clinical trials.

[1]Chronic pain shares many clinical aspects with depression, including pervasiveness, level of disability, non-lethality, and chronicity; it also shares some negative social consequences, such as stigma. However, because chronic pain is not a mental health conditions, the "vulnerability" of its sufferers vis-à-vis clinical trial participation is hardly ever debated.

METHODS

Participants

Recruitment avenues included craigslist.com, flyers, and a list of psychiatric clinic patients who agreed to be contacted for research participation. All participants were 21+ years of age and proficient in the English language, with no cognitive impairment, no prior participation in clinical trials, no somatoform disorders, and with access to medical or mental health care. Depression group eligibility included: diagnosis of major depressive disorder (MDD) as a primary psychiatric diagnosis via the Structured Clinical Interview for DSM-IV (First et al., 2001), and no current pain beyond mild everyday aches or past chronic pain. Chronic Pain group eligibility included: current chronic pain as assessed via the Brief Pain Inventory (Cleeland, 1991; i.e., a score of 5 or above for worst pain), reported ongoing chronic pain management by a medical provider, chronic pain as the primary medical problem, few symptoms of depression on the Inventory of Depressive Symptomatology (Rush et al., 1986), and no current or past MDD diagnoses. Comorbid participants were both diagnosed with MDD via the SCID, and reported current chronic pain as described above. For the present report, data from 179 participants were analyzed (Depression: n=61; Chronic Pain: n=60; Comorbid: n=58); healthy controls were also recruited to this study, but were not examined here.

Measures

Demographic questionnaire assessed, in an interview format, participants' age, race/ethnicity, gender, education, employment, health insurance, and a number of other demographic variables. *Structured Clinical Interview for DSM-IV* (SCID; First et al., 2001) is the gold-standard diagnostic interview for diagnoses according to the DSM-IV (First et al., 2001). Interviewers were advanced clinical psychology graduate students, thoroughly trained in SCID administration. MDD section of Modules A and D as well as Module G were administered to all participants, to screen for past or present mood and somatoform disorders. Other modules were used as needed in order to complete the diagnostic picture and, for the Depression and Comorbid groups, to establish the primacy of Major Depression as a diagnosis. *Mini-Cog* (Borson, Scanlan, Brush, Vitaliano, & Dokmak, 2000) is a screening tool for detecting possible impairments in memory and executive functioning; those with possible impairments were excluded in this study. *Brief Pain Inventory – Short Form* (BPI; Cleeland, 1991) is a well-validated (Cleeland & Ryan, 1994) 9-item measure of pain location, intensity (on a 10-point scale), and interference. *Inventory of Depressive Symptomatology – Clinician* (IDS-C_{30}; Rush et al., 1996) is a 30-item, well-validated (Rush et al. 1996) measure of the level of depressive symptoms.

Decision-making tasks

Standard Gamble (SG)—Participants chose between a certain outcome (living in current depression or current pain) and an uncertain outcome (a hypothetical clinical trial of an "experimental medication", which had one of two possible benefits – perfect health or mild version of the disorder, and a possible risk – immediate death). Levels of "treatment" and risk of the clinical trial were also manipulated; the results of the manipulation are not discussed here. As is standard, utilities were elicited via a series of questions delivered in a

"ping-pong" fashion (over-and under-estimates), which produces increasingly precise estimates and terminates when the state of indifference is attained. For all participants, the initial position of the probabilities were: 70% probability of success and 30% probability of failure.

Time trade-off (TTO)—In this study, participants compared 10 years in a given health state (e.g., one's own depression) to a shorter amount of time in the state of either perfect health or in the state of the "mild" level of disorder. Just as with SG, a ping-pong interview format was used, with the starting point of 7 years in a better health state for all participants.

Procedures

After the initial phone screening (to determine English proficiency, presence of current depression and/or pain, and any clinical trial experience), participants were invited for an in-person interview conducted by advanced clinical psychology graduate students. Participants signed consent, and the Demographics Questionnaire was administered, followed by the Mini-Cog. Those passing the Mini-Cog were administered the SCID, IDS-C30, and the BPI. After completing the clinical interview, the interviewer made the final determination regarding the participant's group (i.e., Depression, Chronic Pain, Comorbid, Healthy Control, or disqualified).

Interviewers then administered the TTO task, followed by the SG task. Each decision task began with a thorough explanation that used illustrations and examples (no numbers were used in examples to avoid anchoring). Single disorder participants evaluated their own health state; Comorbid group participants separately evaluated their depression and their pain. Health states were evaluated using perfect health as a comparison and using a "mild" description as a separate comparison. The "mild" descriptions of depression and pain were created for this study; the equality of severity of pain and depression were standardized in a separate pilot study with an independent sample of participants. The order of whether pain or depression was evaluated first was counterbalanced between participants. Participants also completed other questionnaires and tasks that are not discussed in this report. Participants were paid US$50. All study procedures were approved by the Institutional Review Board of the University of California, San Francisco.

Analytical considerations

To examine the discrepancies between SG and TTO, difference scores were created, by subtracting TTO scores from SG scores. All analyses controlled for age, gender, race (Caucasian/not-Caucasian), and education (less than college/at least some college).

RESULTS

Participants' characteristics can be found in Table 1. Depression group participants were younger ($p<.0001$) and a greater proportion identified as Caucasian ($p=.002$). Pain group had lower depression scores ($p<.0001$), and Depression group had lower pain scores ($p<.0001$).

Discrepancies in utility ratings

ANCOVAs were used to compare the SG-TTO difference scores between Depression group participants evaluating their own depression, and Pain group participants evaluating their own pain. When evaluated against perfect health as the benefit, the Depression group had greater inconsistency than the Chronic Pain group (p=.003). The direction of the difference indicated that SG scores were higher than the TTO scores, which suggested that depressed individuals were more risk averse than the pain group (Table 2). When their health states were evaluated against standardized mild depression or pain, the difference between Depression and Chronic Pain group only reached the level of a nonsignificant trend (p=.075), with the Depression group again being somewhat more risk averse than the Chronic Pain group. (See Footnote [2] for a supplementary analysis.)

Understanding the components of discrepancies

To understand whether greater discrepancies in the Depression group compared to the Chronic Pain group were due to lower scores on the TTO or higher scores on the SG, we compared the two groups' TTO and SG utilities, separately. Regarding SG, ANCOVAs revealed that the Depression group reported somewhat lower utility values for depression than Chronic Pain group did for their pain when evaluated against perfect health, with the difference only attaining the level of a nonsignificant trend (p=.057). No differences were found between the groups when evaluating their health against mild version of the disorder (p=.565). However, the Depressed group reported significantly lower utility values than the Chronic Pain group using TTO, both when evaluated against perfect health (p<.0001), where the difference was substantial, and when evaluated against the "mild" version of the disorder (p=.035). This suggests that depressed individuals dislike their health state more than individuals with chronic pain, but they may not be willing to accept more risk to improve it.

Comorbid group

To understand whether the depression is associated with lower rationality only for decisions about depression or whether the associate extends to co-occurring health conditions, we carried out analyses on the Comorbid group, as that group evaluated both their own depression and their own pain (Table 3). Repeated measures ANCOVAs revealed no differences in SG-TTO discrepancies between evaluations of own depression or own chronic pain, either when evaluated against perfect health (p=.16) or when evaluated against mild condition (p=.30). Further, unlike the comparisons of Depression and Chronic Pain groups, no differences between ratings for depression and pain were observed in the Comorbid groups.

[2]To further understand whether depression is associated with a greater inconsistency between utility ratings without risk (TTO) and utility ratings in the context of a clinical trial (SG), we recoded the SG-TTO difference scores into three categories, based on whether SG scores are noticeably higher than TTO scores (higher than 1 pooled standard deviation of the difference scores above 0), approximately the same (within 1 pooled standard deviation of the difference scores about 0), or noticeably lower (lower than 1 pooled standard deviation of the difference scores below 0). Ordinal logistic regression analyses revealed that, compared to the Chronic Pain group, a higher proportion of the Depression group reported SG scores that were noticeably higher than TTO scores, both when comparing their health to perfect health (39% vs 15.5%; Wald chi-square(1)=6.58, p=.010, OR=3.38, 95%CI=1.33–8.57) and to mild depression or pain (21.3% vs 5.2%; Wald chi-square(1)=4.95, p=.026, OR=3.44, 95%CI=1.16–10.20). This result, once again, suggests that depressed individuals are significantly more risk averse when considering clinical trial participation compared to individuals with chronic pain.

The utility values of the Comorbid group for both depression and pain evaluations were similar to those of the Depression group, and indeed, the only differences between the Comorbid group and the single disorder groups were found for TTO scores for evaluations of own pain (vs. perfect health: $F(1,108)=4.68$, $p=.033$, partial $eta^2=.041$, 90%CI:.002–.117; vs mild: $F(1,108)=9.50$, $p=.003$, partial $eta^2=.081$, 90%CI:.017–.171), with Chronic Pain group giving far higher ratings to their own condition. This suggests that the association between depression and reduced rationality may extend to other co-occurring conditions.

DISCUSSION

The overall finding from this study was that depressed individuals are risk averse when deciding to join a clinical trial. This finding is at odds with the calls for increased protections for depressed individuals, or the concerns that depressed individuals may be prone to make overly risky and “desperate” decisions (Elliott, 1997). However, risk aversion in depression has been reported before (Leahy, 2001), and it would seem reasonable to assume that such risk aversion may be relevant to consequential decisions such as joining risky clinical trials.

Previous research has shown that depressed individuals are able to appreciate the risks of experimental procedures such as deep brain stimulation; however, they were also more pessimistic about personal benefit from this procedure as compared to benefit to others (Leykin et al., 2011). However, pessimism is distinct from risk aversion because pessimism reflects estimates of future probabilities, and risk aversion reflects discomfort with a given estimate. Nonetheless, even when probabilities are known, as they were in this study, a depressed individual may presume that the low-probability bad outcome is still more likely to happen to them than to others. It should be noted that the risk aversion was clearly evident only in the less ecologically valid scenario of using “perfect health”. However, to the extent that it was only attenuated but did not disappear completely when own state was evaluated against “mild” version of depression, it is very likely that discrepancy exists even in more realistic scenarios.

The finding that risk aversion of depressed individuals affects decisions about pain suggests that depression may potentially steer individuals away from otherwise reasonable alternatives regarding their healthcare in general. Indeed, prior research has shown that depression affects decisions about health conditions other than depression (McDade-Montez, Christensen, Cvengros, & Lawton, 2006). More broadly, it corroborates the previously-reported general risk aversion of individuals with depression (Leahy, 2001).

It has been previously suggested that the determination of appropriateness of risk in clinical research should rely on empirical tools from judgment and decision-making (Baron, 2006). The results of this study illustrate the importance of this suggestion.

This study has several limitations. Though we made efforts to improve the ecological validity of the tasks by adding a “mild” condition, the hypothetical clinical trial scenarios within a context of a standard decision task is not the same as making an actual decision to join a real clinical trial. An alternative interpretation of our finding is that individuals with chronic pain but without depression may be overly eager to join risky clinical trials;

however, this does not negate our findings of discrepancies in utility ratings among depressed (and comorbid) participants.

Clinical Implications

The findings from this research may offer guidance to oversight bodies regarding protection of depressed individuals in clinical trials. Specifically, they should alleviate concerns about depressed individuals as a group making irrationally risky or desperate decisions (though as with any other group, some individuals may indeed be overly risk-seeking). If risk aversion is deterring individuals with clinical depression from seeking care options, such a tendency has implications for public health initiatives targeting depression.

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Public Health Significance

This study suggests that concerns about depressed individuals making overly risky decisions when joining clinical trials may be unfounded. Depressed individuals may actually be overly risk averse when joining clinical trials, and this risk aversion may extend to clinical trials for conditions other than depression.

Table 1

Participants' demographics, by group

	MDD (n=61) % or *M(SD)*	Pain (n=60) % or *M*(*SD*)	Comorbid (n=58) % or *M(SD)*	Statistics
Age	40.1 (13.6)[a,b]	48.4 (13.5)[a]	50.9 (11.7)[b]	$F(2,176)=11.53$, $p<.0001$, partial eta^2=.116
% Female	54.1	51.7	60.3	$\chi^2(2,N=177)=1.051$, p=59, Cramer's V = .077
% non-Hispanic White	63.9[a,b]	33.3[a]	41.4[b]	$\chi^2(2,N=179)=12.25$, p=002, Cramer's V = .262
% some college+	86.9	83.3	79.3	$\chi^2(2,N=179)=1.22$, p=.54, Cramer's V = .083
IDS score	30.05 (9.83)[a]	11.62 (6.83)[a,b]	33.45 (9.56)[b]	$F(2,176)=105.2$, $p<.0001$, partial eta^2=.545
BPI "worst" score	0.57 (1.63)[a,b]	6.33 (2.56)[a]	7.00 (2.29)[b]	$F(2,176)=156.7$, $p<.0001$, partial eta^2=.640

Note: BPI "worst" score represents pain at its worst in the past 24 hours. Same superscript letters denote a significant difference.

Table 2

Decision task outcomes for single disorder groups.

	Depression Group Mean (*SD*)	Chronic Pain Group Mean (*SD*)	Statistics
SG-TTO, perfect health	0.257 (0.306)	0.102 (0.300)	F(1,113)=9.22, p=.003, partial eta^2=.075, 90%CI:.009–.180
SG-TTO, mild	0.087 (0.290)	−0.012 (0.210)	F(1,113)=3.24, p=.075, partial eta^2=.028, 90%CI: 0–.094
Own SG, perfect health	0.717 (0.275)	0.814 (0.258)	F(1,113)=3.70, p=.057, partial eta^2=.032, 90%CI: 0–.100
Own SG, mild.	0.880 (0.212)	0.884 (0.224)	F(1,113)=.33, p=.565, partial eta^2=.003, 90%CI: 0–.040
Own TTO, perfect health	0.460 (0.305)	0.712 (0.309)	(F(1,113)=21.09, p<.0001, partial eta^2=.16, 90%CI:.067–.257
Own TTO, mild	0.793 (0.337)	0.895 (0.192)	F(1,113)=4.57, p=.035, partial eta^2=.039, 90%CI:.002–111

Note: “Own” – Depression group evaluating their own depression, chronic pain group evaluating their own pain; “perfect health” – the comparator is perfect health; “mild” – the comparator is the mild version of the disorder (either depression or chronic pain, depending on the group); “SG” – standard gamble; “TTO” – time trade-off; p-values are based on ANCOVAs; utility scores range from 0 to 1, thus, TTO ratings were divided by 10, and SG percentage ratings were expressed as a decimals.

Table 3

Decision task outcomes for the Comorbid group.

	Comorbid Group Evaluating own depression Mean (SD)	Comorbid Group Evaluating own pain Mean (SD)	Statistics
SG-TTO, perfect health	0.185 (0.322)	0.189 (0.290)	F(1,51)=2.00, p=.16, partial eta^2=.04, 90%CI: 0–.151
SG-TTO, mild	0.021 (0.282)	0.058 (0.325)	F(1,51)=1.08, p=.30, partial eta^2=.02, 90%CI: 0–.120
SG, perfect health	0.707 (0.289)	0.761 (0.238)	F(1,52)=0.11, p=.74, partial eta^2=.002, 90%CI: 0–.059
SG, mild	0.831 (0.266)	0.811 (0.252)	F(1,51)=.57, p=.45, partial eta^2=.01, 90%CI: 0–.098
TTO, perfect health	0.522 (0.335)	0.569 (0.323)	F(1,51)=2.18, p=.15, partial eta^2=.04, 90%CI: 0–.16
TTO, mild	0.811 (0.296)	0.753 (0.305)	F(1,51)=.63, p=.43, partial eta^2=.01, 90%CI: 0–.101

Note: “Perfect health” – the comparator is perfect health; “mild” – the comparator is the mild version of the disorder (either depression or chronic pain, depending on what was evaluated); “SG” – standard gamble; “TTO” – time trade-off; p-values are based on repeated measures ANCOVAs; utility scores range from 0 to 1, thus, TTO ratings were divided by 10, and SG percentage ratings were expressed as a decimals.