A Randomized Controlled Clinical Trial of a Patient Decision Aid for Posttraumatic Stress Disorder

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Objective: Patient decision aids have been used in many clinical situations to improve the patient centeredness of care. A patient decision aid for patients with posttraumatic stress disorder (PTSD) has not been developed or tested. The authors evaluated the effects of a patient decision aid on the patient centeredness of PTSD treatment.

Methods: The study was a randomized trial of a patient decision aid for PTSD versus treatment as usual (control group). The participants were 132 male and female veterans who presented to a single U.S. Department of Veterans Affairs hospital with a new diagnosis of PTSD. Patient centeredness was assessed by knowledge of PTSD and its treatment, level of decisional uncertainty, and ability to state a preferred treatment option. Secondary outcomes included treatments received and PTSD symptoms in the six months after study entry.

Results: Compared with the control group (N=65), participants who reviewed the patient decision aid (N=63) had higher scores for PTSD knowledge (p=.002) and less conflict about their choice of treatment (p=.003). In addition, participants who reviewed the patient decision aid were more likely to select and receive an evidence-based treatment for PTSD (p=.04) and had superior PTSD outcomes (p=.004) compared with the control group.

Conclusions: Use of a patient decision aid was associated with improvements in patient-centered PTSD treatment. The patient decision aid was also associated with greater use of evidence-based treatments and improvement of PTSD symptoms. This study suggests that clinics should consider using a patient decision aid for patients with PTSD.

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Posttraumatic stress disorder (PTSD) occurs among individuals who have experienced a traumatic event, defined as "exposure to actual or threatened death, serious injury, or sexual violence" (1). The symptoms of PTSD occur in four separate clusters: intrusion, avoidance, negative alterations in cognition and mood, and alterations in arousal and reactivity (1).

According to the National Comorbidity Survey Replication, almost 7% of U.S. adults experience PTSD at some point in their lifetime (2). The prevalence of PTSD is even greater among U.S. military veterans. Although determining the exact prevalence of PTSD among veterans has been challenging, it is clear that a large number of veterans have developed the disorder. According to the National Vietnam Veterans Readjustment Study, 30% of Vietnam veterans developed PTSD at some point following the war (3). Subsequent analysis of PTSD rates among Vietnam veterans suggested a current rate of 9.1% and a lifetime rate of 18.7% (4). The current prevalence of PTSD among veterans of the wars in Iraq and Afghanistan is 14%, according to an estimate by the Rand Corporation's Center for Military Health Policy Research (5).

Some research has focused on ways to encourage veterans to seek out and remain in treatment for PTSD. Limited research suggests that treatment for PTSD is not consistently patient centered and that gaps in patient centeredness may contribute to nonadherence to therapy (6,7).

More than a decade ago, the Institute of Medicine outlined six aims for high-quality health care—that it be safe, effective, patient centered, timely, efficient, and equitable (6). Attaining the goal of patient centeredness has guided the development of a number of systems of care and clinical practices (8). In fact, much of medicine has embraced the goal of patient centeredness. However, in mental health care, efforts to address patient centeredness remain nascent (9,10). Many authors have outlined the potential value of addressing the aim of patient centeredness in mental health treatment (11,12). Patient-centered mental health practices are mostly found in rehabilitation services for patients with chronic mental illness, such as schizophrenia (13,14). Currently, treatment practices for PTSD have not demonstrated increased patient centeredness.

One strategy to increase patient centeredness is the use of patient decision aids. These aids are "evidence-based tools designed to prepare people to participate in making explicit and deliberated choices among healthcare options" (15).

They augment (rather than replace) clinical staff's input and guidance about options (16). Patient decision aids are available in a number of formats, including Web sites, interactive videos, audiotapes, booklets, and decision boards.

A well-designed decision aid has several essential elements (17). It describes a condition and its prognosis, explains that treatment options are available, and discusses each option, including its protocol, potential risks, and probable benefits. Descriptions are based on the best available empirical evidence.

Patient decision aids are most useful in preference-sensitive decision situations (18). These are clinical situations in which there are two or more reasonable treatment options, none of which can be identified as clearly superior for all patients. As a result, there is no clear consensus that the possible advantages of one option clearly outweigh the possible risks of the other options. Patient decision aids are useful in such situations because they purposefully compare and contrast aspects of the treatment options, including side effects, cost, and convenience (17,19).

The Cochrane Collaboration has systematically reviewed 86 randomized clinical trials of patient decision aids (16). The review confirms that well-designed decision aids can improve the patient centeredness of care, given that they help patients to improve their knowledge of a disease and its treatments, set realistic expectations, involve themselves in active decision making, experience decreased levels of decisional conflict, and choose an option that is consistent with their informed preferences (16). A subsequent Cochrane review focused exclusively on clinical trials of shared decision making in mental health conditions; it found only two studies, one related to schizophrenia and the other related to major depressive disorder (20,21).

PTSD and its treatment present an appropriate situation for using a patient decision aid. First, multiple reasonable therapeutic options are available, and no single treatment is clearly the most effective (22–25). Second, there is notable variation in the time commitment and potential side effects associated with these options.

Given that there are gaps in patient centeredness for PTSD treatment, we developed a patient decision aid for PTSD. The main purpose of this study was to examine the effects of the patient decision aid on patient-centered care of PTSD. Patient-centered care was assessed by patients' knowledge about PTSD and its treatments, self-reported decisional conflict, and ability to indicate a treatment preference. The secondary purpose was to examine the aid's effects on patients' satisfaction with care, PTSD symptoms, receipt of PTSD treatment, and general health. To our knowledge, this patient decision aid is the only one that has been developed for PTSD, and this study was the first randomized clinical trial to examine the effects of a patient decision aid for PTSD.

METHODS

This project was approved by the Dartmouth College Committee for the Protection of Human Subjects. All study participants provided written informed consent.

Participants

To be included, participants were required to meet diagnostic criteria for PTSD and to be seeking referral for PTSD treatment. Exclusions included current substance abuse or dependence, active suicidal ideation, or receipt of any mental health treatment in the past 12 months. A total of 240 male and female veterans were referred to the study. [A CONSORT diagram of the selection of the sample is available online as a data supplement to this article.] All were assessed, and 132 provided consent and were assigned at random to the intervention or control group.

The diagnosis of PTSD was established through the use of the PTSD Checklist (PCL)–Military Version, supplemented by a clinical interview to evaluate trauma exposure. The PCL has excellent sensitivity and specificity for a diagnosis of PTSD and is widely used (26). Each of the 17 symptoms of PTSD listed in DSM-IV is rated on a 5-point scale, for a possible score of 85. We adopted a cutoff score of 45 to indicate PTSD plus a specific symptoms-based diagnostic scoring that counted scores of 3 or higher to indicate symptom presence (27). Thus both a total score of at least 45 plus adequate numbers of symptoms in each symptom cluster were required to meet diagnostic criteria for PTSD. The exclusion criterion of substance use disorder was evaluated by using the Alcohol Use Disorders Identification Test and the Drug Abuse Screening Test (28,29).

Procedures

The study was conducted between July 2008 and September 2011. Participants were typically referred to mental health services by primary care providers. Those interested in participating in the study were assessed according to the study's eligibility criteria. Individuals who met the eligibility criteria were then invited to provide consent and enter the study.

Participants were then randomly assigned either to the intervention arm (viewing the PTSD decision aid) or to the control arm (treatment as usual). Randomization was accomplished through selection of an identical sealed envelope, which contained information about the random assignment. Baseline assessment measures were collected immediately.

Participants assigned to the intervention arm were given a copy of the decision aid immediately after baseline assessment. The decision aid is a 26-page graphically rich booklet that describes PTSD and effective treatments. It was designed in accordance with established standards (17). It includes specific information on the comparative risk, treatment burdens, and effectiveness of PTSD treatments. Participants reviewed the decision aid while sitting in a private clinic room in the presence of a research assistant, without provider or research staff interaction.

All participants received a standard initial mental health evaluation that is used by the clinical program. Clinic providers were blinded regarding the participants' involvement in the study. Participants in the intervention group began their initial mental health evaluation just after reviewing the decision aid. The time between reviewing the decision aid

and starting the mental health evaluation was approximately 15 minutes. Participants in the control arm received the mental health evaluation immediately after completion of random assignment and baseline assessments.

After the standard mental health evaluation, participants in both arms were seen by a research assistant who administered several assessments. These assessments included the Decisional Conflict Scale, PTSD Knowledge Questionnaire, a survey of satisfaction with care provided during the initial visit, and the Treatment Preference Questionnaire. The research assistant was blinded to the participants' treatment assignment.

Over the next six months, participants received care through the mental health services at the medical center. At the end of six months, blinded research assistants reviewed VA electronic medical records to determine the treatments, if any, participants had received. The records include clinical notes, appointments, and pharmacy data. In addition, all participants completed a questionnaire regarding any mental health treatment received outside the VA during the study. The treatment received was compared with VA clinical practice guidelines for management of PTSD (30). In addition, blinded research staff met with participants and collected results of the PCL and the 12-Item Short-Form Survey (SF-12), a questionnaire about involvement in a range of social, employment, and self-care activities.

Outcomes and Measures

The primary outcome of the study was patient centeredness. We conceptualized patient centeredness in terms of patients' knowledge about PTSD and PTSD treatments, their self-reported decisional conflict, and their ability to indicate a treatment preference.

Because there was no existing comprehensive measure of PSTD knowledge, we developed the PTSD Knowledge Questionnaire to assess knowledge about PTSD and its treatment. This instrument is a 24-item true-or-false questionnaire designed to assess objectively participants' basic knowledge of the disorder as well as specific information about the relative risk and benefits of various treatments for PTSD. The number of items correctly answered was summed to yield a measure of overall knowledge.

Decisional conflict is a psychological state experienced by an individual who is uncertain regarding the best course of action (31). High levels of decisional conflict can be associated with considerable distress and can interfere with effective decision making (32). In this study, we used the Decisional Conflict Scale (21), a self-reported questionnaire that is frequently used to assess decision certainty and comfort (16,22). The scale's 16 items assess participants' subjective reports about whether they feel uncertain about which option to choose; uninformed about the options, risks, and benefits; unclear about their personal attitudes toward the decision; inadequately supported; and ineffective in their own decision making. Responses are scored to generate a summative measure of overall decisional conflict. Participants' preferred treatment option was assessed using a categorical question regarding their single preferred treatment (33).

There were several secondary outcomes. Satisfaction with care was assessed by using items from the Survey of Healthcare Experiences of Patients (34,35). We assessed PTSD symptom severity by using the PCL (36). Participant functioning and quality of life were assessed by using the SF-12, which yields summary scores for physical and mental functioning.

Data Analysis

The study groups' baseline demographic and clinical characteristics were compared by using chi square or t tests. The analyses were performed on the intent-to-treat sample by using data from all participants in the randomized groups.

We used t tests and odds ratios (ORs) to address our primary aim of examining the effect of the patient decision aid on patient centeredness, satisfaction with treatment, and treatments received. Because PCL and SF-12 scores were obtained on two occasions, we compared the two study groups' scores on these measures by using repeated-measures analysis of covariance (ANCOVA).

RESULTS

A total of 128 participants completed the study, 63 in the intervention group and 65 in the control group. Four participants withdrew prior to completion of baseline assessments or viewing the decision aid. On average, participants were just under 50 years of age. Almost all (N=113) were Caucasian men. A majority of participants were married (N=73) and received a pension from the Veterans Health Administration for at least partial disability (N=84). The percentages of veterans from the Vietnam era (N=43, 30%) and from the Iraq and Afghanistan wars (N=37, 34%) were similar. At baseline, there were no significant differences in the demographic and other characteristics of the intervention and control groups (Table 1). There were no differences in baseline characteristics of participants who dropped out compared with participants who were retained in the study.

Effects on Patient Centeredness of Care

Participants in the intervention group had a higher mean±SD score on the PTSD Knowledge Questionnaire compared with participants in the control group (t=5.21, p=.002) (Table 2). In addition, they had a lower mean score than the control group on the Decisional Conflict Scale (t=4.37. p=.003). Furthermore, 95% of the intervention group compared with only 38% of the control group were able to arrive at a treatment choice (OR=32.00, 95% confidence interval [CI]=9.05–113.11, p<.001).

Effects on Secondary Outcomes

Both groups appeared equally satisfied with their initial mental health visit (results not shown). Overall, 75% of the intervention group and 57% of the control group received a trial of an evidence-based treatment for PTSD (OR=2.22, CI=1.05–4.71, p=.04).

TABLE 1. Baseline characteristics of 63 recipients of a patient decision aid for PTSD and 65 recipients of treatment as usual[a]

Characteristic	Decision aid (N=63)		Treatment as usual (N=65)	
	N	%	N	%
Age (M±SD)	49.4±14.5		48.4±13.7	
Female	4	6	6	9
Relationship status				
Married	35	55	38	58
Divorced	19	30	17	26
Separated	9	14	7	11
Widowed	0	—	3	5
Era of military service				
Iraq/Afghanistan	18	29	19	30
Vietnam	24	38	19	30
Gulf War	3	5	4	6
Other	14	22	23	35
Disability				
None	26	41	18	28
≤50%	15	24	19	29
≥51%	22	35	28	43
PTSD Checklist (M±SD score)[b]	61.1±10.2		64.7±10.9	
SF-12 component (M±SD score)[c]				
Mental	26.7±9.4		24.8±9.3	
Physical	43.0±12.5		40.0±12.5	

[a] There were no significant differences between groups for any baseline characteristic.
[b] Possible scores range from 17 to 85, with higher scores indicating more PTSD symptom severity.
[c] SF-12, 12-Item Short-Form Survey. Possible scores for both the mental component and the physical component range from 0 to 100, with higher scores indicating better mental or physical functioning, respectively.

To determine whether reviewing the PTSD patient decision aid had an effect on PTSD symptom severity, we compared scores on the PCL for each study group over time (Table 3). The mean score for the intervention group score decreased significantly from the time of entry in the study to the follow-up six months later (61.2 versus 55.5, F=3.98, p<.01). The mean score on the PCL for the control group also dropped, but the difference was not statistically significant. After controlling for baseline score, the analysis of change in the PCL scores demonstrated that PTSD symptoms improved more for the intervention group compared with the control group (F=4.65, p=.004).

To determine whether the PTSD patient decision aid had an effect on general health status, we examined differences between groups in SF-12 scores at the six-month follow-up; the analysis used an ANCOVA and controlled for baseline SF-12 scores. There was no between-group difference in mean scores on the mental functioning component. However, the physical functioning score for the control group worsened during the six-month follow-up period, while the score for the intervention group was maintained. Thus the groups' mean physical functioning scores were significantly different at follow-up (F=3.78, p=.01).

TABLE 2. Measures of patient centeredness of care among 63 recipients of a patient decision aid for PTSD and 65 recipients of treatment as usual

Measure	Decision aid (N=63)		Treatment as usual (N=65)		p[a]
	N	%	N	%	
PTSD Knowledge Questionnaire (M±SD score)[b]	17.0±5.2		13.3±4.9		.002
Decisional Conflict Scale (M±SD score)[c]	32.5±10.5		42.6±14.3		.003
Arrived at a treatment choice	60	95	25	38	<.001

[a] Results for arrived at a treatment choice represent an odds ratio. Other results are from t tests. df=127
[b] Possible scores range from 0 to 24, with higher scores indicating greater PTSD knowledge.
[c] Possible scores range from 0 to 100, with higher scores indicating more conflict and uncertainty.

DISCUSSION

The use of a patient decision aid was associated with observable improvements in patient-centered care—that is, higher levels of patients' knowledge, reduced levels of decisional uncertainty, and higher frequencies of forming a treatment preference. In addition, patients who viewed the patient decision aid were more likely to select treatments that are evidence based and had improved PTSD outcomes.

The clinical implications of these findings are potentially important. The use of a decision aid, such as the one we tested, could foster more patient-centered care. The decision aid appears to have led to improvements in information comprehension, in values clarification, and in patient involvement in care. The findings also suggest that the changes in patient knowledge and awareness led to a higher likelihood of patients opting for evidence-based modalities of care. Such a chain of events could generate better long-term outcomes—all with minimal costs or investment of time by providers (37). It is notable that the design of this study approximated how the patient decision aid could be used during actual clinical practice. For example, a patient could be asked to review the aid in the clinic waiting room during the 15 or 20 minutes prior to an appointment.

Effects were largest for the outcomes measured most proximally to use of the patient decision aid (knowledge and decision certainty), were somewhat smaller for treatment choice, and were smallest for symptom outcomes after six months (PTSD symptoms and functioning). At each consecutive point in time, factors unrelated to the patients themselves may exert a greater effect on the measures.

Our findings are aligned with previously observed effects of a patient decision aid in health

conditions other than mental disorders. Although previous literature regarding patient decision aids for mental health care is limited, our study's findings are similar to those of two prior studies in which decision aids increased patient involvement in care or affected patient attitudes about treatment in positive ways (38,39). However, no study of mental health conditions has found that a patient decision aid affected the care provided or patient outcomes (40,41). It is unclear if the difference in our results is due to our condition of interest (PTSD) or to some aspect of our decision aid.

There were some important limitations to our work. First, the patient decision aid was developed and tested in a clinic with limited patient diversity. The study sample was almost exclusively middle-aged white men. Other patient populations with PTSD may show a different reaction to the decision aid. Moreover, modifications to the decision aid likely would be needed prior to use with women and nonwhite patients.

Second, because we elected to test the effects of the patient decision aid as a stand-alone intervention, it was delivered without provider involvement. Under these circumstances, this patient decision aid appears to be effective as a stand-alone intervention. However, it is unclear whether it would be more or less effective when used in conjunction with discussions with a clinician. Nor can we make general statements about how the decision aid should be incorporated into the regular process of clinical care in different mental health settings.

Third, our results may have been affected by missing data caused by study dropout. At the six-month follow-up collection point, 21% of the intervention group and 18% of the control group had some missing data. The similarity in baseline characteristics among persons who dropped out of the trial and participants who remained in the study leads us to conclude that the between-group comparison at six months is likely valid.

CONCLUSIONS

This study highlights the need to focus more on patient centeredness as a feature of the quality of patient care. Current efforts to improve use of effective treatments or symptom outcomes related to mental illness are laudable. However, they are not the sole aims of care. Models of care that specifically endorse encouraging patients' involvement in guiding their treatment add value to the patients' care in themselves (42). Perhaps, in the context of PTSD, clinicians have not explicitly focused on fostering patient centeredness because few tools or approaches for doing so have been available; our results imply that a PTSD decision aid could serve as a tool to promote patient-centered care.

Although improvements in the use of effective care and in symptom outcomes were not our primary study objectives, the decision aid was associated with positive effects in both. Better understanding the relationship between patient-centered care and effectiveness of care is an important area for future exploration.

TABLE 3. Outcomes at six-month follow-up among 63 recipients of a patient decision aid for PTSD and 65 recipients of treatment as usual

	Decision aid (N=63)		Treatment as usual (N=65)		Test[a]	
Outcome	N	%	N	%	df	p
PCL score (M±SD)[b]					101	.004
Baseline	61.2±10.4		64.6±10.8			
Follow-up	55.5±12.1		61.7±14.3			
SF-12 component score (M±SD)[c]						
Mental					99	.13
Baseline	26.7±9.4		24.8±9.3			
Follow-up	32.4±10.7		30.9±11.1			
Physical					99	.01
Baseline	43.0±12.5		40.0±12.5			
Follow-up	43.0±11.7		36.8±12.5			
Evidence-based treatment for PTSD	47	75	37	57	127	.04

[a] Results for the PTSD Checklist (PCL) and the 12-Item Short-Form Survey (SF-12) are from repeated-measures analyses of covariance. Results for evidence-based treatment represent an odds ratio.

[b] Possible scores range from 17 to 85, with higher scores indicating more PTSD symptom severity.

[c] Possible scores for both the mental component and the physical component range from 0 to 100, with higher scores indicating better mental or physical functioning, respectively.

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