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Patients with Borderline Personality Disorder Not Participating in an RCT: Are They Different?

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Key Words
Randomized controlled trial · Borderline personality disorder · External validity

Abstract
Background: Despite the notion that randomized controlled trials are regarded as the gold standard in psychotherapy research, questions about their generalizability have been raised. This paper focuses on the differences between participants and eligible nonparticipants of a randomized controlled trial for patients with borderline personality disorder (BPD). ***Sampling and Methods:*** One hundred forty-two patients were screened, and 122 were found eligible for study participation. Out of these, 64 patients (52.5%) gave informed consent and were included in the study. ***Results:*** The 58 eligible nonparticipants showed a lower level of functioning (global assessment of functioning score), had a history of more outpatient treatment attempts and were living alone more often. Regarding acute symptoms and severity of BPD as indexed by suicide attempts, inpatient treatments, substance abuse and history of trauma, no differences between the groups could be detected. Moreover, participants showed significantly more eating disorders, whereas nonparticipants presented more affective and anxiety disorders. ***Conclusions:*** The results indicate that lower psychosocial functioning and comorbid affective and anxiety disorders decrease BPD patients' willingness to participate in an RCT.

Introduction

In the last 15 years major randomized controlled trials (RCTs) on treatments for borderline personality disorder (BPD) have been published [e.g. 1–6]. These studies rarely gave detailed information on their recruitment procedures. As a consequence, there is little knowledge about patients who were eligible for the major RCTs but not willing to take part. Studying these patients is of special interest since it helps close the gap between RCT populations and clinical reality [7].

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This paper investigates the differences between participants and eligible nonparticipants of an RCT for the treatment of BPD and the factors that influence a patient's willingness to participate in the RCT. Based on our clinical experience and the very scarce pool of literature on this topic [e.g. 8], we tested the hypothesis that the group of patients who denied participation in the study showed significantly more pathology than the participants.

Method

Background

This study was performed as part of a German/Austrian multicenter RCT [9] comparing the effectiveness of transference-focused psychotherapy [10] to treatment delivered by experienced community psychotherapists for individuals with BPD. The inclusion and exclusion criteria are summarized in table 1.

Procedure

The study was approved by the local ethics committee. The study recruitment took place at the Outpatient Department of a German University Psychiatric Hospital from October 2004 to July 2006. Most patients came on their own initiative or on referral from psychiatric treatment settings (e.g. crisis intervention units, psychiatric hospitals, private practices). During the initial psychiatric interview, the patients were informed about the study procedures and details as well as alternatives to study participation. A notion of preference for 1 of the 2 treatment approaches was strictly avoided. Additionally, the initial psychiatric interview was designed as a clinical screening instrument for study inclusion and exclusion criteria. The interviews lasted about 60 min, and all study interviews were performed by the same psychiatrist (M.R.). Axis I disorders were clinically diagnosed according to DSM-IV criteria and the global assessment of functioning score (GAF; [11]) was recorded. Regarding axis II disorders, the patients received diagnoses based on clinical judgment, focusing on BPD and antisocial personality disorder exclusively. The patients were additionally asked about psychiatric disorders of parents and relatives. Their history of traumatic events was explored in a nonstandardized format. For this, the interviewer typically explored the nature of the trauma and the age at which it occurred. The nature of the trauma was coded as (a) sexual, (b) physical and (c) emotional, and for quantitative analyses, multiple traumatizations were assigned to the category corresponding to the severest trauma ($a > b > c$). Demographic information was obtained from the routine documentation in the patient charts.

Data Analysis

The statistical analyses were carried out with SPSS for Windows (version 14.0). Group differences on continuous data were examined by 2-sided t tests. All variables were tested with regard to normal distribution (Kolmogorov-Smirnov test; $p < 0.05$). For nonnormally distributed variables, the results were confirmed with Kruskal-Wallis H tests. Group differences on categorical data were examined with χ^2 tests.

Table 1. Inclusion and exclusion criteria

Inclusion criteria
Female gender
Age between 18 and 45 years
BPD according to DSM IV
Sufficient knowledge of the German language
Exclusion criteria
Lifetime diagnosis of schizophrenia
Present major affective disorder
Present substance dependency
Obvious mental retardation
Antisocial personality disorder

Results

One hundred forty-two patients were screened. Out of these, study participation was offered to 122 female patients with a clinical diagnosis of BPD. Eleven patients showed exclusion criteria: 2 were male, 8 were diagnosed as having present alcohol or substance addiction, and 1 patient suffered from schizophrenia. Moreover, 9 patients did not fulfill the diagnostic criteria of BPD according to DSM-IV.

Sixty-four patients (52.5%) agreed to participate, and 58 (47.5%) rejected the offer to take part in the study. After completing the assessment procedure, none of the 64 participants had to be rejected due to clinically undetected exclusion criteria. Among the 58 nonparticipants, 20 patients (34.5%) were interested in a specific treatment, e.g. DBT, which was not offered in the study protocol. Six patients (10.3%) did not want to give up the therapist treating them before study enrollment. Three individuals (5.2%) did not agree to be randomized, 5 patients (8.6%) were searching for inpatient treatment due to a crisis situation, and 24 individuals (41.4%) stopped contacting the research team for unknown reasons.

Group differences with regard to symptom severity, comorbidity, trauma history and family history are displayed in table 2.

Nonparticipants yielded a significantly lower GAF score in the assessment. Only 1 patient with a GAF score <40 was willing to participate, whereas 16 patients in the group of nonparticipants were assigned a GAF score <40. In terms of demographic variables, only the patients' living situation was different; nonparticipants were more likely to live alone ($p < 0.01$). With respect to education and employment situation, there was a trend below the level of statistical significance: participants showed a

Table 2. Comparison between nonparticipants and participants

	Nonparticipants (n = 58)	Participants (n = 64)	χ^2	p value
GAF	42.4 ± 7.2	52.4 ± 6.8		<0.001
Outpatient psychotherapies	1.9 ± 2.3	1.2 ± 1.2		<0.05
Psychiatric inpatient treatments	3.2 ± 3.7	2.4 ± 2.5		n.s.
Suicide attempts	1.4 ± 3.3	1.4 ± 2.1		n.s.
Age, years	30.4 ± 9.4	28.9 ± 7.1		n.s.
Age at first diagnosis of psychiatric symptoms, years	19.6 ± 7.2	19.2 ± 7.2		n.s.
Age at diagnosis of BPD	25.4 ± 8.2	25.7 ± 6.9		n.s.
Present comorbidity	26 (43)	26 (41)		n.s.
Major depressive disorder	6 (10)	1 (2)	11.93 (d.f. = 4)	<0.5
Eating disorders	13 (22)	23 (36)	10.20 (d.f. = 7)	<0.5
Present and lifetime diagnosis of substance abuse	31 (53)	35 (55)		n.s.
History of trauma (sexual, physical, emotional)	36 (62)	40 (63)	2.24 (d.f. = 3)	n.s.
Psychiatric disorders in relatives				
Parents	24 (41)	31 (48)	3.36 (d.f. = 5)	n.s.
Grandparent, uncle/aunt, sibling	12 (21)	20 (31)	4.55 (d.f. = 5)	n.s.

Results are expressed as means ± SD or numbers with percentages in parentheses.

slightly higher level of education (higher level of school degree 32.8 vs. 22.4%, $\chi^2 = 7.31$, p = 0.19) and were working full time more frequently (work full time 31.2 vs. 12.1%, $\chi^2 = 11.92$, p = 0.06).

Discussion

This paper explores the differences between study participants and nonparticipants in an RCT for BPD patients. Two major findings emerge from this study. The first one is that borderline patients who did not participate in the RCT did not differ from participants in acute symptoms and severity of BPD nor in factors often regarded relevant to the etiology of BPD (e.g. suicide attempts, substance abuse, history of trauma, parents' and relatives' psychiatric disorders, as well as educational and occupational situation). The second finding is that nonparticipants were different from patients who chose to participate in variables of general functioning and comorbidity. Eligible nonparticipants showed worse psychosocial functioning and a higher number of previous outpatient psychotherapies, and tended to live alone more frequently than participants. They also showed different comorbid axis I disorders, with nonparticipants presenting pathology in the areas of affective and anxiety disorders, whereas participants more frequently suffered from eating disorders. We conclude that especially patients with a GAF score <40 may be at the limit of outpatient treatability and can be considered as a group of individuals more often in need of hospitalization, perhaps with subsequent outpatient treatment.

The group of patients who finally participate in an RCT is determined by several steps in the patient flow. First, inclusion and exclusion criteria filter out a group of patients and then, the patients' willingness to participate yields the final sample. The external validity of a study can be limited by rigid inclusion and exclusion criteria, which in turn makes inclusion unlikely for a vast majority of the ordinary clinical population [12–14]. With a proportion of 86% (122 of 142) of all screened patients found eligible for study participation, our enrolment protocol seems to be acceptably close to 'real-life' conditions. This is remarkably higher than the ratio reported by Clarkin et al. [4] in a study with a similar design. In this study 207 patients were screened and only 109 were offered study participation, resulting in a ratio of 52.7% [15].

Still there are some serious limitations to the approach presented in this paper. First, the diagnosis of the group of nonparticipants is based on a clinical interview only. This makes the assumed diagnosis of a BPD likely but not confirmed by standardized instruments. While planning this study we found it difficult to implement a more complicated design due to the fact that the vast majority of nonparticipants was not willing to undergo any scientific protocol, making it nearly impossible to collect as-

sured data on this special subgroup of patients. Second, the part of patients, who – after the first interview – never contacted the research team again (24 individuals) is rather high, which might reflect that study participation was 'not attractive to patients'. It may well be due to the fact that the German health care system provides quite some comfort to patients seeking psychotherapy. Besides taking over the therapist fees, health insurance concedes the chance to meet several therapists in up to 5 sessions on a probationary basis. To our knowledge, many of the potential study participants were in this process of finding the therapist who really 'fits' and study participation was just one possibility of finding treatment among many. There may also be other aspects in terms of requirements to participate in our study that might have deterred patients from participation.

Further research should study eligible nonparticipants as well as dropouts in detail in order to help identify so-called endophenotypes of BPD [16] as a basis for the development of more syndrome-tailored treatment approaches.

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