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What Are the Risks and Side Effects of Psychotherapy? – Development of an Inventory for the Assessment of Negative Effects of Psychotherapy (INEP)

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Keywords

Psychotherapy research · Therapy outcome · Therapeutic alliance · Adverse effects · Side effects · Unethical therapist behavior · Negative treatment effects

Summary

Background: Potential negative effects of psychotherapeutic treatment have not been studied systematically to date. The current report describes the development of a self-report instrument for assessing negative effects of psychotherapy. Patients and Methods: Items assessing negative effects of psychotherapy in different areas of life (intrapersonal change, relationships, friendships, family, malpractice, and stigmatization) were generated via literature research and presented to a group of psychotherapy experts. Items were created with a bipolar scale to avoid negative priming. Additionally, patients' attributions regarding the cause of negative effects were assessed. Between November 2010 and February 2011, 195 former psychotherapy patients (74.9% female, age M = 38.4 years, SD = 11.8) took part in an online survey, also reporting on treatment conditions during therapy. Results: Of 195 participants, 93.8% (n = 183) have reported to have experienced negative effects in or after psychotherapy. The highest rates of negative effects were reported for intrapersonal changes (15.8%), stigmatization (14.9%), and relationships (12.0%). Reports of malpractice were few, with 2.6% sexual harassment, or 1% physical violence. On the basis of item analysis and content criteria, the Inventory for the Assessment of Negative Effects of Psychotherapy (INEP) comprising 21 items was created (Cronbach's $\alpha = 0.86$). **Discussion:** A significant number of negative effects were reported within the therapeutic setting (e.g., feeling offended by what the therapist said; stages of dejection). Additionally, patients who described the therapeutic alliance as poor also reported a high number of negative effects. Conclusion: Negative effects of psychological treatment can be identified and systematically assessed via patient survey and INEP. Further evaluation in different clinical subpopulations is needed.

Schlüsselwörter

Psychotherapieforschung · Therapieergebnisse · Therapeutische Beziehung · Unerwünschte Effekte · Nebenwirkungen · Unethisches Therapeutenverhalten · Therapieschäden

Zusammenfassung

Hintergrund: Negative Effekte von Psychotherapie sind bis heute wenig systematisch untersucht. Diese Studie stellt die Konstruktion eines Selbstbeurteilungsverfahrens zur Erfassung negativer Effekte von Psychotherapie vor. Patienten und Methoden: Ein Itempool zur breiten Erfassung möglicher erlebter negativer Veränderungen durch Psychotherapie in den Bereichen intrapersonelle Veränderungen, Partnerschaft, Freunde und Familie, Arbeitsplatz, therapeutisches Fehlverhalten und Stigmatisierung wurde über Literaturrecherchen und Expertenbefragungen generiert. Items wurden bipolar formuliert, um ein negatives Priming zu verhindern. Zusätzlich wurde die jeweilige Attribution der Veränderung auf die Psychotherapie oder andere externe Ursachen erfragt. Im Zeitraum von November 2010 bis Februar 2011 nahmen 195 ehemalige Psychotherapiepatienten (74,9% weiblich; Alter M = 38,4 Jahre; SD = 11,8) an einer Onlineuntersuchung teil, bei der auch die Rahmenbedingungen der Psychotherapie erfragt wurden. **Ergebnisse:** Von 195 Befragten gaben 93,8% (n = 183) an, negative Effekte durch ihre Psychotherapie erlebt zu haben. Die höchsten Raten erlebter negativer Effekte ergaben sich in den Bereichen intrapersonelle Veränderungen (15,8%), Stigmatisierung (14,9%) und Partnerschaft (12,0%). Schwerwiegendes therapeutisches Fehlverhalten wie sexuelle Belästigung (2,6%) oder körperliche Gewalt (1%) durch den Therapeuten hatten eine geringe Prävalenz. Anhand von Itemanalysen sowie inhaltlichen Kriterien wurde das Inventar zur Erfassung negativer Effekte von Psychotherapie (INEP) mit 21 Items erstellt ($\alpha = 0.86$). **Diskussi**on: Ein Großteil der negativen Veränderungen trat innerhalb des therapeutischen Settings auf (z.B. verletzende Aussagen des Therapeuten, Phasen der Niedergeschlagenheit). Zudem wurden mehr negative Effekte genannt, wenn die therapeutische Beziehung als negativ beschrieben wurde. Schlussfolgerung: Negative Effekte von Psychotherapien sind feststellbar und können mittels Patientenbefragungen und einer systematischen Analyse via INEP erfasst werden. Die Analyse des Instruments in weiteren klinischen Subpopulationen ist notwendig.

Introduction

There is no doubt about the effectiveness of psychotherapy. Numerous studies have provided clear evidence of the successful treatment of various mental disorders by state of the art therapies [Smith and Glass, 1977; Wampold, 2001]. Efficacy research, however, as we know from medicine, deals not only with investigation of the main effects, but also with the potential negative effects of a treatment; any intervention into biochemical, physical or even mental processes in humans will almost inevitably have such negative effects.

The study of negative effects has so far been largely neglected in psychotherapy research. A review of the literature in German and English specialized publications in 2012 located only a few studies and shows that research into possible negative effects of psychotherapeutic interventions is quite underrepresented, especially in comparison to efficacy research. It is also clear that the existing studies discuss various concepts such as treatment failure, therapeutic risk, costs, and harmful effects or side effects, even though there has hitherto been no uniform use of these terms. A definition of terminology is therefore of the utmost importance. As in pharmacological efficacy research, so in psychotherapeutic efficacy research, the terms 'main effects' and 'side effects' are of course used. According to the legal definition, however, the term 'side effects' only covers 'unintended harmful reactions when used as directed' (German Drug Law (AMG), § 4, para. 1, sentence 13). Changes and harmful effects as a result of treatment errors are thereby excluded. Since the quality of treatment is, however, much more difficult to determine in psychotherapy, a term is therefore needed that covers both changes and harmful effects in various areas of life and function after lege artis therapies and also negative effects resulting from treatment errors by the therapist. Therefore, we propose the concept of negative effects, defined as follows.

Negative Effects of Psychotherapy

Negative effects of psychotherapy are defined as changes that are experienced as negative by the patient and that have direct or indirect harmful effects, or that are experienced by the affected person as detrimental. This change would have to occur in at least one area of function and/or the life of the patient and during the period of therapy, immediately afterwards or after a delay and would have to be attributed by the patient to the therapy and not to other external influences. Unethical behavior and malpractice by the therapist are also classified as negative effects.

Previous studies with naturalistic clinical samples [Lambert and Ogles, 2004; Mohr, 1995] on the negative effects of psychotherapy report deterioration rates of 5–10% on the symptom level. A few studies have reported negative effects in other areas of patients' lives, such as dependence upon the therapist as a life coach, without whom no independent decisions can be made [Schmoll, 2012], or more problems in part-

nership after successful psychotherapy [Hand and Lamontagne, 1976]. Other negative effects are hopelessness and lack of motivation because of lack of success and initial setbacks, problem actuation or increased anxiety, e.g., in the context of exposure therapy, 'overtraining' in social skills, egocentricity, fear of being stigmatized or problems with insurance following treatment (for a detailed discussion, see Nestoriuc and Rief [2012]). Thus negative effects can occur independent of the success or failure of the psychotherapy regarding the main symptoms. For example, a patient may experience an improvement in his or her depression, while experiencing more conflicts with family and friends because he or she had learned during therapy to stand up for his or her own needs, which he or she had not previously done. These problems, apart from the successfully treated symptoms, can cause new psychological strain. This poses an ethical obligation to inform patients, in order to allow informed decision making for or against the treatment, and also a moral and practical obligation to recognize negative effects in order to discover individual coping strategies. Up to now this obligation cannot be adequately met, since scientific evidence is lacking about what negative effects are actually experienced with what frequency by the patient.

Table 1. Socio-demographic and clinical characteristics of the sample (self-reporting by participants)

Characteristics	N = 195
Gender (female), n (%)	146 (74.9)
Age, M (SD), range	38.4 (11.8), 18–75
Living alone, n (%)	96 (49.2)
Education ^a , n (%)	
No degree	2 (1)
Secondary general school	13 (6.7)
Intermediate secondary school	62 (32.1)
Baccalaureate	56 (29)
University degree	59 (30.6)
Other degree	1 (0.5)
Profession ^b , n (%)	
Employee	89 (46.3)
Self-employed	18 (9.4)
Housewife/-husband	6 (3.1)
School child/student/trainee	33 (17.2)
Retired	29 (15.1)
Unemployed	17 (8.9)
Mental diagnosis ^c , n (%)	
Depression	121 (62.1)
Anxiety disorder	103 (52.8)
Personality disorder	52 (26.7)
Eating disorder	40 (20.5)
Schizophrenia	4 (2.1)
Other	10 (5.1)

M = mean; SD = standard deviation.

^aDue to missing data, n = 193

^bDue to missing data, n = 192

^cMultiple answers possible.

Table 2. Characteristics of psychotherapy (self-reporting of participants)

Characteristics	N = 195
Therapist gender (male), n (%)	65 (33.3)
Treatment setting, n (%)	
Outpatient	146 (74.9)
Inpatient	49 (25.1)
Treatment modality, n (%)	
Individual	147 (75.4)
Group	2(1)
Individual + group	46 (23.6)
Therapeutic sessions, n (%)	
1–5	14 (7,2)
6–25	54 (27.7)
26–120	85 (43.6)
121–300	29 (14.9)
300	13 (6.7)
Theoretical concept (according to the patient), n (%)	
Behavioral therapy	74 (37.9)
Psychodynamic therapy	61 (31.3)
Nondirective therapy	40 (20.5)
Other	20 (10.3)
Premature termination of therapy, n (%)	43 (22.1)
Patients with more than one prior psychotherapeutic treatment, n (%)	123 (63.1)
Time since end of therapy, in years, M (SD), range	1.99 (2.56), 0-12.33
'Overall, my expectations from the therapy were fulfilled/ not fulfilled,'	0.3 (2.3) -3-3
M (SD), range,	
'I experienced my relationship with my therapist as overall positive/negative,' M (SD), range	1.3 (1.8) –3–3
M = mean; SD = standard deviation.	

The goals of the current study are therefore to develop and evaluate an instrument for the systematic assessment of negative effects of psychotherapy and to analyze the frequency of negative effects and their correlates for both the patient and therapist.

Patients and Methods

Item Design

An item pool of 120 possible negative effects was assembled through a literature review, including various types of therapeutic malpractice. This pool was submitted to a group of 8 expert psychotherapy researchers in Germany and was rated qualitatively for relevance, clarity and redundancy. Utilizing these assessments and taking content into consideration, W.R. and Y.N. selected 52 suitable items, which were empirically evaluated in the present Internet study. The goal was to create an economical questionnaire for the assessment of negative effects of psychotherapy. The items are, as far as possible, formulated in a 7-step bipolar format (-3 = definitely a negative effect; 0 = unchanged; 3 = definitely a positive effect) to detect not only deteriorations but also improvement or lack of change, and to prevent negative priming [Heuer et al., 2007]. If a bipolar format was not appropriate to the content, a 4-stage unipolar response format was chosen instead (0 = disagree/not applicable; 3 = fully agree). For each item, the attribution was stated from the patient's perspective ('What caused this outcome?' - 'the therapy' or 'other circumstances in life'). Only negative effects that were attributed by the patient directly to the psychotherapeutic treatment were considered for the analysis.

In addition to the 52 items, 15 questions were added that cover: expectations of psychotherapy (6 items); quality of therapeutic relationship (6 items) and overall treatment outcome (3 items). The response format of these questions corresponded to that for negative effects.

Data Collection and Participants

The current study uses an online survey. The survey utilized Unipark software version 6.1. A total of 586 people visited the survey website, and 319 of them agreed to participate. Of these 319 participants, 200 people (61%) completed the survey. This attrition rate of 39% corresponds to the loss rates in other Internet studies [Westermann et al., 2012].

Former psychotherapy patients were invited to participate by notices posted on websites or written notifications sent to members of various registered associations that provide aid and self-help to mentally ill people, as well as by notices posted on social networks:

- Angst-Hilfe e.V. DASH/MASH (Help for Anxiety DASH/MASH) (www.panik-attacken.de)
- Counseling and Information for Eating Disorders (www.ab-server.de)
- Gegen-Missbrauch e.V. (Against Abuse) (www.gegen-missbrauch.de)
- Deutsche Gesellschaft Zwangserkrankungen e.V. (German Society for OCD) (www.zwaenge.de)
- Chronic Fatigue Syndrome Forum (www.cfs-treffpunkt.de)
- Anxiety and Panic Forum (www.angstforum.info)
- Deutsches Bündnis gegen Depressionen e.V. (German Alliance against Depression)
- Facebook; StudiVZ.

The written appeal for participation was the same for all forums: 'Do you have experience with psychotherapy? Participants wanted for survey! If you have participated in psychotherapy and are interested in sharing

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Negative effects that are attributed to psychotherapy.	nnegative (%)	nunchanged (%)	n _{positive} (%)	M (SD)	Median	Range
Intrapersonal changes, N = 195						
1. More tense/ more relaxed*	29 (14.9)	6 (3.1)	101 (51.8)	0.8 (1.7)	1	-3-3
2. Unhappier/happier*	29 (14.9)	6 (3.1)	94 (48.2)	0.6 (1.6)		-3-3
3. Less confident/more confident	25 (12.8)	7 (3.6)	94 (48.2)	0.7 (1.5)	1	-3-3
4. Less hopeful/more confident*	32 (16.4)	5 (2.6)	92 (47.2)	0.6 (1.6)		-3-3
5. More/less guilt	19 (9.7)	7 (3.6)	81 (41.5)	0.6 (1.3)	1	-3-3
6. More/less shame	24 (12.3)	6 (3.1)	71 (36.4)	0.5 (1.3)	0	-3-3
7. More/less lonely	21 (10.8)	7 (3.6)	46 (23.6)	0.2 (1.2)	0	-3-3
8. More/less anxious	26 (13.3)	7 (3.6)	91 (46.7)	0.5 (1.4)	1	-3-3
9. More/less sadness *	34 (17.4)	5 (2.6)	68 (34.9)	0.3 (1.4)	0	-3-3
10. Symptoms are worse/better	31 (15.9)	7 (3.6)	101 (51.8)	0.7 (1.7)	1	-3-3
11. More difficult/easier to trust others*	30 (15.4)	6 (3.1)	49 (25.1)	0 (1.3)	0	-3-3
12. Self-acceptance more difficult/easier	19 (9.7)	10 (5.1)	85 (43.6)	0.5 (1.3)	1	-3-3
13. Dealing with conflicts worse/better	13 (6.7)	11 (5.6)	91 (46.7)	0.6 (1.2)	1	-3-3
14. Worse/better dealing with past events*	54 (27.7)	4 (2.1)	63 (32.3)	0 (1.5)	0	-3-3
15. Easier/more difficult to make decisions on my own*	15 (7.7)	6 (3.1)	64 (32.8)	0.5 (1.1)	0	-3-3
16. Longer periods when things were not going well*	83 (42.6)	8 (4.1)	ı	-0.9(1.1)	-2	-3-0
17. Less secure, more labile or less resilient*	70 (35.9)	12 (6.2)	I	-0.7 (1.1)	7-	-3-0
18. Became a worse person*	37 (19)	40 (20.5)	I	-0.4 (0.8)	0	-3-0
19. More/less frequently physically ill	15 (7.7)	7 (3.6)	37 (19)	0.2 (1.1)	0	-3-3
20. More/less alcohol, pills or other drugs	19 (9.7)	3 (1.5)	31 (15.9)	0.2 (1.1)	0	-3-3
21. More/fewer suicidal thoughts	25 (12.8)	8 (4.1)	47 (24.1)	0.3 (1.3)	0	-3-3
22. Suicidal thoughts/intentions for the first time*	29 (14.9)	10 (5.1)	I	-0.3 (0.7)	0	-3-0
The rapeutic malpractice, $N = 195$						
23. Hurtful statements by the therapist*	109 (55.9)	85 (43.6)	I	-0.9 (1)	7	-3-0
24. Felt personally ridiculed by my therapist*	44 (22.6)	151 (77.4)	I	-0.3 (0.7)	0	-3-0
25. Sexual harassment by my therapist*	5 (2.6)	190 (97.4)	I	0 (0.2)	0	-3-0
26. Therapist attacked me physically*	2 (1)	190 (97.4)	I	0 (0.3)	0	-3-0
27. Therapist forced me to do certain parts of the treatment (e.g., confrontation, role play, etc.) *	61 (31.3)	134 (68.7)	ı	-0.5 (0.8)	0	-3-0
28. Therapist violated confidentiality*	15 (7.7)	180 (92.3)	ı	-0.2 (0.6)	0	-3-0
Intimate relationship, N = 114						
29. Relationship with partner worse/better	16 (14)	2 (1.8)	33 (28.9)	0.3 (1.4)	0	-3-3
30. More/less conflict in relationship*	21 (18.4)	4 (3.5)	25 (21.9)	0 (1.3)	0	-3-3
31. Partner complains less/more about problems	11 (9.6)	3 (2.6)	13 (11.4)	0 (0.9)	0	-3-3
32. Separation during or after treatment	13 (11.4)	8(7)	I	-0.3(0.9)	0	-3-0
33. Partner avoids important topics of conversation	9 (7.9)	5 (4.4)	I	-0.1(0.6)	0	-3-0
34. My partner is or has been jealous of my therapist*	11 (9.6)	3 (2.6)	ı	-0.2(0.5)	0	-3-0
35. Partner notes negative changes	15 (13.2)	6 (5.3)	1	-0.3 (0.8)	0	-3-0

Table 3. Item parameters (continued)

Negative effects that are attributed to psychotherapy.	n _{negative} (%)	nunchanged (%)	n _{positive} (%)	M (SD)	Median	Range
Family and friends, N = 195						
36. Worse/better relationship with family*	28 (14.4)	4 (2.1)	59 (30.3)	0.2 (1.4)	0	-3-3
37. Worse/better understood by the family	23 (11.8)	8 (4.1)	46 (23.6)	0.2 (1.3)	0	-3-3
38. Worse/better relationship with friends*	16 (8.2)	3 (1.5)	46 (23.6)	0.3 (1.1)	0	-3-3
39. Worse/better understood by friends	12 (6.2)	4 (2.1)	46 (23.6)	0.3 (1.1)	0	-3-3
40. Approaching other people is harder/easier	14 (7,2)	2(1)	68 (34.9)	0.4 (1.2)	0	-3-3
Work, N = 152						
41. Tasks on the job/in apprenticeship/at the university and/or in the household are harder/easier	12 (7.9)	2 (1.3)	43 (28.3)	0.3 (1.2)	0	-3-3
42. Concentration on work is worse/better	10(6.6)	1 (0.7)	42 (27.6)	0.3 (1.1)	0	-3-3
43. Absenteeism from work more/less frequent	9 (5.9)	5 (3.3)	26 (17.1)	0.3 (1.2)	0	-3-3
44. More/fewer conflicts with classmates/fellow students/colleagues/ superiors	8 (5.3)	5 (3.3)	21 (13.8)	0.2 (0.9)	0	-3-3
45. I am anxious that classmates/fellow students/colleagues could find out about my therapy*	13 (8.6)	13 (8.6)	I	-0.1(0.5)	0	-3-0
46. Excluded by classmates/fellow students/colleagues	9 (5.9)	10 (6.6)	I	-0.1(0.5)	0	-3-0
47. More careless in everyday work	11 (7.2)	9 (5.9)	I	-0.1(0.5)	0	-3-0
Stigma, N = 195						
48. Anxiety about an increased cost of insurance (life insurance, disability insurance)*	31 (15.9)	8 (4.1)	I	-0.4(0.9)	0	-3-0
49. Problems with insurance after completing therapy*	36 (18.5)	8 (4.1)	I	-0.5 (1)	0	-3-0
50. More financial worries*	31 (15.9)	6 (3.1)	I	-0.4(0.9)	7	-3-0
51. Career opportunities have decreased/increased	26 (13.3)	5 (2.6)	40 (20.5)	0.1 (1.3)	0	-3-3
52. I feel bad/good about the fact that I underwent psychotherapy.	21 (10.8)	7 (3.6)	63 (32.3)	0.5 (1.5)	0	-3-3
Total negative effects						
Total number of negative effects, $k = 52$	I	1	I	6.8 (7.1)	4	0–39
Total number of negative effects without therapeutic malpractice, $k = 46$	I	I	I	5.6 (6.4)	3	0–35
The rapeutic malpractice, $k = 6$	ı	ı	I	1.2 (1.3)	1	9-0
Intrapersonal changes, $k = 21$	I	I	I	3.4 (4.1)	2	0-19
In timate relationship, friends and family, $k = 12$	1	I	I	1.0 (1.8)	0	0-10
Work, $k = 7$	1	ı	I	0.4 (1.0)	0	9-0
Stigmatization, $k = 5$	I	I	I	0.7 (1.2)	0	0-5
Dependency, $k = 1$	ı	I	I	0.1 (0.3)	0	0-1

'Items that are part of the Inventory for the Assessment of Negative Effects of Psychotherapy (INEP). M = mean; SD = standard deviation; k = number of items

Table 4. Summary of stepwise hierarchical regression analysis to predict the number of reported negative effects of psychotherapy (N = 195)

Variable	В	SE B	ß
1. Step (constant)	5.885	0.427	
'Overall, my expectations from the therapy were not fulfilled'.	-1.185	0.188	-0.41**
2. Step (constant)	5.122	0,481	
'Overall, my expectations from the therapy were not fulfilled'.	-1.180	0.183	-0.41**
Setting: inpatient hospital stay	3.062	0.960	0.21*
3. Step (constant)	6.028	0.605	
'Overall, my expectations from the therapy were not fulfilled'.	-0.737	0.257	-0.26**
Setting: inpatient hospital stay	2.936	0.950	0.19**
'I experienced my relationship with my therapist as overall negative'.	-0.790	0.326	-0.22*
4. Step (constant)	4.920	0.774	
'Overall, my expectations from the therapy were not fulfilled'.	-0.672	0.256	-0.24*
Setting: inpatient hospital stay	2.734	0.944	0.18**
'I experienced my relationship with my therapist as overall negative'.	-0.846	0.324	-0.23*
Patients with more than one prior psychotherapeutic treatment	1.915	0.850	0.14*

R2 = 0.17 for step 1; Δ R2 = 0.04 for step 2; Δ R2 = 0.02 for step 3; Δ R2 = 0.02 and R2corr = 0.24, F (4.188) = 16.38 for step 4 (p > 0.01). *p>0.05; **p > 0.01.

your experiences, we would like to invite you to participate in our online survey'.

Former psychotherapy patients were able to participate from November 2010 to February 2011. Inclusion criteria were: at least 18 years of age, adequate knowledge of German and prior psychotherapeutic treatment. After an explanation of the content of the study and confirmed consent for participation, the subjects were initially presented with 52 items regarding possible negative effects of their psychotherapy, and their expectations with respect to the treatment were recorded. The participants were also asked about the quality of the therapeutic alliance (6 items). If the subjects had completed more than one course of psychotherapy, they were instructed to refer to the most recent one. Then they were asked for personal socio-demographic characteristics (age, gender, nationality, marital status, educational level and occupational status) and the nature of the prior psychotherapy. The questionnaire recorded the therapeutic setting (outpatient/inpatient), duration of treatment, theoretical concept and specific interventions, number of sessions, gender of therapist, whether there was a change of therapist, premature termination of therapy, whether the patient had had more than one course of therapy and diagnosis at beginning of treatment. The data consisted of patients' self-reporting, without any official documents regarding their treatment.

To minimize distortion effects of memory of past psychotherapy, an outlier analysis was performed for the variable 'time since the end of therapy'. The variable was standardized (Z-transformed) to find a suitable cutoff. According to Bortz and Schuster [2010], values that are more than 2 standard deviations from the mean are defined as outliers (Z value > 3.29). For this reason, 5 people were excluded from the analysis, since their psychotherapy had occurred more than 5.255 days previously, i.e. more than 14 years. In the newly created sample (n = 195), the treatment had occurred an average of 1.99 years previously (standard deviation (SD) = 2.56 years; range = 0–12.33 years). The subsequent analyzes were first carried out for both samples to determine the impact of outliers. The results differ only slightly, with the sample with extended variance (n = 200) suppressing a few effects. Therefore the results of the adjusted sample (n = 195) are reported in the following Results section.

Statistical Analysis

The statistical analysis was performed with SPSS version 17.0. First of all, descriptive analyzes were performed and item parameters were calculated. Then a principal component analysis was performed to examine the

underlying structure of the questionnaire. A stepwise hierarchical regression was calculated to obtain preliminary information about possible correlates of negative effects of psychotherapy.

Results

Sample

The study participants included 195 men and women who had previously experienced psychotherapy. Table 1 gives an overview of the socio-demographic and clinical characteristics of the sample. The average age is 38.4 years (SD = 11.8; range = 18–75). 74.9% of participants are women; 96.1% of the participants are German citizens. The educational level in the sample is high, with 30.6% having a university degree, 29% a baccalaureate and 32.1% a secondary school-leaving certificate (Comparable to an American high school diploma – translator's note). The majority of patients is employed (72.9%); the proportion of salaried employees is 46.3%; 17.2% are school children, students or apprentices. The patients are predominantly diagnosed with depressive disorders (62.1%) and anxiety disorders (52.8%), according to the participant's own characterization.

Table 2 provides an overview of the previous treatments. 66.7% of participants had a female therapist; a majority was in outpatient care (74.9%). Most psychotherapies took place in an individual setting (75.4%), lastet between 26 and 120 h (43.6%) and took place about 2 years ago (range = 0–12.33 years). 35 people (18%) were still in psychotherapy at the time of the survey. Over half of the patients reported more than one previous treatment (63.1%), and approximately one-fifth (22.1%) had prematurely terminated their treatment. Individual expectations of the psychotherapy were, on average, more often fulfilled than not (median (M) = 0.3, SD = 2.3).

The response behavior shows a U-shaped frequency distribution: 37.4% (n = 73) of respondents indicated that their expectations of the treatment were not met (values from -1 to -3); 56.9% (n = 111) said that their expectations were fulfilled. The patients mostly experienced their relationship with the therapist as positive, while 18% (n = 35) reported a negative therapeutic alliance (values between –1 and –3).

Frequencies of Negative Effects and Item Parameters

Table 3 shows item parameters for negative effects of psychotherapeutic treatment in the following areas of life: intrapersonal changes, intimate relationship, family and friends, work, stigmatization and therapeutic malpractice. The only effects considered were those that the participants explicitly attributed to the psychotherapeutic treatment. If a participant indicated that he or she felt more stressed after the therapy, but did not directly attribute this to the treatment, this was not considered a negative effect of the psychotherapy. Since the items are formulated in the bipolar response format, there are a total of 3 categories of effects: negative (-3 to -1), unchanged (0), and positive (1-3). In addition to frequencies of negative effects, the mean, standard deviation, median, and item range are specified. The internal consistency of the total questionnaire (k = 52) has a Cronbach's α of 0.94 and is therefore to be assessed as high.

183-195 respondents in the sample indicated that they had experienced at least one negative effect after or during their psychotherapy. The frequencies of individual negative effects ranged from 1% ('My therapist attacked me physically') and 55.9% ('I felt offended by what the therapist told me'). On average, the participants in the online survey indicated that they had experienced 7 negative effects (SD = 7.1, range = 0-39) that they attributed to their treatment. Setting aside the attribution, the participants reported about twice as many negative effects (M = 12.3, SD = 7.9, range = 0–39).

The mean values and frequencies for the individual areas of life are given in table 3. Participants on average experienced the most negative effects in the area of 'intrapersonal changes', with 15.8% (range = 6.7–42.6%; most frequent item: 'Since the end of my therapy I have had longer periods when things were not going well'). The second most frequently mentioned item was the experience or fear of stigmatization, with an average frequency of 14.9% (range = 10.8–18.5%; most frequent item: 'Since completing my treatment, I have had trouble obtaining insurance'). After that came 12% negative effects in the intimate relationship (range = 7.9–18.4%; most frequent item: 'Since the end of my therapy, I have been experiencing more conflicts in my relationship'), as well as 9.6% negative effects regarding family and friends (range = 6.2-14.4%; most frequent item: 'Since the end of my therapy I have had a worse relationship with my family'). The average reported negative changes in the workplace were at the lowest end of the scale (6.8%; range = 5.3–8.6%; most frequent item: 'Since the end of my therapy I have been suffering from anxiety that my colleagues could find out about my therapy'). 5 female participants reported sexual harassment by their (also female) therapist and 2 of them reported physical attacks by the same therapist.

Correlates of Negative Effects of Psychotherapy

A stepwise (hierarchical) regression was performed to investigate possible determinants of negative effects of psychotherapeutic treatment. The outcome measure used was the absolute number of reported negative effects (M = 6.8; SD = 7.1; range = 0-39) (cumulative value, adjusted for the items due to the rapeutic malpractice, k = 46). The variables that were included in the model were, due to a significant bivariate correlation, chosen with regard to the outcome measure. There were significant correlative relationships between the number of negative effects and a negatively described therapeutic relationship ($r_{Pearson} = 0.41$, p < 0.01), unfulfilled treatment expectations ($r_{Pearson} = 0.43$, p < 0.01), the treatment setting ('inpatient hospitalization'; $r_{Spearman} = 0.27$, p < 0.01), more than one prior psychotherapy treatment ($r_{Pearson} = 0.18$, p < 0.05), premature termination of therapy in the past ('dropout'; $r_{Spearman} = 0.17$, p < 0.05), occupational status ('unemployed'; $r_{Spearman} = 0.27$, p < 0.01), intimate relationship status ('living alone'; $r_{Spearman} = 0.16$, p < 0.05) and the diagnosis of 'personality disorder' ($r_{\text{Spearman}} = 0.14$, p < 0.05); there was no relationship to any of the other variables (e.g., Axis-1 diagnoses, age, type of therapy). All significant correlates were then included in a stepwise hierarchical regression (table 4). Only the variable 'Overall, my expectations from the therapy were not fulfilled' is included in Step 1 of the hierarchical regression. The highest increase of explanatory power comes from the variable 'treatment in inpatient setting' (Step 2; ΔR^2 = 0.04; p < 0.01). In the next steps, the variables 'negative therapeutic alliance' (Step 3; $\Delta R^2 = 0.02$; p < 0.01) and 'more than one prior psychotherapeutic treatment' (Step 4; $\Delta R^2 = 0.02$; p < 0.01) were added. Overall, the model resolves over 20% of the variance ($\Delta R^2_{\text{corr.}} = 0.24$; F(4,188) = 16.4; p < 0.01). The increase of explanatory power is significant for each step. Thus there were more negative effects when the participant evaluated the therapeutic alliance negatively, had been given inpatient treatment, had previously had more than one psychotherapeutic treatment and/or felt that his or her expectations had not been met by the psychotherapy.

Constructing the Inventory for the Assessment of Negative Effects of Psychotherapy (INEP)

The design of the inventory took into account patient's different areas of life and functioning. Factor analysis was used to study whether these theoretical constructs are also statistically reflected in the data. First, a principal component analysis with varimax rotation was calculated on the 52 items. Further analysis with Velicer's MAP test resulted in a 7-factor structure and a 5-factor solution with parallel analysis. Then confirmatory factor analyses were calculated for both solutions, whereby the 5-factor structure explained

Table 5. Confirmatory 7-factor solution inclusive of Cronbach's α for each factor

Items	Factor 1	Factor 2	Factor 3	Factor 4	Factor 5	Factor 6	Factor 7
$1 = interpersonal \ changes, \alpha = 0.93$							
01. More tense	0.743			0.290	-0.225	-0.514	0.237
02. Unhappier*	0.771				-0.345	-0.507	0.239
03. Less confident	0.772			0.226	-0.240	-0.508	0.314
04. Less hopeful*	0.800	0.220			-0.312	-0.429	0.246
05. More guilt	0.569					-0.233	0.282
06. More shame	0.592				0.269	-0.302	0.278
07. More lonely	0.543		0.291		-0.288	-0.305	0.513
08. More anxious	0.713			0.283	-0.342	-0.421	
09. Sadder*	0.802			0.241	-0.224	-0.431	0.310
10. Symptoms are worse*	0.736			0.327	-0.253	-0.498	0.209
11. 11. More difficult to trust others*	0.575		0.281	0.318	-0.321	-0.565	0.406
12. Self-acceptance more difficult	0.741				-0.274	-0.352	0.249
13. Dealing with conflicts worse	0.639			0.327	-0.390	-0.385	
14. Less troubled by my past*	0.518			0.314		-0.239	0.341
15. More difficult to make decisions on my own	0.580				-0.394	-0.203	
19. More frequently physically ill	0.412			0.465	-0.372	-0.205	0.394
20. More alcohol, pills or other drugs	0.293			0.240		-0.204	0.341
21. More suicidal thoughts	0.631			0.317		-0.229	
40. Approaching other people is harder	0.636			0.337	-0.388	-0.411	0.412
$2 = intimate relationship$, $\alpha = 0.79$							
29. Relationship with partner worse	0.303	0.470			-0.527	-0.281	0.434
30. More conflict in relationship		0.440			-0.578	-0.207	0.399
31. Partner complains more about problems		0.319			-0.565		0.420
32. Separation during or after treatment		0.816					
33. Partner avoids important topics of conversation		0.827					
34. My partner is or has been jealous of my therapist*		0.772					
35. Partner notes negative changes	0.204	0.711			-0.216		
47. More careless in everyday work		0.413	0.253	0.234	-0.201		
$3 = \text{stigmatization}, \alpha = 0.67$							
45. I am anxious that classmates/fellow students/colleagues could find out about my therapy*			0.701				
46. Excluded by classmates/fellow students/colleagues		0.333	0.735			-0.204	
48. Anxiety about an increased cost of insurance (life insurance, disability insurance)*			0.719				
49. Problems with insurance after completing therapy [*]			0.623				
50. More financial worries"	0.357		0.629	0.364		-0.410	0.208
52. I feel bad about the fact that I underwent psychotherapy.	0.578		0.259		-0.282	-0.456	
$4 = \text{emotions}, \alpha = 0.72$							
16. Longer periods when things were not going well*	0.239			0.757			
17. Less secure, more labile or less resilient*	0.223			0.743			0.251
18. Became a worse person*	0.336			0.583		-0.390	0.293
22. Suicidal thoughts/intentions for the first time *				0.485			-0.324

Table 5. Confirmatory 7-factor solution inclusive of Cronbach's α for each factor (continued)

Items	Factor 1	Factor 2	Factor 3	Factor 4	Factor 5	Factor 6	Factor 7
$5 = \text{job}, \alpha = 0.79$ 41. Tasks on the job/in apprenticeship/at the university and/or in the household are harder	0.575			0.314	-0.579	-0.357	
42. Concentration on work is worse	0.488		0.302	0.327	-0.655	-0.357	0.226
43. Absenteeism from work more frequent	0.341			0.284	-0.588	-0.335	
44. More conflicts with classmates/fellow students/colleagues/ superiors	0.211				-0.551	-0.237	
51. Career opportunities have decreased	0.509		0.271	0.323	-0.417	-0.417	0.234
$6 = \text{therapeutic malpractice}, \alpha = 0.73$							
23. Hurtful statements by the therapist*	0.246			0.363		-0.761	
24. Felt personally ridiculed by my therapist			0.456			-0.685	0.246
25. Sexual harassment by my therapist*			0.524			-0.371	0.258
26. Therapist attacked me physically*			0.211		0.287	-0.267	0.442
27. Therapist forced me to do certain parts of the treatment (e.g., confrontation, role play, etc.)	0.253		0.231			-0.657	0.303
28. Therapist violated confidentiality*			0.555	0.318		-0.557	0.370
7 = family and friends, $\alpha = 0.74$							
36. Worse relationship with family*	0.364			0.260	-0.278	-0.304	0.698
37. Worse understood by the family	0.310	0.218	0.227		-0.249	-0.218	0.708
38. Worse relationship with friends	0.584		0.401		-0.267	-0.372	0.353
39. Worse understood by friends	0.589		0.439		-0.335	-0.287	0.237

Base: 195 former psychotherapy patients; total variance explained: 55.8%; extraction method: principal component analysis, values according to varimax rotation with Kaiser normalization; Items that are part of the Inventory for the Assessment of Negative Effects of Psychotherapy (INEP) factor loadings below 0.2 are not listed.

46.7% of the variance, and the 7-factor structure yielded an explained variance of 55.8%. After examination of the individual factor structures and item loading as well as considerations of content, the 7-factor structure was determined to be the most appropriate. In cases of double loadings, the items were assigned to a corresponding factor based on content considerations. The characteristic values of the confirmatory analysis with 7 factors are to be found in table 5.

The first factor (intrapersonal changes) comprises 19 items and describes, in the broadest sense, negative effects on emotional experience and social functioning. The second factor (intimate relationship) records 8 items with negative effects within the relationship that were triggered by the therapy. Factor 3 (stigmatization; 6 items) describes fears of being stigmatized by others and actual discrimination because of having been a psychotherapy patient. The 4 items in factor 4 (emotions) describe negative effects that resemble depressive symptoms. Factor 5 (workplace; 5 items) and factor 7 (family and friends; 4 items) describe negative effects in these areas of life. Factor 6 comprises 6 items and describes therapeutic malpractice by the practitioner. Item 23 ('I felt offended by what the therapist told me') and item 27 ('During therapy, my therapist forced me to do things that I really did not want to do') were assigned, based on their content, to the factor 'therapeutic malpractice'. The items in the questionnaire have the same response format with 2 different scales and have a high internal consistency, which may explain some of the common loadings.

The INEP was constructed using statistical and content criteria, with the aim of producing an economical instrument. Items for detecting therapeutic malpractice (factor 6) were included in the INEP, regardless of their frequencies, because these phenomena, although rare, are particularly serious and thus should always be recorded. Later on, negative effects were selected that recorded high factor loading (factor loadings > 0.5; cross-loading > 0.35) and/or were the most commonly reported (excluding the first quartile, i.e. frequency > 16%). These criteria were chosen to identify the relevant items per factor and to eliminate rare negative effects. After applying the considerations of content and the statistical criteria of 'factor loading' and 'frequency', the number of items was reduced to 26 (table 5). These items were then checked for possible inter-correlations in order to avoid redundancies. If this inter-item correlation exceeded 0.60, the items were merged on a content basis to form a new item. Thus items 1, 2, 4, 9, 10 as well as items 16 and 17, and items 48 and 49 were merged because of the high inter-item correlations (r_{pearson} between 0.65 and 0.74) and now read as follows:

 Items 1, 2, 4, 9, 10: 'Since completing my treatment, I feel better/worse'.

- Items 16, 17: 'Since completing my therapy, I have had longer periods when things were not going well'.
- Items 48, 49: 'Since completing my therapy, I have had problems with insurance (e.g., life insurance) or anxiety that problems could arise'.

The total questionnaire consisted of 20 items. At the suggestion of a psychodynamic therapy expert, a new item was generated that, along with item 15, was intended to assess dependence on the therapist ('Since completing my therapy, I have felt dependent on my therapist'). The internal consistency of the items included in the final version (k=21) was a Cronbach's α of 0.86. Finally, two open questions were added about additional negative effects and other causes of negative effects aside from psychotherapy, in order to obtain information about other negative changes and to take them into account in the further development of the instrument. The 7-point bipolar response format (4-stage for unipolar items) was maintained. These 21 items (excluding the two open questions) are now included in the INEP.

Discussion

The goal of this study was to obtain first data on prevalences and correlates of negative effects of psychotherapy. For this purpose, we developed an economic and reliable self-assessment instrument, the INEP, with 21 items.

It can be generally stated that, in addition to positive effects, a significant number of negative effects of psychotherapy were reported. Only a small percentage of participants reported no negative changes as a result of their treatment. The prevalence of individual negative effects ranged from 1 to 55.9%, with mean frequencies ranging from 6.8 to 15.8%, depending on the area of life involved. These prevalences are thus slightly higher than in comparable studies of treatment failure [Lambert and Ogles, 2004]. On average, the former psychotherapy patients reported the most frequent negative changes in their own thoughts and feelings (15.8%) - that is where the risk of negative effects seems to be particularly great. This could be directly related to the fact that a majority of psychotherapeutic interventions involve precisely this area and therefore could cause the most harm. On the other hand, these frequencies could also be explained by an increased sensitivity to changes in the patient's own thoughts and feelings, which the patient learned through psychotherapy.

For the domain of intimate relationships, Hand and Lamontagne [1976] found that 33% of patients experienced increased conflicts with their partners after treatment for agoraphobia. In the sample described here, the frequency of negative effects in the relationship turned out to be lower – 12% on average. For the individual items, 7.9-18.4% of respondents reported negative effects of psychotherapy on their intimate relationships. Considering only the patients with a diagnosis of anxiety disorder (n = 103), an average of 7.8% of re-

spondents reported negative effects on their relationships; patients with depression reported somewhat more (8.5%). Patients with personality disorders described on average fewer negative effects (6.3%) within the relationship. However, the validity of the self-reported diagnosis must be considered.

In addition to these effects, patients also described serious and worrisome changes. A substantial number of participants (14.9%) said they had experienced suicidal thoughts for the first time in the context of the treatment. In addition, 1–2.6% of the participants reported sexual harassment and physical attacks by the therapist – therapeutic malpractice, which could lead to further negative changes for the patient. These figures are somewhat lower than those reported in previous studies. Thus, Tschan [2005] reports that there is sexual contact between therapist and patient in about 10% of psychotherapies. These findings support the ethical and legal relevance of the topic and make it imperative to deal with the negative effects of psychotherapeutic treatment.

The newly developed inventory has proven to be objective and reliable. The theoretically constructed classification of the negative effects in various areas of life and function was confirmed by factor analysis and utilized to create an economical instrument (the INEP). Follow-up studies should examine replicability of the factor structure.

No statements can be made yet regarding the validity of the INEP. The regression analysis carried out here gives preliminary indications of possible correlates of the negative effects of psychotherapy, but the directionality of the correlations is still unclear. A poor therapeutic alliance and unfulfilled treatment expectations on the part of the patient seem to be risk factors for negative effects. Negative effects are also more common in the inpatient clinical setting than in outpatient treatment. One reason for this may be the greater symptom severity of hospitalized patients, which would tend to promote the perception of a therapeutic effect as negative. In this study, however, the data necessary to assess the symptom severity of the participants was not available. It is common that only a few individual sessions are conducted for inpatient treatments and therapists change not infrequently, making it more difficult to establish trust between patient and therapist. In addition to these specific characteristics of the therapy, patients diagnosed with a personality disorder had a tendency to greater experience of negative effects. It is likely that this result is closely related to the lack of interpersonal skills of this group of patients and thus, in the therapeutic context, problems may arise that increase the risk of subjectively experienced negative effects. The reasons for the correlations mentioned above are certainly diverse, but could only be subjected to speculation here.

No correlations were found between the total number of negative effects and the socio-demographic patient characteristics or specific therapeutic methods. However, differences among schools of psychotherapy did appear on the item level: Patients undergoing behavioral therapy (BT) more frequently reported that they had been forced by their therapist to undergo certain interventions (36.5%). For comparison: patients in psychodynamic therapy (PD; 23.0%), nondirective therapy (NT; 30.0%) and other forms of therapy (40.0%). Patients in NT in the current sample stated that they had longer episodes of depression after therapy (NT = 50%; other = 50.0%; BT = 40.5%; PD = 37.7%), while patients undergoing PD more frequently felt offended by what their therapist told them (PD = 65.6%; NT = 60%; BT = 50%; other = 40.0%).

These variables are preliminary indications of convergent and divergent constructs and must be investigated further in follow-up surveys. An interesting question for follow-up studies would be whether the negative effects occur, for example, even after successful therapy, or whether they increase after treatment failure.

Limitations and Future Research

Even though it could be shown that negative effects occur as a result of psychotherapeutic treatment and can be detected using the INEP, the current study is still limited in some respects. The participants were exclusively people who had experience in psychotherapy and were recruited via the Internet. The results therefore cannot be readily generalized and should be verified in other patient samples. Nor can it be ruled out that there was a self-selection bias in the current sample. However, from subsequent qualitative interviews with some subjects (n = 35), we know that some patients who took part said they were very positive about their treatment, while others were unhappy with it. In regard to the representativeness of samples, Gosling and colleagues [2004] compared several Internet samples with traditional paper-andpencil samples and came to the conclusion that the validity of the data collected was identical in the two types of studies.

Within our newly developed definition of negative effects, the effects studied are described as negative even if the valence of the individual effect is not directly accessed by the questionnaire. We tried to approximate this valence indirectly via the bipolar item format. In addition, it can be assumed from the effects that were queried that they initially represent a stressor for the patient and are therefore at first perceived as negative. Thus separation from one's partner, even if this is desired, is a high distress factor. Yet it cannot be ruled out that a negative effect for the individual patient could later be seen to also have positive aspects. However, this is not the subject of the questionnaire and the study.

A further limitation is that the INEP assesses only the client's perspective, and thus lacks the external validity that might be provided by the practitioner's perspective. Although the subjective experience of the patient is of central importance and must not be omitted in the study of negative effects, the instrument does not allow crosschecking of the experienced negative effects with the effects observed by therapists. For this purpose, Haupt and Linden [2011] developed an in-

strument that detects unexpected effects from the therapist's perspective and could be a useful complement to the INEP.

In addition, the validity of some patient data must be considered uncertain in the context of the survey (e.g., diagnoses, therapeutic approaches). The entire survey was carried out retrospectively, such that varying lengths of time had elapsed among the different participants since the termination of therapy, and thus the responses might be of varying quality.

Implications

The prevailing opinion up until now has been that in the 'worst case', psychotherapy does not have any effect at all; and unlike other, especially medical, interventions, it may have only a few or no negative effects and, if properly carried out, the patient cannot be harmed. However the current study shows that psychotherapy, in addition to all its positive effects, also might have unwanted negative effects. Clinicians should be aware that psychotherapy has potentially good and bad influences beyond the main symptoms, extending to other areas of life and function. Clients as well as therapists and therapists-in-training should be aware of the possibility of negative effects and be sensitive to it. This could be done in a way similar to the assessment of criteria for success, using a standard evaluation of negative effects. Even if some (but by no means all) negative effects can be seen as part of the therapeutic process and perhaps even as necessary, it would still be desirable to reduce their frequency. In compliance with the legal obligation (Patientenrechtegesetz, the German law for patients' rights) to inform patients in psychotherapy before starting treatment about possible negative effects, the INEP provides a valuable source of information. In addition to these clinical implications, the systematic study of negative effects in different settings and from different perspectives must be continued. Only then will we be able to better understand how and under what circumstances negative effects are reported by patients and how we want to deal with these in the future.

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