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Effectiveness and safety of the adjunctive use of an internet-based self-management intervention for borderline personality disorder in addition to care as usual: results from a randomised controlled trial

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ABSTRACT

Importance Borderline personality disorder (BPD) is a severe mental disorder that is often inadequately treated.

Objective To determine if adding a self-management intervention to care as usual (CAU) is effective and safe.

Design Randomised, controlled, rater-blind trial. Duration of treatment and assessments: 12 months.

Setting Secondary care, recruited mainly via the internet.

Participants Patients with BPD and BPD Severity Index (BPDSI) of at least 15.

Interventions CAU by treating psychiatrist and/or psychotherapist alone or adjunctive use of an internet-based self-management intervention that is based on schema therapy (priovi).

Main outcome measure Outcomes were assessed by trained raters. The primary outcome was change in BPDSI. The safety outcome was the number of serious adverse events (SAEs). The primary outcome time point was 12 months after randomisation.

Results Of 383 participants assessed for eligibility, 204 were included (91.7% female, mean age: 32.4 years; 74% were in psychotherapy and 26% were in psychiatric treatment). The slope of BPDSI change did not differ significantly between groups from baseline to 12 months ($F_{3,248}$= 1.857, p=0.14). At 12 months, the within-group effect sizes were d=1.38 (95% CI 1.07 to 1.68) for the intervention group and d=1.02 (95% CI 0.73 to 1.31) for the control group. The between-group effect size was d=0.27 (95% CI 0.00 to 0.55) in the intention-to-treat sample and d=0.39 (95% CI 0.09 to 0.68) for those who used the intervention for at least 3 hours (per-protocol sample). We found no significant differences in SAEs.

Conclusions We have not found a significant effect in favour of the intervention. This might be due to the unexpectedly large effect in the group receiving CAU by a psychiatrist and/or psychotherapist alone.

Trial registration NCT03418142.

Strengths and limitations of this study

- This is the first randomised controlled trial (RCT) testing the effectiveness and safety of an internet-based self-management interventions (SMIs) for borderline personality disorder (BPD).
- Regarding internal validity, adherence to the intervention was high and strict rater blinding procedures were in place for the primary outcome measure.
- With respect to external validity, about half of all participants were excluded before randomisation, mainly because they did not return a form by their treating psychiatrist or psychotherapist confirming that they are eligible for the study.
- Given the large treatment gap for BPD, a larger RCT with less stringent inclusion criteria should be conducted because SMIs can easily be distributed widely and, therefore, the small effect on an individual level might still have a considerable societal impact.

INTRODUCTION

Borderline personality disorder (BPD) is a common, debilitating and costly mental disorder.[1 2] A broad range of effective psychotherapeutic approaches exist,[3–5] but fewer than one in four patients with BPD have access to them.[6] Current efforts to reduce this treatment gap focus on increasing access to psychosocial treatments for patients with BPD,[7] for example, through expanding the availability of liaison psychiatry services for patients presenting to the emergency department following self-harm.[8]

The treatment gap can also be reduced with internet-based self-management interventions (SMIs) that are based on evidence-based psychotherapies. SMIs can be used in

self-guided and guided versions as well as in a blended format. In blended interventions, SMIs may serve as an adjunct to face-to-face psychotherapy (ie, as parallel interventions) or they can be integrated into face-to-face therapy (eg, by relying on the same treatment rationale and/or selecting modules according to the individual course of face-to-face therapy).[9] The efficacy of SMIs has been demonstrated in meta-analyses for numerous mental disorders.[10 11] However, no large randomised controlled trial (RCT) has tested the effectiveness of these interventions in the treatment of BPD. We are aware of only one RCT of a psychoeducational SMI specifically targeting patients with BPD.[12] Another pilot trial targeted suicidal individuals engaging in heavy episodic drinking[13] and examined the efficacy of an SMI based on dialectical behavioural therapy (DBT), an established psychotherapy for BPD. Both trials demonstrated the effectiveness of the respective intervention, suggesting the potential of SMIs in this population. Furthermore, several smartphone applications have been tested in RCTs but all of them targeted patients with elevated symptoms of BPD (eg, suicidality) rather than patients with a BPD diagnosis. None of them yielded positive results with regard to BPD symptoms.[14]

In summary, the results from the currently available trials of SMIs in the treatment of BPD are mixed. It has also been argued that for the treatment of BPD, blended therapy is preferable to a self-guided or guided SMI because of safety concerns in this patient population that frequently engages in self-harm behaviours.[15–17] Therefore, we conducted the Research Evaluating the EffectiVeness of Adding an Internet-Based Self-Management Intervention to Usual Care in the Treatment of Borderline Personality Disorder (REVISIT-BPD) trial to test the effectiveness and safety of the adjunctive use of the SMI priovi in addition to care as usual (CAU) provided by a psychiatrist/psychotherapist. We hypothesised that the addition of this intervention to CAU will be safe and lead to a greater reduction of BPD symptom severity than CAU alone. It is the first large RCT of an SMI for BPD. Whereas most SMIs are based on cognitive behavioural therapy (CBT), this is the first RCT of an SMI based on schema therapy (ST), an established psychotherapy for BPD that is generally regarded as belonging to the 'third wave' of CBT.

METHODS

The REVISIT-BPD trial was a randomised (1:1), controlled, parallel group and rater-blind trial that adhered to methodological recommendations for RCTs of psychological interventions.[18 19] It was prospectively registered at ClinicalTrials.gov and the protocol and statistical analysis plan have been published.[20] Documented monitoring visits were conducted regularly to ensure adherence to the study protocol.

Procedures

Study participants were mainly recruited online, but they could also be referred by other means (eg, their treating clinician). After providing online informed consent, all participants completed an online questionnaire and a telephone interview to check inclusion criteria. At the end of this interview, an individual crisis plan was established; crisis contacts included both professionals and friends. Next, eligible participants had to ask their treating psychiatrist or psychotherapist to complete a form confirming BPD diagnosis and suitability for the study. After receipt of this confirmation, participants were randomised. They were contacted again at 3 months, 6 months, 9 months and 12 months after randomisation. All assessments included an online questionnaire and a telephone interview, except for the 9-month assessment (online only).

Participants

Patients were included with a total score of at least 15 on the clinician-rated BPD Severity Index (BPDSI)[21 22] and a diagnosis of BPD according to DSM-IV (at least five definite criteria), as assessed by the structured clinical interview for DSM-IV (SCID).[23 24] Patients were also included with a probable BPD diagnosis (three definite and at least two probable DSM-5 criteria), but only if they had already received a BPD diagnosis by their treating clinician. They had to be at least 18 years old, provide informed consent, have an adequate command of the German language and provide confirmation of their diagnosis and their suitability for the study from their psychiatrist/psychotherapist. Exclusion criteria were psychotic disorder, primary diagnosis of substance use disorder or schizotypal disorder.

Interventions

Following a pragmatic design approach, all participants could use any form of usual care by their psychiatrist and/or psychotherapist. More specifically, participants were free to start, continue or discontinue any additional treatment, including but not limited to psychotherapy and psychopharmacotherapy. Participants in the control condition only received CAU in addition to information regarding freely available self-help online material. They were offered access to the SMI after the last assessment.

Participants in the intervention group received access to the SMI priovi in addition to CAU. In eight modules, it covers most of the content of ST (psychoeducation, imagery techniques and cognitive restructuring) but does not include chair work techniques and offers less scope for personalisation.[15 17 20] The modules are organised in simulated dialogues aimed at tailoring content delivery at the individual user. The SMI also offers daily text messages and a collection of exercises. It is recommended to use this SMI two times per week for half an hour. The first phase covers psychoeducation on human needs and emotions as well as BPD-specific modes. Exercises in the second phases are tailored to the modes of each patient and increasingly demanding depending on the capacity of the individual user. Participants can complete the full content in about 6 months, but it is recommended to use the intervention for an entire year. It was offered in an unguided format, but

participants could contact a hotline for technical support. Usage was logged automatically by the intervention and periods of inactivity of 5 min or longer were subtracted in the computation of the total usage time.

Outcome measures

The primary outcome time point was 12 months. The primary outcome measure was the BPDSI,[21 22] a clinician-rated semi-structured interview based on the DSM-IV criteria for BPD. It assesses the frequency of BPD symptoms during the past 3 months. Internal consistency of the BPDSI in our dataset was excellent (Cronbach's α=0.90). The main safety outcome was serious adverse events (SAEs), that is, life-threatening incidents (eg, self-injury, drug intoxication, accidents, etc), hospitalisation and suicide attempts. SAEs as well as one secondary study outcome (diagnosis of BPD according to DSM-IV criteria[23 24]) were also assessed via clinician ratings. Further details on rater training and the SAE assessment are described in the study protocol.[20]

The following secondary outcomes and safety parameters were assessed using self-report: BPD severity (BPD Checklist),[25] depressive symptoms (9-item Patient Health Questionnaire),[26] anxiety symptoms (7-item General Anxiety Scale),[27] quality of life (five-dimension three-level version of the EuroQoL questionnaire),[28] uncontrolled internet use[29] and negative treatment effects (Negative Effects Questionnaire).[30] Furthermore, all patients in the intervention group completed an 8-item measure of general satisfaction (ZUF-8).[31] All measures were used in their German version; they have adequate psychometric properties.

Sample size

Sample size calculation was based on the expected BPDSI difference between the intervention and the control group after 12 months. Based on an estimated effect size of Cohen's d of 0.40, a power of 0.80 and an alpha level of 0.05, 100 participants were required in each condition resulting in a target sample size of N=200. The effect size estimate was based on a meta-analysis,[32] where the between-group effect for add-on designs (in which both groups received CAU and one group received an additional BPD therapy) was g=0.40.

Randomisation

Participants were randomised equally (1:1) into intervention or control groups. Randomisation was stratified by the presence of a diagnosis of BPD (probable vs definite diagnosis). The allocation sequence was created by an independent investigator and kept concealed from participants and trial staff. Raters were blind to randomisation outcome. Further details are described in the study protocol.[20]

Statistical methods

Missing values for the continuous outcomes were substituted using multiple imputations (50 imputations per missing value). The imputation method we used is based on fully conditional specification, where each incomplete variable is imputed by a separate model.[33] To ensure congeniality between the imputation and the analysis model, we included the group variable into the imputation model.[34] In keeping with current recommendations,[35] we conducted inferential statistics only for the main hypotheses of our study, namely, the primary outcome (BPDSI) and one safety outcome (any SAE). These statistical analyses were performed on the intention-to-treat sample (ITT analysis: all randomised participants) using SPSS V.25.0. We provide descriptive statistics and effect sizes for all outcome measures. Effect sizes were labelled as small (d=0.2), medium (d=0.5) and large (d=0.8).

Main analyses

The primary outcome was analysed as change from baseline using a linear mixed model (LMM) analysis with adjustment for baseline measure. As random effects, we had intercepts for participants as well as by participant random slopes. The following fixed effects were entered: time, study group, diagnosis of BPD and time by group interaction. A first-order autoregressive covariance structure with heterogeneous covariances was chosen based on Akaike's information criterion from a fixed set of candidate structures. The study hypothesis was tested on the main effect of group. For the safety outcome (any SAE), we calculated logistic regression analyses adjusted for baseline severity of BPD (BPDSI).

Secondary analyses

We conducted a prespecified per-protocol analysis for the main outcome (BPDSI) that included only participants from the intervention group who used the intervention for at least 3 hours and compared these to all participants in the control group. We also performed two prespecified subgroup analyses to establish whether certain subgroup variables moderate the effect of the intervention on the BPDSI. In one subgroup analysis, we tested the influence of a definite SCID diagnosis of BPD. In another subgroup analysis, we tested the influence of concomitant psychotherapy.

Patient and public involvement

Patients and the public were not involved in the design of this study. They did, however, contribute to the dissemination of information about the study and thus contributed to recruitment. The burden of the intervention was assessed using a standardised side effect scale and a client-satisfaction scale.

RESULTS

Recruitment and participant flow

Recruitment lasted from February 2018 to December 2018. The last assessment was performed in December 2019. The full participant flow is displayed in figure 1. Briefly, 831 participants expressed interest in study participation; of these, 383 could be reached for eligibility assessment and 204 were included into the trial (53.3%).

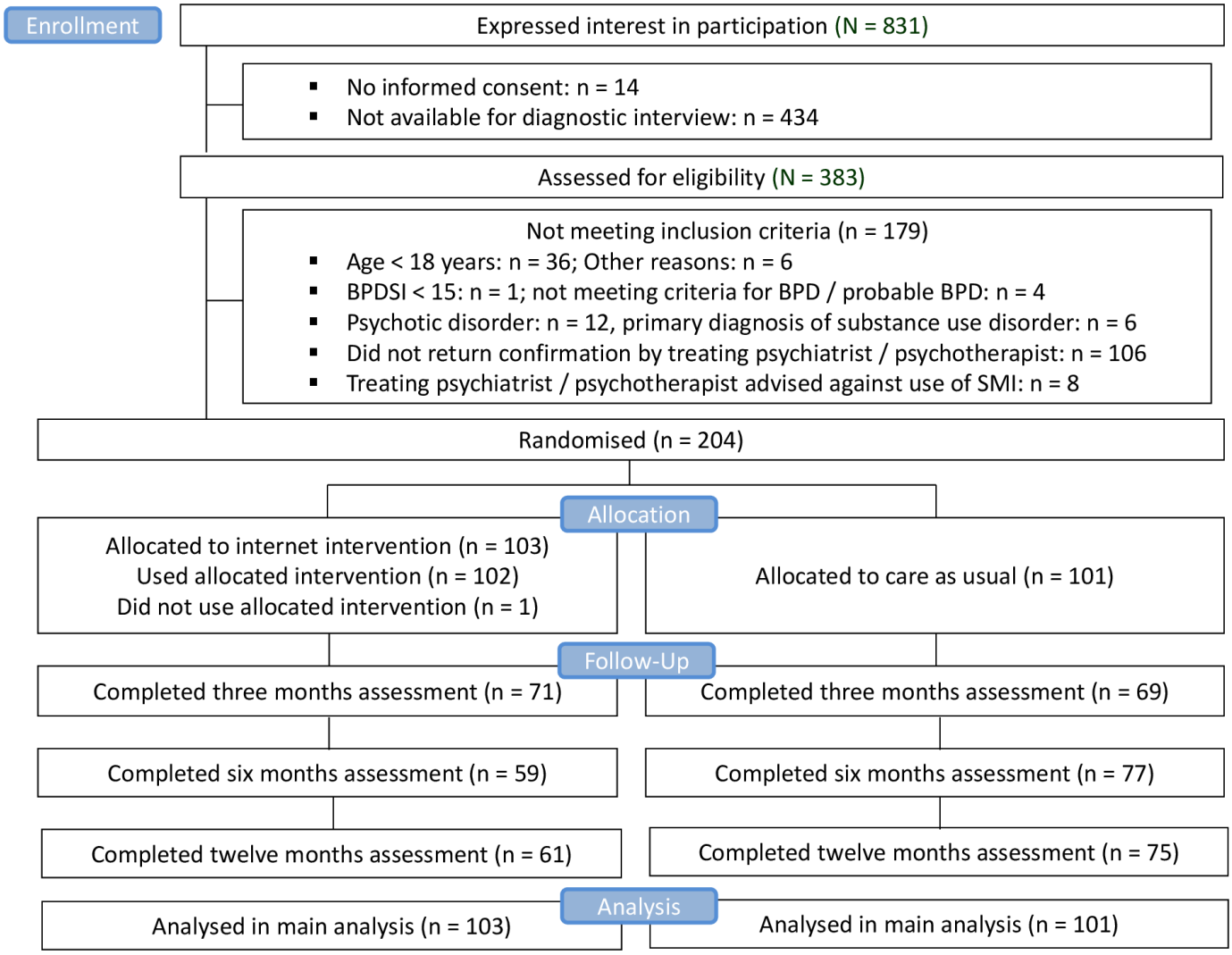

Figure 1 Patient flow. Trial design and flow of patients throughout the assessment time points for the primary outcome measure. BPD, borderline personality disorder; BPDSI, BPD Severity Index; SMI, self-management intervention.

The most common exclusion criterion was not returning the confirmation of diagnosis and study suitability by psychiatrist/psychotherapist (59.2%). Most patients were recruited via Google ads (52%) or Facebook ads (25%). Other recruitment sources included internet forums (9.8%). Only a few patients were recruited by their treating clinician (6.7%).

Retention rates for the primary outcome measure ranged from 68.6% for the 3-month assessment to 66.6% for the 9-month and the 12-month assessments. We computed a logistic regression analyses to explore whether any of the following variables were associated with drop-out: randomisation group, age, gender or baseline BPDSI. Not participating in any of the assessments after baseline was entered as dependent variable and the above-mentioned potential predictors of drop-out were entered as independent variables. None of the variables were significantly associated with drop-out status (Nagelkerke's R^2=0.057, Model $\chi^2(4)$=6.624, p=0.157).

Participant characteristics

Mean age of participants was 32.4 years (SD: 9.7), 91.7% were female and 71.5% were single. The most common education status was lower secondary education (43.2%) and 44.3% were unemployed. At baseline, 74% were in psychotherapy (of these, 88.1% were also in psychiatric treatment) and 26.0% were in psychiatric treatment only. Psychotherapy was mostly outpatient individual therapy (84.1%) or combined outpatient group and individual therapy (11.7%). Over the observation period, there was a slight increase in the ratio of patients who reported being in psychotherapy (online supplemental table 1 in the online supplemental file 1).

Intervention usage

A total of 103 patients were randomised to the intervention group. Almost all (99.0%) used the intervention at least once. The mean number of usage days was 41.44 (SD: 56.0) and mean usage duration was almost 11 hours (641.03 min, SD: 611.11). The mean number of sessions

Table 1 Results for the primary outcome using the BPDSI and the main safety outcome (SAEs)

	Intervention (N=103)		Control (N=101)					Effect size	
Primary outcome: BPDSI									
	M	SD	M	SD	Adjusted mean difference	95% CI	P value	Cohen's d	95% CI
Baseline	34.05	7.77	33.84	7.16	n.a.			−0.03	−0.30 to 0.25
3 months	27.85	7.42	29.47	8.40	1.50	−0.42 to 3.42	0.13	0.20	−0.07 to 0.48
6 months	26.98	8.36	26.97	9.27	0.57	−1.73 to 2.88	0.62	0.00	−0.28 to 0.27
12 months	23.49	7.50	25.69	8.69	2.34	0.02 to 4.66	<0.05	0.27	0.00 to 0.55
Main safety outcome: SAE									
	n	%	n	%	Wald $\chi 2_1$		P value	OR	95% CI
Baseline	29	29.0	30	29.4	n.a.			0.98	0.53 to 1.82
3 months	17	24.6	23	32.4	1.037		0.31	0.68	0.32 to 1.42
6 months	22	28.6	18	30.5	0.081		0.77	0.90	0.42 to 1.91
12 months	21	28.0	12	19.7	1.213		0.27	1.58	0.70 to 3.54

BPDSI, borderline personality disorder severity index; M, mean; n.a., not applicable; SAE, serious adverse event.

per month steadily declined from about eight sessions in the first month to fewer than one session in the final month (online supplemental table 2 in the online supplemental file 1). Satisfaction rating (ZUF-8) was 24.41 (SD: 5.09) after 12 months, reflecting a generally positive appraisal of the intervention (the range of ZUF-8 scale is 8–32).

Outcomes

Descriptive statistics, test statistics and effect sizes for the primary outcome and for SAEs are summarised in table 1. All other outcomes are compiled in table 2 and online supplemental table 3 in the online supplemental file 1.

Main analyses

Regarding the primary outcome, BPDSI scores decreased in both groups (figure 2). The LMM analysis of the ITT sample showed that the average decrease in BPDSI was 2.27 points greater in the intervention group than in the control group (SE: 1.31, 95% CI −0.31 to 4.84). This difference was not statistically significant, however (t=1.728, p=0.08). Regarding safety, we found no significant difference between both groups at any of the assessment time points for the outcome 'any SAE'.

Effect sizes

For the BPDSI, the between-groups effect size at 12 months was d=0.27 (95% CI 0.00 to 0.55) and the pre–post effect sizes were d=1.38 (95% CI 1.07 to 1.68) for the intervention group and d=1.02 (95% CI 0.73 to 1.31) for the control group. With respect to BPDSI subscales, between-groups effects at 12 months ranged between d=0.36 (95% CI 0.09 to 0.64) in favour of the intervention for the 'Relationship' subscale and d=−0.09 (95% CI −0.37 to 0.18) in favour of the control group for the 'Affective Instability' subscale (online supplemental table 4 in the online supplemental file 1).

Secondary analyses

On the prespecified per-protocol analysis, including only those participants from the intervention group who used the intervention for at least 3 hours, we did find a statistically significant intervention effect: here, the average decrease in BPDSI was 2.72 points greater in the intervention group (SE: 1.35, 95% CI 0.07 to 5.37; t=2.013, p=0.04) and Cohen's d at 12 months was 0.39 (95% CI 0.09 to 0.68). Regarding the prespecified subgroup analyses, neither the 'intervention by diagnosis' interaction (t=1.149, p=0.25) nor the 'intervention by concurrent psychotherapy' interaction (t=0.747, p=0.46) was statistically significant.

DISCUSSION

In the REVISIT-BPD study, we examined effectiveness and safety of the adjunctive use of an SMI for BPD in addition to CAU offered by a psychiatrist and/or psychotherapist. Although we observed large pre–post reductions in the severity of borderline symptoms in both groups, the between-groups difference was not statistically significant. Regarding safety measures, we found no differences in SAEs between both groups.

Comparison with earlier research

The between-groups effect size observed in this study was smaller than anticipated. Sample size calculation was based on a between-groups effect of d=0.40.[32] A current review suggests that compared with CAU, effect sizes of psychotherapy for BPD can reach d=0.52.[5] In our study, the observed effect size was d=0.27 at the 12-month

Table 2 Results for selected secondary and safety outcomes

	Intention-to-treat sample						Per-protocol sample	
	Intervention (N=103)		Control (N=101)		Effect size		Effect size	
Diagnosis of BPD	**n**	**%**	**n**	**%**	**OR**	**95% CI**	**OR**	**95% CI**
Baseline	97	94.2	95	94.1	1.08	0.30 to 3.86	2.38	0.48 to 11.90
3 months	97	94.2	93	92.1	1.54	0.47 to 5.08	1.27	0.38 to 4.22
6 months	49	83.1	68	88.3	0.71	0.25 to 1.98	0.76	0.27 to 2.16
12 months	41	67.2	62	82.7	0.44	0.19 to 1.00	0.44	0.19 to 1.05
PHQ-9	**M**	**SD**	**M**	**SD**	**Cohen's d**	**95% CI**	**Cohen's d**	**95% CI**
Baseline	17.43	4.96	18.22	4.93	0.16	−0.11 to 0.43	0.18	−0.11 to 0.47
3 months	14.84	5.55	15.97	5.28	0.21	−0.07 to 0.48	0.29	−0.01 to 0.58
6 months	14.65	4.62	16.33	5.95	0.31	0.04 to 0.59	0.38	0.09 to 0.68
9 months	14.62	4.89	14.90	6.18	0.05	−0.22 to 0.33	0.14	−0.16 to 0.43
12 months	13.53	5.08	15.18	6.08	0.29	0.02 to 0.57	0.40	0.10 to 0.69
EQ-5D-3L	**M**	**SD**	**M**	**SD**	**Cohen's d**	**95% CI**	**Cohen's d**	**95% CI**
Baseline	0.51	0.21	0.49	0.21	0.10	−0.17 to 0.38	0.12	−0.17 to 0.42
3 months	0.54	0.21	0.52	0.20	0.13	−0.15 to 0.40	0.17	−0.12 to 0.47
6 months	0.54	0.20	0.53	0.22	0.04	−0.23 to 0.31	0.10	−0.19 to 0.40
9 months	0.53	0.22	0.56	0.23	−0.10	−0.38 to 0.17	−0.04	−0.34 to 0.25
12 months	0.60	0.18	0.57	0.22	0.16	−0.11 to 0.44	0.23	−0.06 to 0.53
NEQ symptoms	**M**	**SD**	**M**	**SD**	**Cohen's d**	**95% CI**	**Cohen's d**	**95% CI**
3 months	8.02	6.21	11.42	10.10	0.41	0.13 to 0.68	0.42	0.13 to 0.72
6 months	8.40	6.72	10.48	10.24	0.24	−0.04 to 0.52	0.23	−0.07 to 0.52
9 months	6.99	5.65	10.15	10.69	0.37	0.09 to 0.65	0.43	0.14 to 0.73
12 months	7.50	6.42	8.55	9.39	0.13	−0.14 to 0.41	0.19	−0.10 to 0.49
NEQ hopelessness	**M**	**SD**	**M**	**SD**	**Cohen's d**	**95% CI**	**Cohen's d**	**95% CI**
3 months	2.29	2.75	3.83	4.01	0.45	0.17 to 0.73	0.48	0.19 to 0.78
6 months	2.64	3.29	3.98	4.26	0.35	0.08 to 0.63	0.38	0.08 to 0.67
9 months	2.36	2.64	3.95	4.39	0.44	0.16 to 0.72	0.46	0.17 to 0.76
12 months	2.46	3.22	3.24	3.80	0.22	−0.05 to 0.50	0.32	0.02 to 0.61
NEQ failure	**M**	**SD**	**M**	**SD**	**Cohen's d**	**95% CI**	**Cohen's d**	**95% CI**
3 months	1.30	2.05	3.31	3.65	0.68	0.40 to 0.96	0.66	0.35 to 0.96
6 months	1.89	2.58	2.94	3.57	0.33	0.06 to 0.61	0.33	0.04 to 0.63
9 months	1.34	1.78	3.03	3.93	0.56	0.28 to 0.84	0.58	0.28 to 0.88
12 months	1.35	2.26	2.57	3.22	0.44	0.16 to 0.72	0.51	0.21 to 0.80

BPD, borderline personality disorder; EQ-5D-3L, five-dimension three-level version of the health-related quality of life questionnaire developed by the EuroQoL group; NEQ, Negative Effects Questionnaire; PHQ-9, 9-item Patient Health Questionnaire.

assessment. We believe that this between-groups effect size has to be interpreted against the background of an unexpectedly large pre–post effect in the comparison group (d=1.02). The size of this effect is comparable to the pre–post effect after 12 months observed in previous RCTs investigating intensive specialised BPD treatment, which ranged from d=0.94 for transference-focused therapy[36] to d=1.23 for highly intensive DBT.[37]

This magnitude of pre–post effect for active therapies is much larger than that reported for control therapies in a systematic review of psychotherapy for personality disorders (waiting list or non-specific control: d=0.25)[38] and a more recent RCT of DBT for BPD (clinical case management control: d=0.36).[39] Finally, in a study comparing online psychoeducation with an untreated control group, the intervention group had a pre–post effect of d=0.75 after 12 months, while in the control group the effect was d=0.00.[12] These results suggest that all participants in our study received high-quality treatment that was very effective. This suggestion is supported by the fact that more

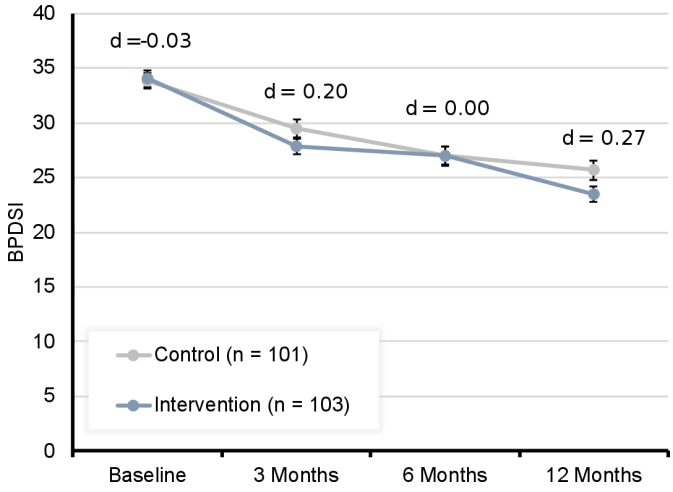

Figure 2 Means and SEs of the BPDSI score from baseline to 12 months. BPDSI, Borderline Personality Disorder Severity Index.

than three out of four patients received psychotherapy at baseline as well as during the entire study period. Given this highly effective CAU, the SMI we studied could only add very little additional benefit.

The patient satisfaction ratings reflect a generally positive appraisal of the intervention and confirm earlier findings for the use of another SMI in patients with severe depression.[40] Overall, the mean values for the intervention usage variables were very satisfactory, but variability in usage was high. Drop-out from the SMI was higher than in face-to-face ST: fewer than 50% of patients used the SMI in the fourth month of the intervention. By contrast, fewer than 10% of patients dropped out of treatment in the first year of a 3-year face-to-face treatment.[30] Of note, the intervention effect is statistically significant in the pre-planned per-protocol analysis of those participants who used the intervention for at least 3 hours. Here, the between-group effect is larger (d=0.39) suggesting that SMIs might have greater effects in those who adequately engage with them.[41]

Strengths and limitations

Regarding internal validity, we identified the following strengths[42]: patients adhered to the intended interventions (eg, almost all patients randomised to the SMI used it and participants in both groups did not differ with respect to concomitant psychotherapy), all our analyses were prespecified in the protocol and strict rater-blinding procedures were established. However, we did not systematically assess whether accidental unblinding occurred.

With respect to external validity,[43 44] the clinical and demographic characteristics of participants in our trial were similar to those from other trials investigating specialised BPD treatment.[36 37] However, only 53.3% of patients who were assessed for eligibility were randomised. By far, the most common reason for not being included was failure to return the required diagnostic confirmation by the treating clinician. It should also be noted that participants for this trial were mainly recruited via the internet and not from clinical settings. This suggests that our results can only be generalised to patients with BPD who are interested in using SMI and who are currently in specialist care by a psychiatrist or psychotherapist.

An additional strength of our study is that we assessed SAEs using a semi-structured interview. The assessment is based on the definition of SAEs in the good clinical practice (GCP) consensus guideline (https://ichgcp.net/1-glossary). Our semi-structured interview is an improvement on current GCP procedures in that most clinical trials assess the SAE variable based on patients spontaneous reports (for an example in psychotherapy research, see Meister *et al*[45]). However, the SAE assessment has not been psychometrically validated yet.

Future research

Given the small between-group effect size observed in this study, future trials of this SMI should be conducted with larger samples to increase statistical power. Because even if the effect we have observed is only small, it is important to consider that unguided forms of digital interventions can be disseminated widely at a low cost. Therefore, the small individual effect might still have a considerable societal impact. In these larger trials, participants should not be required to provide confirmation of their suitability for the study. This confirmation might have led to a selection of patients already receiving adequate treatment. A recent much larger study of an internet intervention for depression showed that the effect of the intervention was greater in those participants who did not receive concomitant psychotherapy.[46] This suggests that the intervention for BPD might prove to be effective in a larger RCT in currently untreated patients. These future trials should follow an implementation research framework[47 48] and include long-term follow-up, assessments of cost effectiveness and reach, as well as mediators of treatment effects. Putative mediators include the therapeutic alliance with the SMI.[49 50]

CONCLUSIONS

This study demonstrated the safety but not the effectiveness of priovi in the treatment of BPD. Further research and funding efforts should focus on SMIs as well as other strategies to increase access to care for patients with BPD.

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Competing interests AH-vM, GJ, JM and BW are employees of GAIA AG, Hamburg, Germany, the company that owns and runs the self-management interventions (SMI) tested in this trial. Both EF and GJ have received payments for training and published books/DVDs on schema therapy (ST) and treatment of borderline personality disorder. AH-vM receives payments for an ST card set published by Beltz. JPK received funding for clinical trials (German Federal Ministry of Health, Servier: distributor of the SMI 'Deprexis'), payments for presentations on internet interventions (Servier) and payments for workshops and books (Beltz, Elsevier and Hogrefe) on psychotherapy for chronic depression and on psychiatric emergencies.

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