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ORIGINAL PAPER

Promoting stigma coping and empowerment in patients with schizophrenia and depression: results of a cluster-RCT

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Abstract

There is a need for interventions supporting patients with mental health conditions in coping with stigma and discrimination. A psycho-educational group therapy module to promote stigma coping and empowerment (STEM) was developed and tested for efficacy in patients with schizophrenia or depression. 30 clinical centers participated in a cluster-randomized clinical trial, representing a broad spectrum of mental health care settings: in-patient (acute treatment, rehabilitation), out-patient, and day-hospitals. As randomized, patients in the intervention group clusters/centers received an illness-specific eight sessions standard psychoeducational group therapy plus three specific sessions on stigma coping and empowerment ('STEM'). In the control group clusters the same standard psychoeducational group therapy was extended to 11 sessions followed by one booster session in both conditions. In total, $N = 462$ patients were included in the analysis ($N = 117$ with schizophrenia spectrum disorders, ICD-10 F2x; $N = 345$ with depression, ICD-10 F31.3–F31.5, F32–F34, and F43.2). Clinical and stigma-related measures were assessed before and directly after treatment, as well as after 6 weeks, 6 months, and 12 months (M12). Primary outcome was improvement in quality of life (QoL) assessed with the WHO-QOL-BREF between pre-assessment and M12 analyzed by mixed models and adjusted for pre-treatment differences. Overall, QoL and secondary outcome measures (symptoms, functioning, compliance, internalized stigma, self-esteem, empowerment) improved significantly, but there was no significant difference between intervention and control group. The short STEM module has proven its practicability as an add-on in different settings in routine mental health care. The overall increase in empowerment in both, schizophrenia and depression, indicates patients' treatment benefit. However, factors contributing to improvement need to be explored. The study has been registered in the following trial registers. ClinicalTrials.gov: https://register.clinicaltrials.gov/ Registration number: NCT01655368. DRKS: https://www.drks.de/drks_web/ Registration number: DRKS00004217.

Keywords Stigma · Stigma coping intervention · Cluster-RCT · Depression · Schizophrenia

Introduction

Although psychiatric treatment and mental health care have improved in the last decades, people with mental illness still suffer from stigma and discrimination [1–3]. Even broad national anti-stigma programs showed only small effects in reducing public stigma of mental illness on the population level [4–6]. There is also evidence that the extent of the public stigma of mental illness has not changed (regarding depression) or has even increased (regarding schizophrenia)

Wolfgang Gaebel and Harald Zäske contributed equally to trial development and implementation as well as the preparation of this paper.

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[7]. Thus, for the next future people with mental illness will have to deal even more with experiences of stigmatization and discrimination [8]. The ways how people experience and react to being (potentially or actually) stigmatized and discriminated is usually subsumed under the term personal stigma [9], comprising enacted stigma (or discrimination experiences [10]), anticipated stigma [11], and (internalized) self-stigma [12]. In addition, stigma was conceptualized by some researchers in the context of stress and coping [13] especially regarding maladaptive coping strategies and its negative impact on self-esteem [14].

Consequences of the stigma of mental illness can be summarized by a general psycho-social impairment and reduced social participation, associated with reduced self-esteem, impaired quality of life, and reduced self-efficacy [1, 11, 12, 15], resulting in reduced engagement and feelings of powerlessness. Furthermore, self-stigmatizing attitudes are also associated with lower treatment adherence [15] and delayed use of treatment services already in the early illness course [16]. Against this background, a target of increasing importance for mental health care providers is to support patients with mental illness in coping with the different forms of stigma and particularly in reducing self-stigma, thereby strengthening empowerment [17]. Accordingly, psychosocial interventions have been developed aiming to reduce self-stigma by modifying patients' dysfunctional beliefs and attitudes and to empower patients by increasing self-esteem and self-efficacy [18–20]. However, sound evidence for efficacy of such interventions is still lacking [21–24].

In the present study, a psycho-educational group intervention to improve coping with stigma and to promote empowerment (STEM) for patients with schizophrenia or with depression has been tested for efficacy within a cluster-randomized multi-center clinical trial. Improvement of quality of life (QoL) after 12 months was analyzed as primary outcome criterion. Secondary outcomes comprised symptoms, functioning, self-stigmatization, self-esteem and empowerment. In addition, subgroup analyses for diagnostic groups will be conducted exploratively as post hoc analyses.

Method

Sample and design

In order to test the hypothesis of advantages of an (additional) intervention to improve coping with stigma and to promote empowerment (STEM) compared to a stigma non-specific psychoeducational group intervention (PE) regarding primary (QoL) and secondary outcome measures, a multi-center cluster-randomized trial was conducted according to the principles of the Declaration of Helsinki and audited by the Düsseldorf Coordinating Center for Clinical Trials. Ethical approval was first obtained by the local ethics committee of the coordinating center in Düsseldorf and subsequently by the ethics committees under responsibility of the other study centers. All participants filled in a written informed consent after they had been informed about the aim of the study, benefits and possible risks. Requirements for data privacy protection were assured by the Düsseldorf Coordination Center for Clinical Trials. The trial has been registered in an international (ClinicalTrials.gov: NCT01655368) and national study register (DRKS: https://www.drks.de/drks_web/: DRKS00004217). Study procedures and data assessment took place between May 2012 and June 2015.

Study inclusion criteria were defined by the following characteristics: clinical treatment diagnosis of a schizophrenia spectrum disorder or a depressive episode (according to ICD-10: F2, F31.3−F31.5, F32−F34, and F43.2); age (18−65 years according to the German mental health care structure), eligibility for regular psycho-educational group therapy, a written informed consent. Exclusion criteria were insufficient German language competence, as well as acute psychotic or dissociative symptoms.

The study was designed as a cluster-randomized control-group study with two study arms (intervention/"STEM" and control; see CONSORT chart in Fig. 1). Clusters were represented by 30 mental health services which were recruited out of different mental health settings: eight psychiatric wards at university or general hospitals, six wards from psychiatric rehabilitation clinics, eight day-units located at university or general hospitals, and eight outpatient psychiatrist practices or psychiatric outpatient departments. Initially it was intended to recruit eight centers for each setting, but two psychiatric rehabilitation centers withdrew their participation shortly before the recruitment of patients started so that substitute centers could not be found in the remaining time.

Participants of both the intervention and control group received regular treatment as usual in their mental health care setting. In addition, participants attended a psycho-educational group therapy (either for depression or for schizophrenia, [26, 27]) which regularly comprised eight manual-based sessions. For the intervention group three manual-based psycho-education group sessions about stigma coping and empowerment including also strategies of cognitive restructuring [28] were added which followed the regular 8-session psycho-education group therapy. The intervention-specific group sessions addressed the topics experiences of stigma and self-stigma, dealing with self-stigma and coping strategies, as well as self-disclosure of the own illness (see Table 1 for the contents of the intervention). The therapeutic approach is based on cognitive–behavioral therapy by focusing on the identification of negative self-related cognitions, on the development of alternative cognitions to replace self-devaluating cognitions, and the

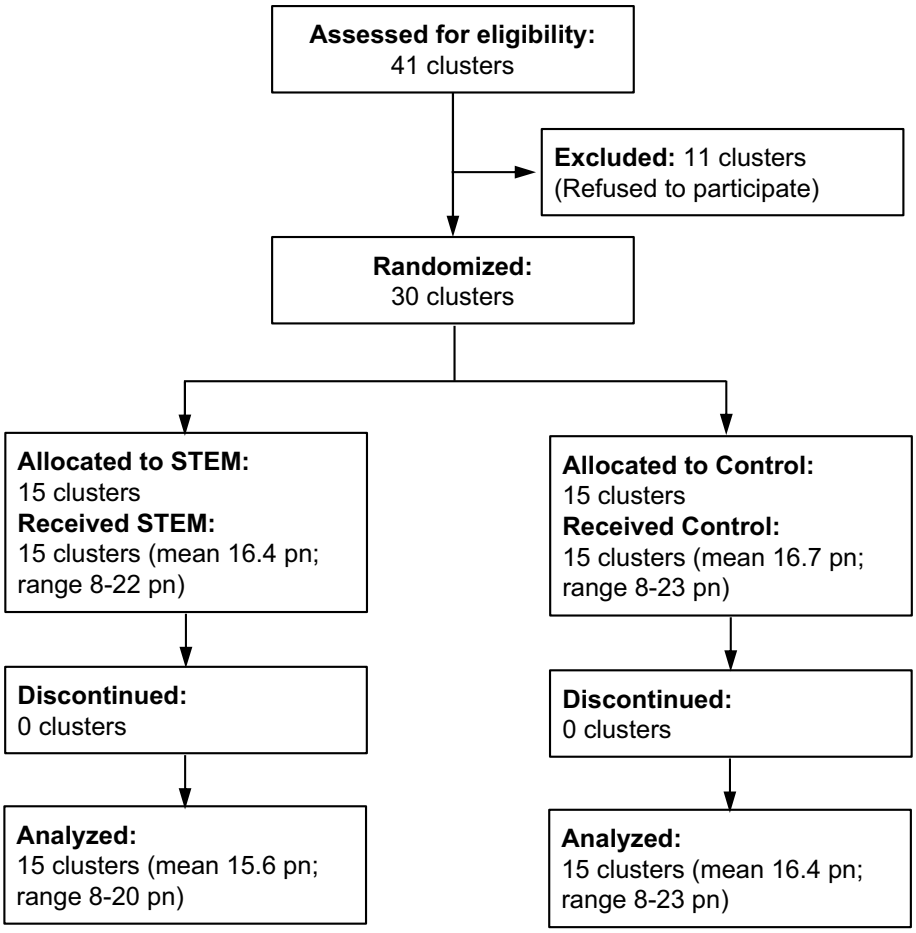

Fig. 1 Consort chart of the STEM trial (according to [25])

use of exercises as role plays and home exercises. Even if more sophisticated interventions have been developed in the last years (e.g., 'photovoice' or 'narrative enhancement' see [29]) we decided for this (short) add-on of a psychoeducational stigma intervention including also elements of cognitive restructuring to enable a pragmatic and broad implementation across the whole German mental health care structure, since psychoeducational groups are broadly distributed in Germany. The control group received the respective psycho-education treatment in which the topics of the 8 regular sessions were extended to 11 sessions by doubling single sessions about specific topics, e.g., medication. In both, treatment and control groups, an additional booster session was conducted 6 weeks after the last of the 11 group sessions. Two study centers deviated from the protocol scheme for the intervention/STEM-group of 8 regular, 3 stigma-related and 1 booster sessions (8-3-1) due to organizational reasons. The therapeutic schedule was shortened due to logistic reasons in one center, resulting in schedules of 6-2-1, 5-3-1, and 4-3-1 (with frequency of "regular"—"stigma-related"—"booster" sessions, respectively) which were conducted in one group each. A second study center conducted an additional booster session in one group after 6 months (8-3-2). Depending on the mental health service setting and the center-specific circumstances, the time required for the first 11 group sessions varied from less than 4 weeks with up to four sessions per week (in most rehabilitation clinics) to 11 weeks with one session per week (in most outpatient departments and day-hospitals).

Instruments and assessments

All clinical ratings and self-ratings were assessed at five assessment points: before the regular group sessions (pre), directly after completing all treatment sessions (post), 6 weeks (W6), 6 months (M6), and 12 months after the sessions (M12). The analyses for efficacy included data from the pre and M12 assessments.

Clinical ratings were conducted by clinical raters who were not involved in the psycho-educational groups, however no formal means for rater blinding were provided. The topics assessed and the used scales were as follows (see also Table 3): symptoms (HAM-D for patients with depression [30]; PANSS for patients with schizophrenia [31]), clinical global status CGI [32], general functioning GAF [33], and compliance (Kemp Compliance Scale [34]).

Table 1 Contents of the STEM intervention group sessions [25]

Session	Contents	
	Schizophrenia	**Depression**
1.-8. Regular Psycho-Education	• Introduction • Illness concept and symptoms • "Somatic bridge" • Vulnerability-stress model • Medication and side effects • Psychotherapy • Psycho-social therapies • Relapse prevention / crisis plan	• Introduction • Illness concept and symptoms • Vulnerability-stress model • Treatment: medication • Treatment: psychotherapy • Rising pleasant activities • Negative thoughts / crisis intervention • Relapse prevention
9. Experienced stigma and self-stigma	• Exchange of experiences • Introduction to the concepts of stigma and self-stigma	
	Home exercise: to write down individual self-stigmatizing thoughts	
10. Self-stigma	• Recapitulation: Self-stigma, dealing with self-stigma: alternative cognitions (practical exercises)	
	Home exercise: alternative cognitions for three own self-stigmatizing thoughts	
11. Coping strategies	• Recapitulation: alternative cognitions • Disclosure of the own illness: chances and risks (role plays)	
Booster (6 weeks later)	• Exchange of experiences (practical transfer in the last weeks) • Recapitulation of important contents • Alternative thoughts • Role plays and feedback	

Self-ratings included the following topics and scales: quality of life (WHO-QOL-BREF [35]), internalized stigma (ISMI [36]), empowerment (BUES [37]), self-esteem (Rosenberg SES [38]), and general symptoms (SCL-27 [39]).

In addition, various socio-demographic data were collected (see also Table 2): age, gender, family status, level of education (low education: no formal degree, basis education or secondary education until 15/16 years; medium: secondary education until 18 years or professional training,

Table 2 Sample characteristics ($N=462$)

	Total	STEM	PE	*p*
Participants (*N*/%)	462 (100%)	227 (49.1%)	235 (50.9%)	
Setting (*N*/%)				0.56
Psychiatric in-patient services	125 (27.1%)	63 (27.8%)	62 (26.4%)	
Psychiatric day-units	136 (29.4%)	62 (27.3%)	74 (31.5%)	
Psychiatric out-patient services	111 (24.0%)	60 (26.4%)	51 (21.7%)	
In-patient psychiatric rehabilitation services	90 (19.5%)	42 (18.5%)	48 (20.4%)	
Age (years; mean/SD)	41.4 (11.7)	42.1 (11.8)	40.7 (11.5)	0.19
Gender (*N*/%)				0.80
Female	268 (58.0%)	133 (58.6%)	135 (57.4%)	
Male	194 (42.0%)	94 (41.4%)	100 (42.6%)	
Family status (*N*/%)				0.25
Married	131 (28.4%)	67 (29.5%)	64 (27.2%)	
Unmarried but living together with partner	44 (9.5%)	22 (9.7%)	22 (9.4%)	
Widowed	16 (3.5%)	11 (4.8%)	5 (2.1%)	
Living apart	17 (3.7%)	11 (4.8%)	6 (2.6%)	
Divorced	52 (11.3%)	19 (8.4%)	33 (14.0%)	
Unmarried without partner	197 (42.6%)	95 (41.9%)	102 (43.4%)	
Other	5 (1.1%)	2 (0.9%)	3 (1.3%)	
Diagnosis (*N*/%)				0.068
Depression	345 (74.7%)	161 (70.9%)	184 (78.3%)	
Schizophrenia	117 (25.3%)	66 (29.1%)	51 (21.7%)	
Age at first treatment of the mental illness (years; mean/SD)	32.0 (12.4)	32.6 (12.8)	31.5 (12.0)	0.35

high: general qualification for university entrance or study), nationality and ethnic background, age at first treatment of a mental illness. Likewise, various socio-economic and other variables (working status, concomitant therapy, service utilization, and social activities; CSSRI [40]) were documented to enable an economic analysis which will be reported elsewhere.

For more detailed analyses of treatment specific effects, each group session was documented by the therapist including therapy time (in minutes per session) for each individual participant, topics addressed using a list of 12 topics (e.g., "self stigma", "illness model"), specific methods applied, and timeliness and cooperation of all participants. The respective analyses will be provided in a separate paper.

Statistical analysis

For testing pre-treatment group differences, the following bivariate tests were used: Chi-square tests, Fisher's exact tests, *t* tests for independent samples and one-way ANOVAs. Overall change in primary and secondary outcome measures for both treatment groups together were tested by *t* tests for paired samples. To test the main hypothesis for efficacy of the STEM intervention (greater improvement of the quality of life WHO-QOL total score in the intervention group between pre and M12) mixed models analyses were conducted including study site/cluster (as random effect), study arm and therapy setting (as fixed effects). In addition, variables in which pre-treatment differences occurred (see below: CGI, GAF, PANSS, diagnosis) were included as covariates. Since the PANSS was only assessed in patients with schizophrenia and the HAM-D in those with depression, the respective scores were transformed to *z* scores to form one variable for 'symptoms'. Group differences in secondary outcome measures (CGI, GAF, PANSS/HAM-D, compliance, ISIMI, BUES, SES and SCL) were tested accordingly.

A respective sample size calculation was conducted for a *t* test with $\alpha=0.05$ and $1-\beta/\text{power}=0.80$ (one-sided) and an estimated effect size of $d=0.3$. Based on an estimated intra-cluster-correlation (ICC) of 0.03 a total of $N=485$ persons resulted finally (which considers also a 30% drop-out rate). The diagnostic subgroup analyses were not considered in the sample size calculation and hence were conducted exploratively as post hoc analyses.

Results

Study sample

In total, $N=486$ patients were recruited in 30 study centers (clusters). The intention-to-treat (ITT) population as basis

for the analysis comprises $N = 462$ patients. $N = 24$ patients were excluded because of organizational reasons, consent withdrawal, or violation of inclusion criteria. The number of patients (ITT) in each cluster ranged from 8 to 23 with a mean value of 15.4 (SD = 3.1). In total, 66 groups were conducted (average number of groups per cluster: 2.2), 34 intervention groups in 15 study centers and 32 control groups in 15 centers. Two centers conducted one group each, 19 centers two groups each, and seven centers three groups each, and one center conducted four groups. Group sizes (number of initial participants in a group) ranged from 3 to 11 with a mean of 6.7 (SD = 2.0).

Follow-up rates were 78.8% (post), 74.0% (W6), 67.5% (M6), and 68.6% (M12) with a somewhat higher dropout rate in the STEM intervention group only at the first post assessment (STEM = 72.2%; control = 85.1%; Fisher's exact test $p = 0.001$) but not at the assessments W6 (STEM = 71.4%; control = 76.1%), M6 (STEM = 67.0%; control = 68.1%), and M12 (STEM = 67.8%; control = 69.4%; Fisher's exact tests $p > 0.05$). Overall dropout reasons were as follows: the participant could not be reached anymore (18.8%), withdrawal of informed consent (4.3%), severe adverse events (0.9%), other reasons (7.8%), or without giving any reasons (1.7%) with no significant differences between study groups.

The attendance rates for all 12 sessions were (on average) 10.9 sessions for the STEM/intervention group (SD = 2.7) and 11.1 sessions (SD = 2.5) for the control group (not statistically different, $p = 0.56$). Likewise, there was no significant difference in attending the sessions 9–11, in which the stigma-specific interventions were provided in the STEM-group (mean attendance rate 2.5 sessions; SD = 1.0) and (further on) illness-specific psychoeducational contents in the control group (mean attendance rate 2.6 sessions, SD = 1.1; $p = 0.15$).

Sample characteristics are presented in Table 2. Analyses yielded no significant pre-treatment differences between intervention and control group in various variables except for some significant advantages for STEM in CGI, GAF ($p < 0.001$, respectively) and PANSS ($p = 0.005$; assessed only in schizophrenia, see Table 3).

Outcome differences in primary (QoL) and secondary outcome measures

Mixed models procedures were conducted to test the primary hypothesis (greater improvement of the quality of life WHO-QoL total score in the intervention group between pre and M12) and differences in various secondary outcome measures (see Table 3).

As shown in Table 3, quality of life improved steadily and significantly but there was no significant difference between intervention and control group to be found ($p = 0.7$). Highest improvement evolved from pre- to post-intervention assessment, further significant improvements from post to W6 and from M6 to M12, similarly in both treatment groups. Likewise, no significant differences between STEM and PE evolved in different secondary measures like CGI ($p = 0.49$), GAF($p = 0.35$), PANSS/HAM-D ($p = 0.36$), compliance ($p = 0.42$), ISMI ($p = 0.83$), BUES ($p = 0.91$), SES ($p = 0.35$) and SCL ($p = 0.80$). Nevertheless, improvements (also steadily and significantly) were obtained in all secondary outcome measures for both treatment groups, predominantly from pre- to post-intervention assessment (see Table 3). Besides improvements in symptoms (PANSS, HAM-D, CGI, SCL-27) and functioning (GAF) the more treatment specific outcome measures like internalized stigma (ISMI), empowerment (BUES) and self-esteem (SES) did also improve (significantly) from pre to post, from post to W6 and from M6 to M12, however uniformly in both treatment groups.

In addition, setting was included in the analyses to control for moderator effects. However, neither a main effect of setting nor an interaction effect with treatment evolved in different outcome parameters (QoL, internalized stigma/ISMI, empowerment/BUES and self-esteem/SES).

Differences between patients with depression vs. schizophrenia

To test for outcome differences between the diagnostic groups additional mixed-model procedures have been performed, regarding 'main effects' (differences between depression and schizophrenia) as well as 'interaction effects' (differential effects for intervention and control group depending on diagnosis). Accordingly, several 'main effects' evolved, all in favor of patients with depression. Improvement for them was (significantly) higher in QoL ($p = 0.003$), symptom reduction ($p = 0.01$), empowerment (BUES; $p = 0.01$) and self-esteem ($p = 0.002$) as compared to patients with schizophrenia (independent of treatment group). Interestingly, also two interaction effects evolve in the mixed model procedure indicating a stronger improvement for schizophrenia patients in QoL ($p = 0.04$) and self-esteem ($p = 0.02$) in the intervention (STEM) group as compared to the control group, whereas patients with depression have similar treatment effects in both groups. However, post hoc performed t tests comparing STEM with PE only in patients with schizophrenia regarding these two outcome measures did not reach significance level (each $p > 0.2$).

Discussion

In the present study, the efficacy of an intervention to improve stigma coping and empowerment (STEM) as an add-on module to psycho-educational group therapy in

Table 3 Primary (WHO-QoL) and secondary outcome measures for intervention (STEM) and control (PE)

	Pre MW (SD)	Post MW (SD)	W6 MW (SD)	M6 MW (SD)	M12 MW (SD)	p^3
WHO-QoL						
PE	12.2 (2.4)	13.6 (2.4)*	14.0 (2.7)*	13.8 (2.6)	14.1 (2.7)*	0.7
STEM	12.2 (2.2)	13.4 (2.5)*	13.8 (2.5)*	13.7 (2.5)	13.9 (2.7)*	
CGI						
PE	4.5[1] (0.9)	3.7 (1.1)*	3.4 (1.2)*	3.4 (1.4)	3.2 (1.3)*	0.49
STEM	4.1 (0.9)	3.5 (1.1)*	3.3 (1.2)*	3.3 (1.2)	3.2 (1.3)*	
GAF						
PE	5.8[1] (1.2)	6.7 (1.3)*	7.0 (1.4)*	7.2 (1.5)*	7.5 (1.5)*	0.35
STEM	6.3 (1.2)	7.1 (1.3)*	7.3 (1.4)*	7.4 (1.4)*	7.5 (1.6)*	
PANSS						
PE	2.5[2] (0.9)	2.3 (0.7)*	2.2 (0.7)*	1.9 (0.7)	1.9 (0.8)	0.36#
STEM	2.2 (0.8)	1.9 (0.8)*	1.7 (0.7)*	1.7 (0.6)	1.8 (0.6)	
HAM-D						
PE	18.5 (7.9)	12.1 (7.7)*	11.1 (8.1)*	12.1 (8)	10.1 (8.2)*	0.36#
STEM	16.9 (7.8)	10.8 (7.3)*	10.3 (7.7)*	10.2 (7.8)	10.0 (8.5)*	
Kemp compl.						
PE	6.3 (1.3)	6.7 (0.9)*	6.7 (1.1)	6.6 (1.2)	6.7 (1.1)	0.42
STEM	6.5 (1.0)	6.8 (0.8)*	6.6 (0.9)	6.8 (0.5)	6.6 (1.0)	
ISMI						
PE	79.0 (14.0)	85.0 (14.5)*	87.7 (14.8)*	86.8 (15.4)	89.0 (15.0)*	0.83
STEM	78.3 (15.1)	84.6 (14.2)*	86.4 (14.5)*	87.1 (15.4)	87.1 (16.7)*	
BUES						
PE	75.9 (9.3)	79.3 (10)*	80.6 (11.2)*	80.7 (10.7)	81.8 (11.3)	0.91
STEM	74.6 (10.2)	78.0 (10.4)*	79.6 (10.2)*	79.8 (10.6)	79.7 (10.5)	
SES						
PE	25.5 (6.5)	28.3 (6.2)*	29.1 (6.6)*	28.9 (6.8)	29.6 (6.7)*	0.35
STEM	24.9 (6.5)	27.8 (6.3)*	28.9 (6.2)*	28.5 (6.9)	28.9 (7.2)*	
SCL-27 GSI						
PE	1.7 (0.7)	1.5 (0.6)*	1.3 (0.7)*	1.4 (0.7)*	1.3 (0.7)*	0.8
STEM	1.8 (0.7)	1.5 (0.7)*	1.4 (0.7)*	1.4 (0.7)*	1.4 (0.7)*	

[1] Single comparison control vs. intervention *t* test for independent samples $p < 0.001$

[2] Single comparison control vs. intervention *t* test for independent samples $p = 0.02$

[3] *p* for testing differences in change from 'pre' to 'M12' between PE and STEM based on mixed model procedures

[#] PANSS and HAM-D converted to *z* scores and tested together

[*] Significant differences to preceding assessment for both treatment groups together

CGI Clinical Global Impression Scale [32]; range: 1−7; higher values represent a more severe illness; *GAF* Global Assessment of Functioning [33]; range: 1−10; higher values represent a better functioning; *PANSS* (only for patients with schizophrenia) Positive and Negative Syndrome Scale [31]; range: 1−7; higher values represent a higher symptom load; *HAM-D* (only for patients with depression): Hamilton Depression Scale [30]; range: 0−66; higher values represent a higher symptom load; Kemp Compliance Scale [34]; range 1−7; higher values represent better compliance; *WHO-QOL* WHOQOL-BREF Quality of Life assessment [35]; range: 4−100; higher values represent better quality of life; *ISMI* Internalized Stigma of Mental Illness Scale [36]; range: 29−116; higher values represent less internalized stigma burden; *BUES* Boston University Empowerment Scale [37]; range: 28−112; higher values represent better empowerment; *SES* Rosenberg Self-esteem Scale [38]; range: 10−40; higher values represent better self-esteem; *SCL-27 GSI* Symptom Checklist 27 [39]; range: 0−4; higher values represent higher symptom load

patients with schizophrenia and depression was examined in a multi-center cluster-randomized clinical control group trial. Overall, quality of life of the participants as primary outcome improved significantly over time; however, this effect was not significantly different between the intervention and control group. Current reviews about anti-stigma

interventions with focus on patients as target group [18, 22–24] report a similar picture of weak or no effects in controlled trials addressing self-stigma or empowerment.

For this main result contrary to the hypothesis several possible reasons are to be discussed. First, the interventions' efficacy may not have evolved due to heterogeneous study conditions, mainly given by the two different diagnoses studied in various health care settings resulting in high variability which might have contributed to 'error' variance and lack of significant results. In addition, the applied standard treatment "TAU" including evidence based drug and different psychosocial interventions in both groups may have overruled a possible interventional effect [41]. Secondly, QoL is a rather global and 'distal' outcome measure depending on various factors and circumstances. Accordingly, a rather small intervention (restricted to the issue of stigma coping and empowerment and the amount of three group sessions) might be not powerful enough in relation to the other potential factors contributing to changes in quality of life.

A third possible explanation refers to a certain similarity of the interventions in both study conditions. Thus only three group sessions out of 12 were content-specific to stigma coping and empowerment in the intervention group. The idea to develop a therapy module that can be included into common psycho-education instead of a whole group therapy for stigma coping and empowerment was due to the assumed better practicability of an integrated therapy module. In addition, first analyses of the documentation of the therapy sessions indicate that therapists and/or patients do not follow as strictly as desired the manual especially in the psycho-education only control group. Accordingly, 27% of the patients in the control group discussed also the intervention-group specific topic "self-stigma", and about 15% of the patients in the intervention group miss to address stigma-specific topics, in nearly all cases because patients missed the relevant group sessions (session numbers 9−11) in which the stigma-related content was scheduled. A possible explanation for the rather high amount of self-stigma-related contents in the psychoeducational control group may be that group participants have a need to address stigma-related issues by their own. Since the therapists were encouraged not to suppress topics which were addressed by participants, this finding may reflect a high interest of these patients in the issue of self-stigma and stigma coping.

Finally, general psychoeducational contents might have also had impact on the stigma-specific outcomes thus reducing the differences between both groups, because imparting detailed knowledge about diagnosis, possible causes for the illness and treatment options is suggested to reduce stereotype endorsement, which is a core aspect of self-stigma [42].

Similar to the results regarding primary outcome, various secondary outcome measures like clinical (PANSS/HAM-D, CGI, SCL-27) or functional scales (GAF), compliance and also the more stigma and empowerment related measures (ISMI, BUES, SES) show significant improvements for patients, but again intervention and control group do not differ significantly. Although contrary to our expectations, all this corresponds to Mittal et al. [18] who concluded, outcome effects for interventions addressing people with mental health problems are small, if at all. It remains open to further research whether this is a problem of the assessed criteria and their measurement, or of the applied interventions.

The results regarding differences between the two diagnostic groups (depression and schizophrenia) that show throughout advantages in treatment course for patients with depression are in line with an overall less favorable outcome for patients with schizophrenia [43]. However, the results here indicate that this might be also the case regarding the specific factors relevant for stigma coping and empowerment [44]. Thus, such interventions need to take into account also specific illness characteristics and should be tailored accordingly.

Study limitations

The study was designed as a cluster-randomized clinical trial with the aim to rule out possible methodological artifacts, in particular regarding possible knowledge transfers between participants of the intervention and control group. The following restrictions should be noted: the study centers (clusters) were recruited selectively, however representing a broad range of mental health care in Germany. The number of clusters (30) is rather small. The number of groups per cluster and patients per groups varied, which might have decreased statistical power.

The primary outcome criterion quality of life (assessed by the WHO-QOL BREF) is a self-rating questionnaire. In addition, quality of life can be influenced by external factors that have not all been controlled for.

Other personal stigma concepts (stigma experiences and anticipated stigma [9]) have not been included into the assessment. However, a valid self-rating scale for stigma experiences (e.g., [45]) was not available during study implementation. Regarding anticipated stigma (e.g., the devaluation-discrimination scale [11]), we abstained from including it into the analysis, because the practical meaning for patients with mental illness is rather conflicting and complex (cf. [46]).

Conclusions

The stigma of mental illness causes severe impairment and burden in affected patients. Activities that fight stigma and its causes are important, but as long as stigmatization and

stigma experiences do not diminish, there is also a need for supporting patients to cope with these burdens [18] in particular since patients often employ negative strategies to cope with stigma and discrimination (cf. [47]). Contrary to the hypothesis, the results of the present study did not provide evidence for an efficacy of the STEM manual, a short add-on intervention in routine care psychoeducation, regarding quality of life or other secondary outcome measures. Nevertheless, study results show an overall increase also in measures assessing stigma coping and empowerment in both, patients with schizophrenia and depression. This indicates a need and a potential for improving stigma coping and empowerment, but contributing factors have to be further explored to develop more efficacious interventions.

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Compliance with ethical standards

Conflicts of interest J. Gallinat has received research funding from the German Federal Ministry of Education and Research, German Science Foundation, and speaker fees from Lundbeck, Janssen-Cilag, Lilly and Otsuka. All other authors state that they have no conflicts of interest.

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