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ORIGINAL PAPER

Efficacy of bifocal diagnosis-independent group psychoeducation in severe psychiatric disorders: results from a randomized controlled trial

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Abstract Despite evidence for its efficacy, diagnosis-specific psychoeducation is not routinely applied. This exploratory randomized controlled trial analyses the efficacy of an easily implementable bifocal diagnosis-mixed group psychoeducation in the treatment of severe psychiatric disorders regarding readmission, compliance and clinical variables, for example global functioning. Inpatients of the Psychiatric Hospital of the University of Basel ($N = 82$) were randomly assigned to a diagnosis-mixed psychoeducational (PE) or a non-specific intervention control group. Relatives were invited to join corresponding family groups. Results at baseline, 3- and 12-month follow-ups are presented. Better compliance after 3 months and a lower suicide rate were significant in favour of PE. For most other outcome variables, no significant differences, however advantages, in PE were found. In summary, it can be concluded that diagnosis-mixed group psychoeducation is effective in the treatment of severe psychiatric disorders. The effects can be classified as induced by distinctive psychoeducational elements. Findings similar to those on psychosis-specific programmes justify clinical application and further investigation.

Keywords Psychoeducation · Group psychoeducation · Diagnosis-independent · Diagnosis-mixed

Introduction

Psychoeducation (PE) is defined as a therapeutic intervention that implies the provision of illness- and treatment-related information, supportive elements and the promotion of management and coping strategies. It is mainly offered in groups for psychiatric patients and/or their relatives/carers [1, 2]. By now, PE is recommended in most evidence-based guidelines for a variety of diseases [3–5]. Trials and reviews report favourable effects, for example in depression and bipolar disorder [6, 7]. The Cochrane-analysis on findings in schizophrenia—its main application area—has shown a significant decrease of relapse and readmission rates in the intervention group. A tendency towards better adherence and gain of knowledge was found [8]. Family involvement reduced the relapse rate and readmission rate by 20% compared to PE directed at patients alone, improved social functioning and decreased relatives' burden [9–11]. A recent meta-analysis on psychoeducation in psychotic disorders revealed significantly reduced relapse and rehospitalization rates and better knowledge gain at post-treatment up to the 12 months follow-up, if families were included. No effects on symptoms, functioning and medication adherence were found. All effects achieved for PE directed at patients alone were not significant [12]. Meanwhile, new studies have been published, most of them including family members, and with significant results regarding various aspects [13]. In the updated guidelines of the National Institute for Health and Clinical Excellence (NICE) for the treatment of schizophrenia, the evidence was considered not recent and robust enough to make a specific recommendation. However, "related recommendations" were given [1].

Even in the treatment of schizophrenia, the employment of PE in clinical practice falls far short of the recommendations [14, 15]. A survey at all psychiatric hospitals in Germany, Switzerland and Austria revealed that only 21% of all schizophrenic inpatients and 2% of their relatives received PE. As main single reason lack of time and staff was accused, and the largest factor comprehended "other reasons", primarily "not enough patients with the same

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diagnosis available". The extremely rare application to family members has been striking [16]. The analysis concerning anxiety disorders revealed similar results [17].

To facilitate the implementation of psychoeducation in clinical routine and to consider that its main topics should be similar for a variety of severe psychiatric diseases [18], Rabovsky and Stoppe developed a diagnosis-mixed group programme [19, 20]. To date, only one comparable curriculum is available [21], and the efficacy has not been tested yet. Considering the evidence for combined programmes regarding compliance [22], the curriculum integrates cognitive-behavioural and interactive elements besides pure knowledge transfer, but still focuses on the provision of information and the promotion of management/coping strategies. Insofar, it is in accordance with the definition of the NICE-Guideline Development Group (GDG) as well as that of the German expert group [1, 2].

The bifocal programme is based on well-proven disorder-specific concepts [2, 23]. In contrast to traditional curricula, patients with all severe psychiatric diseases are admitted, especially those with schizophrenia, schizoaffective disorder, depression, bipolar, personality or anxiety disorders. Patients with organic brain and addiction disorders were excluded. The programme for patients consists of 10 sessions, 45–60 min each, and takes place semi-weekly. The setting is open, with at most 10 participants per group. The group for relatives is closed, consists of 5 sessions a 90 min, taking place (bi)weekly. With regard to contents, both programmes cover the classic psychoeducational topics like information on psychiatric symptoms and diseases, medication and other therapeutic options ("information-sessions"). Special emphasis is placed on cognitive-behavioural "training-sessions" that focus on skills to implement acquired knowledge in everyday life, for example medication management and coping strategies. The sessions are conducted by two trained group-leaders, one medical doctor or psychologist and one non-academic staff member (e.g. nurse) as co-therapist. Their attendance of supervision/intervision sessions assures stable performance quality (programme overview for patients and relatives see [20][1]).

[1] Topics of the 10 sessions for patients are as follows (I = Information-session, T = Training- session, D = Discussion): (1) I: Mental functioning and disorders and the vulnerability-stress-model; (2) I: The brain and the neurobiological disease-model; (3) T: Coping with symptoms; (4) I: Treatment options and medication; (5) T: Handling of medication and coping with side-effects; (6) I: Social aspects of mental diseases; (7) T: Communication skills; (8) D: Coping with stigmatization; (9) I: Preparation of discharge and relapse prevention; (10) T: Detecting early symptoms and "My individual crisis strategy". The program for relatives consists of 5 sessions including the topics of sessions 1, 2, 4, 6, 7 and 10 of the patient-version in a slightly modified form and additionally: Detection and management of challenging situations (T); Coping with feelings of shame and guilt (T); Stress reduction and problem solving strategies (T).

In order to test the hypothesis that this programme would be effective regarding readmission outcome, compliance, insight, social functioning, quality of life and other clinical parameters, we designed a small-scaled randomized controlled clinical trial with a follow-up period of one year as an explorative study. Both groups—psychoeducation (PE) and the control condition (CG)—were offered in addition to routine care. To explore the therapeutic impact of distinctive psychoeducational elements (like knowledge transfer), we tested against a control group that was very similar formatted except for those—presumably active–PE-specific features (non-specific group intervention).

Subjects and methods

Participants

The study was conducted from November 2007 to January 2010 on the inpatient wards of the Department of General Psychiatry of the Psychiatric Hospital of the University of Basel (UPK) in Basel/Switzerland. The study was approved by the local ethics committee of Basel (Ethikkommission beider Basel).

Inclusion criteria were as follows: at study entry 18–64 years old, inpatient of the UPK with one of the following diagnoses: Schizophrenia or psychotic disorder (ICD-10 F2: F20–schizophrenia, F22–persistent delusional disorder, F23–acute psychotic disorder, F25–schizoaffective disorder), affective disorder (F31–bipolar disorder, F32–depressive episode, F33–recurrent depression) or another severe psychiatric disease like anxiety or personality disorder (F4: neurotic, stress related and somatoform disorders, F60/61: personality disorders). Patients of the two latter categories were included only if the index admission was preceded by at least two hospitalizations or if the patient was invalid. Written informed consent had to be on hand. Exclusion criteria were as follows: organic brain disorder or IQ < 80, severe addiction disorder, severe physical comorbidity, pregnancy, lack of competence in German and ongoing disturbance of the study programme.

The patients ($n = 176$) were screened in order of their admission by the main investigator (KR) or another trained psychiatrist. $N = 87$ (49.4%) of them were included. Most of the other 89 patients (50.6%) refused informed consent; in some cases, the screening procedure revealed before unknown exclusion criteria. Five patients had to be belatedly excluded as protocol violators (PE: $n = 3$; CG: $n = 2$).

The randomization was performed in blocks of 20 patients and stratified with respect to sex (m/w), age (18–34, 35–49, 50–64 years) and diagnostic group (ICD-10

F2; F32/33; F31; F4/F6). An independent external centre performed the group assignment by a computerized random sampling and communicated it back by phone or email. 43 patients were allocated to PE and 44 patients to CG. The psychologists, who performed the assessments, were blinded to the assignment.

Study intervention

In addition to routine treatment, patients of the PE condition immediately after baseline assessment started the psychoeducational patient group programme, and patients of the control condition entered the open "social-activity-group". After the patients' discharge from hospital, the completion of the curriculum as outpatients was recommended. If the patients gave their consent, the relatives were motivated to join the corresponding family groups.

Structure, contents and characteristics of the psychoeducational curriculum have been described above [20].[1]

The control group was likewise led by an academic professional who was mostly supported by a nurse. The sessions for patients took place weekly, lasted 90–120 min each and covered both "theoretical" sessions (conversation with communication skill training elements, easy concentration training, etc.) as well as physically active collective leisure time activities (visiting the zoo etc.) and basic social skill training elements. The spectrum of contents was quite broad, and only distinctive psychoeducational elements were excluded. The control group for relatives was designed as a (bi)weekly conducted closed relaxation and stress management group, consisting of 4 or 5 sessions, and managed by a psychologist and physiotherapist.

Outcome measures and assessment instruments

Main outcome criteria were the rehospitalization rate (percentage of readmitted patients per group, RR), the total number of rehospitalizations (RA), and accumulated days in hospital (DIH), the two latter per group per patient, up to 12 months after finishing the programme. Compliance was assessed by a 14-point self-rating questionnaire (CFB), which covers not only medication compliance, but also general aspects as the avoidance of risk factors. The whole questionnaire can be seen in Fig. 1. The single items were judged with a Likert scale; the sum score was used for analysis. It is also available as versions for relatives and therapists. In this paper, exclusively the score from the patients' version is taken into account, because only few relatives and therapists participated, and the comparable sample would have become too small.

Secondary outcome variables were the clinical global impression (CGI) [24], global functioning (GAS) [25], quality of life (global score of WHO-QOL-BREF, German version: QOL) [26], insight into the disease (Insight Scale: IS) [27] and the therapeutic alliance ("Therapeutische Arbeitsbeziehung": TAB) [28] at baseline and at 3- and 12-month follow-up. All these tests are sufficiently validated, well proven and widely used in clinical research. The Insight Scale of Markova was used in the modified form published in 2003 [27] and translated into German by

1. I attend the appointments with my psychiatrist …
2. If I notice signals of a declining state of my health (by early symptoms like increasing irritability or sleep disturbance), I tell that to my family / friends or my physician …
3. Definitely by the time a new disease-episode appears, as indicated by typical symptoms, I talk about that to my family / friends or my physician
4. I comply with my physicians recommendations concerning physical examinations (e.g. laboratory tests, ECG, EEG or the like) …
5. I take the psychotropic drugs (medication against mental symptoms) exactly in the prescribed dose …
6. Independent of the exact dose, I take the prescribed psychotropic drugs at least in principle (so I don't skip any remedy completely)…
7. I take additional medication that is not prescribed (e.g. to remove tension, to change a bad mood, against pain, or the like) …
8. I consume alcohol …
9. I consume drugs like cannabis, ecstasy, heroin or cocaine …
10. If my doctor sets some specific „homework" to me (i.e. to keep a diary about eating or sleep) I do that homework …
11. If my psychiatrist recommends additional therapies (like psychological group therapy, occupational therapy, or similar), I follow his advice …
12. To keep me healthy and fit, I go to sleep not later than midnight …
13. I sleep at least 6 to 8 hours per night …
14. To promote my health, I try to protect me from harmful stress, i.e. by stress management strategies like *(example)*, …

Possible Answers (depending on what fits):

never	□	not more than once a month	□	several times per month	□	several times a week	□	daily	□

never	□	rarely	□	often	□	mostly	□	always	□

Fig. 1 Outline of the Compliance-Questionnaire—version for patients

the corresponding author (KR). Additional qualitative data were recorded, but will not be discussed in this paper.

Data were recorded at study entry (baseline, BL), after finishing the programme (which normally took 5–7 weeks, post-test) and 3, 6 and 12 months after post-test (3MO, 6MO, 12 MO). To cover the whole time course, we report the data of BL, 3MO and 12MO. Because of the inconsistent study compliance of several participants, the examination dates of 3MO and 12MO differ by up to 4 weeks from the scheduled calendar date. The rehospitalization parameters (RR, RA, DIH) were counted retrospectively for precisely 3 and 12 months after post-test.

Data analysis and statistical methods

Group differences (e.g. man/woman) were counted by chi-square test according to Pearson. If the requirements for using the chi-square test were not given, the Likelihood-Quotient-Chi-Square was indicated. Student's *t*-test was employed for comparisons of means between PE and CG concerning illness duration and clinical variables (CGI, GAS, IS, QOL, TAB and CFB). To test differences concerning rehospitalizations, the more robust Welch-test "w" was used instead of the classical Student's *t*-test, because the criterion for homogeneity of variance was not met [29]. In drop-out analyses, frequency distributions and mean comparisons concerning the above-mentioned variables were calculated with the same tests.

To analyse changes over time (baseline-3MO–12MO), a series of MANOVAs with time as within-subject factor (BL-12MO, 3MO–12MO) and group as between-subject factor (PE/CG) was conducted. In case of a diverging sphericity, degrees of freedom have been corrected according to Greenhouse-Geiser, the primary degrees of freedom being indicated by the corresponding Greenhouse-Geiser ε.

All findings (mean comparisons, effect sizes, rehospitalization rate, etc.) and post hoc analyses refer to the completers' data at 3MO and 12MO, respectively.

The criterion for considering results to be statistically significant was set at $\alpha = 0.05$. The present study has explorative character—therefore, following Harris et al. [30], we set aside the alpha correction.

Furthermore, we were interested in whether considerable effect sizes could be found in group comparison. Therefore, the effect sizes according to Cohen were analysed [31, 32]. For single measuring points, Cohen's *d* was counted, applying the following rules: $0.20 \geq d \geq 0.49$: small effect size (without practical significance); $0.50 \geq d \geq 0.79$: medium effect size (moderate practical significance); $d \geq 0.80$: large effect size (high, crucial importance).

The statistical package SPSS 17.0 for Windows was used (SPSS Inc.; Chicago, Ill.).

Results

Sample

The CONSORT flow diagram depicts the timeline and distribution of the study population at any study period (Fig. 2) [33].

Of 87 initially included patients, 5 (PE: $n = 3$, CG: $n = 2$) were belatedly excluded from the study population as protocol violators because they withdrew their consent during the allocation procedure or no longer fulfilled the inclusion criteria, or exclusion criteria arose (withdrawal of consent: 2 patients, change of diagnosis: 3 patients).

Of the remaining 82 patients (PE: $n = 40$; CG: $n = 42$), 7 patients from PE and 9 patients from CG did not receive enough (<4/5) group sessions or did not attend any assessment except at baseline, so that no comparable data are available. The numbers of dropouts were comparable in both groups (PE: 7/40, 17.5%; CG: 9/42, 21.4%) and did not differ considerably from other studies [34]. Most of them were due to consent withdrawal (PE: $n = 7$, CG: $n = 8$), and one patient committed suicide (CG). There was no significant difference between dropouts and completers with respect to relevant socio-demographic or illness-related variables or baseline scores of the target variables.

Of the remaining 66 study patients (PE: $n = 33$, CG: $n = 33$), $n = 54$ stayed in the study until 3MO; however, 3 patients could not be analysed due to missing 3MO-data (completer-analysis 3MO: PE: $n = 27$, CG: $n = 24$). $N = 43$ patients were assessed at 12MO (PE: $n = 22$, CG: $n = 21$). Reasons for study discontinuation (PE: $n = 11$, CG: $n = 12$) were mostly withdrawal of consent (PE: $n = 10$, CG: $n = 9$), three suicides (PE: $n = 0$, CG: $n = 3$) and one death by accident (PE: $n = 1$, CG: $n = 0$).

Those lost to follow-up (LTFs) have to be considered as intervention related. They were comparable in PE and CG concerning absolute numbers and percentage (PE: 10/33, 30.3%, CG: 12/33, 36.4%) and did not exceed accepted standards [35]. There was a significant group difference regarding the suicide rate (PE: 0/33, CG: 3/33, $\chi^2 = 4.302$, $P = 0.038$*).

Taking together the "early" and the "late" (LTF-) dropouts, rates were comparable in both groups. There was no significant difference between dropped out and remaining study patients with regard to any relevant socio-demographic and illness-related variable or the baseline scores of the clinical target variables, except of insight into the disease (IS), which was significantly lower in the dropout population ($t = 2.054$, $P = 0.043$*). Once again the suicide rate—as one reason for drop-out—was significantly higher in CG than in PE (PE: 0/40, KG: 4/42, $\chi^2 = 5.548$, $P = 0.019$*).

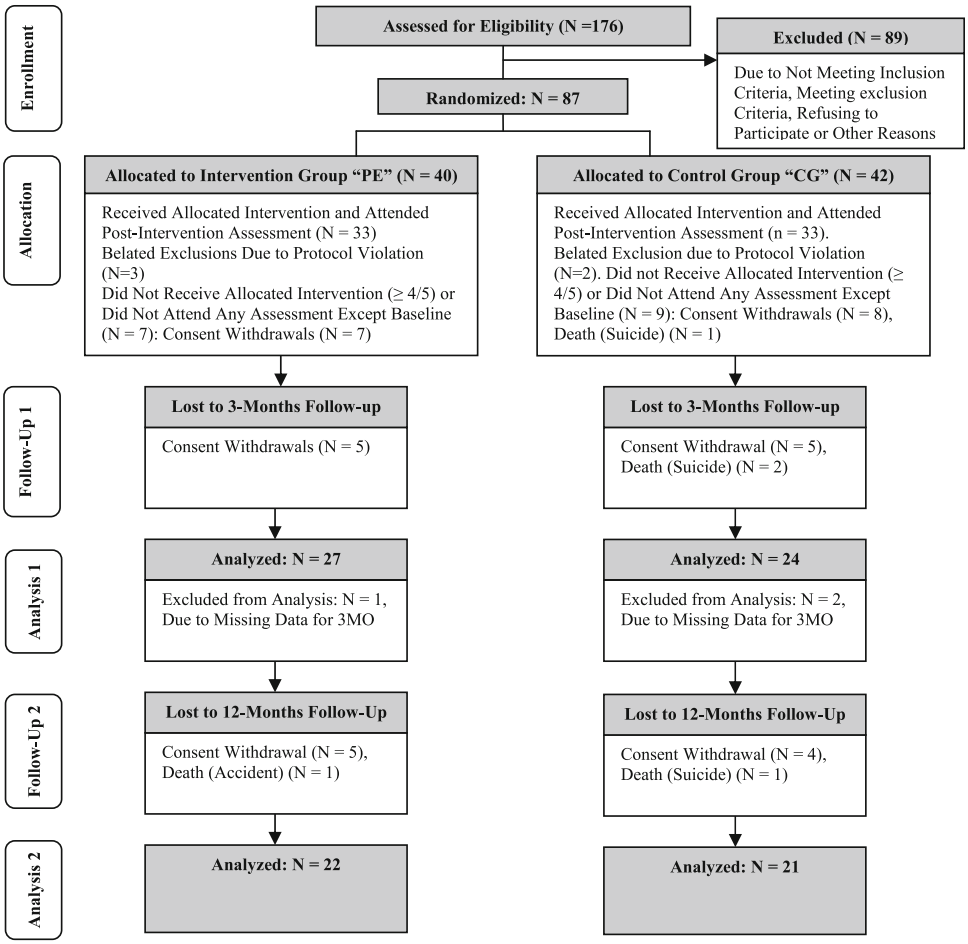

Fig. 2 Consort flow diagram of the progress through the phases of the study

It has to be taken into account that some patients (PE: 2 at 3MO, 3 at 12MO; CG: 5 at 3MO, 1 at 12MO) refused to show up for the assessments, but agreed to fill out the posted questionnaires. So the clinical assessment by the examinator (CGI, GAS) is missing in these cases, whereas the self-rated scores (QOL, IS, etc.) are available. Missing data for one variable and consecutively varying numbers of participants for several parameters at the same examination indicate the fluctuating study compliance of the patients, who sometimes refused to fill out one or another questionnaire. Objective variables (readmission outcome parameters) are constantly available and counted for the completers of each study visit.

Basic demographic and clinical data of all randomized patients baseline are presented in Table 1.

The intervention group (PE, $n = 40$) did not differ from control group (CG, $n = 42$) in terms of any relevant sociodemographic (age, sex, educational level, etc.) or illness-related data (diagnoses, duration of the disease, etc.), family involvement during the study or baseline status of any clinical variable (CGI, GAS, etc.). Only the number of previous hospitalizations was significantly higher in CG (PE: $M = 3.60$, SD = 3.89; CG: $M = 7.86$, SD = 9.31; $t(80) = 2.68$, $P = 0.009$*). In terms of diagnoses, schizophrenia and related disorders (ICD 10-F2), especially schizophrenia (F20), predominated considerably in both groups (PE: 60%/50.0%; CG: 71.4%/64.3%), followed by affective disorders (ICD 10-F3) (PE: 25.0%, CG: 16.7%). Only few patients with other disorders (F6: PE: 7.1%, CG: 9.5%; F4: PE: 2.5%, CG: 2.4%) were included. There was no significant group difference concerning family involvement, the attendance of relatives altogether being poor (PE: 10/40, CG: 9/42, $\chi^2 = 0.147$, $P = 0.702$) (Table 1).

Effects at 3 (3MO)- and 12-months (12MO)–follow-up

Rehospitalization outcome

One main study criterion was the rehospitalization outcome up to 12 months after the end of the programme. The tendency switched in favour of the intervention group the longer the study period lasted: Whereas RR, RA and DIH were even higher in PE at 3MO, this effect had switched at 12MO. At 12MO, RR for PE was 27.2% (6/22), compared to 42.9% (9/21) in CG. Less than half as many readmissions per person per group occurred in PE compared to CG

Table 1 Description of study patients

Characteristic	PE ($N = 40$)	CG ($N = 42$)	Test	Value	P	d	Total ($N = 82$)
Age, mean, year (SD)	37.7 (9.6)	38.3 (11.3)	*t*-test	−0.27	0.79		38.0 (10.4)
Sex, %			χ^2-test	0.51	0.48		
male/female	28.3/20.2	32.3/18.1					60/39
Diagnosis (ICD 10), %			χ^2-test	9.94	0.42		
Schizophrenia and delusion. Disord. (F2)	65	71.4					68.3
Schizophrenia (F20)	50	64.3					57.3
Delusional disorder (F22)	5	0					2.4
Psychotic episode (F23)	7.5	2.4					4.9
Schizoaffective disorder (F25)	2.5	4.8					3.7
Affective disorder (F3)	25	16.6					20.7
Bipolar affective disorder (F31)	12.5	9.5					11
Depressive episode (F32)	2.5	4.8					3.7
Recurrent depressive disorder (F33)	10	2.4					6.1
Neurotic disorders (F4)	2.5	2.4					2.4
Phobic disorders (F40)	2.5	0					1.2
Obsessive disorders (F42)	0	2.4					1.2
Personality disorders (F6)	7.5	9.5					8.5
Specific personality disorders (F60)	7.5	4.8					6.1
Combined and other pers. Disord. (F61)	0	4.8					2.4
Illness duration, mean ± (SD), y	9.6 (8.8)	12.3 (9.6)	*t*-test	−1.33	0.19		11.0 (9.3)
Prev. hospitalizations, mean, d (SD)	3.6 (3.9)	7.9 (9.3)	*w-test*	−2.73*	<0.01*		5.8 (7.5)
Family status, %			χ^2-test	0.24	1		
Married	10	11.9					11
Divorced	15	14.3					14.6
Single	65	64.3					64.6
Partnership	10	9.5					9.8
Family involvement, number	10	9	χ^2-test	0.15	0.7		19
Habitation, %			χ^2-test	3.41	0.7		
Alone	57.1	57.1					58.5
With parents/siblings	12	12					12.2
With partner/child	17.5	12					14.6
With others	2.5	2.4					2.4
Assisted living	0	7.1					3.7
Other	7.5	9.5					8.5
Education, %			χ^2-test	1.82	0.93		
Elementary school	37.5	35.7					36.6
Apprenticeship	32.5	40.5					36.6
Secondary school	10	11.9					11
University/of applied science	17.5	9.5					13.5
Other	2.5	2.4					1.2
Psychotropic drugs, mean, number (SD)	2.0 (0.9)	2.24 (1.12)	*t*-test	−1.17	0.25		2.1 (1.0)
Dropouts, number	17	21	χ^2-test	0.46	0.5		38
BL clinical status, mean, score (SD)							
CFB	48.1 (7.3)	46.1 (6.1)	*t*-test	1.32	0.19	0.3	47.1 (6.7)
CGI	4.7 (0.7)	4.8 (0.9)	*t*-test	−0.61	0.54	0.1	4.8 (0.8)
IS	27.4 (6.7)	28.7 (4.3)	*t*-test	−1.08	0.28	0.2	28.1 (5.5)
GAS	55.4 (8.1)	52.0 (8.7)	*t*-test	1.83	0.07	0.4	53.7 (8.5)
QOL	5.9 (2.2)	5.5 (1.9)	*t*-test	0.92	0.36	0.2	5.7 (2.0)

Table 1 continued

Characteristic	PE ($N = 40$)	CG ($N = 42$)	Test	Value	P	d	Total ($N = 82$)
TAB	62.6 (10.6)	58.6 (14.6)	t-test	1.44	0.16	0.3	60.5 (12.9)

χ^2: Fisher's exact test (except sex, family involvement and dropouts: Pearson's chi-square test)

Effect sizes (Cohen's d): Small effect size: $0.49 \geq d \geq 0.20$; medium effect size: $0.79 \geq d \geq 0.50$; large effect size: $d \geq 0.80$

PE = Intervention Group, CG = Control Group, BL = Baseline, CFB = "Compliance-Fragebogen" = Compliance-Questionnaire, CGI = Clinical Global Impression, IS = Insight Scale, GAS = Global Assessment Scale, QOL = Quality of Life-Questionnaire, TAB = "Therapeutisches Arbeitsbündnis" = Therapeutic Alliance-Questionnaire

* significant mean difference

(PE: 0.45, KG: 1.05), and the DIHs in PE added up for less than 2/3 of those in CG (PE: 20.3, CG: 31.0). However, statistical significance was failed (Table 2). Between 3MO and 12MO, RA and DIH increased considerably stronger in CG than in PE (increasing number of readmissions between 3MO and 12MO: PE: small effect size, Cohen's $d = 0.34$, CG medium effect size, Cohen's $d = 0.67$; increasing days in hospital between 3MO and 12MO: PE: small effect size, Cohen's $d = 0.23$, CG: medium effect size, Cohen's $d = 0.60$; Table 3).

Compliance (CFB)

As defined from the applied questionnaire, compliance was better in PE compared to CG at 3MO and at 12MO with medium effect sizes (Cohen's d[3MO] = 0.64, Cohen's d[12MO] = 0.51). The factor *Time* showed large effect size (Cohen's $d = 0.80$) regarding the improving compliance in PE between BL and 12MO. At 3MO, the group difference was statistically significant (52.48 vs. 49.52, total $N = 50$, $t(48) = 2.27$, $P = 0.028$*, Cohen's $d = 0.66$) (see Tables 2 and 3, also for the following results).

Clinical global impression (CGI)

The CGI was used to assess the global clinical impression of the study patients. The mean value in PE was found to be better (= lower score) than in CG at 12MO, with medium effect size (Cohen's $d = 0.54$), improving over time between BL and 12MO with large effect size (Cohen's $d = 0.97$). The effect was not significant between groups at any time, but showed a tendency in favour of PE (3MO: 4.13 vs. 4.58, total $N = 43$, $P = 0.193$; 12MO: 3.75 vs. 4.40, total $N = 40$, $P = 0.094$).

Insight into the disease (Insight Scale, IS)

In spite of PE starting with a slightly lower mean score at BL, at 3MO, a group difference in favour of PE with medium effect size (Cohen's $d = 0.55$) arose, which diminished to a small effect size at 12MO (Cohen's $d = 0.24$). PE and CG improved over time with large effect size (3MO–12MO PE: Cohen's $d = 0.85$, CG: Cohen's $d = 0.96$). There was no significant difference between PE and control group at any time point.

Global assessment of function (GAS)

The mean value of GAS was found to be higher at 3MO in PE (medium effect size, Cohen's $d = 0.56$), but the effect was nearly equalized until 12MO by a medium-sized improvement in CG between BL and 12MO. The group differences did not achieve statistical significance at any study visit.

Quality of life (global score of the WHO-QOL-BREF, German version)

The global score of the WHO-QOL-BREF was slightly higher at BL and slightly lower at 3MO in PE versus CG. Over time (BL–12MO) the QOL score of PE improved with moderate effect size (Cohen's $d = 0.67$), and at 12MO, the group difference in favour of PE had reached a moderate effect size (Cohen's $d = 0.61$). However, no statistically significant group difference could be shown.

Therapeutic alliance ("Therapeutisches Arbeitsbündnis", TAB)

The therapeutic alliance was assessed by the questionnaire "Therapeutisches Arbeitsbündnis", which was applied in the version for patients and the one for therapists. In this paper, we only present the patients' version, because not all therapists participated in the study. On a descriptive level, the mean score rose stronger in CG than in PE, even if ending up still lower than the latter. However, no significant difference was found between the groups (Cohen's $d = 0.09$ at 3MO and at 12MO).

Table 2 Clinical target variables at 3MO and 12MO

	PE	CG	N (PE/CG)	*P*	d
3MO					
Compliance, mean (SD)[a]	52.5 (4.5)	49.5 (4.7)	27/23	0.028*	0.6
CGI, mean (SD)[a]	4.1 (1.1)	4.6 (1.2)	24/19	0.193	0.5
IS, mean (SD)[c]	29.4 (3.7)	25.9 (8.2)	27/24	0.064	0.6
GAS, mean (SD)[a]	60.7 (8.1)	55.5 (10.1)	24/19	0.071	0.6
QOL, mean (SD)[a]	6.5 (1.7)	7.0 (1.5)	27/23	0.337	0.3
TAB, mean (SD)[a]	65.4 (11.9)	61.2 (14.4)	26/23	0.278	0.1
RA, mean (SD)[a]	0.22 (0.4)	0.17 (0.4)	27/24	0.626	0.1
DIH, mean (SD)[a]	11.4 (27.9)	5.5 (21.8)	27/24	0.405	0.2
RR, frequency (%)[b]	6/27 (22.2)	4/24 (16.7)	27/24	0.618	
12MO					
Compliance, mean (SD)[a]	53.3 (5.6)	49.4 (9.3)	22/21	0.102	0.5
CGI, mean (SD)[a]	3.8 (1.2)	4.4 (1.2)	20/20	0.094	0.5
IS, mean (SD)[a]	32.2 (4.6)	33.4 (5.4)	22/21	0.439	0.2
GAS, mean (SD)[a]	59.3 (18.8)	57.4 (12.3)	20/20	0.714	0.1
QOL, mean (SD)[w]	7.1 (1.0)	6.4 (1.9)	22/21	0.166	0.6
TAB, mean (SD)[a]	66.5 (10.0)	65.5 (11.2)	22/20	0.761	0.1
RA, mean (SD)[a]	0.5 (0.9)	1.1 (1.8)	22/21	0.178	0.4
DIH, mean (SD)[a]	20.3 (47.5)	31.0 (55.9)	22/21	0.503	0.2
RR, frequency (%)[b]	6/22 (27.3)	9/21 (42.9)	22/21	0.284	

Effect sizes for *t*-tests (Cohen's *d*): small effect size: $0.49 \geq d \geq 0.20$; medium effect size: $0.79 \geq d \geq 0.50$; large effect size: $d \geq 0.80$

3MO = follow-up after 3 months, 12MO = follow-up after 12 months, RA = number of readmissions (per person per group), DIH = accumulated days in hospital (per person per group), RR = rehospitalization rate (percentage per group)

* significant mean difference

[a] *t*-test, [b] chi-square test, [c] Welch-test

Table 3 Effect size (*d*) variation in time

Variables	Group	
	PE	CG
BL–12MO		
CFB	0.80	0.41
CGI	0.97	0.41
IS	0.85	0.96
GAS	0.27	0.51
QOL	0.67	0.45
TAB	0.38	0.53
3MO–12MO		
RA	0.34	0.67
DIH	0.23	0.60

Values are effect sizes for *t*-tests (Cohen' s *d*). Small effect size: $0.49 \geq d \geq 0.20$; medium effect size: $0.79 \geq d \geq 0.50$; large effect size: $d \geq 0.80$

Discussion

This first randomized controlled trial on disorder-independent psychoeducation was conducted to test the hypothesis that a bifocal diagnosis-mixed group programme would be effective regarding rehospitalization outcomes and several clinical variables. We were also interested in whether distinctive psychoeducational elements beyond mere unspecific factors (regular meetings of a professionally conducted group, etc.) caused the effects.

A strength of our study is the design of the control group. Its very similar format with an unspecific intervention added on routine care provides a solid foundation for interpreting the results as specifically induced by distinctive psychoeducational features. Those PE-specific elements are namely the interactive transfer of illness- and treatment-related knowledge and management/coping strategies, as defined in the Consensus paper of the German PE-expert-group and by the NICE-GDG [1, 2]. Suchlike designed control groups are not standard in clinical trials on psychoeducation, especially not for relatives. It is obvious that the format of the control condition has an impact on effect sizes [1, 12].

In sum, the group comparison revealed advantages for PE. In line with results from previous studies on diagnosis-specific psychoeducation in schizophrenia, our findings suggest that the diagnosis-independent form has a favourable effect on readmission outcomes. The compliance score was significantly higher in the intervention group 3 months after the end of the programme and was accompanied by an advantage concerning insight and global functioning. In the following 9 months, the rehospitalization rate, the total number of readmissions and accumulated days in hospital increased considerably less in PE, ending up with clear advantages for PE after 12 months, but significance was failed. In the same time period, quality of life and the clinical global impression improved. On a descriptive level, the group comparison after one year showed advantages in favour of PE regarding all readmission outcome parameters as well as the clinical global impression, quality of life and compliance (Table 2). No clear

explanation can be presented for the fluctuating course of the IS-mean score (worsening from BL to 3MO, then rising steeply, without significance) and the relatively stronger improvement over time of the therapeutic alliance (measured by TAB-patient version) in CG. Concerning the latter a ceiling effect in PE, which already started with a mean score above the cut-off (over 60/80 = good therapeutic alliance), could be one reason.

The drop-out analysis revealed a significantly higher suicide rate in the control group. Further statistically significant group differences especially concerning rehospitalization outcome variables, as published in some papers on diagnosis-specific psychoeducation—nota bene with participation of at least one key relative as inclusion criterion—failed to appear [36].

However, our study provides similar results as are presented in recent trials and meta-analyses on psychoeducation for psychotic disorders. In an analysis that separated PE directed at patients only from family directed PE, Lincoln et al. showed, that the effect for reduced relapses and rehospitalizations remained stable and significant up to one year only in the family-including setting [12]. This is of crucial importance, because exclusively patient-focused interventions are by far the most common setting in clinical reality [16], as is also reflected by our sample. No integrated effect for PE in terms of compliance at post-treatment, or functional outcome or symptoms at 7- to 12-month follow-up could be shown in this review [12]. Disregarding the partially different measuring tools and methods our diagnoses-mixed sample achieved comparable results with slight disadvantages in some domains but advantages in others—especially if the poor attendance (altogether less than 25%) of the relatives is taken into account. Moreover, this is the first study to show a significant favourable effect of psychoeducation on the suicide rate [1], which should be interpreted carefully because this was no defined endpoint of the trial. Although highly speculative at that time, the hypothesis seems plausible that the diagnosis-mixed and interactive approach could help to reduce mutual stigmatization between patients with different mental disorders as well as associated subjective hopelessness and insofar be especially promising for severely ill individuals in this respect.

As limitations, the small sample and the comparatively short follow-up period should be mentioned. Both are in line with the exploratory character of the study, and it is supposed that enlarged designs within future trials will enhance the effects. The limitation became extremely obvious in terms of the readmission outcome. Whereas Pitschel-Walz et al. [36] could report a significant difference with rehospitalization rates of 21% (PE) versus 38% (CG), after one year (total $N = 163$), in our study significance was failed at 12MO with an RR of 27% (PE) versus 43% (CG) with a total completer-N of 43. Due to the small N, it was not possible to differentiate validly between family-including PE and PE directed at patients alone.

Another limitation is the measurement of compliance, for which we used a yet not validated questionnaire. We are aware that this tool may not exceed the validity of a structured self-report. But as is known from compliance literature, the results on medication adherence in psychiatry are mainly based on methods of this or lower quality [12, 37]. Insofar, our findings are at least not less reliable than those of previous studies.

Conclusion

Diagnosis-mixed group psychoeducation can be recommended for adults with severe psychiatric diseases. One advantage is its easier practicability, which may facilitate the more extensive supply of this cost-economic therapeutic option. Its effectiveness regarding readmission outcomes and relevant clinical variables is comparable to that of psychosis-specific forms. The design of our control condition allows to substantially ascribe the improvements to the distinctive psychoeducational elements.

Further research on diagnosis-independent psychoeducation should concentrate on the effects of the intervention directed at patients alone, which is the most common setting in clinical routine. If evidence for exclusively patient-focused PE persistently fails to appear, an adjustment of the guidelines in the sense of obligatory family involvement—if possible—could be appropriate.

A more subtle analysis in terms of symptom domains or diagnosis-related outcomes could make it possible to compare the effects of diagnosis-mixed PE on the level of syndromes or disorders. It is still unexplored which patients benefit remarkably more by a group that is specifically tailored to their personal or illness-dependent characteristics, and exactly which patient-related trait should serve as the most promising criterion for a diversification of PE groups. Besides diagnostic categories, for example, sex, age and the educational background are worthy of consideration. Larger study samples and longer follow-up periods may allow conclusions on subgroups and promote statistical significance, respectively.

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Conflict of interest The authors declare that they have no conflict of interest.

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