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Long-term effects of a psychoeducational psychotherapeutic intervention for schizophrenic outpatients and their key-persons – results of a five-year follow-up*

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Abstract The study examines long-term effects on re-hospitalization rates of a psychoeducationally and cognitive-behaviorally oriented intervention for schizophrenic outpatients and their key-persons. 191 patients and their key-persons were allocated by random into four different treatment groups and one control group. Five years after completion of treatment 126 patients were reexamined by interviews or case notes. The rate of patients experiencing psychiatric rehospitalization during the follow-up was assessed in each respective treatment group. Concerning rehospitalization rates there was no significant difference between controls ($n = 35$) and patients of the four treatment groups ($n = 91$). There were, however, fewer rehospitalized patients in the group with combined psychoeducational and cognitive treatment, including key-person counselling (42%), than in the control group (69%). Regarding the overall functioning, the patients in this treatment group did slightly better than those in the control group. These results are in accordance with the findings of comparable studies.

Key words Schizophrenia · Psychoeducation · Key-person counselling · Long-term course

Introduction

Since Goldstein et al. (1978) published their data on the short-term efficacy of crisis-oriented family-therapy for schizophrenic patients in preventing relapse, there have been numerous controlled studies dealing with the long-term effectiveness of behaviorally oriented interventions for families (Falloon et al. 1985; Leff et al. 1985; Tarrier et al. 1989; Hogarty et al. 1991). Though these family interventions differ in procedure and content, they share a predominantly psychoeducational and coping oriented approach, orientation towards the vulnerability-stress-coping-paradigma (Nuechterlein and Dawson 1984; Liberman 1986) as well as the inclusion of patients living predominantly within families with a high level of expressed emotion (high-EE). Concerning therapeutic efficacy, these investigations unequivocally showed that, compared to standard treatment, psychoeducational family interventions can reduce relapse rates of schizophrenic patients within the two years following discharge by 20% on average (cf. Mari and Streiner 1994; Dixon and Lehman 1995).

To date, there has been only one controlled study revealing a relevant influence on relapse rates in the long-term as well. Whereas analysis of the clinical development of patients involved in the intervention by Goldstein et al. (1978) showed no long-lasting effect detectable after three to six years (Strachan 1986), there was a marked prophylactic effect in the Salford Family Intervention Project covering periods of five and eight years (Tarrier et al. 1994). Over five years, the authors noted a relapse rate of 62% in the family intervention group in contrast to 83% in the high-EE control group. Another three years later, the rates had risen to 67% and 88%, respectively.

In our prospective study with schizophrenic outpatients and their key-persons (Buchkremer and Hornung 1995), the long-term relapse rates of patients were also taken into account. The study was aimed at providing a

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comprehensive psychoeducational psychotherapeutic treatment program which would keep schizophrenics from being rehospitalized. It offered different treatment strategies, i.e., psychoeducational training, cognitive psychotherapy for patients, and key-person counselling, in various combinations. The methodological details of this controlled study are outlined elsewhere (Hornung et al. 1995, 1996; Buchkremer et al. 1997).

In the one-year follow-up we found no significant prophylactic effect of either of the treatment strategies (Hornung et al. 1995). Within a two-year-period, however, patients being treated with the most intensive treatment combining psychoeducational training, cognitive psychotherapy for patients, and key-person counselling show markedly lower rehospitalization rates compared to controls (24% vs. 50%). The results of this evaluation are outlined in an earlier analysis (Buchkremer et al. 1997). Although there was no selection of patients with respect to their state of expressed emotion, these figures correspond roughly to those of other studies involving families of schizophrenic patients (Falloon et al. 1985; Leff et al. 1985; Tarrier et al. 1989; Hogarty et al. 1991).

Encouraged by these positive results we carried out a five-year follow-up. The purpose of the study presented here was

- (a) to examine whether the treatment program outlined above, involving schizophrenic patients and their key-persons, had a long-lasting positive impact on the number of patients being rehospitalized;
- (b) to evaluate the long-term development of psychopathology within these probands.

Methods

Selection and assignment of patients

Schizophrenic patients from the outpatient departments of seven psychiatric hospitals and psychiatric practices in the area of Muenster/Germany were enrolled. They met the following inclusion criteria: (a) schizophrenia according to DSM-III-R 295 without 295.7 (American Psychiatric Association 1987); (b) at least two acute psychotic episodes within the past five years; (c) at least four weeks psychopathological stabilization; (d) indication for long-term neuroleptic medication; (e) no secondary psychiatric diagnosis. The diagnosis of DSM-III-R 295.7 was excluded because of the intention to include a homogeneous sample of patients having a presumably comparable course of illness.

In order to attain structural homogeneity of the treatment groups, a randomization procedure balancing the prognostic criteria of gender, prognostic score (Strauss et al. 1977) and medication compliance was carried out to eliminate any significant differences in the balancing factors among the groups. The allocation ratio for assigning patients to one of these five groups was 1 : 1 : 1 : 1 : 2. A little difference in sample size results from the matching procedure before randomization.

Table 1 Patients' characteristics at baseline (N = 191)

	Mean	(SD)
Age (years)	31.3	(7.0)
Age at onset of illness (years)	22.9	(5.8)
Months of relapse prevention with neuroleptics	78.2	(57.1)
Number of hospitalizations before baseline	4.7	(3.6)
Global Assessment Scale (GAS) ¹		
Total Score	55.1	(10.4)
Brief Psychiatric Rating Scale (BPRS) ²		
Total Score	29.4	(7.4)
Scale for Assessment of Negative Symptoms (SANS) ³		
Total Score	6.6	(4.0)

¹Endicott et al. (1976),

²Overall and Gorham (1962),

³Andreasen (1989)

A total of 191 patients (111 male, 80 female) who met the inclusion criteria were randomized to one control group and four treatment groups providing different combinations of the following treatment strategies: 1) a Psychoeducational Training for Medication Management (Kieserg and Hornung 1994), 2) cognitive psychotherapy (D'Zurilla and Goldfried 1971) and 3) key-person counselling (Buchkremer et al. 1987). 32 patients were assigned to the psychoeducational training alone, 34 to psychoeducational training in combination with cognitive psychotherapy, 35 to psychoeducational training in combination with key-person counselling, and 33 to psychoeducational training and cognitive psychotherapy in combination with key-person counselling. The 57 patients in the control group received a structured but non-specific leisure-time group. In order to control the effect of professional commitment, the patients solely assigned to the condition psychoeducational training were offered a leisure-time group at the end of the psychoeducational training. Treatment groups for patients and key-persons and leisure-time groups were run at all seven study centres. Each of the locations provided the complete set of treatment groups.

Patients' characteristics

A description of the study sample is given in Table 1.

Study intervention

After randomization treatment started, with ten sessions of the psychoeducational training, the first five at weekly and the remaining five at 14-day intervals, followed by 15 sessions of cognitive psychotherapy, seven at weekly and eight at 14-day intervals. Each of the groups consisted of six to eight patients. The psychoeducational training was aimed at improving knowledge about schizophrenic illness and its treatment and at promoting medication and crisis

management skills. Following the procedure proposed by D'Zurilla and Goldfried (1971), cognitive psychotherapy aimed at improving problem-solving skills by providing a structured planning of coping behaviour. Key-person counselling was aimed at the relatives of the patients. For those patients who lived at a distance from their families or did not want to have closer contact to them it was aimed to find care-givers being involved in the treatment program. Key-person counselling represented an expert-initiated self-help group; the first ten of the 20 sessions were run by staff members who subsequently attended every third session in order to initiate a self-help structure. It was intended to improve the knowledge about schizophrenia and the coping skills of key persons in the management of schizophrenia. Patients of the control group pursued regular leisure-time activities organized by students of psychology or educational sociology. It was ensured that there was no specific psychotherapeutic treatment. All group sessions were supervised at regular intervals in order to ensure that treatment would be carried out according to protocol.

At least partial attendance was observed in 59 patients of the four treatment groups and 22 patients of the control group. Partial attendance was defined as attendance of at least 40% of treatment sessions.

Evaluation of outcome and outcome measures

Patient examinations took place at baseline, immediately after completion of the treatment phase and after one, two, and five years. As far as the five-year follow-up is concerned, raters were blind to the treatment conditions. Whenever possible, patients were examined by face to face interview. If necessary, information was completed by referring to patients' case notes and/or hospital records.

The main focus of this long-term follow-up was the rehospitalization rate of the patients of the four treatment groups within the five-year period following completion of therapy. (Using this definition only clinically relevant relapses with a true need for hospitalization were assessed.)

Psychopathological symptoms were rated with the Brief Psychiatric Rating Scale (Overall and Gorham 1962) as well as the Scale for the Assessment of Negative Symptoms (Andreasen 1989). Overall functioning was assessed with the Global Assessment Scale (Endicott et al. 1976). The raters were trained to use these measures by psychiatrists not directly involved in the evaluation procedure (T. R.; W.P.H.).

Drop-outs

We applied a modified intention-to-treat approach. All patients who attended at least one group session were included in the main analysis. Patients who dropped out of study before treatment had been started were excluded. An intention-to-treat analysis in the stricter sense demands for inclusion of all randomized patients to ensure maximum adherence to the randomization. Since 44 out

of 191 patients (representing 17 patients = 29% of the control group and 27 patients = 20% of the total treatment group) dropped out after randomization but before the beginning of the therapy, we found it more adequate to exclude these patients from the main analysis because no treatment effect can be expected in these patients. The percentage of participation in treatment of the remaining patients is not taken into account by intention-to-treat-analysis. The excluded patients ($n = 44$) and the remaining sample ($n = 147$) showed no significant difference with respect to the balancing factors of the randomization. However, the excluded patients had a higher level of symptomatology and a higher dose of neuroleptics at baseline compared to the remaining group.

At the five-year follow-up, information about psychiatric rehospitalizations or other relevant events of 129 patients of the remaining 147 patients was gained. Four patients had died, one of natural causes, two of unknown causes (one in the group with psychoeducational training plus cognitive psychotherapy and one in the group with psychoeducational training plus key-person counselling) and one by suicide (in the control group). The suicide was classified as rehospitalization representing the unfavorable course of illness or failure of the therapeutic intervention. Patients who had died of natural or unknown causes were excluded from the final calculation. Thus, rehospitalization data of 126 participants served as a basis for the present evaluation. As far as the balancing factors of randomization and a wide range of other relevant variables were concerned, there were no significant differences between the patients of the control group ($N = 35$) and those of the four treatment groups ($N = 91$).

Statistical analysis

The randomization was conducted by an independent Institute (Institute of Medical Biometry and Informatics at the University of Heidelberg). A sample size estimation based on a statistical power of 75% for detecting a reduction of 20% in the rehospitalization rate recommended an optimal sample size of 180 patients. The central statistical issue in terms of confirmatory hypothesis testing of this follow-up study was a comparison between the patients of the four treatment groups and the controls. The respective χ^2 Test of four-fold tables was conducted with a level of significance of 5%. Because of the problem of multiple testing all other tests of significance are exploratory tests. Statistical tests for secondary endpoints included χ^2 Tests and, according to their distributional characteristics, Student's *t* Tests and Mann-Whitney-Wilcoxon-U Tests.

Results

Rehospitalization

The main hypothesis, a significant difference between the four treatment groups and the control group, was not con-

Table 2 Number and percentage of participants experiencing at least one rehospitalization within the follow-up

		PT ¹	PT + CP ²	PT + KC ³	PT + CP + KC	Control
1 year	n	26	25	26	26	35
Patients readmitted	n	8	8	7	4	8
	%	30.8	32.0	26.9	15.4	22.9
2 years	n	25	25	23	25	34
Patients readmitted	n	11	11	9	6	17
	%	44.0	44.0	39.1	24.0*	50.0*
5 years	n	25	19	23	24	35
Patients readmitted	n	16	13	13	10	24
	%	64.0	68.4	56.5	41.7**	68.6**

¹ PT = psychoeducational training for medication management,

² CP = cognitive psychotherapy,

³ KC = key-person counselling;

comparison between group PT + CP + KC and control group:

* two-year follow-up: $\chi^2 = 4.09$, DF = 1, $p = 0.043$;

** five-year follow-up: $\chi^2 = 4.51$, DF = 1, $p = 0.034$

firmed. The rehospitalization rates of the patients of the four treatment groups and the control group within the five-year follow-up were 57.1% and 68.6%, respectively ($\chi^2 = 1.38$; $p = 0.24$).

The rehospitalization rates of each treatment group within the five years are shown in Table 2.

Within the two and five year follow-up, the rehospitalization rates in the treatment groups covering the psychoeducational training with or without cognitive psychotherapy but without key-person counselling are consistently higher than in the other two treatment groups including the key-persons of the patients. Though the rehospitalization rates in the treatment group with the most comprehensive intervention, i.e., psychoeducational train-

ing and cognitive therapy for patients and key-person counselling, are consistently the lowest. At the two- and five-year follow-up, the difference between this treatment group and the control group was nominally significant, as long as not adjusted for multiple testing. The 95% confidence intervals for the rates of this combined treatment group and the control group cover the range of 20–64% and 53–86%, respectively.

Psychopathological symptoms and overall functioning

Regarding psychopathological symptomatology and in particular negative symptoms, no differences between the treatment group and the control group could be noted. The figures for the different follow-up measurements are shown in Table 3.

Discussion

The patient population evaluated here can be regarded as a group of schizophrenic outpatients with medium-grade negative rather than positive symptoms and relatively good overall functioning who have sustained multiple relapses. Because of their participation in a randomized trial, it must be assumed that they had above-average motivation at baseline. There was no selection of families with high expressed emotion. The sample analyzed at the 5-year follow-up did not differ from the original sample with respect to the balancing factors of randomization.

However, at baseline the remaining patients showed slightly fewer symptoms and needed less medication. Thus, the more disturbed patients were more likely to be excluded from the study sample. These characteristics must be borne in mind when discussing the results of this study.

As far as the methodological procedure is concerned, it has to be noticed that the statistical analysis was based on a modified intention-to-treat model taking no account of the overall frequency of attendance. This approach re-

Table 3 Development of psychopathological symptoms and overall functioning in patients within each treatment condition and in the control group from baseline to five years after the intervention

		PT	PT + CP	PT + KC	PT + CP + KC	Control
BPRS score ¹	baseline	26.5 (22.75/34)	28 (23/30)	27 (23/30)	29.5 (24/34)	28 (25.5/33)
	1 year	31 (21.75/35.5)	33 (27/38)	29 (24/32)	29 (23.5/33.75)	31 (23/39)
	2 years	25.5 (22.25/30.75)	29 (22.5/32.5)	26 (23/30)	27 (21/32)	31 (24.5/36)
	5 years	36.5 (32.25/45.75)	36 (29.5/46.5)	32 (27/48.5)	36.5 (28.8/42.5)	39 (32.5/44)
SANS score ¹	baseline	7 (3.75/11.25)	6.5 (4/9)	4.5 (2/7)	7.5 (4/9.8)	6.7 (3/8.9)
	1 year	6 (1/14)	6 (1.5/10)	3 (2/7)	4 (1/8.25)	6 (3/10)
	2 years	5.5 (1.25/12.25)	7 (2.75/10.5)	6 (1/7)	5 (4/10)	6 (3/7.5)
	5 years	7.5 (3.75/9.75)	6.5 (4.75/10.5)	5 (3.5/9.5)	7 (5/9)	7 (4.5/11.5)
GAS score ²	baseline	55.0 (13.0)	56.8 (10.7)	58.4 (12.7)	53.6 (7.5) ³	56.1 (8.1) ³
	1 year	56.1 (13.0)	58.3 (8.8)	60.0 (11.3)	60.1 (10.0)	57.8 (8.3)
	2 years	65.2 (13.7)	62.6 (12.6)	63.6 (13.1)	63.75 (11.5)	58.5 (11.8)
	5 years	59.8 (9.1)	57.6 (6.3)	58.0 (9.5)	58.3 (7.9) ³	56.0 (6.9) ³

¹ median (1st/3rd quartile);

² mean (SD);

³ Student's t-Test: $t = 1.66$, $p = 0.105$ (The differences between pre- and post-values were compared among the group PT + CP + KC and the control)

flects the daily experience that patients and their key-persons do not attend all group sessions regularly. Therefore, these results provide primarily information on the effects of various degrees of attendance at psychoeducational intervention including minimum attendance.

The focus of this evaluation was the rehospitalization rate, which is only a rough and not mainly psychopathological outcome criterion. On the other hand, within this extensive sample rehospitalization could be assessed in a "blind" and economic way. Furthermore, it was assured by definition that the fact of rehospitalization meant a very serious event. The different criteria for referral constitute a variance-generating factor, though one which is controlled by randomization. The possibility of different referral criteria having systematically influenced the study results can be excluded, for all treatment conditions were ruled out at all study centres.

As shown in an earlier analysis (Buchkremer et al. 1997), at each respective follow-up point the treatment groups including the key-persons of the patients had the best outcome compared to those not including key-person counselling. The very best result was achieved in the group with the combined psychoeducational and cognitive-behavioral treatment, including counselling of key-persons. This was nominally significant at the two- and five-year follow-up. Though, these data must be seen as preliminary as statistical significance can only be reached if adaptation for multiple testing is not performed. On the other hand, the rehospitalization rates of the treatment group with the most comprehensive treatment program and the control group cover ranges of confidence intervals comparable to those reported by Tarrier et al. (1994).

Additionally, the five-year figures also correspond with those of the Salford study (Tarrier et al. 1994). Expressed in absolute terms, the relapse rates in the Salford study are higher than those in the Muenster study. Over five years, 62% of the patients in the family intervention group experienced a relapse whereas 83% did in the high-EE control group. In the Muenster study, the readmission rates were 42% and 69%, respectively. One reason for the higher rehospitalization rates in the Salford study might be the restriction to patients living in families with high expressed emotion. As shown in a recent meta-analysis (Butzlaff and Hooley 1998) covering 27 original studies, these patients have a much higher risk for relapse than those from families with a low level of expressed emotion. An additional reason might be a selection bias in the Muenster study resulting in a sample with a lower degree of psychopathology and therefore with a somehow better prognosis. However, the differences in relapse rates between therapy and control groups are similar (21% in the Salford vs. 27% in the Muenster study, respectively). Inclusion of relatives of the patients within the treatment program is an important factor influencing the therapeutic outcome. The respective relapse rates of each treatment condition indicate that there is a relevant decline of rehospitalization rates only by including the relatives. This finding is supported by other results that, in the long-term, psychosocial treatment of the patients alone

did not reduce relapse rates significantly (Scott and Dixon 1995).

The Muenster study also shows that a psychoeducational psychotherapeutic intervention over a period of nine months covering patients as well as their key-persons can favorably influence the long-term course of schizophrenic illness, not only in terms of rehospitalization rates. Using the GAS (Endicott et al. 1976) showed that the patients in the most comprehensive treatment group had a slightly better outcome than those in the control group. This difference was, however, not statistically significant. These overall results are in agreement with the findings of Schooler et al. (1997) indicating the positive impact of a relatively time-limited and, therefore, economically favorable treatment procedure. However, our results show that the extent of an intervention must reach a certain therapeutic minimum. The group receiving psychoeducation and key-person counselling without cognitive psychotherapy only had an intermediate course of illness. It needs further evaluation whether this is due to the time restriction of this treatment condition or to the fact that this group did not receive the specific cognitive psychotherapy.

It must be noted that the treatment procedure used here was different from those of other studies. However, the interventions covering schizophrenic patients and their key-persons showed the best results. From a clinical point of view, this is the most relevant finding. Our data support the statement of Tarrier et al. (1994) that the reduction in relapses (re-admissions) is sustained and, as can be added that the course of illness is positively influenced over a long period of time.

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