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L-B. Merinder · A.G. Viuff · H.D. Laugesen
K. Clemmensen · S. Misfelt · B. Espensen

Patient and relative education in community psychiatry: a randomized controlled trial regarding its effectiveness

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Abstract *Background*: Family psychoeducation has a well-documented effect on the short-term prognosis in schizophrenia. Less is known about the effectiveness of shorter programmes with the main focus on information for patients (patient education) or for patients and relatives (family education). *Methods*: A randomized study of the effectiveness of an eight-session psychoeducational programme for patients with schizophrenia and for their relatives was conducted in two community mental health centres, in Århus and Viborg (Denmark). Patient outcome measures were knowledge, relapse, compliance, insight and satisfaction, and relative outcome measures were knowledge and satisfaction. Postintervention outcome and follow-up evaluation 1 year after the start of the intervention are presented. *Results*: A statistically significant increase in knowledge of schizophrenia in both relatives and patients was demonstrated at postintervention and a non-significant trend at 1-year follow-up. Statistically significant changes in the Verona Service Satisfaction Scale Scores in the subdimension of satisfaction with Relatives involvement were demonstrated both for patients and relatives postintervention and for patients at 1-year follow-up. There was a tendency that time-to-relapse increased in the intervention group at postintervention and that the schizophrenia subscore of the Brief Psychiatric Rating Scale was reduced in the intervention group at 1-year follow-up. No differences were found between the groups regarding compliance, insight into psychosis, psychosocial function (General Assessment of Function) or in relatives' expressed emotion scores postintervention or at 1-year follow-up. *Conclusion*: A short patient and relative education programme seems to be able to influence knowledge and some aspects of satisfaction, but does not seem to be sufficient to influence important variables such as relapse, compliance, psychopathology, insight or psychosocial functioning.

L-B. Merinder (✉)
Department of Psychiatric Demography,
Institute for Basic Psychiatric Research,
Psychiatric Hospital in Aarhus,
DK-8240 Risskov, Denmark
e-mail: ph.ph1.lm@aaa.dk, Fax: +45-86 17 74 55

A.G. Viuff
Community Psychiatric Service Team 1,
Herning Central Hospital, Herning, Denmark

H.D. Laugesen
Department S,
Psychiatric Hospital in Aarhus, Risskov,
Denmark

K. Clemmensen
Department B,
Psychiatric Hospital in Aarhus,
Risskov, Denmark

S. Misfelt
Community Psychiatric Service Team South,
Søndersøparken Psychiatric Hospital,
Viborg, Denmark

B. Espensen
Department of Psychiatry,
Herning Central Hospital,
Herning, Denmark

Introduction

Family psychoeducation has a well-documented effect on the short-term prognosis in schizophrenia [1–4].

Family intervention studies have used comprehensive interventions involving psychoeducation, behavioural problem solving, family support and crisis management [5], using very different combinations, intensities and durations [6, 7].

Studies looking at effects on short-term prognosis for patients have often focussed on patients living with families with high EE (expressed emotion) [8].

Less is known about the effectiveness of less comprehensive (shorter) programmes, with the main focus on information for patients (patient education) or for patients and relatives (family education), not using high EE as the primary mediator of change.

Randomized controlled studies of patient education have indicated effects upon illness-related knowledge, relapse, insight and illness attitudes, compliance, positive and negative symptoms, quality of life and social functioning. However, the results have been inconsistent, with the most consistent finding being increase in illness-related knowledge [9–13], and with the most impressive results being reported in a study including both patients and relatives in the intervention [14, 15]. Studies of the effects of relative education have focussed on patient outcomes or family outcomes or both. Studies involving only relative education, not including the patient, have shown less of an impact on readmission rates and symptomatology in patients than have family intervention programmes [8, 16, 17]. Studies have indicated other effects on relatives' outcomes, such as illness-related knowledge [17–20], relatives' self-efficacy [21], EE (expressed emotion) [16, 18], family burden [20], and satisfaction [22]. However, these effects have often seemed limited due to the short duration and low intensity of the interventions [8, 22, 23] and absence of behavioural elements in the interventions [8], and have seemed to depend on the amount of day to day contact between relatives and patients [18].

Shorter and less comprehensive educational programmes for patients (and relatives) are important to evaluate, both because comprehensive family interventions are impossible to implement in all psychiatric services, and because a decision regarding the optimal content, intensity and duration of these interventions could make psychoeducation a more specific and effective intervention.

Furthermore, because fewer severely mentally ill patients in Western countries now live with their families, studies not using EE as the main impetus for change are important to evaluate.

The aim of this study was to analyse the effectiveness of an eight-session educational intervention for patients with schizophrenia and their relatives on relapse, compliance, knowledge of schizophrenia, psychopathology, psychosocial function, satisfaction with services and expressed emotion in relatives. A further aim was to study the eligibility for participation in the programme.

Subjects and methods

All patients aged 18–49 years of age with a clinical ICD-10 diagnosis of schizophrenia (F20.0–F20.9) (ICD-10, Danish version [24]) and in treatment at the time of inclusion at one of two community psychiatric centres, which were located in Århus (280,000 inhabitants) and Viborg (41,000 inhabitants), were identified from the local case registers. Patients were included on the basis of clinical diagnoses, which were validated by use of OPCRIT (operational criteria checklist for psychotic and affective illness, version 3.31, Life Time Rating [25]) on case records. A total of 135 patients fulfilled the inclusion criteria and were invited to participate in the study. Of these, 46 (34%) agreed to participate, 27% refused to participate and 39% were non-responders. Patients were asked to give permission for the participation of their relatives. Permission was given by 36/46 patients (78.3%), and 35/55 (63.6%) of the relatives, contacted by mail, agreed to participate. Eighteen percent of the relatives were refusers and 18% were non-responders. Diagnostic reclassification showed that 34 had an ICD-10 diagnosis of paranoid ($n = 24$) or undifferentiated ($n = 10$) schizophrenia and five had a diagnosis of schizoaffective disorder manic ($n = 3$) or depressive ($n = 2$) type. One patient was classified as having delusional disorder, four a diagnosis of other non-organic psychotic disorders, and two could not be diagnostically classified by OPCRIT 3.31 on the basis of the existing case records.

The sociodemographic and clinical characteristics of the participating patients were compared with those of the non-responders/refusers and with all actual and former patients with a schizophrenia diagnosis in the Danish National Psychiatric Register [26] living in the city of Århus (Table 1).

The only statistically significant difference between the participants and the reference groups was that a diagnosis of self-destructive behaviour (suicide attempt or self-mutilation) was more common among the participants. There were non-significant trends that the participants had shorter duration of illness, that fewer had a previous substance abuse diagnosis and that fewer had experienced a previous compulsory admission.

Five patients (10.9%) and two relatives (5.7%) took part in fewer than 50% of the educational sessions. In comparison with the completers, these patients were younger and patient and relative dropouts had a higher initial total satisfaction with services. There were no other clinical or sociodemographic differences between completers and dropouts. Six patients (13.0%; two intervention and four control patients) and eight relatives (22.9%; three from the intervention group) dropped out before the postintervention or follow-up interview. Eight patients (17.4%; four intervention and four control patients) were partly lost to follow-up of compliance or relapse data, as they were referred to private practitioners for further treatment ($n = 5$) or moved to another county ($n = 2$). One patient in the control group committed suicide during the follow-up period.

Table 1 Representativity analysis of participants versus non-responders/refusers and a reference group of patients with schizophrenia from the municipality of Aarhus[a]

	Participants ($n = 46$) vs Refusers/non-responders ($n = 89$)		Participants ($n = 33$) vs Aarhus Reference group ($n = 646$)	
	OR[b]	95% CI	OR[b]	95% CI
Illness duration (long vs short)	0.44	0.17–1.10	0.44	0.19–1.02
Substances abuse (ever vs never)	0.31	0.09–1.01		
Self-destructive behaviour (ever vs never)	3.33	1.04–11.1		
Compulsory admission (ever vs never)			0.40	0.15–1.08

[a] All variables with an association with group membership of $P < 0.1$ and age and sex are included in the logistic regression model
[b] The confidence interval of the OR is computed according to Hosmer and Lemeshow [52]

Randomization

The patients were block-randomized, stratified for gender and for illness duration (dichotomized to a duration of illness of more or less than 5 years). The randomization was carried out by an independent institution (Department of Biostatistics at the University of Aarhus, Denmark).

Study design

Intervention

The control group received the usual treatment provided in community psychiatry, i.e. psychopharmacological treatment, psychosocial rehabilitation efforts and to some extent supportive psychotherapy. The experimental group received an eight-session intervention [27] using a mainly didactic interactive method and focussing on the following headings:

1. Introduction
2. What is schizophrenia? Diagnosis, prognosis, symptoms
3. What causes schizophrenia?
4. Medication: effect and side effects
5. Psychosocial treatment
6. Stress and early signs of relapse, emergency plan
7. What can you and your family do about it?
8. Laws and regulations

The programme was standardized with a manual for group leaders, overhead presentations and a booklet for participants, to increase comparability of the intervention between centres. Further, teachers had regular meetings with the aim of increasing the commitment to the intervention protocol. Patient and relative interventions were conducted separately, with group sizes in both patient and relative groups of five to eight participants. The programme was the same for both patients and relatives. Sessions were weekly.

Measurement

The following scales and questionnaires were used

Patients; scales

OPCRIT (Operational Criteria checklist for psychotic illness) [25]. OPCRIT is a 90-item checklist of signs and symptoms that makes it possible to use case notes to generate diagnoses according to the operational criteria of 12 major classificatory systems [28].

BPRS (Brief Psychiatric Rating Scale) [29]. BPRS is an 18-item scale for rating of schizophrenic and depressive symptoms. In this study BPRS is rated according to the scoring instructions of Bech et al. [30], with five scale steps for each item rated (0–5).

GAF (Global Assessment of Function) [31]. GAF is a 90-point rating scale that assesses psychological, social and occupational functioning. It is included in axis V in DSM-III-R.

Patients; questionnaires

IS (Insight Scale) [32]. Insight Scale is an eight-item questionnaire assessing insight in psychosis and scoring three factors – Awareness of illness, Need for treatment, and Attribution of symptoms – on a three-point scale. It has been reliability tested and tested for construct, concurrent and criterion validity by the author of the scale.

VSSS (Verona Service Satisfaction Scale) [33]. The Verona Service Satisfaction Scale (54 items, patient's and relatives' version) is a questionnaire that covers seven dimensions of satisfaction with service: Overall satisfaction, Professionals' skills and behaviour, Information, Access. Efficacy, Types of intervention and Relatives' involvement [34]. The VSSS satisfaction ratings are given on a five-point Likert scale. The instrument has been validated in community psychiatric samples [35, 36].

Knowledge of schizophrenia (available from the first author). Knowledge of schizophrenia is an ad hoc categorical measure, developed by the first author, closely related to and covering the illness-related topics covered by the education programme.

Relatives; questionnaires

VSSS (Verona Service Satisfaction Scale; Relatives' version) [33].
FQ (Family Questionnaire) [37]. The Family Questionnaire is a 20-item questionnaire developed to be a less time-consuming evaluation of EE (expressed emotion) in relatives. It covers the two dimensions of Criticism and Emotional overinvolvement, and the items are scored on a four-point scale. The concurrent validity of the questionnaire has been tested against the much used semi-structured CFI (Camberwell Family Interview) [38].

Knowledge of schizophrenia (available from the first author). Where no Danish translation of questionnaires was available the instruments were translated from English (VSSS, IS) or English and German (FQ) under supervision of the first author according to the guidelines of Guillemin et al. [39].

The ratings of psychopathology and psychosocial function and the completing of questionnaires by the patients and relatives were made on three occasions.

1. Baseline (before randomization)
2. Postintervention (PI)
3. Follow-up (FU) (12 months after the start of the intervention)

The ratings of psychopathology and psychosocial function were performed by researchers not involved in the intervention and not informed of the treatment allocation of the patient. However, it was not possible to maintain blindness to the treatment allocation. After the PI and FU interviews, the raters guessed the allocation of the patients and guessed wrong in only 17% of the cases. Case records were used at baseline to obtain information on OPCRIT diagnosis and at baseline and at the end of FU to obtain information on relapse, compliance and medication before and after the intervention. The rating was done by researchers blind to the allocation of the patients. Three levels of relapse were rated as follows:

1. Aggravation of symptoms without change of treatment (medication or admission)
2. Aggravation of symptoms with change in medication (without admission)
3. Aggravation of symptoms with admission

A non-compliance episode was rated if case notes indicated that the patient did not receive medication for a period of 14 days. This "unit" of non-compliance enabled a comparison of compliance between patients receiving depot medication and those taking daily oral medication, and was the basis of the analysis of the effectiveness of the programme on non-compliance reduction. The comparison of baseline medication in allocation groups was based on transformation of medication data to DDD (Defined Daily Doses) [40].

Reliability of ratings

The reliability of use of the OPCRIT diagnoses rated by the first author was checked by kappa analysis of the authors ratings of 30 case abstracts from the OPCRIT reliability study [28] with the ratings of a participant in the study (Ole Mors, MD, Ph.D.). The overall kappa value for the ICD-10 categories was 0.6228. However, concerning schizophrenia, there was only misclassification in the subtyping. the video-interviews of BPRS and GAF of 23 (50%) of

the patients were independently rated by the researchers. There were no statistically significant differences in total scores or subscores on BPRS or on total score on GAF between any of the rater pairs.

Statistical methods

Differences between after and before the intervention were computed for continuous outcomes, and the association to treatment allocation was analysed by the Mann-Whitney-U test, or by the independent samples *t*-test where the assumptions of normality and homogeneity of variances seemed acceptable. To adjust for possible confounding, relevant outcomes were further analysed in a regression model as dependent variables. Treatment allocation, insight into psychosis, psychopathology, psychosocial function, sex and age were included as independent variables. For the relatives, EE score was included as a potential confounder. In cases where more than one relative to a patient participated, the outcome assessed could not be assumed to be independent. In these cases we chose to repeat the analyses using a mean score of the relatives of the same patient. When this was done the trend was the same but results were only significant concerning knowledge change in relatives.

In the representativity analysis dichotomous variables were analysed with the Chi-square test, or Fischer's exact test when appropriate. To adjust for possible confounding, relevant outcomes were included in a logistic regression model. Independent variables included in the regression model were: psychopathology, psychosocial function, sex and age. In the analysis of relapse data, time to first relapse of any kind was used as outcome in the Cox regression analysis [41].

Patients data were censored when they were referred to private practitioners or moved out of the country. In all outcome analyses both an "analysis per protocol" and an "intention to treat" approach was taken. As both approaches yielded very similar results with one exception (stated in the Results section) only results from the intention to treat analysis are documented here. The level of significance was chosen as $P < 0.05$.

Table 2 Sociodemographic and clinical characteristics of included patients ($n = 46$) (*BPRS* Brief Psychiatric Rating Scale, *GAF* General Assessment of Functioning)

Sex (M)	24	(52.3%)
Living conditions		
Alone	30	(65.2%)
With parents	2	(4.3%)
With partner or children	6	(13.0%)
Group home/hostel	7	(15.2%)
Other	1	(2.2%)
Occupational situation		
Paid work	1	(2.1%)
Disability pension	39	(84.8%)
Other	6	(13.0%)
Compulsory admission (ever)	8	(17.5%)
Alcohol abuse diagnosis (ever)	5	(10.4%)
Substance abuse diagnosis (ever)	4	(8.7%)
Self-destructive behaviour (ever)[a]	9	(19.6%)
Insight (low)	9	(19.6%)
Non-compliance[b]	14	(30.4%)
	Median	Interquartile range
Age at inclusion	35.9	(30.30–39.62)
Age at first admission	24.7	(20.63–29.80)
Duration of illness (yrs)	8.2	(4.99–14.79)
No. of earlier admissions	5.0	(3.00–8.25)
No. of earlier inpatient days	398.5	(146.50–719.50)
Inpatient days per year	43.7	(26.24–71.29)
Psychopathology (BPRS)	10	(5.75–16.25)
Psychosocial functioning (GAF)	53	(45.00–56.50)

[a] Suicidal act or an act of self-mutilation
[b] At least one non-compliance episode of 14 days in preceding year

Results

The sociodemographic and clinical characteristics of the included patients are displayed in Table 2.

There were no statistically significant differences in baseline scores on study instruments between allocation groups or centres. Further, there were no statistically significant differences between allocation groups in baseline or follow-up medication dose measured by DDD (defined daily doses). There were no significant clinical or sociodemographic predictors for change in knowledge in the patient group.

Postintervention (PI), there was a statistically significant effect ($P = 0.02$) of the intervention on knowledge of schizophrenia in patients. There was also a significant effect on the subscore satisfaction with Relatives' involvement (information provided to and involvement of the relatives in the treatment process) [34] from the VSSS in patients ($P = 0.01$), reproduced in the multivariate analysis (Table 3).

In relatives, the treatment effects on knowledge of schizophrenia ($P = 0.02$) and satisfaction with relatives' involvement ($P = 0.04$) were also significant when adjusted for the EE score at baseline (Table 4).

Table 3 Postintervention impact in patients on different outcome measures (intention to treat) (*IS* Insight Scale, *VSSS* Verona Service Satisfaction Scale)

Outcome measures	Intervention group ($n = 23$)			Control group ($n = 23$)			Significance (P)
	Mean change	SD	n	Mean change	SD	n	
Psychopathology (BPRS)							
Total score	−0.09	5.90	22	2.63	8.04	19	0.23
Schizophrenia score	0.32	3.59	22	2.52	6.25	19	0.16
Psychosocial function (GAF)	0.14	13.61	22	−4.74	14.80	19	0.89
Knowledge of schizophrenia	2.04	1.68	22	0.63	2.06	19	0.02
Insight (IS)	0.18	1.76	22	0.16	1.49	19	0.96
Satisfaction (VSSS)							
Total score	9.47	17.46	18	7.32	16.48	14	0.72
Relatives' involvement	4.09	4.21	18	0.16	4.08	14	0.01

Table 4 Postintervention impact in relatives on different outcome measures (intention to treat) (*FQ* Family Questionnaire)

Outcome measures	Intervention group (n = 23)			Control group (n = 23)			Significance (P)
	Mean change	SD	n	Mean change	SD	n	
Expressed emotion (FQ)	−0.61	3.43	18	2.64	8.01	11	0.14
Knowledge of schizophrenia	1.77	2.15	18	0.31	1.25	13	0.02
Satisfaction (VSSS)							
Total score	9.56	28.73	10	1.25	16.05	7	0.50
Information	1.85	3.10	17	0.59	1.88	11	0.24
Relatives' involvement	2.92	5.55	15	−1.43	3.35	10	0.04

At 1-year follow-up (FU) the gains in satisfaction with Relatives' involvement were still maintained for patients (P = 0.04) (Table 5) but not for relatives. The knowledge gains were not maintained at 1-year FU for patients or relatives.

There was a trend that the schizophrenia subscore of the BPRS was reduced in the intervention group at the 12-month FU compared with the control group (P = 0.07) (analysis per protocol P = 0.06) (Table 5).

There was a non-significant trend (P = 0.24) that time to (any level of) relapse was longer for patients in the intervention group compared with the control group. A Kaplan-Meier plot regarding survival as non-relapsed is presented in Fig. 1.

No differences were found in insight into psychosis (Insight Scale) or psychosocial function (GAF) at the PI interview or at the FU. No significant reduction in the number of non-compliance episodes was found at FU in the intervention group compared to the control group. There were no statistically significant changes in relatives' EE (Family Questionnaire) scores at the PI or at the 1-year FU.

There were no differences in outcome between the patients in the intervention group who had a relative involved and the patients who did not have a relative involved.

Discussion

The few patient education trials published study different interventions and different outcomes over different follow-up periods, often in mixed diagnostic samples. Methodological flaws such as lack of randomization or control groups, non-blind outcome assessment, no control for changes in medication in intervention groups and non-validated assessment instruments also limit the validity and generalizability of many studies. Advantages of the present study were that a standardized intervention was used on a sample of patients with schizophrenia with a clinical diagnosis validated by use of OPCRIT. Further, different levels of relapse were measured and relapse and compliance were assessed blindly by the researchers. The study used mainly validated and reliable instruments, tested inter-rater reliability, and included control of medication dose. However, a blind assessment of psychopathology (BPRS) and psychosocial function (GAF) was not attained. The use of a non-validated ad hoc instrument to measure knowledge and a compliance measure based on case records, which did not include urine testing or pill count, to some extent also limits the validity of findings. Furthermore, the power of the study and the generalizability of the findings are limited by the low eligibility of patients to the study and the resulting small sample size. The representativity analysis indicated that the sample was skewed in the direction of more self-destructive behaviour diagnoses, fewer substance abuse diagnoses and towards shorter illness duration.

The basic requirement for a patient education programme should be that it increases knowledge of the illness and treatment, supposing that this can change illness related behaviour [14, 42] and enables the patients and the relatives to use the mental health care system

Table 5 One-year follow-up impact in patients on different outcome measures (intention to treat)

Outcome measures	Intervention group (n = 23)			Control group (n = 23)			Significance (P)
	Mean change	SD	n	Mean change	SD	n	
Psychopathology (BPRS)							
Total score	−2.63	5.17	22	−0.39	7.11	18	0.26
Schizophrenia score	−0.95	3.75	22	1.89	5.90	18	0.07
Psychosocial function (GAF)	9.77	14.75	22	4.50	12.45	18	0.24
Knowledge of schizophrenia	1.68	1.72	22	0.94	1.73	18	0.19
Insight (IS)	1.09	2.19	22	0.13	2.41	18	0.20
Compliance	0.25	1.26	20	0.68	4.31	18	0.64
Satisfaction (VSSS)							
Relatives' involvement	4.47	3.13	15	0.12	4.42	15	0.004

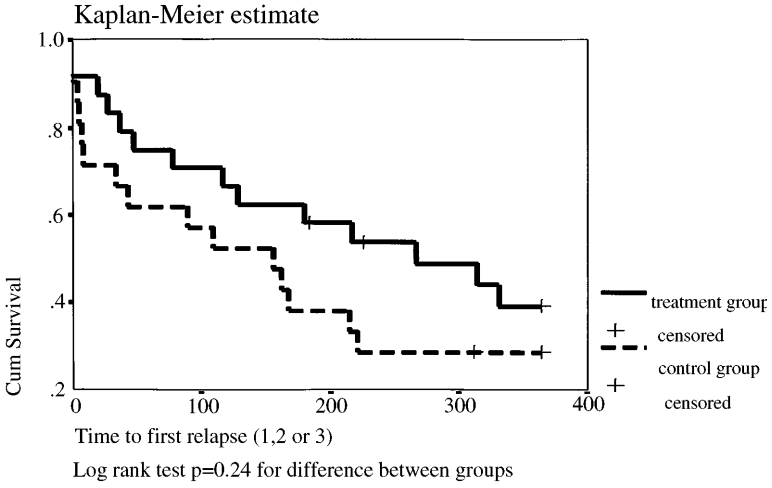

Fig. 1 Time to relapse in treatment groups

more effectively [43]. Knowledge is the main outcome measure in patient education studies with schizophrenic patients, and a majority of randomized controlled studies show statistically significant gains in the area [9–11]. The present study showed that a short psychoeducational programme for patients and relatives could improve the level of knowledge of schizophrenia at PI, but that this improvement was not retained at 1-year FU. Further, satisfaction with Relatives involvement increased both for patients and relatives at PI, and this gain was retained at the 1-year FU by the patients. This is important, as satisfaction with services is a well-known predictor of the use of health care services [44]. Neither Hornung et al. [45], nor Kelly and Scott [46] could demonstrate the effectiveness of a patient education programme on satisfaction. One explanation could be that the few studies that have included satisfaction among outcome measures have used unidimensional satisfaction measures, thereby decreasing the sensitivity of satisfaction assessments [47, 48].

There was a marginally significant tendency that the schizophrenia subscore of the BPRS was reduced in the intervention group at the 1-year FU compared with the control group. Other patient education studies have shown effects on psychopathology [46, 49], but the mechanisms are complex and rarely discussed [49]. In the present study no concomitant improvement of compliance with medication could explain the finding.

There was only a weak tendency that time to relapse was longer in the participants ($P = 0.23$). Family psychoeducation studies have established a firm association between psychoeducational interventions and reduction of relapse [5, 6], but educational interventions without behavioural elements do not seem able to reduce relapse [1]. This was borne out by the present study, in which the programme only comprised a presentation of the techniques used for relapse prevention, but no training, and no effect was shown on compliance. Patient compliance is a very complex process dependant on cognitive, affective and behavioural elements [43]. Assuming that programmes with purely didactic content would have insufficient effect on affective or behavioural components of compliance would be reasonable. Indeed, patient education programmes including behavioural elements seem to be more able to improve compliance [45, 46], although methodological weaknesses make this conclusion less firm. In the present study no compliance training was included. The reason for the lack of statistically significant changes in the relatives' EE (Family Questionnaire) scores PI and at the 1-year FU could be that the duration of the intervention was insufficient for marked changes in the emotional relations between relatives and patients to occur. Mari and Streiner [50] in a meta-analysis of family interventions only found marginally significant changes in EE status in spite of reduction of relapse. This indicates that EE in relatives of patients with schizophrenia can be difficult to influence even by more comprehensive interventions. Unlike most family intervention studies, this study did not focus primarily on patients living with families or with families with a high EE. In our study 65.2% of the participants lived alone and only 13.4% of the relatives had high EE prior to the intervention.

No differences were found in insight into psychosis or psychosocial function (GAF) in patients at the PI interview or at FU. The reasons for this could be that the baseline insight was very high, making changes less possible, and that the brevity of the programme made it difficult to interact sufficiently with patients in order to influence often long-standing beliefs regarding illness [51]. Dixon and Lehman [5] in a review of family interventions conclude that few studies have shown effect on psychosocial functioning and that the reason may be that these effects are "indirect and delayed beyond the measurement of these studies".

Conclusion

Many studies have shown that extensive (and expensive) family psychoeducational programmes are effective in

improving prognosis in schizophrenia. The present study indicates that a short educational programme for patients and relatives can be effective in influencing important variables as knowledge and satisfaction with involvement of relatives. Beyond this the impression was that a group educational intervention like this could influence non-specific factors such as communication with professionals, relatives and peers concerning issues of illness and treatment as well as more existential concerns.

However, a short educational programme for patients and relatives does not seem to be sufficient to influence important variables such as relapse, compliance, psychosocial functioning or insight as reported using more intensive interventions. This area needs to be further developed both clinically and in research. There is a lack of research on the optimal intensity and duration of patient and relative education programmes to influence relevant outcomes. Furthermore, very little is known of the comparable efficacy of patient education programmes in newly diagnosed populations.

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