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A Controlled Trial of Social Intervention in the Families of Schizophrenic Patients: Two Year Follow-up

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Summary: The two-year follow-up results are reported of a trial of social intervention in families of schizophrenic patients in high social contact with high-expressed emotion (EE) relatives. For those patients who remained on anti-psychotic medication throughout the two years, the social intervention significantly reduced the relapse rate. In those experimental families where relatives' EE and /or face-to-face contact was lowered, the relapse rate was 14%, compared with 78% for control patients on regular medication ($P = 0.02$).

Over the course of 20 years, a series of naturalistic studies has established a firm link between relatives' expressed emotion (EE) and the course of schizophrenia. The findings of British research (Brown *et al*, 1962, 1972; Vaughn & Leff, 1976a) have been replicated in California (Vaughn *et al*, 1984) and in Chandigarh, North India (Leff *et al*, unpublished). In both British and American studies, it appeared that the association between a high-EE home and relapse of schizophrenia was modified by two factors—maintenance with neuroleptic drugs and low face-to-face contact between the patient and the high-EE relative(s). Furthermore, these two factors in combination seemed to confer added protection against the stressful atmosphere in a high EE home. Because of the nature of naturalistic studies, the interpretation that high-EE attitudes have a causal influence on relapse, and that low contact and maintenance neuroleptics have a protective effect can readily be challenged. It is just as plausible to argue that some characteristic of the patients provokes high-EE responses in the relatives and also renders the patients more likely to relapse. In the same vein, patients with a good premorbid personality, and hence an intrinsically better prognosis, are likely to have extensive social networks, enabling them to remain in low face-to-face contact with their relatives. This form of argument cannot be applied to the protective effect of maintenance neuroleptics, since numerous double-blind, placebo controlled studies have provided convincing evidence for this (e.g. Hogarty *et al*, 1979).

To determine whether relatives' EE has a causal effect on schizophrenic relapse and low face-to-face contact a protective effect, it was decided to mount a controlled trial of social intervention. This is analogous to a controlled drug trial, but the nature of social treatments dictates various modifications to the design (Leff, 1981). The aim was to determine whether reducing relatives' EE and/or face-to-face contact from high to low would *add to* the beneficial effect of maintenance neuroleptics on schizophrenic relapse, so that it was crucial that patients should remain on their maintenance drugs throughout the trial. Initially, the follow-up period was set at nine months after discharge, in conformity with the earlier naturalistic studies of relatives' EE. If the associations repeatedly found in the previous studies did indeed represent causal relationships, then we would expect the nine-months relapse rate of patients in high EE homes maintained on drugs to be close to 54%. By contrast, patients whose relatives' EE and/or face-to-face contact was altered from high to low by the intervention should have a relapse rate of about 15% (Vaughn & Leff, 1976a). In fact, the relapse rates found in the nine-month follow-up of our trial were 50% for the control group and nil for those experimental families in which we were successful in achieving the aims of our intervention (Leff *et al*, 1982). The closeness of these findings to our theoretical expectations led us to conclude that over the nine-month period following discharge, high-EE attitudes do indeed exert a deleterious influence on the course of schizophrenia, and reduction in face-to-face contact is genuinely protective. The results also provided evidence for the effectiveness of our social intervention in altering the family atmosphere in the desired direction, an aim which was achieved in three-quarters of the experimental families.

A longer follow-up was clearly desirable to determine whether there was any persisting advantage of social intervention, and therefore a two-year was used in the present study. A follow-up of this length has been attempted in only two of the naturalistic studies—that by Vaughn & Leff (1976a) in London, and the Chandigarh study (from which data have yet to be analysed). The two-year follow-

up of the London study included data on 25 of the 26 eligible patients who remained well for the first nine months—a 96% success rate (Leff & Vaughn, 1981). The cumulative relapse rates over the whole two-year period were 62% for high-EE patients and 20% for low EE patients (exact $P = 0.015$). Hence, the significant association between high EE and relapse was found to persist over at least two years. If this reflects a causal relationship, then the two-year follow-up of our intervention trial should reveal a significantly better outcome for patients living in families where we successfully achieved our therapeutic aims, than in control patients.

Method

The design of the trial and methods of assessment are described in detail in Leff *et al*, (1982). Briefly, patients were assessed with the Present State Examination (PSE) and the data processed by the Catego program to give a standardised diagnosis (Wing *et al*, 1974). The patients were selected from recent admissions to the Bethlem Royal & Maudsley Hospital, the Southwestern Hospital, and St. Pancras Hospital. Selection criteria were: age 16–65, living with relatives continuously for three months prior to admission, residence within reasonable commuting distance from the hospital concerned, and spending more than 35 hours per week in face-to-face contact with one or more relatives (determined by constructing a time budget of a typical week). If a patient satisfied these criteria, the relative or relatives were interviewed with the Camberwell Family Interview (CFI) and ratings of EE made from an audiotape of the interview (Brown & Rutter, 1966; Vaughn & Leff, 1976a, 1976b). If one or more relatives in the household were rated as high-EE, the family was included in the trial and randomly assigned to experimental or control groups.

All patients in the trial were prescribed regular anti-psychotic medication. We recommended to the clinicians responsible for the patients' care that they be given long-acting injections, and this was done in 21 out of the 24 cases. The other three patients were put on oral neuroleptics and instructed to take them regularly.

Control relatives were given no further attention by the research team. We had had to choose between administering some treatment to the control relatives which we did not expect to be effective, or giving them no attention at all; both strategies entail disadvantages and risks—a dilemma which stems directly from the uncomfortable fact that there can be no placebo for a social treatment (Leff, 1981). In the event, we decided not to offer any treatment to the control relatives, knowing that we were not controlling for the attention given to the experimental relatives, and that we were taking a risk that the patients' clinicians might arrange treatment for the control relatives. As it happened, only one control family received treatment of the quantity and intensity offered to the experimental families; the wife of a control patient was seen fortnightly by a social worker throughout the first nine months of the trial, without, however, showing any reduction in her level of EE at follow-up. Experimental relatives received a package of social interventions which consisted of three main components: a short educational programme of two sessions on the aetiology, symptoms, course and management of schizophrenia (Berkowitz *et al*, 1984), a relatives' group which included both high-EE and low-EE relatives (Berkowitz *et al*, 1981), and family sessions which included the patient and were held in the home.

Follow-up procedures for the initial nine months' period were the administration of the PSE and a history of medication taken at the time of relapse or at the nine-month point if the patient remained well. A history of life events was taken at the same time (Leff *et al*, 1983). The relative or relatives were re-interviewed with the CFI, if possible by the same person as on the first occasion, and EE ratings were made. The assessment of EE was usually conducted independently by two raters, who were not, however, blind to the treatment group to which the families belonged. To check on any bias resulting from this knowledge, a representative selection of eight follow-up interviews was assessed by a blind rater; his reliability with the definitive raters was calculated, using the intra-class correlation coefficient. This was found to be 0.88 for overinvolvement and 0.60 for critical comments. The latter figure is unsatisfactorily low, but this is partly due to one outlying relative; this individual was given the highest score on critical comments by both raters, 32 by one and 12 by the other. If this outlying subject is omitted, the intra-class correlation coefficient increases to 0.75.

After the nine-month point, the procedures for follow-up remained the same with two exceptions. Patients who had already relapsed within the first nine months after discharge were not followed-up any further, although we continued to offer help to their families if they were in the experimental group. The CFI was not administered routinely at the two-year point—an omission we were to regret. A time budget was constructed for each patient by the psychiatrist administering the PSE, which enabled us to assess social activities quantitatively, though not qualitatively.

Results

We showed in the previous paper that the randomisation procedure was effective, since the control and experimental patients did not differ significantly on any feature of their clinical state assessed on admission. The same was true of the demographic and historical characteristics of the patients, with one exception: the experimental patients had a significantly ($P < 0.05$) greater duration of unemployment before admission than the control patients.

Medication: When patients' adherence to prophylactic medication was reviewed at the two-year follow-up, it was discovered that two control patients had discontinued their anti-psychotic drugs during the nine months after discharge. One had been on oral medication and remained well (Control Case 5), while the other had been receiving long-acting injections and relapsed (Control Case 8).

Between the nine-month and two-year follow-ups, a further three patients discontinued medication—one from

the control group and two from the experimental group. All three relapsed between one and four months after stopping their medication. Thus, five patients in all stopped their prophylactic neuroleptic drugs during the two years following discharge. If these patients' outcome results were to be included in our analyses, we would be examining the question of the effectiveness of social intervention in assuring drug compliance. This was not the aim of the trial, which was to examine whether social intervention could add anything to the known benefits of maintenance drug treatment; therefore, we have excluded these patients from further analyses. We can compare our exclusion rate of five out of 24 (21%) with the equivalent rate of 17% in one of the few controlled drug trials in schizophrenia to continue for two years (Hogarty *et al*, 1979). This indicates that although the pressure on our patients to comply with prescribed regimes was not as intense as in a controlled drug trial, the degree of adherence achieved over two years was comparable.

Bias introduced by patients discontinuing medication: As stated above, although the number of subjects was relatively small, the randomisation procedure effectively produced two matched groups, with the exception of a single feature—duration of unemployment before admission. After excluding the five non-compliant patients, it is necessary to check whether the remaining experimental and control subjects are still as closely matched as at the beginning of the trial, since a selective non-compliance rate could easily introduce a new bias. The remaining ten experimental and nine control subjects were compared on all the clinical, historical, and demographic data collected initially. There was no difference between the two groups with regard to the presence or absence of any of the 38 Syndromes derived from the PSE by the Catego program (Wing *et al*, 1974). One experimental and one control patient were classified by Catego as schizophrenic, class 'P' (paranoid schizophrenia); the remainder in both groups were classified as schizophrenia, class 'S' (nuclear schizophrenia).

All other comparisons revealed no significant differences between the experimental and control patients, with two exceptions (Table I).

It can be seen that the bias found in the total sample for the experimental patients to have a greater duration of unemployment before admission remains when the non-compliant patients are excluded. An additional bias has been introduced, towards a greater mean age in the experimental than in the control patients. Since either bias could affect the patients' outcome, it is necessary to analyse the relationship between these two characteristics and the various measures of outcome employed.

The whole sample of 24 patients was stratified by age, and the relationships with schizophrenic relapse and with treatment failure (to be defined later) during the two years examined; these procedures were repeated for duration of unemployment. None of the relationships examined proved to be significant. Hence, we conclude that neither effect introduced by the exclusion of patients discontinuing medication can account for any differences in outcome between the experimental and control groups.

TABLE I

Demographic and historical characteristics of patients remaining on medication

	Experimental	*Control*
Number	10	9
Male/Female	5/5	4/5
Living group: parents	5	5
spouse	5	4
Mean age	41	30*
Education: CSE or above	3	3
Ever Married	5	6
Ever divorced or separated	0	2
Mean number of children	0.4	0.9
Drop from highest sociosexual achievement	3	1
Occupation: 3 non-manual or above	4	1
Mean length of unemployment before admission in months	19.7	5.1*
Employed at admission	3	5
Abnormal premorbid personality	6	3
First admission	3	2
Mean number of previous admissions	2.3	1.3
Age at first onset	36	26

*$P < 0.05$

Professional attention to families between nine-month and two-year follow-ups: Careful records were kept of the amount of professional time spent with each experimental family over the whole two years of the follow-up. Although the intervention officially ended after nine months, relatives were welcome to continue attending the group and were encouraged to keep in contact by telephone. In a small number of families, sessions in the home were continued.

Up to the nine-month point, experimental families attended the relatives' group a median of 10.8 times (range 6–21), received a median of 4.7 family sessions in the home (range 1–25), and made phone calls to members of the intervention team lasting a total of 40 minutes on average. Between the nine-month and two-year follow-ups, excluding the experimental patient who had relapsed earlier, family members attended the group a median of 1.1 times, were visited at home a median of 1.1 times, and spent a mean of 32 minutes on the phone to team members.

This attention was not spread evenly among the experimental families, as two declined any further help after the nine-month point, while the remainder took advantage of some, but not all, facilities offered during the rest of the two-year period.

During the first nine months following the patient's discharge, only one control relative received regular professional help with problems associated with caring for the patient. This wife, already referred to, continued to see a social worker once every two weeks for a period of 19 months after the patient's discharge; she then failed several successive appointments, and the social worker closed the case. The patient had discontinued maintenance neuroleptics some months previously and relapsed in the 20th month of the follow-up; because he stopped his

drugs before relapsing, he was excluded from the analysis of outcome along with the other drop-outs. Apart from this family, control relatives received no professional attention between the nine-month and two-year follow-ups. Considering only those patients who were well at nine months and who continued on drugs, seven of the nine experimental families received professional help, while no control relatives did so.

Changes in face-to-face contact between nine-month and two-year follow-ups: Regrettably, the entire CFI was not administered to relatives at the two-year point. However, one small section of it, the time budget, was constructed by questioning the patients. From this, it is simple to calculate the number of hours in a typical week that patients and relatives spend in face-to-face contact, more than 35 hours representing high contact.

Of the six control patients who remained well at the nine-month follow-up, four were in high contact with their relatives, while two were in low contact. During the succeeding period up to relapse or to the two-year follow-up for those who remained well, no changes occurred in these contact patterns. Of the 11 experimental patients who were well at the nine-month point, six were in high contact and five in low contact with their relatives. During the remainder of the two-year follow-up period, changes in contact occurred in two families. The wife of one patient who had been in high contact left him (Experimental Case 3). In another marital couple, contact had fallen to a low level by the nine-month point, but increased subsequently to become high again. The patient discontinued her medication and relapsed in the 23rd month, which was hardly surprising since her husband was still highly critical of her, when assessed at the nine-month point (Experimental Case 8); this patient, being a drug defaulter, was excluded from the analysis of outcome. Thus, of the 13 patients who were well at nine months and who continued on drugs, only one showed a change in the level of face-to-face contact during the rest of the two-year period.

Outcome of patients remaining on medication: As in the earlier studies of EE, relapse of schizophrenia was defined as Type I—the reappearance of schizophrenic symptoms in patients who had been free of them at discharge, or Type II—the exacerbation of schizophrenic symptoms which had stabilised at a steady level by discharge (Brown *et al,* 1972; Leff *et al,* 1982). Of the nine relapses on medication during the two years, all but one were Type I in nature. Seven of the relapses occurred among the nine control patients (78%), while the other two relapses were among the ten experimental patients (20%). This is a highly significant difference ($P = 0.017$). All non-parametric comparisons involved the use of Fisher's exact test.

This relapse rate in the experimental group underestimates their psychiatric morbidity, since two patients attempted suicide, one successfully, while the other survived with severe brain damage and died later. The relatives had not noticed any overt expression of schizophrenic symptoms in either patient immediately prior to the suicide, but one cannot rule out this impetus to suicide in a patient who has suffered from schizophrenia in the past. This high suicide rate (17%) among the experimental patients might be attributed to our intervention, on the assumption that it was disturbing to some patients. This interpretation is unlikely, since three of the control patients (25%) made suicidal attempts during the two-year period. Each of these attempts was an overdose, and was severe enough for the patient to be admitted; in two cases, the patients were transferred to a psychiatric ward for further treatment. The third patient was discharged home, but had to be readmitted three months later for an exacerbation of his schizophrenia.

Whether or not the suicides in the experimental group were the consequence of a return of schizophrenic symptoms, they undoubtedly represent failures of management. When these are included with the overt schizophrenic relapses, the treatment failure rate in the experimental group becomes four out of ten (40%) which is almost half the rate for the control patients (78%) but is not significantly different.

Our trial had two principal aims; firstly, to test the hypothesis that high EE and high contact have a direct causal influence on the course of schizophrenia, and secondly, to determine whether social intervention with families can improve the outlook for schizophrenic patients. So far, we have only considered the therapeutic effectiveness of our social intervention. To test the causal hypothesis, it is necessary to compare the relapse rate in the control group with that in the experimental families in which we succeeded in lowering EE and/or contact. We achieved our therapeutic aims in nine families, but in two of these the patients discontinued medication and relapsed. In the remaining seven families, there was only a single relapse over the two-years—a relapse rate of 14%. This is significantly different ($P = 0.020$) from the relapse rate of 78% in the control group. Both suicides were in experimental families in which we had failed to achieve either of our aims, as assessed at the nine-month follow-up.

Quality of life: It has been argued that the strategies we use to keep patients from relapsing lead to an impoverishment of their quality of life. To check on this, we need to consider the life style of the six patients in the experimental group who remained well or stable over the two-years of the follow-up. The information was derived from the time-budget—a structured interview which is part of the CFI.

Case 1. This man of 25 had spent a short period in a hostel, but discharged himself, and was back living with his parents and a brother. His weekdays were fully occupied with attendance at a job. He went out to a pub two evenings a week with his stepfather, and went out on his own on Saturday nights. His free time was occupied with watching television, drawing and painting, and taking the dog out for walks.

Case 2. This married woman of 55 had retired prematurely from work because of ill-health. Her husband had also retired, and they spent weekday mornings in domestic chores, including shopping together. In the afternoon, the patient would go to the library, the hairdresser or a

chiropodist; evenings were spent sitting together, reading or watching television. Each weekend, they went to their country cottage, where they were both fully occupied with domestic and gardening activities.

Case 4. This married man of 49 could not work because of cardiovascular disease. He was living with his wife and their son, who also suffered from schizophrenia. The patient spent much of the day out of the house, visiting friends. In the evening, he would sit with his wife watching television, their son usually remaining in his own room.

Case 5. This man, aged 57, was living with his wife and four children. Weekdays and some weekends were occupied with a full-time job as a security guard. His leisure time was spent with his family and friends.

Case 6. This married man of 58 lived with his wife, who worked part-time. The patient remained at home and carried out domestic chores very efficiently, including cooking and shopping. His leisure time was spent together with his wife, and involved considerable activity in the local church.

Case 7. This divorced woman of 42 lived with her elderly mother. She attended a hospital as a day patient on a ward; she knew the longer stay patients on the ward quite well and spent much of her time in social activities with them. At home, she spent all her leisure time with her mother, including regular visits to her extended family.

In summary, two of the patients were in full-time work; one was a day patient, two were fully occupied with domestic activities, and one spent most of the day visiting friends. Four of the patients pursued active leisure interests, while the other two probably did little more than watch television in company. No patient was idle during the day and no-one was socially isolated.

Discussion

We were not in charge of the clinical care of the patients in the trial and so were reliant on the clinicians to ensure that patients adhered to the prescribed drug regimes. Despite the indirect nature of our control over medication, 79% of patients took regular maintenance neuroleptics throughout the two years of the trial—a comparable proportion to that in controlled drug trials of the same duration. For those patients who remained on drugs, the professional attention given to the experimental relatives was of a quite different order of magnitude from that received by the control relatives. In fact, throughout the two-year period, no professional help directed at the problems of living with the patient was given to the relatives of control patients who remained on drugs. Hence, we can ascribe any difference in outcome between the two groups of drug-compliant patients to the social intervention received by the experimental families.

The social intervention, in combination with maintenance neuroleptics, conferred a significant advantage on patients in terms of overt schizophrenic relapse, over a period of two years. However, when outcome was broadened to include suicide, the treatment failure rate in the control and experimental groups was not significantly different. This result was due to two experimental patients who committed suicide. Relatives' EE remained high in both families, in one of which the patient, a young girl, was very concerned to loosen her attachment to her mother, but was unable to do so, even with our help. In the other family, the patient's wife left him, taking their children with her; the patient was left alone in a large flat, with no social contacts and very little to do. He remained free of schizophrenic symptoms, but was significantly depressed. Two months before the two-year follow-up he visited his family at Christmas. A family row flared up, following which he returned home and took a fatal overdose. In both these cases, we had ceased to have any contact with the families for some months, and the possibility has to be considered that the suicides might have been prevented had we kept in touch with these families. It is now our policy to maintain some contact with families, however tenuous, indefinitely.

Taken by itself, the effect of our intervention on the outcome of schizophrenia might not be considered impressive enough to justify the incorporation of work with relatives of schizophrenic patients into routine clinical practice. However, it is not an isolated finding. Since we began the trial in 1977, three similar studies have been published (Goldstein *et al,* 1978; Anderson *et al,* 1981; Falloon *et al,* 1982); all examined the effect of combining therapeutic work with relatives with maintenance neuroleptics. Although the theoretical orientation of each group is different, the overlap in approaches to working with the families is considerable (Leff, 1985), and the short-term outcome of these three studies and our own (Leff *et al,* 1982) is remarkably similar. In all four studies, the relapse rate of schizophrenia has been about 50% for control patients and less than 10% for experimental patients. Falloon *et al,* 1985 have now completed their own two-year follow-up: schizophrenic relapse of patients remaining on medication was 83% in the control group and 12% in the experimental group, which is closely similar to our figures of 78% and 20% respectively.

It is not possible to determine from any of these studies whether it was the attention paid by professional staff to the families or one or more specific aspects of the therapy that produced the benefit. This is because none of the designs included a control for the amount of attention given

to the families. The consistency of these findings now justifies a new generation of studies, aimed at answering this question.

Having considered the therapeutic implications of our findings, we can now turn to the theoretical issues this study was designed to examine. From this viewpoint, the two-year results complement the findings of the nine-month follow-up, since the group with the best outcome consisted of those experimental patients remaining on medication in whose families a reduction had occurred in EE and/or face-to-face contact from high to low at the nine-month assessment. The relapse of these patients was only 14% over two years, which is significantly lower than the rate of 78% among control patients on drugs. From the time budgets, we determined that the contact patterns of these experimental patients remained unchanged between the nine-month and two-year follow-ups. Unfortunately, we did not repeat the EE assessments at the two-year point, so that we do not know whether EE levels were similarly stable. This omission weakens the evidence that a reduction in EE and/or face-to-face contact exerts a beneficial effect on schizophrenic relapse over a two-year period following discharge.

In considering the pathogenic effects of high EE, we do not assume that the direction of influence is entirely one-way from relatives to patients. We are well aware of the ways, sometimes subtle, sometimes blatant, in which patients provoke criticism and overinvolvement in relatives. What we conclude is that the influence of relatives on patients is a sufficiently major component of their interaction for its modification to effect a substantial reduction in the patient's relapse rate. The processes that may intervene between the expression of relatives' emotional attitudes towards the patient in an assessment interview and the reappearance of schizophrenic symptoms in the patient are discussed by Leff (in press).

It is salutory to consider the outcome of patients in this study who discontinued antipsychotic medication, and thus dropped out of the trial proper. There were five patients of this kind—three control and two experimental; four of them relapsed, three within a month of stopping medication, the fourth four months later. The two experimental patients were living with relatives whose EE level remained high, despite our intervention. In both cases, the patients had reduced contact below 35 hours per week by the nine-month point, but one had drifted back into high contact by the time of relapse. Both control patients who relapsed off medication were living with high-EE relatives at the nine-month follow-up, one being in high contact, the other low. The only patient in this group off medication who remained well for two years was living with her sister, who spontaneously changed from high to low EE over the nine months following discharge. It appears from these results that as long as relatives remain high-EE, it is unjustified to allow patients to discontinue medication, even if they are in low contact. The clinicians in charge of these patients' care were evidently not sufficiently aware of the risk patients were running in receiving no medication, while continuing to live with high-EE relatives.

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