Impact of brief psychosocial intervention on key relatives of patients with schizophrenia: A randomized controlled trial

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ABSTRACT

Background: Caregivers of patients with schizophrenia often experience high burden of care and have deterioration in the quality of their life. This study attempted to assess the efficacy of a brief psychosocial intervention (BPI) on the burden of care and quality of life (QOL) of key relatives of patients with schizophrenia and its subsequent effect on QOL of their patients (if any).

Methods: A total of 66 patients and their key relatives were included in the study. Patients were assessed for psychopathology (by applying Positive and Negative Syndrome Scale and World Health Organization QOL scale [WHOQOL-BREF]) and relatives were assessed on Burden Assessment Schedule and WHOQOL scale (WHOQOL-100). Thirty-three patients and their key relatives were randomly allocated to BPI group and nonspecific control intervention group.

Results: There was a statistically significant reduction in burden of care \((P = 0.004)\) and improvement in QOL of relatives \((P = 0.024)\) as well as in QOL scores of patients \((P = 0.0028)\) in the BPI group.

Conclusion: BPI is associated with a significant improvement in QOL as well as burden of care of key relatives of patients with schizophrenia, which, in turn, results in improvement in QOL of their patients.

Key words: Brief psychosocial intervention, key relatives, nonspecific control intervention, schizophrenia

INTRODUCTION

Chronic illnesses are known to adversely affect the lives of patients and their caregivers.[1] The impact of chronic illness can be physical as well as psychological and often influenced by the characteristics of patients, their relatives, their relationship, and their environment.[2] Schizophrenia is a chronic and severe form of mental disorder with debilitating course and poor outcome. The current management approach to schizophrenia involves a multifaceted management aimed not only limited to ameliorating symptoms, but also extending to optimization of functioning and improving quality of life (QOL). Various nonpharmacological techniques have been developed to address these concerns.[3,4]

Living with and caring for a person suffering from schizophrenia is often challenging. Several studies...
revealed that caregivers of patients with schizophrenia face considerable stress and anxiety, experience high burden, and often could not receive adequate assistance, which lead to deterioration in quality of their life.\[5\] Therefore, it is imperative to provide support to the caregivers of patients with schizophrenia. Family interventions have demonstrated a considerable reduction in negative symptoms, illness relapse, and inpatient service utilization.\[4\] Family interventions decrease the risk of relapse and hospitalization, improve illness awareness of the caregivers and reinforce healthy interpersonal relationships in the family,\[16\] and reduce distress and burden on the key relatives.\[9\]

In India, family plays a crucial role in the management and care of patients with schizophrenia; in contrast, in the West, patients have access to well-developed health-care infrastructure and support system.\[10\] Although several studies have investigated family burden and QOL in caregivers of patients with schizophrenia, not many studies have investigated change in these variables prior to and after intervention, especially in the Indian context.\[11\-14\]

Existing evidences suggest that positive psychosocial environment has a positive impact on the outcome of schizophrenia.\[15\] Preliminary evidences from a recent Cochrane database review also suggest the beneficial role of brief psychoeducational intervention in reducing relapses and improving treatment adherence in schizophrenia.\[16\] Another recent Cochrane database systematic review on family intervention (brief) for schizophrenia had concluded that the results are not outstanding due to small sample size and poor quality of studies, which had attributed to low to very low quality of evidences.\[19\] This review also emphasized the need of brief family intervention in the treatment of schizophrenia, considering the scarcity of resources. Although family intervention in schizophrenia is recommended by many guidelines considering its positive impact on the treatment outcome, delivery of the intervention for every patient is a challenge.\[17\]

Clearly, there is a distinct need to understand the extent and nature of burden experienced by the caregivers of patients suffering from schizophrenia and to develop brief and practical intervention modules to reduce burden of care and enhance QOL. Most importantly, these interventions measure suitability in the Indian circumstances, characterized by shortage of health-care resources, low mental health awareness, and high levels of stigma and poverty in general. In view of these facts, we planned this study to evaluate the feasibility and effect of a brief psychosocial intervention (BPI) module for key relatives of schizophrenic patients in terms of change in burden of care and QOL. This study aimed to assess the effect of this intervention on the psychopathology and QOL of the patients whose caregivers received BPI.

**METHODS**

This study was a single-blind, randomized controlled trial conducted between June 2009 and June 2010, at a tertiary care center of North India after obtaining approval from the institutional ethics committee. Patients comprised of diagnosed cases of schizophrenia (as per the International Classification of Diseases-10 diagnostic criteria for research), aged between 18 and 50 years, those with illness duration of at least 1 year, and those residing close to the study center. Patients suffering from any other psychiatric disorder and/or any major medical illness, requiring significant care, were excluded from the study. The key relatives of the patients included in the study were aged between 18 and 60 years and had been taking care of the patient at least for the last 1 year. Those key relatives who were suffering from, or had a past history of any major psychiatric illness, and/or who were having any physical illness which was likely to significantly interfere with caregiving were excluded from the study. Informed consent was obtained from all the key relatives and/or the patients. These participants were assigned serial numbers in order of their inclusion in the study. They were then randomly allocated to the BPI group and nonspecific control intervention group (NCI group), using random allocation tables. The numbering was serial and continuous throughout the study.

**Intervention**

In the BPI group, the key relatives of the patients received two sessions of psychoeducation 1 week apart (lasting for 1 h each) individually on the basis of a particular format made for this purpose. These sessions comprised rapport building, education about the disorder (biological basis, treatability, clarifications of myths/misconceptions, etc.), concept of expressed emotions and their role in outcome, role of key relatives and family, information about drugs and their side effects, compliance issues, information on access to clinical resources, problem-solving techniques/skills, and coping and communication skills. The queries raised by the participants were also addressed. These were followed by six group therapy sessions for the key relatives every 2 weeks within a period of 3 months. The group therapy sessions comprised of 6–15 key relatives and lasted for 60–90 min. The group was an open group (i.e. the caregivers after enrollment to the study were expected to attend the group sessions together and if a caregiver missed a session due to personal reasons, he / she were allowed to join the session in the next visit, rather then being allocated to a different group). The participant who has completed psychoeducation sessions was included in the group. Each session of group therapy started with introductions, recapitulation of previous sessions, and with summing up by the moderator. The group discussed the illness of their patients, problems they faced, the methods they employed to cope, etc. All the psychoeducation and group sessions were moderated by the same investigator (who was a postgraduate trainee in psychiatry). For this study, the moderator adopted
a more supportive approach in general and gave inputs to clarify misconceptions (about illness, treatment, outcome, marriage of the patient, etc.) and answered queries, wherever required. The moderator encouraged the participants to ask questions, facilitated discussion among the caregivers, and helped in resolving conflicts/contradictions (if any) among the participants. After completion of the planned sessions, final evaluation of the patients and key relatives was done. Those who could not come for group therapy sessions were contacted and called for evaluation. If they had attended both psychoeducation sessions and at least two group therapy sessions, then the last observation was carried forward for the purpose of analysis. The reason for not coming in most of the cases was difficulty in traveling and loss of earnings of that day, however it was not assessed qualitatively. The patients and key relatives in the NCI group (control group) were called for the follow-up every 2 weeks to the outpatient department (OPD) and were seen by either of the investigator, and this was followed for 3 months after which the final evaluation was done. The key relatives of patients in the control group did not receive any special intervention. They were provided general information and support (nature and course of illness, possible outcomes, need of compliance to treatment, and possible side effects of medications), which is usually provided on an outpatient basis by the same investigator. Additional queries (if any) of the caregivers were also answered.

The primary outcome variables were changes in QOL of key relatives and change in burden of care of key relatives and secondary variables were changes in QOL of patients and changes in the psychopathology of patients. There was no direct intervention provided to the patients, other than the treatment as usual (pharmacotherapy and psychoeducation as per the need of the client). As improvement in QOL of the caregivers is expected to influence the care and support toward their patients, it was planned to measure the QOL and psychopathology of the patients as secondary outcome.

These participants were assigned a serial number in order of their inclusion in the study. They were then randomly allocated to the BPI group and NCI group, using random allocation tables. The numbering was serial and continuous throughout the study.

Tools used were a semi-structured pro forma for patients and key relatives, the Positive and Negative Syndrome Scale (PANSS),[18] the Burden Assessment Schedule (BAS),[19] the World Health Organization-QOL (WHO-QOL) 100,[20] and WHOQOL-BREF.[21] Hindi versions of the latter two instruments (i.e., WHO-QLS 100 and WHOQOL-BREF) were prepared for this study by the investigators using translation–retranslation method.

After selection and allocation to either group, identification data, demographic profile, and clinical evaluation details of patients and their key relatives were recorded on appropriate pro forms. Evaluation of patients on the PANSS and WHOQOL-BREF and of their key relatives on BAS and WHOQOL-100 was conducted in both the groups before the start of intervention.

**Statistical procedures**

Comparative analysis of sociodemographic variables of patients and key relatives in the two groups was done using Chi-square test. Analysis of changes in the PANSS, WHOQOL-BREF, BAS, and WHOQOL-100 scores, before and after BPI/NCI sessions, was done by using paired “t” test. Statistical comparison, of changes recorded on the above-mentioned tools between the two groups, was carried out by using unpaired “t” test.

**RESULTS**

A total of 131 patients were screened for the study. Thirty-seven patients did not fulfill the selection criteria. Of these 37 patients, 6 patients were aged more than 50 years, 9 patients had illness duration of <1 year, 5 patients were suffering from co-morbid psychiatric illness/major physical illness, and 17 did not give consent for the study. Hence, out of the 131 patients, key relatives of 94 patients were assessed on the selection criteria. Of these 94 key relatives, 28 were excluded. Eight were aged more than 60 years, 3 were caring for patients for less than a year, 8 were not willing to participate, 6 had a major physical disorder, and 3 suffered from major psychiatric disorder. Thus, a total of 66 patients and their key relatives satisfied the selection criteria for the study and were included in the study, 33 in each group. Out of the 33 included in the BPI group, 24 were eligible for the final assessment having attended two psycho-education sessions and at least two group therapy sessions. Out of the 33 patients and family members included in the NCI group, 23 were eligible for the final assessment. The sociodemographic structure of the sample, clinical variables of the patients (type of schizophrenia and duration of illness), and relationship between the key relatives and the patients did not show any statistically significant difference between the BPI and NCI groups. Thus, the BPI and NCI groups were well matched and comparable.

The family members in the BPI group showed significant improvement in their total adjusted BAS score in comparison to the NCI group, but improvement was mainly in the external support, caregiver routines, and other relative subsections of BAS [Table 1]. There was a significant improvement in WHOQOL-100 score in favor of the BPI group, but the significant improvement was only in the psychological health domain [Table 2]. The improvement in QOL of patients of family members in the BPI group was found to be significantly higher as compared to those in the NCI group. This was mainly in the physical health
Table 1: Burden assessment schedule scores among the key relatives of patients with schizophrenia

| Subgroups                     | Group BPI (n=24) | Group NCI (n=23) | Change in BPI group (A) | Change in NCI group (B) | Test of significance A versus B (t, P) |
|-------------------------------|------------------|------------------|-------------------------|-------------------------|----------------------------------------|
| Spouse related, mean±SD      | 1.79±3.64        | 1.54±3.56        | 0.9010, 0.3768          | 1.04±2.35               | 1.447, 0.1619                          |
| Physical and mental health, mean±SD | 13.6±3.64       | 11.5±4.12        | 4.329, 0.0002*          | 10±2.00                 | 3.724, 0.0012*                         |
| External support, mean±SD    | 9.58±2.28        | 8.25±2.15        | 3.314, 0.0030*          | 8.39±1.90               | 2.336, 0.0290*                         |
| Caregiver’s routines, mean±SD| 10.71±2.25       | 8.42±1.95        | 6.392, 0.0001*          | 8.26±1.94               | 3.006, 0.0065*                         |
| Support of patient, mean±SD  | 8.58±2.34        | 7.96±1.99        | 8.181, 0.0786           | 7.33±1.47               | 2.554, 0.0181*                         |
| Taking responsibility, mean±SD| 10.04±1.81       | 8.67±1.90        | 3.817, 0.0009*          | 8.70±1.82               | 2.717, 0.0108*                         |
| Other relatives, mean±SD     | 9.08±2.17        | 7.08±2.81        | 3.258, 0.0035*          | 6.57±1.95               | 1.00, 0.3282                           |
| Patient’s behavior, mean±SD  | 6.92±2.64        | 5.88±2.03        | 2.112, 0.0448*          | 5.74±1.79               | 4.592, 0.0001*                         |
| Caregiver’s strategy, mean±SD| 8.04±1.88        | 7.04±2.03        | 2.449, 0.0223*          | 7.30±1.40               | 1.073, 0.2591                          |
| Total adjusted BAS score (0-100) | 70.92±13.09     | 59.63±12.07      | 6.490, 0.0001*          | 58±8.02                 | 3.566, 0.0017*                         |

*P<0.05 indicates statistically significant change. BPI – Brief psychosocial intervention; NCI – Nonspecific control intervention; BAS – Burden Assessment Schedule; SD – Standard deviation

Table 2: WHO-Quality of Life 100 scores among the key relatives of patients with schizophrenia

| Subgroups                          | Group (BPI) (n=24) | Group (NCI) (n=23) | Change in BPI group (A) | Change in NCI group (B) | Test of significance A versus B (t, P) |
|------------------------------------|--------------------|--------------------|-------------------------|-------------------------|----------------------------------------|
| Overall QOL and general health, mean±SD | 53.75±21.21      | 60.96±15.04       | 2.550, 0.0179*          | 1.04±2.35               | 2.437, 0.0233*                         |
| Physical domain, mean±SD           | 60.92±16.73       | 66.29±15.11       | 2.330, 0.0289*          | 70.48±13.57             | 0.7799, 0.4437                         |
| Psychological health domain, mean±SD| 63.63±14.01       | 73±8.10           | 3.612, 0.00015*         | 65.78±11.25             | 2.332, 0.0299*                         |
| Level of independence domain, mean±SD| 69.04±15.62      | 74.21±12.65       | 2.557, 0.0176*          | 74.61±11.23             | 1.359, 0.1881                          |
| Social relationship domain, mean±SD| 57.92±16.67       | 62.13±15.75       | 1.484, 0.1515           | 70.17±12.72             | 3.170, 0.0044*                         |
| Environmental domain, mean±SD      | 56.13±12.67       | 59.42±10.00       | 1.755, 0.0925           | 62.04±10.28             | 0.5635, 0.5788                         |
| Spiritual domain, mean±SD          | 77±8.94           | 78.17±7.96        | 0.4982, 0.6231          | 76.78±10.58             | 0.4187, 0.6795                         |
| Total average score, mean±SD       | 62.68±10.86       | 67.33±7.64        | 4.239, 0.0003           | 70.13±7.59              | 3.705, 0.0012*                         |

*P<0.05 indicates statistically significant change. QOL – Quality of life; BPI – Brief psychosocial intervention; NCI – Nonspecific control intervention; SD – Standard deviation
Table 3: WHOQOL-BREF scores of patients with schizophrenia

| Subgroups/domains                  | Group (BPI) (n=21) | Group (NCI) (n=19) | Change in BPI group (A) | Change in NCI group (B) | Test of significance A versus B (t, P) |
|------------------------------------|--------------------|--------------------|------------------------|------------------------|---------------------------------------|
| Overall QOL and general health, mean±SD | 49.10±23.74       | 60.67±21.72        | 11.57±21.04            | 3.84±7.22              | 1.521, 0.1366                         |
| Physical health domain, mean±SD     | 60.38±12.90        | 67.43±11.02        | 7.05±12.43             | 0.37±2.85              | 2.286, 0.0279*                       |
| Psychological health domain, mean±SD| 68.14±16.97        | 65.38±15.51        | 6.71±14.28             | 2.11±3.51              | 1.527, 0.1351                        |
| Social relationship domain, mean±SD | 39.55±19.10        | 36.29±16.52        | 3.26±6.03              | 0.039±2.31              | 2.191, 0.0204*                       |
| Environment domain, mean±SD         | 46.15±50           | 52.62±15.87        | 6.47±11.34             | 0.53±2.82              | 1.384, 0.1214                        |
| Total average score, mean±SD        | 48.57±11.86        | 65.77±13.46        | 17.2±17.34             | 1.17±2.94              | 3.191, 0.0028*                       |

Here, n=21 for BPI group and n=19 for NCI group as three patients in the BPI group and four patients in the NCI group were either uncooperative or had formal thought disorder. Hence, this instrument could not be applied on them. *P<0.05 indicates statistically significant change. QOL – Quality of life; BPI – Brief psychosocial intervention; NCI – Nonspecific control intervention; SD – Standard deviation
Many Western studies\cite{25-27} have shown similar beneficial effects like our study, although the intervention in most of these studies lasted for a longer period of 6–12 months as compared to 3 months in the present study. The present study, therefore, highlights the fact that even a brief intervention might be helpful in reducing the caregiver burden to a significant degree.

Earlier research works support that group sessions, where family members share their experiences (about similar circumstances) in dealing with their patients, improve their illness awareness, coping skills, and perceived social support as well as reduce their burden and distress.\cite{28,29}

In addition, the moderator in group therapy sessions in the present study was more active than that in regular group sessions (in which, one only intervenes when the conversation veers away from the topic). We adopted a more eclectic approach and gave inputs to clarify misconceptions and answer queries, wherever required. The efficacy of such a brief intervention as has been observed in our study may be because the Indian people accept more active role of the moderator in the psychological intervention.

**Quality of life of key relatives**

The QOL of key relatives improved in both groups. However, a significantly higher improvement in the QOL of key relatives in the BPI group was observed as compared to the NCI group [Table 2]. Thus, it was concluded that a BPI produces a significantly greater improvement in the QOL of key relatives of patients with schizophrenia. Other studies have reported similar results.\cite{14,30} A significant improvement was found in the QOL of families who received psychosocial intervention as compared to those who received standard psychiatric care. It should be noted that these studies employed interventions of longer duration and other methods such as psychological therapies and spiritual therapies also. Similar results were obtained in the present study with a BPI of 3 months alone. Once again, the variance of our approach in terms of being a combination of psychoeducation and group therapy and in being more supportive in nature might be the contributor.

**Quality of life of patients**

Three patients in the BPI group and four in the NCI group could not be assessed on the WHO-QOL-BREF as they were either uncooperative or had a formal thought disorder. Analysis of the remaining data revealed statistically significant improvement in the QOL of patients in both groups. Statistical comparison of the improvements observed in both groups revealed significantly higher improvement in the QOL of patients in BPI group [Table 3]. This might be due to improvement in the QOL of the caregivers, which might have facilitated in providing better care to their patients. Increased awareness, availing support
from all possible resources, and reduced expression of negative emotions (expressed emotions) toward their patients might be the key determining factors for these beneficial outcomes in the patients.

The authors could find only a single study which assessed the impact of psychosocial intervention on the QOL of patients with schizophrenia. Significant improvement in insight, QOL, social functioning, and activities of daily living was reported in patients who received both pharmacological and psychosocial interventions as compared to those who received pharmacological treatment alone. However, some studies have assessed the effect of family intervention on certain aspects of QOL of the patient, mainly functioning, and found a positive relationship between the two.

**Psychopathology**

In the present study, patients in both the BPI and NCI groups showed a significant improvement in the positive, negative, general psychopathology, and total PANSS scores [Table 4]. Although the change in psychopathology was greater in the patients of BPI group, this difference did not turn out to be statistically significant. Thus, it was inferred that there was no significant effect of BPI on the psychopathology of the patients. Improvements observed in both the groups may be attributed to ongoing pharmacological treatment. In their study, Devaramane et al. found significant improvement in psychopathology (from baseline to 3-month follow-up) following BPI.

Several studies have shown a positive impact of psychosocial interventions with family members, on the psychopathology of patients with schizophrenia. These studies, however, employed interventions which were substantially longer in duration. Possibly, the intervention duration of 3 months in our study was too short to have any measurable impact on psychopathology. Future studies with longer interventional period might be more useful in bringing the changes in psychopathology. Similarly, long-term outcome of these psychosocial interventions also needs to be evaluated in future research.

**Limitations**

The present study had a small sample size, which limits the generalizability of the results. The long-term effects of BPI could not be assessed. Furthermore, the WHO-QOL-BREF used in this study is a generic instrument and does not assess QOL objectively. An instrument more specific for assessing QOL in patients with schizophrenia would allow a more confident interpretation. The other major setback in the present study was the poor attendance which is evidenced by the high number of dropouts in both groups, despite the investigator’s repeated attempts to persuade key relatives to attend the sessions. This probably reflects the poor confidence the general public has in psychotherapeutic treatment modalities in a developing country like India.

An important concern in the context of BPI in India is the form and content of the same. Our study suggests that a brief and supportive intervention focusing primarily on the education of patients and their family members, improving medication adherence, and providing support could turn out to be the crucial elements of family interventions. Another important area of concern is the high number of dropouts. High drop outs are possibly indicative of a lack of trust in the intervention, poor awareness of benefits of such intervention, several logistic issues (example: travel to attend the session, paucity of time, etc) and financial problems in our population. However, once the effective interventions are readily available, it is likely that more people will demand for the same and therapist will offer it with more confidence.

**CONCLUSION**

This study concludes that a BPI in group therapy session in caregivers of schizophrenic patients leads to improvement in their burden of care and QOL of their patients.

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**Conflicts of interest**

There are no conflicts of interest.

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