Original Article

Clinic-based Group Multi-professional Education Causes Significant Decline in Psoriasis Severity: A Randomized Open Label Pilot Study

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Abstract

Background: The evidence for efficacy of psychoeducational interventions in psoriasis is not well researched. **Objective:** The objective of this study was to assess the benefits of a group, multi-professional, psychoeducational training in psoriasis. **Materials and Methods:** Adults with moderate-to-severe psoriasis were randomized into psychoeducational intervention plus treatment (intervention arm [IA]) and treatment as usual alone (control arm [CA]) groups using random number tables. The primary efficacy measures were mean changes in Psoriasis Area Severity Index (PASI) and Dermatology Life Quality Index (DLQI) at 6months from the end of intervention. The secondary efficacy measures were the mean changes in the WHO-5 well-being index (WHO-5) and the subsets of the patient health questionnaire (PHQ), namely, PHQ-9, generalized anxiety disorder (GAD)-7, andPHQ-15. Datawere analyzed by intention-to-treat analysis. **Results:** One-hundred and three participants were randomized into IA (*n* = 54) and CA (*n* = 49). The prevalence of psychiatric disorders in the entire population was 26.2% and was similar in both groups.Following intervention, there was statistically significant improvement in the mean scores in PASI, DLQI, and WHO-5 in the IA unlike that seen in the CA. There was statistically significant improvement in PHQ-9 scores in IA and CA. The scores on PHQ-15 and GAD-7 did not show any change. Intergroup comparisons showed that PASI was reduced significantly in IA as compared to CA. More participants in CA dropped out of the study than in the IA. **Limitations:** Modest sample size and lack of blinding of the participants and the administrators were the limitations of this study. **Conclusion:** Group psychoeducational intervention resulted in overall improvement in both clinical and psychological outcome measures in psoriasis patients.

Keywords: *Psoriasis, psycho-education, psychological morbidity, quality of life*

Introduction

Psoriasis patients suffer from significant physical and psychological consequences including depression, anxiety, and feelings of being stigmatized and embarrassed regarding their appearance, which may also lead to suicidal ideation.[1-3] In addition, lack of knowledge regarding the disease can lead to delayed treatment seeking and worse disease outcomes.[4] The stress of chronic illness, disfigurement, and stigma may contribute to increased psychological distress and morbidity leading to reduced quality of life (QOL).[5-7]

The recognition and importance of this comorbidity is reflected in the increasing amount of research into psychological interventions in psoriasis.[8] In addition to psychological interventions, educational interventions in combination with the former one are also being tried.[9] The present study was designed as a pilot randomized controlled study to assess the effect of a simple, pragmatic, multi-professional, group psychoeducational training delivered to patients with psoriasis in addition to standard treatment. The primary objective was to assess the impact of the group psychoeducational intervention on Psoriasis Area Severity Index (PASI) andDermatology Life Quality Index (DLQI) of the patients at 6 months. The secondary objectives studied were improvement in WHO-5 well-being index (WHO-5) and the scores on the subsets of Patient Health Questionnaire (PHQ). These were PHQ-9 for severity of depressive symptoms, Generalized Anxiety Disorder (GAD)-7 for anxiety symptoms, and PHQ-15 for somatic symptoms.

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Materials and Methods

Setting

The study was carried out in the psoriasis clinic of a teaching hospital in North India from July 2014 to December 2015. The study was approved by the institute's Ethics Committee and all the study participants signed an informed consent form (NK/1783/study/1842).

Study design

A randomized controlled design was adopted. Standardized assessment tools were used at the beginning and end of the intervention by a dermatologist and the self-rated instruments by the participants (described below). Wherever the second assessment was not possible, the result of the first assessment was carried forward in an intention-to-treat (ITT) analysis.[10]

Patients

Participants were approached and recruited by a dermatologist (TN) and randomized using random number tables into an intervention arm (IA) and a control arm (CA). Given the exploratory nature of this pilot study and the need to be able to detect small differences, we aimed at a standardized effect size of 0.2 and a sample size of 40 in each arm was calculated.[11] Assuming an attrition rate of 20%, a total of at least 100 participants were recruited.

The inclusion criteria were patients of moderate and severe chronic plaque psoriasis defined as PASI >6 or DLQI >6 who were more than 15 years. Patients of pustular psoriasis and erythrodermic psoriasis, pregnant patients, patients with concomitant psoriatic arthritis and other medical comorbidities such as coronary artery disease, stroke, hepaticorenal dysfunction, and patients with current suicidal ideation were excluded from the study.

Assessment tools

Sociodemographic and clinical data were obtained from all patients at baseline. Psoriasis severity was assessed using PASI,[12] and dermatological QOL was assessed using DLQI.[13] Subjective psychological well-being was assessed using the WHO-5which is a Likert scale.[14] This scale generates raw scores from 0 to 25 which is then transformed to 0–100 by multiplying by 4 for ease of understanding and use. Higher percentage scores indicate more well-being. The psychiatric diagnoses at baseline were generated using the PHQ which is a self-rated questionnaire-based instrument. The PHQ contains five modules that generate five common psychiatric diagnoses, namely, depressive disorder, somatoform disorder, anxiety disorder, alcohol use disorder, and eating disorder. Depression, anxiety, and somatic symptom severity were assessed using the PHQ-9, GAD-7, and PHQ-15 subscales of the PHQ, respectively. AH in diversion of the PHQ was used.[15,16]

Assessment time points

Participant assessments were done twice. In the IA, the first assessment took place immediately before the first psychoeducational session. Psychiatric diagnoses were assessed using PHQ at baseline. The second assessment took place 6 months after the end of the study intervention. At both time points, PASI, DLQI, WHO-5, and PHQ subscales were assessed. Beyond this time point, no follow-up assessment for purpose of this study was done.

In the CA, the same assessments were done at recruitment and at follow-up at similar time points as the IA. The patients in this group received treatment as usual.

Intervention

Psoriasis patients were recruited in batches of 10–15 and randomized by nursing staff using computer- generated random number sequences. Allocation concealment was done using sequentially numbered opaque-sealed envelopes. The intervention consisted of three fortnightly group sessions which were conducted in the dermatology outpatient department. The sessions followed a semi-structured format lasting 30–45 min. The first session was conducted by a dermatologist and started with a talk which covered education about the nature, outcome, and course of psoriasis, precipitating factors, skin hygiene and lifestyle modifications, and management options. This was followed by a question-answer session and feedback. The second session was conducted by a psychiatrist and included the association, recognition, and management of depression and anxiety in psoriasis. This was followed by an interactive session with a clinical psychologist. The areas covered were the alleviation of self-stigma using cognitive behavior techniques, distraction techniques, imagery training, and thought stopping. In addition, patients were demonstrated the autogenic relaxation technique.[17] As the name suggests, this relaxation technique uses self-visualization and self-instruction to produce feelings of warmth and heaviness in the body, thus producing a state of relaxation. This was followed by a feedback and interactive session. The final session was again conducted by a dermatologist. This session included a précis of the earlier sessions, group interactions, sharing of personal experiences and solutions to problems encountered, and feedback regarding perceived usefulness of the intervention.

Statistical analysis

Statistical analysis was performed using appropriate tests with the Statistical package for social sciences version 18 software.[18] For analyzing significant changes in measures on continuous variables in IA and CA, the nonparametric Wilcoxon signed-rank test was performed. The continuous variables analyzed included age in years, years of education, duration of illness in years, and scores on PASI, DLQI, WHO-5, PHQ-9, GAD-7, and PHQ-15. Intergroup

assessment for changes in scores at the end of study was done using Mann–Whitney U-test. For all tests, $P < 0.05$ was considered statistically significant.

Results

Patients

One hundred and fifty-six patients were screened for the study and 103 participants were randomized into IA *(n* = 54) and CA *(n* = 49). In the IA, 48 patients (88.8%) attended all the three sessions.

Baseline characteristics

The baseline sociodemographic and clinical data of the participants are summarized in Table 1. Twenty-seven participants (26.2%) had at least one diagnosable psychiatric disorder at baseline as per the PHQ. Alcohol abuse was the most common diagnosis with 16 participants (15.5%) endorsing the same. Fifteen participants (14.6%) had a depressive syndrome. The prevalence of psychiatric disorder across IA and CA was similar (IA = 11, 22.44% and CA = 16, 29.62%). There was no difference in the treatment modalities used in both the groups; topical therapy (coaltar, calcipotriol, clobetasol), systemic (methotrexate, acitretin, and cyclosporine), and combination treatment (systemic and topical) being used by 34 (31.4%), 39 (36.1%), and 18 (16.6%) participants, respectively.

Primary and secondary efficacy measures

The results of the primary and secondary efficacy measures are summarized in Table 2. The participants in the IA showed significant improvement in both the primary outcome measures, PASI and DLQI at 6 months from the end of the intervention ($P < 0.01$). However, no statistically significant changes were seen in either of the primary efficacy measures in the CA.

Among the secondary outcome measures, a statistically significant improvement in the subjective psychological well-being as measured by the WHO-5 was seen in the IA only ($P < 0.01$). Depression severity (as measured on the PHQ-9) showed statistically significant improvement in both the IA and the CA ($P < 0.01$). The scores on PHQ-15 and GAD-7 were not significantly different in both the arms.

The intergroup comparison with regard to the mean differences in the scores analyzed at the end of the study is also presented in Table 2.

Table 1: Baseline sociodemographic and clinical data of the participants

Clinico-epidemiological variables	Mean (SD)	
	IA	CA
Sex		
Male	41 (75.9)	36 (73.5)
Female	13 (24.1)	13 (26.5)
Age (years)	37.28 (14.80)	39.55 (14.35)
Education (years)	13.10 (3.44)	12.53 (3.02)
Duration of illness (years)	8.75 (7.99)	9.58 (8.56)
PASI	9.59 (5.47)	8.88 (7.87)
DLQI	9.72 (7.65)	7.21 (5.91)
WHO-5	53.76 (27.00)	54.55 (31.02)
PHQ-9 depression severity	5.43 (4.94)	5.11 (4.94)
GAD-7 anxiety severity	1.87 (2.26)	2.23 (2.40)
PHQ-15 somatic symptom severity	3.83 (3.72)	3.49 (2.97)

PASI: Psoriasis Area and Severity Index, DLQI: Dermatology Life Quality Index, WHO-5: WHO-5 well-being index, PHQ: Patient Health Questionnaire, GAD-7: Generalizsed Aanxiety Ddisorder, CA: Control arm, SD: Standard deviation, IA: Intervention arm

Study attrition

In both the groups, a total of 32 (31.1%) patients were lost to follow-up at 6 months (IA = 12, 22.2% and CA = 20, 40.8%). The data from these participants entered the ITT analysis. Attrition was significantly more in the CA as compared to the IA. We tried to contact the patients who dropped out and found that lack of improvement and side effects of the systemic drugs were the most common causes of attrition in the CA. In the IA, the causes reported were clearance of disease, shifting to a different city, and two participants reported lack of improvement in disease severity or drug adverse effects. We did not go into more detailed inquiries or analysis of this matter as the study was not designed for the same.

Intervention feedback

Although we did not specifically measure these attributes, the most common themes that emerged out of the sessions were the following. Most participants (68%) had poor or no knowledge about psoriasis and its management. This lack of knowledge and the resulting uncertainty and feeling of lack of being in control were found to be extremely distressing by most participants. Many of the participants and their family members thought that psoriasis is a contagious disease and some had stopped touching the affected member of the family or had a separate set of utensils for their use. This increased their feelings of stigma. Most participants found the sessions useful and liked the program content.

Discussion

Psoriasis is a chronic disorder with multiple comorbidities.[19] Psychological distress in psoriasis patients may be due to the direct effect of the illness and the stress of chronic health and treatment–related consequences. Being a disfiguring and visible disorder, patients have difficulties in interpersonal relationships and in carrying out activities of daily living.[20] Given the obvious importance of psychological factors in psoriasis, interventions targeting

Table 2: Primary and secondary efficacy measures in both the groups

Variables	CA			IA			*P* (intergroup comparison of mean differences in scores, Mann–Whitney U-test)
	At 6-month follow-up mean (SD)	Mean difference (SD)	Wilcoxonsigned-rank test (*P*)	At 6-month follow-up mean (SD)	Mean difference (SD)	Wilcoxonsigned-rank test (*P*)	
PASI	4.75 (4.31)	−4.71 (6.46)	<0.05	7.33 (8.17)	−1.62 (4.62)	0.07	<0.05
DLQI	7.24 (7.61)	−2.50 (6.61)	<0.05	6.72 (5.73)	−0.52 (6.80)	0.70	0.09
WHO-5	64.06 (25.06)	10.18 (20.83)	<0.05	57.27 (28.20)	1.67 (28.84)	0.34	0.44
PHQ-9 depression severity	4.38 (4.27)	−1.03 (4.75)	<0.05	4.48 (4.23)	−0.83 (3.81)	<0.05	0.76
GAD-7 anxiety severity	1.94 (2.66)	−0.07 (2.59)	0.75	1.60 (1.93)	0.57 (2.36)	0.16	0.67
PHQ-15 somatic symptom severity	3.66 (4.15)	−0.16 (2.34)	0.56	3.33 (2.62)	−0.16 (2.85)	0.62	0.78

PASI: Psoriasis Area and Severity Index, DLQI: Dermatology Life Quality Index, WHO-5: WHO-5 well-being index, PHQ: Patient Health Questionnaire, GAD-7: Generalized anxiety disorder, SD: Standard deviation, CA: Control arm

these in addition to usual pharmacological treatment of the skin condition should be useful. Previous studies in this area have numerous methodological limitations.[8,9] To the best of our knowledge, there are no such studies from India. This may be due to time constraints and a large patient load. Thus, this study was planned to add to the data base in this area.

We hypothesized that, in addition to routine pharmacological treatment, a simple, easily administered group psychoeducational package may lead to better outcomes in patients with psoriasis. Our psychoeducational package was designed to be semi-structured and brief, encompassing the physical as well as psychological aspects of psoriasis, free of excessive technicality and jargon, and easily delivered. The study was randomized, controlled, had a reasonable sample size, and used validated and robust outcome measures that comprehensively assessed psoriasis severity, QOL and wellness, and psychological distress. Our study used a theory-based psychological intervention delivered in a simple way. Thus, we tried to overcome most methodological issues confronting the existing literature in this area.[9] Rather than focusing on the immediate effects of the intervention, the outcome measures in our study were assessed at 6 months and thus show the sustained effect of intervention at this point of time rather than immediately postintervention when it would be expected to be most pronounced.

Our results show that the IA and CA were comparable on sociodemographic and clinical variables and were comparable within the limits set by the inclusion criteria. The results of the intragroup changes on various parameters show that there was a sustained, clinically relevant improvement (~50%) in the PASI scores, a modest improvement in QOL as measured by DLQI(~20%), wellness as measured by the WHO-5 (~10%), and statistically significant but clinically minor improvement in depressive symptoms as measured by the PHQ-9. The scores in CA did not show any statistically significant change except for a minor one in the PHQ-9. Inter group differences in mean change in scores also showed that there was significantly more improvement in psoriasiss severity as measured by the PASI in the IA than the CA. Improvement in QOL was also pronounced but did not achieve statistical significance.

Our study showed that the delivery of a psycho education package was associated with better outcome at 6 months in patients with psoriasis with regard to disease severity and dermatological QOL when compared to treatment as usual. The psychoeducational package was also associated with significant improvements in well-being but showed only minor improvements in depressive symptom severity. The results of the present study are in line with that of previous studies that have indicated psychoeducational interventions to be beneficial in psoriasis.[17,21] Our study adds to the previous studies in that this improvement is present at upto 6 months and is associated with improvements in QOL and possibly well-being. Our study also shows that treatment attrition is a common problem. Other studies in psoriasis have also reported similar attrition rates but have not examined it in detail.[22] However, it is likely to be common and multifactorial.[23]

The primary result was an improvement in dermatological clinical variables in the IA. This is similar to some other studies in the past.[17,21,24,25] The reas ons behind this association could be the following. The psychoeducation intervention could increase treatment compliance and

adherence by educating the patient on the natural disease course, treatment options, and possible adverse effects. Previous studies have shown that worry and diverging beliefs are significantly associated with psychological distress and poor treatment outcome.[26-28] The educational component of the intervention targeted the misconceptions and lack of knowledge surrounding the illness. The intervention also reduced the stigma and confusion surrounding affective and anxiety responses to the disease as something to be expected and managed. Similar approaches have been tried in other chronic disorders with beneficial results.[29] It is possible that, along with cognitive factors, emotional factors may have played a role. The psychological components of the package may have been helpful in tackling feelings of despondency and hopelessness, reduced anxiety and depressive symptoms, and thus made patients more participative in their treatments. However, the scores of PHQ subscales did not indicate any such change in an objective manner. It is possible that this may be a methodological problem and other clinician-rated instruments may be more sensitive to change which was not detected in our study. It is also possible that the psychological aspects of improvement were not as stable as the clinical improvement in psoriasis severity. Nonspecific factors such as increased clinician involvement as part of the study may also have played a role in better treatment adherence. Attrition may have also played an important role in the results of the study. Our study shows the feasibility and usefulness of administering a theory-based psychoeducational package in a dermatology outpatient service of an Indian government hospital. We explained with examples, cognitive behavioral, distraction, imagery, and stopping techniques to control dysfunctional cognitions when faced with distress in social situations. These techniques were also demonstrated through roleplaying by the clinical psychologist using vignettes derived from participant experiences. We found that our participants were able to follow concepts and facts with ease not withstanding their socioeconomic and educational background. It was possible to cover all these concepts using practical demonstrations and roleplaying in a short duration of time. Participants were asked to use these techniques and found them to be useful. We tried our intervention to cover both the educational and psychological needs of the participants which we thought were the felt needs.

The limitations of the study are the modest sample size, the lack of blinding of the participants and the administrators of the intervention, and exclusion of patients with severe forms of psoriasis such as pustular psoriasis and psoriatic arthritis. Hence, the generalizability in patients not included in this study cannot be commented upon. We also did not explore for any psycho-social or other factors post intervention and reasons for attrition that may have influenced the outcomes or the reasons for attrition that seem to play an important role in outcome. In addition, there was no standardization in the treatment-as-usual protocol. Thus, the psychoeducational package cannot definitely be said to be the only reason for the improvement in the patients of the IA.

Conclusions

Our study shows that the benefits of the study extended beyond the immediate duration of the intervention. This suggests that such interventions make lasting changes.

Dermatologists need to work in a more holistic way to provide quality care to psoriasis patients, meeting their psychological and dermatological needs. In developing countries like India, where single dermatologist caters for a large number of patients, time constraints may hamper the delivery of one-to-one psychoeducational interventions. Thus, a group psychoeducational intervention may be more feasible.

Important issues that remain unresolved are the length of intervention required, whether literature or video sessions are as effective as sessions in person, optimum therapy time required, appropriate setting for these interventions, level of therapist contact or expertise required to produce optimum results, and the acceptable content of psychosocial interventions. The operational component of the intervention also needs to be studied further. The direction and relationship of the improvement in measures of psoriasis severity and psychological distress also requires elucidation. Furthermore, future research needs to be conducted to establish which psychological and/or educational interventions are most effective for specific subpopulations of psoriasis patients and who may best benefit from such interventions.

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Conflicts of interest

There are no conflicts of interest.

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