Original Article

Effect of psychoeducation in late life depression: A randomized controlled trial

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Abstract

Background: Depression is one of the leading causes of disability worldwide, and after the global pandemic COVID-19, it has become even more worse. The treatment of depression should involve pharmacological treatment along with the various kinds of psychotherapies (non-pharmacological management). This study aims to determine the result of psychoeducation in late-life depression by using Hamilton Depression Rating Scale 17 items (HAMD) and Geriatric Depression Scale (Hindi version) (GDS-H). **Material and Methods:** The study was registered on the Control Trial Registry of India (CTRI) via CTRI/2019/05/018956. It is a prospective randomized controlled trial of 4 weeks, where 154 patients aged more than 60 years were randomized into two groups, case group (A) (n = 83) who received psychoeducation along with treatment as usual, whereas control group (B) (n = 71) who received placebo along with treatment as usual. The patients were assessed using Hamilton Depression Rating Scale 17 items (HAMD), Geriatric Depression Scale (Hindi version) (GDS-H) on baseline visit (Day 0), on first follow-up (Day 14), and second follow-up (Day 28). Hindi Mental Status Examination (HMSE) was used on the baseline visit to rule out primary cognitive impairment. **Results:** The results were analyzed, and it was concluded that both the groups have significant decrease in HAMD-17 and GDS-30 scores over a period of time with a *P*-value of <0.001 in both.

Keywords: Depression, GDS-30, HAMD-17, older adults

Introduction

Depression is one of the most debilitating health problems worldwide. It is an illness with an estimated 3.8% of the population affected, including 5.0% among adults and 5.7% among adults older than 60 years.[1]

In 2008, the World Health Organization (WHO) ranked major depression as the third cause of burden of disease worldwide and projected that the disease will rank first by 2030.[2]

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Late-life depression or depression in older adults' remains under diagnosed/undiagnosed/untreated/under treated in most of the population. The treatment plans used for depression are diverse. Mental health professionals recommend psychological treatments, such as psychoeducation, behavioral activation, cognitive behavioral therapy, and interpersonal psychotherapy, as well as antidepressant medication, such as selective serotonin reuptake inhibitors (SSRIs) and tricyclic antidepressants (TCAs), depending on the severity and pattern of depressive episodes over time. As American Psychological Association (APA) mentions that the duration of treatment for psychological problems inevitably varies from person to person. Essentially, treatment (type and duration) should always be appropriate to the nature and severity of individual's difficulties. For any treatment to be successful be it pharmacological treatment or psychotherapy or both, the patient will not get results overnight, and therefore, one needs to stick to the treatment and follow it over a course of time. As a result, if one treatment is 'not working, consider combining them. All

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forms of psychotherapies can be beneficial even for patients who do not respond well to drugs.[3] The studies on psychoeducation for mental illness in Indian context are scarce in number; hence, to fill this lacuna, the present study was undertaken. The protocol of the study is published elsewhere.[4]

Aim

The aim of the study was to compare combined pharmacotherapy and psychoeducation vis-a-vis only pharmacotherapy, as interventions in cases of late-life depression.

Study Design and Method

The study is a part of Doctoral (PhD) thesis of the first author.

A total of 154 patients aged 60 years and above with first episode of depressive disorder were screened [Figure 1]. The diagnosis of the patients was confirmed on Mini-International Neuropsychiatric Interview 6.0 (MINI 6.0.0),[5] and for the assessment of cognitive status, Hindi Mental Status Examination (HMSE)[6] was applied, and those scoring =>24 on HMSE were invited to participate in the study. The patients having any severe medical illness or with hearing impairment or language problem or any other issue, which can be a serious impediment to the study, were excluded.

Once written informed consent was obtained from the invited patient or the primary caregiver, the patients were assessed on Hamilton Depression Rating Scale (HAM-D),[7] Geriatric Depression Scale (GDS)[8] for baseline depression, and Knowledge Attitude Experience (KAE) Questionnaire. Then patients were randomized to either the case group (Group A) or control group (Group B). The sequence generation was done from "https://www.graphpad.com/quickcalcs/randMenu/." The case group was given intervention of 'psychoeducation' through a video of duration 6 minutes 30 seconds, which covered various points like the symptoms of depression, the etiology, the treatment and management plan, the possible side effects of the medication, etc., and the control group was shown 'placebo psychoeducation' through a video of duration 6 minutes 10 seconds, which consisted of the general information of the elderly population. Both videos were validated by the experts. The subjects were shown video individually. The duration of the video was similar for both the groups. Giving equal time to both the groups will eliminate time factor, and hence, the focus was only on the content of the psychoeducation. Both the groups were also given treatment as usual.

For both the groups, the first follow-up was held at 2 weeks +/- 4 days from the baseline day, in which the information discussed in the baseline session was reinforced. The patients were also assessed on HAM-D and GDS in this visit. For both the groups, the second follow-up was at 4 weeks +/- 4 days from the baseline in which the subjects were assessed on KAE Questionnaire and HAM-D, and GDS was applied. The results were statistically calculated.

Brief Description of Tools

Hindi Mental Status Examination (HMSE)

HMSE is used for the assessment of cognition. It contains domains like orientation to time and place, registration, immediate and delayed recall, attention, naming, repetition, sentence formation, and copying. It is a 22 questions based scale with a maximum score of 30, and the cutoff score is 24.[6]

Mini-International Neuropsychiatric Interview 6.0.0 (MINI 6.0.0)

This tool is designed as a brief structured interview for the major Axis I psychiatric disorders in DSM-IV. It is divided into modules identified by letters, each corresponding to a diagnostic category. At the beginning of each diagnostic module (except for psychotic disorders module), screening question (s) corresponding to the main criteria of the disorder are presented in a gray box. At the end of each module, diagnostic criteria are met.[5]

Hamilton Depression Rating Scale (HAM-D)

HAM-D is used to assess the initial severity. This tool consists of 21 items; the scoring is based on the first 17. The cutoff score is as follows: 0–7 = Normal, 8–13 = Mild Depression, 14–18 = Moderate Depression, 19–22 = Severe Depression, ≥ 23 = Very Severe Depression.[7]

Geriatric Depression Scale (GDS)

GDS is a self-administered tool to assess depression. The Hindi version of the scale was used. It consists of 30 items. The cutoff score is as follows: 0–9 = Normal, 10–19 = Mild Depression, and 20–30 = Severe Depression.[8]

Psychoeducation module and placebo module

For case group, the psychoeducation module has been developed and validated by the Department of Psychopharmacology, National Institute of Mental Health and Neurosciences (NIMHANS), Bangalore. For this study, the module has been translated into Hindi through the standard procedure of translation as per World Health Organization (WHO),[9] whereas, for the control group, placebo psychoeducation module has been developed in Hindi by the Department of Geriatric Mental Health, KGMU, and has been validated by three experts of the field. Since the study is a randomized controlled trial, so the case group was given intervention and the control group was given placebo.

Results

Table 1 displays the socio-demographic profile of all the subjects in the case (A) and control (B) group. All the socio-demograhic variables are equally distributed among both the groups. No significant difference has been observed here. In the above Table 2, 53.01% of the total subjects in the case group and 50.70% of the total subjects in the control group belonged to moderate levels of depression at day_0.

Table 3 shows the change in scores when case group (A) was compared with the control group (B). Both groups showed statistically significant improvement over time from Day 0 to Day 14 to Day 28 in HAMD ($P < 0.001$) and GDS ($P < 0.001$). Graphically shown in Figures 2 and 3.

After the *t*-test and ANOVA, a *post hoc* test was also applied. Table 4 shows the *post hoc* results. It states that the critical value of Scheffe's test for HAMD in case group (A) is 6.06 and in control group (B) is 6.08. The difference of mean of Day 0, Day 14, and Day 28 is more than the critical value, signifying that there is significant difference in HAMD scores in both the groups over time.

Table 1: Distribution of Socio-demographic variables of case group (A) (TAU + Psychoeducation) and control group (B) (TAU + Placebo)

Characteristics	Case (A) *n*=83	Control (B) *n*=71	*P*
Gender, *n* (%)			
Male	58 (69.88%)	46 (64.79%)	0.50
Female	25 (30.12%)	25 (35.21%)	
Age in years Mean Age±SD	66.57±5.40	67.45±6.55	*t*=0.36
Education, *n* (%)			
0-5 years	36 (43.37%)	31 (43.66%)	0.48
6-10 years	20 (24.1%)	19 (26.76%)	
11-15 years	18 (21.69%)	18 (25.35%)	
15 and more year	9 (10.84%)	3 (4.23%)	
Marital Status, *n* (%)			
Married	67 (80.72%)	49 (69.01%)	0.24
Widow/Widower	15 (18.07%)	21 (29.57%)	
Unmarried	1 (1.2%)	1 (1.41%)	
Domicile, *n* (%)			
Rural	42 (50.6%)	37 (52.11%)	0.92
Semi-Urban	6 (7.23%)	4 (5.63%)	
Urban	35 (42.17%)	30 (42.25%)	
Family Type, *n* (%)			
Single	6 (7.23%)	12 (16.9%)	0.06
With Family	77 (92.77%)	59 (83.1%)	

Table 2: Clinical characteristics: Severity of depression

Severity (Based on HAMD-17 at Day_0)	Case (A) *n*=83	Control (B) *n*=71	*P*
Mild, *n*(%)	31 (37.34%)	28 (39.44%)	0.30
Moderate, *n*(%)	44 (53.01%)	36 (50.70%)	
Severe, *n*(%)	6 (7.23%)	5 (7.04%)	
Very Severe, *n*(%)	2 (2.41%)	2 (2.81%)	

HAMD-17, 17-item Hamilton Depression Rating Scale

Table 5 shows the *post hoc* results stating that the critical value of Scheffe's test for GDS in case group (A) is 6.07 and in control group (B) is 6.08. The difference among mean of Day 0, Day 14, and Day 28 is more than the critical value, signifying that there is significant difference in GDS scores in both the groups.

Discussion

Patients with late-life depression are usually treated just with antidepressants, but the response to these medications is not good.[10] Apart from antidepressants, the patients also need to be given non-pharmacological management like various kinds of psychotherapies. The patients also need to be educated about the nature, cause, symptoms, prognosis, and treatment, which will provide a deep insight about their illness. We gathered a wealth of knowledge on what patients with low levels of education and poverty know and believe about depression and its treatment, and we may use the results of this study to guide future research in the area.

A randomized controlled trial concluded that using psychoeducation as an intervention can be effective for such patients with depression who have not been treated with antidepressant medication.[11] Psychoeducational intervention should be taken into consideration before using an antidepressant.[10] A study on "Psychoeducation (brief) for people with serious mental illness" concluded that a brief psychoeducational method may be useful, but more substantial; high-quality studies are required to support or disprove its approach.[12] The current study aims to address the issue of educating patients and their caregivers about late-life depression and seeing its effects through psychoeducation.

In this research, 154 subjects were included and randomized in the case (A) and control (B) groups. Out of which, 83 were allocated to the case (A) and 71 were allocated to the control (B) group. Two scales of depression namely HAMD-17 and GDS-30 were applied at baseline, at a two-week follow-up from baseline and at four-week follow-up from baseline in both the groups.

The results showed that in both the groups, there was a decrease in HAMD-17 and GDS-30 score from the baseline to follow-up. This can be attributed to the fact that though the case group (A) was given 'psychoeducation' and control group (B) was given 'placebo' but both the groups were also given treatment as usual as per their illness. Considering the fact that both the groups had access to medicines, which might have helped in the treatment of their depression and gradually improved the outcome in both the groups. However, one important finding of the study was that the attrition

Table 3: Effect of psychoeducation: Change in symptom severity scores over 28 days between two groups

Variable	Groups	Day 0[a]	Day 14[b]	Day 28[c]	*F*-ANOVA	Post hoc	*P*
HAMD (Mean±SD)	Case (A)	14.36±3.22	11.53±3.59	8.61±3.82	45.50	c < b < a	<0.001*
	Control (B)	14.42±3.66	12.44±3.50	9.68±3.55	39.72	c < b < a	
GDS (Mean±SD)	Case (A)	20.23±4.72	16.60±5.60	12.92±5.52	42.65	c < b < a	<0.001*
	Control (B)	20.58±4.55	18.08±4.97	14.80±5.97	19.57	c < b < a	

HAMD, Hamilton rating scale for depression; GDS, Geriatric depression scale. Repeated-measures ANOVA, $P<0.05$ significant

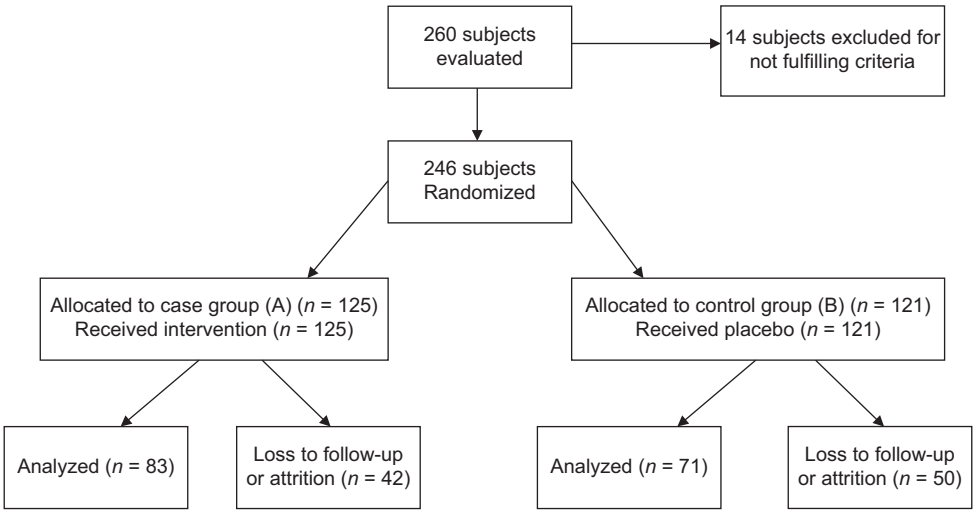

Figure 1: The flow of participants from screening to analysis

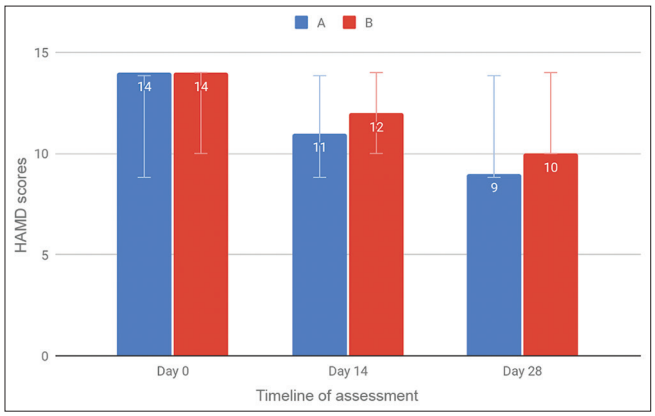

Figure 2: Graph below showing the change in HAMD scores between case (A) and control (B) group from Day 0 to Day 28

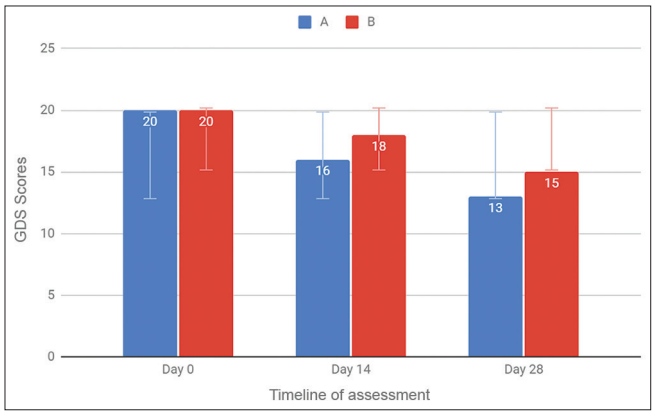

Figure 3: Graph below showing change in GDS scores between case (A) and control (B) group from Day 0 to Day 28

rate was more in the control group (B) (41.32%) in comparison with the case group (A) (32.60%). This may lead us to conclude that psychoeducation can be helpful in treatment adherence, compliance, providing knowledge about the illness, busting myths about the illness, changing the attitude toward illness, etc., and may not wholly be responsible for the treatment of depression without

Table 4: Post hoc Scheffe's test for HAMD

Scheffe's Test	Case Group (A) Critical Value -6.06	Control Group (B) Critical Value - 6.08
M_0-M_{14}	25.6	11.4
M_0-M_{28}	28.4	20.8
M_{14}-M_{28}	107.9	63.0
M_0-M_{14}	Significant	Significant
M_0-M_{28}	Significant	Significant
M_{14}-M_{28}	Significant	Significant

M_0=Mean of Day_0, M_{14}=Mean of Day_14, M_{28}=Mean of Day_28

Table 5: Post hoc Scheffe's test for GDS

Scheffe's Test	Case Group (A) Critical Value -6.07	Control Group (B) Critical Value – 6.08
M_0-M_{14}	19.8	7.9
M_0-M_{28}	21.1	13.2
M_{14}-M_{28}	81.9	41.6
M_0-M_{14}	Significant	Significant
M_0-M_{28}	Significant	Significant
M_{14}-M_{28}	Significant	Significant

M_0=Mean of Day_0, M_{14}=Mean of Day_14, M_{28}=Mean of Day_28

the pharmacological treatment. It can be especially useful when the patients have little or knowledge about the type of their illness and the treatment being provided, and thus, it also becomes the ethical duty to educate the patient and their caregivers about the illness so that they are compliant toward their treatment plan.[13] There can be many positive changes over time when people with severe mental illness and their families learn more about the condition and how to lessen its effects, such as fewer relapses, less time spent in psychiatric hospitals, a decreased sense of stigma, a sense of better control over life, better medication adherence, having better social living and problem-solving skills among patients, better overall family functioning, and fewer occurrences of depression.[14]

Hence, psychoeducation can be considered as an adjunct in the treatment of psychiatric disorders along with the pharmacological management.[15]

Ethical approval

The project was approved by the Institutional Ethics Committee with 90th ECM II B-Ph.D./P2, and the study was registered on the Control Trial Registry of India (CTRI) via CTRI/2019/05/018956.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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