Original Article

Effect of psychoeducation on short-term outcome in patients with late life depression: A randomized control trial - Protocol

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Abstract

Background: This is the PhD thesis protocol of an ongoing study entitled 'Effect of Psychoeducation on short- term outcome in patients with Late Life Depression: A Randomized Control Trial'. Psychoeducation is a proof-based therapeutic intervention for patients and their caretakers/family members that provides plenty of information and support for better understanding and coping up with the illness, which is being diagnosed. **Aim:** The aim is to examine the effect of psychoeducation on short- term outcome in patients with late life depression. **Hypothesis:** The hypothesis is that psychoeducation will improve outcome in patients with late life depression at 4 weeks. The sample size is 154. **Material and Methods:** The methodology is that patients aged 60 years and above coming to Out Patient Department (OPD) of the Department of Geriatric Mental Health, King George's Medical University and having the first episode of depression, which has been clinically diagnosed, will be taken. Then, Mini International Neuropsychiatric Interview (MINI) 6.0.0 will be applied for the confirmation of diagnosis. After confirmation, Hindi Mental Status Examination (HMSE) will be done to know the cognitive status, those scoring 24 and above on HMSE will be included in the study. The included patients will be evaluated on Hamilton Depression Rating Scale (HAM-D), Geriatric Depression Scale (GDS) and Knowledge Attitude Experience (KAE) Questionnaire. Next, the patients will be randomized in case group and control group. Case group will be given intervention of 'psychoeducation' through a video, and control group will be given 'placebo' through a video. For both the groups, the first follow up termed as 'booster session' will be at 2 weeks +/- 4 days from the baseline and second follow up will be at 4 weeks +/- 4 days from the baseline. **Statistical Analysis:** Data will be recorded on the spreadsheet and the results will be analyzed using the statistical software.

Keywords: Late life depression, older adults, psychoeducation, randomization

Background

Aging is a universal process, which can be complicated by the development of various physical and psychiatric illnesses. During later life, maintaining a proper mental well being is a tough task to do. Out of all, depression is one of the major mental illnesses and a debilitating health problem. About one third of the Indian elderly population suffers from depression with females being more prone to it.[1]The goals in treating depression in elderly population includes remission of symptoms, which further leads to decreased rates of relapse and recurrence, and improvement in functional capacity. This cannot be solely done by the prescription of anti-depressant drugs. As response to the anti-depressant medicines is quite unsatisfactory for this age group of patients, there is an urgent requirement for evidence-based non-pharmacological treatment choices.[2] So in this aspect, psychotherapies like psychoeducation play a very vital role in the management of old age depression. It has been found that psychoeducation and its efficiency is a neglected subject in depression in India. Hence, this current study will work a step

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forward in filling up this gap. This study is relevant to the practice of family physicians because while providing psychoeducation the physicians and therapists get a chance to work with the patient and their family members, which deepens the understanding of the disease, removes various myths regarding illness and the medication, and prevents its aggravation as well as recurrences.[3] Patients diagnosed with mental and physical illness must be educated about the nature of their illness and its management. This is an ethical requirement, which forms the further basis for the therapeutic relationship, allows the patient to make rational decisions regarding the treatment and course of life, and improves treatment adherence and follow - up.

Psychoeducation is a proof-based therapeutic intervention for patients and their caretakers/family members that provides plenty of information and support for better understanding and coping up with the illness, which is being diagnosed.[4] Psychoeducation is most commonly used with serious mental diseases, like schizophrenia, psychosis, clinical depression, dementia, personality disorders, anxiety disorders, eating disorders, and it is also used for physical illnesses, like cancer as well. It also provides insight into illness and helps in removing stigma related to mental illnesses.[5] Why psychoeducation is currently a thought of necessary because a great deal of information regarding illness and medicines passes onto the patients and caregivers, then it becomes quite difficult and sometimes confusing to grasp and deal with it in an effective way. Therefore, not solely giving information by the medical health professionals but also conjointly eliminating misunderstandings and myths of the illness, improving knowledge, and evaluating the way of addressing issues encompassing the illness is important. Thus, it is referred to as 'psychoeducation', not merely 'education'. This is not only limited to psychiatry patients but also includes those tormented by cancer, AIDS, and strokes.[3] In one of the review articles, it was found that psychoeducation is one of the main and core components that yield promising results out of the various psychosocial interventions.[6]

Psychoeducation specifically has more importance while dealing with late life depression. It has been documented that older adults are more susceptible to psychiatric and psychological problems, and out of all, depression is the most common psychiatric disorder in the geriatric population.[7] It is also an independent predictor of mortality in the older population.[8] Psychoeducation can enhance a patient's confidence in the treatment of their illness. Furthermore, for those patients who harbour any sort of myths about the nature of depression and antidepressant drugs being used; these can be identified, noted, and resolved during the psychoeducational sessions.[9]

A meta-analysis found that brief psychoeducational interventions for depression and other such illnesses can decrease the symptoms. Brief passive psychoeducation programmes are simple for implementation, can be applied immediately when needed and are also cost effective. In this regard, the quality of psychoeducation should be important.[10] It has also been indicated that brief psychoeducation appears to reduce the relapse within the medium term, and promote medication compliance and adherence within the short term.[11] Psycho educating patients also helps in reducing the duration of hospital stay.[12] Family psychoeducation in patients with depression improves the functioning of the patient and also the well being of family caregivers.[13]

Evidence-based guidelines for the treatment of bipolar disorder as per the third edition recommendations from the British Association for Psychopharmacology said medication (treatment as usual) should be integrated with psychoeducation.[14] Giving psychoeducation is an efficient way of treating depression in the population, which is not receiving any kind of antidepressant. Therefore, before taking anti-depressant, firstly psychoeducational intervention should be given.[15] Depressive symptoms were remarkably reduced after completion of the psychoeducation and skill training course in elderly female patients.[16] It is a feasible alternative for older adults with depression.[2] So, psychoeducation along with pharmacological treatment plays a vital role. Hence, psychoeducation of patients and care giving family members must be an essential part of all the treatment related to the management of depression.[17]

Aim

The aim of this study is to examine the effect of psychoeducation on short-term outcome in patients with late life depression.

Hypothesis

The hypothesis is that psychoeducation will improve outcome in patients with late life depression at 4 weeks.

Study design and method

The study will be conducted in the Department of Geriatric Mental Health, King George's Medical University, U.P., Lucknow. Patients will be taken from the outpatient clinic of the department.

It will be a randomized controlled trial (RCT). The trial design will be parallel. The individual randomization of 1:1 will be done.

Inclusion criteria

- Patients aged 60 years and above
- Patients giving the written informed consent
- Patients with first episode of depression and no previously diagnosed psychiatric disorder
- Patients who have been clinically diagnosed with depression
- Patients' diagnosis will be confirmed on Mini International Neuropsychiatric Interview 6.0 (MINI 6.0.0)
- Patients scoring 24 and above on Hindi Mental Status Examination (HMSE)

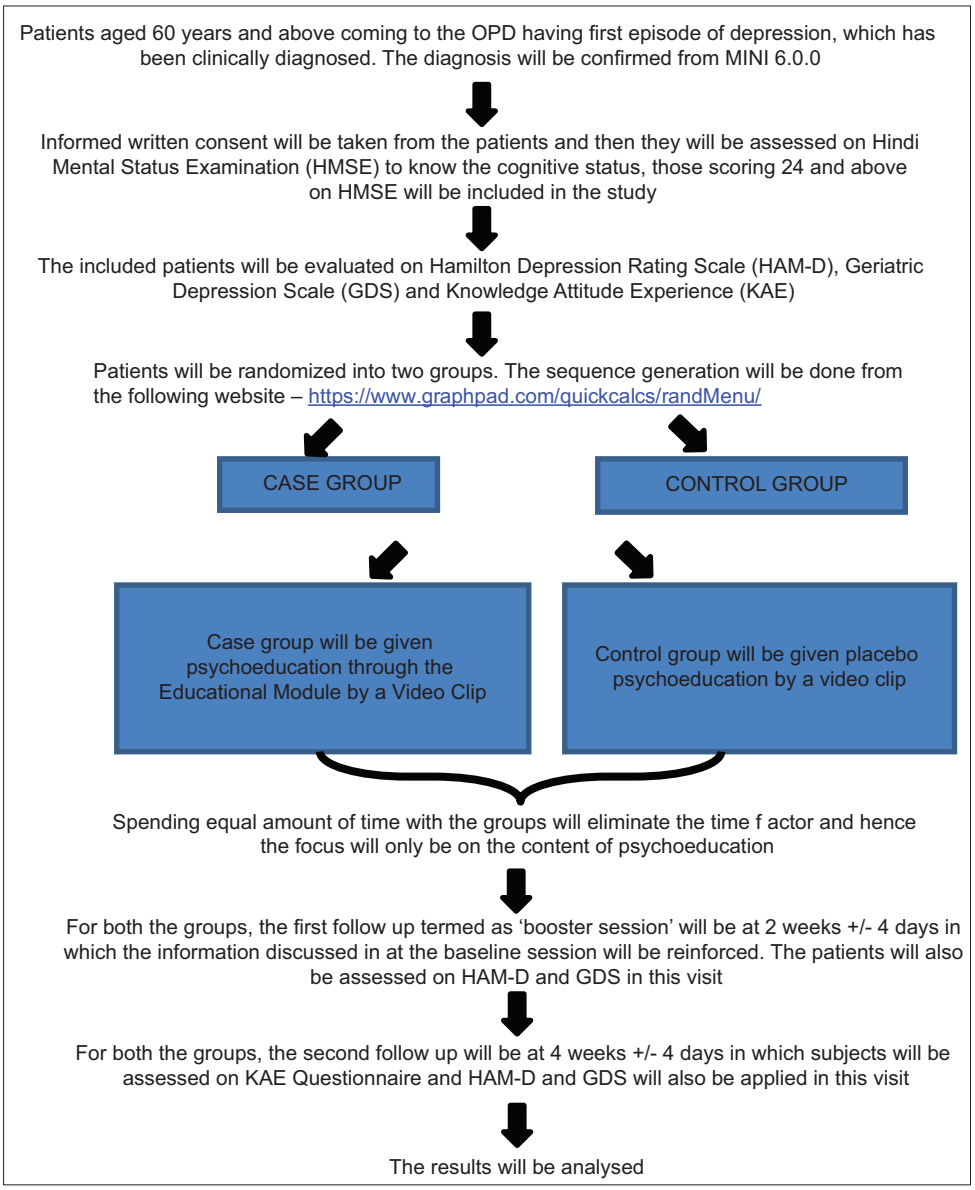
Exclusion criteria

- Patients having any severe medical illness
- Patients with hearing impairment or language problem or any other issue, which can be serious impediment to the study

Methodology

Patients aged 60 years and above coming to the Out Patient Department (OPD) of the Department of Geriatric Mental Health, King George's Medical University having the first episode of depression, which has been clinically diagnosed will be screened. For confirming the diagnosis, MINI 6.0.0 will be applied. Those patients having confirmed diagnosis on MINI 6.0.0, informed written consent will be taken from them and then they will be assessed on Hindi Mental Status Examination (HMSE) to know the cognitive status, those scoring 24 and above on HMSE will be finally included in the study. The included patients will be evaluated on Hamilton Depression Rating Scale (HAM-D), Geriatric Depression Scale (GDS) to assess the initial severity of depression and on Knowledge Attitude Experience (KAE) Questionnaire. Next, the patients will be randomized into two groups namely the case group (which will be given intervention) and control group (which will be given placebo). The sequence generation will be done from - **https://www.graphpad.com/quickcalcs/randMenu/. C**ase group will be given intervention of 'psychoeducation' through a video. On the other hand, the control group will be given 'placebo psychoeducation' through a video. Giving equal time to both the groups will eliminate time factor and hence the focus will only be on the content of the psychoeducation. Both the groups will also be given standard treatment.

For both the groups, the first follow up termed as 'booster session' will be at 2 weeks +/- 4 days from the baseline day, in which the information discussed in the baseline session will be reinforced for both the groups. The patients will also be assessed on HAM-D and GDS in this first follow up visit. For both the groups, the second follow up will be at 4 weeks +/- 4 days from the baseline in which the subjects will be assessed on KAE



Flowchart: Depicting Methodology

Questionnaire and HAM-D and GDS will also be applied in this second follow up visit. Finally, the results will be analysed.

Sample size

A sample of 77 participants in each group will be selected over a period of six months for each of the case and control group. The sample size is calculated as follows:

Number of patients with depression attending outpatient services at Department of Geriatric Mental Health: 152/year (as per OPD record from 01/01/2015 to 31/12/2015)

Hence, number of patients with depression in six months = 152/2 = 76

Sample Size (n) = N/1 + N (e)^2 (Slovin's Formula)

=76/1 + 76 (0.05)^2 = 76.19 = 77

(Where, n = sample size

N = total number of patients with depression in six months

e = the level of precision = 0.05 (the 50% of the maximum width of the confidence interval of any proportion estimate)

The sample size for the current study requires inclusion of 77 participants in each of the two groups. Hence, a sample of 154 participants will be included in the study.

Brief description of tools to be used

1. **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, copying. It is a 22 questions based scale with a maximum score of 30 and the cut off score is 24.[18]
2. **Mini International Neuropsychiatric Interview 6.0.0(MINI 6.0.0)** – It was designed as a brief structured interview for the major Axis I psychiatric disorders in DSM – IV and ICD – 10. 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.[19]
3. **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 cut off score is as follows: 0–7 = Normal, 8–13 = Mild Depression, 14–18 = Moderate Depression, 19–22 = Severe Depression, ≥ 23 = Very Severe Depression.[20]
4. **Geriatric Depression Scale (GDS) –** GDS is used to diagnose depression. The Hindi version of the scale developed by Ganguly *et al.* will be used. It consists of 30 items. The cut off score is as follows: 0–9 = Normal, 10–19 = Mild Depression, 20–30 = Severe Depression.[21,22]
5. **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. 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 control trial, so the case group will be given intervention and the control group will be given placebo.
6. **Knowledge Attitude Experience (KAE) Questionnaire** This KAE questionnaire consists of 70 questions (Section A to F). This has been developed by the Department of Psychopharmacology, National Institute of Mental Health and Neurosciences (NIMHANS), Bangalore. As this was in English Language, so it was translated into Hindi through the standard procedure of translation and few questions where required were modified. This was done to suit the need of the patients coming to the OPD.

Data management and analysis

All the data will be recorded on the spreadsheet. Continuous variables will be compared between groups using the independent sample t-test and across time using the paired t-test; where data were not normally distributed, the Mann–Whitney test will be applied. *t*-test will be used for comparing scores of HAM-D and GDS between case and control group at baseline, first follow - up and second follow - up separately. ANOVA (Analysis of Variance) will be used for the comparison of scores within the groups at three points of the study. The analysis will be done on IBM SPSS (Statistical Package for Social Sciences) Statistics 24.

Ethical clearances

The ethical consideration has been obtained from the Institutional Ethics Committee, King George's Medical University and the trial has also been registered on Control Trial Registry of India (CTRI) via CTRI/2019/05/018956. The study is designed and will be reported according to the principles as per the CONSORT (Consolidated Standards of Reporting Trials) guidelines.

Discussion

It is hoped that this intervention will have a positive impact on the patients as it is one of the holistic approaches to the treatment of depression. This trial also includes a variety of depressive elderly patients. It is hoped that results from this study will be highly generalisable to the clinical practice because of the proven fact that it is neither expensive nor complicated.

Declaration of patient consent

This is just a study protocol and the author certifies that while data collection all the appropriate and necessary written consent

will be taken from the patients and the patients will be explained that their names and initials will not be published and due efforts will be made to conceal their identity..

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Nil.

Conflicts of interest

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