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Research Article

DESIGN OF A PSYCHOTHERAPEUTIC NURSING INTERVENTION PROTOCOL TO ADDRESS POST-STROKE DEPRESSION, ANXIETY AND RESILIENCE OUTCOMES FOLLOWING STROKE

Betty Koshy and Kritagna Sinh Vaghela

Parul Institute of Nursing, Parul University, Vadodara, Pin Code: 391760, Gujarat, India
Department of Psychiatry, PIMSR, Parul University, Vadodara, Pin Code: 391760, Gujarat, India

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ABSTRACT

Psychiatric complications following a stroke such as post-stroke depression (PSD), anxiety, emotional incontinence, anger issues, and fatigue significantly hinder recovery, functioning, and overall quality of life. Despite the high prevalence of these issues, there is currently a lack of psychological treatments specifically tailored to address the unique needs of stroke survivors experiencing depression and anxiety. This study aims to implement and assess a psychotherapeutic nursing intervention package designed to enhance emotional resilience and improve long-term patient-centered outcomes. This prospective, 4-week, non-randomized, placebo-controlled trial will involve screening stroke survivors for depression and anxiety. Seventy participants aged 18-70 years, meeting the inclusion and exclusion criteria with mild to moderate PSD, will be recruited and non-randomly assigned to either an experimental or control group. The experimental group will receive two sessions per week of Cognitive Behavioral Therapy (CBT) combined with Problem-Solving Therapy (PST) over four weeks. At the end of each week, participants will also receive a need-based psychoeducation session. The primary outcome will be measured in week five using the 17-item Hamilton Depression Rating Scale (HAMD-17), focusing on a ≥50% reduction in HAMD-17 or Hamilton Anxiety Rating Scale (HAM-A) scores, along with increased resilience measured by the Connor-Davidson Resilience Scale. Logistic regression analysis will be used to assess data. This protocol outlines a non-randomized trial to explore the effectiveness and feasibility of a psychotherapeutic nursing intervention for stroke survivors. If successful, it could inform a scalable, cost-effective care model involving trained mental health paraprofessionals.

Keywords: Stroke Survivors, Post-Stroke Depression, Anxiety, CBT, Therapy.

INTRODUCTION

Stroke is a global health problem. It is the second common cause of death and fourth leading cause of disability worldwide (Strong *et al*., 2007). Approximately 20 million people each year will suffer from stroke and of these 5 million will not survive (Dalal & Bhattacharjee, 2007). In developed countries, stroke is the first leading cause for disability, second leading cause of dementia and third leading cause of death. Stroke is a life-changing event that affects not only the person who may be disabled, but their family and caregivers. those at risk as being worse than death (AHA, 2006). Depression is common after stroke, affecting approximately one third of stroke survivors at any one time after stroke (compared with 5%-13% of adults without stroke), with a cumulative incidence of 55% (Hasin *et al*., 2005; Kessler *et al*., 2005; Ayerbe *et al*., 2013). Approximately one third develop PSD at some point after stroke. The frequency is highest in the first year, at nearly 1 in 3 stroke survivors, and declines thereafter (Towfighi *et al*., 2017). Around 20% of people will develop anxiety, most commonly in the first 3-4 months after stroke. Post-stroke anxiety is closely associated with PSD (Campbell Burton *et al*., 2013). Anxiety and depression can often occur concurrently after stroke and also is unrecognized and undiagnosed in stroke survivors (Hackett *et al*., 2005) If Post-Stroke depression and anxiety identified early, this offers the opportunity to institute therapies that may positively impact patient outcomes. Early identification

*Corresponding Author: Ms. Betty Koshy, Ph.D Scholar, Parul Institute of Nursing, Parul University, Vadodara, Pin Code: 391760, Gujarat, India. Email: bettygeorge2912@gmail.com.

may offer opportunities for prompt initiation of therapies and prevention of poor outcomes and early death. Patients with stroke with disability may face psychological distress. Resilience was an independent predictor of quality of life beyond anxiety and depression in patients with ischemic stroke. Interventions aimed at improving resilience at acute hospitalization might be a worthwhile addition to improve quality of life early after stroke and would also be helpful to cultivate hope for reintegration, recovery with mitigation of depressive symptoms. Both pharmacological and non-pharmacological treatment modalities are widely used across the country to combat this disease but in this study the focus would be to evaluate the effectiveness of psychotherapeutic interventions with the standard treatment or usual treatment thus helping to improve the overall functioning of life and also to establish the importance of psychiatric screening in inpatient and outdoor clinics. This study also aims to find out the selected psychiatric co morbidity among stroke survivors with a intent to implement psychotherapeutic interventions to treat depression and anxiety and to strengthen emotional resilience of patients. Psychiatric morbidity in stroke can be post stroke depression, anxiety disorders, emotional incontinence, anger process and post-stroke fatigue. The impact of this psychiatric co-morbidity in patients has detrimental effect on recovery, functioning and quality of life. The rate of suicide in post-stroke depression is an issue that has to be addressed and can be successfully prevented with early interventions. However, screening for these post-stroke comorbidities remains infrequent in stroke prevention clinics and hospitals as the focus is only on medical attention and neurological rehabilitation (Towfighi *et al*., 2017; Hackett *et al*., 2005). Many studies have been conducted and published on stroke patients but data or information pertaining to psychiatric co-morbidities post stroke is limited with a handful of studies done in India and is descriptive in nature. Studies on treatment efficacy of pharmacological and non-pharmacological interventions has to be done with highest priority on psychiatric screening of stroke patients in hospitals which is either not practiced or implemented in majority of hospitals (Cheung, 2019; Wang *et al*., 2018). The topic was considered significance in terms of identification of psychiatric co-morbidity in stroke patients by proper screening/ assessment tools and thereby implementing psychotherapeutic interventions to manage the problems. Psycho therapeutic nursing intervention with underlying principles of therapeutic nurse patient relationship would also promote emotional resilience which is considered as a powerful psychological indicator and outcome and would be a road to recovery. Addressing and strengthening the psychological indicator will increase the client's will to actively participate and cope up with the distress in disabled situation. The selected psychological interventions will be targeting stroke survivors with psychiatric conditions making the patients emotionally resilient that is needed to improve long-term patient-centered outcomes and quality of life. The secondary objective would also be to establish protocol for screening the stroke patients for psychiatric conditions in hospitals and outpatient clinics which clearly indicates the double implications of the study. The aim of the study was to find out the Effectiveness of Cognitive Behavioral Therapy for People with Depression. Post-stroke depression (PSD) is a common psychiatric manifestation of stroke, which has a devastating impact on survivors' quality of life with an increasing burden on caregivers and the public medical system. Even so, no meta-analysis on specific psychotherapeutic treatment has been conducted. How effective is cognitive behavioral therapy (CBT) in reducing depressive symptoms in randomized-controlled trials (RCTs) targeting community-dwelling stroke survivors with PSD. Through systematic procedures of screening and data extraction, four RCTs were synthesized for meta-analysis (N= 270) and effect size was estimated. Score reduction from baseline and post-treatment between- group difference in the CBT group for each study ranged from 2.64 to 10.97 and -2 to - 6.65, respectively. Two studies showed significant between-group differences ($p < .05$ and $p < .001$), one showed a tendency of improvement in CBT ($p = .51$), and one showed no significant results ($p > .05$). Overall, CBT groups showed significant improvement in depression compared with controls. Methodological quality, intensity of CBT, and duration of post-treatment follow-up proved critical to treatment effects (Cheung, 2019). Both English (PubMed, PsycINFO, Embase) and Chinese (WanFang Database, Chinese National Knowledge Infrastructure and SinoMed) databases were systematically searched. Weighted and standardized mean differences (WMDs/SMDs), and the risk ratio (RR) with their 95% confidence intervals (CIs) were calculated using the random effects model. Altogether 23 studies with 1,972 participants with PSD & PSA were included and analysed. Of the 23 RCTs, 39.1% (9/23) were rated as high quality studies, while 60.9% (14/23) were rated as low quality. CBT showed positive effects on PSD &PSA compared to control groups (23 arms, SMD = −0.83, 95% CI: −1.05 to −0.60, P < 0.001). Both CBT alone (7 arms, SMD = −0.76, 95% CI: −1.22 to −0.29, P = 0.001) and CBT with antidepressants (14 arms, SMD = −0.95, 95% CI: −1.20 to −0.71, P < 0.00001) significantly improved depressive symptoms in PSD & PSA. CBT had significantly higher remission (6 arms, RR = 1.76, 95% CI: 1.37–2.25, P < 0.00001) and response rates (6 arms, RR = 1.41, 95% CI: 1.22–1.63, P < 0.00001), with improvement in anxiety, neurological functional deficits and activities of daily living. CBT effects were associated with sample size, mean age, proportion of male subjects, baseline depression score, mean CBT duration, mean number of CBT sessions, treatment duration in each session and study quality (Shi-Bin Wang *et al* ,2018).

MATERIALS AND METHODS

As shown in Figure 1 The prospective study is a 4-week, non- randomized, placebo-controlled trial. Samples will be

screened for depression and anxiety. Seventy eligible participants on the basis of inclusion and exclusion criteria with mild to moderate PSD aged between 18 years and 70 years will be recruited and will be non-randomly assigned to either experimental or control group. The experimental group will receive 2 sessions of CBT paired with PST (Problem Solving Therapy) per week for 4 weeks, at the end of each week client will receive need-based psycho-education programme. The primary outcome is the proportion of participants having an improvement at week 5 according to the Hamilton Depression Rating Scale 17-Item (HAMD-17) score, including the proportion of participants having a decrease of ≥ 50% in HAMD-17 score or HAM-A with increased resilience measured by Connor Davison Resilience Scale. Data will be analyzed by logistical regression analyses. (Connor, KM & Davidson, JRT, 2003).

Study Type/ Design

The study type is the prospective study is a 4-week, non-randomized interventional design with control group in which a 4-week psychotherapeutic nursing intervention will be compared with a controlled intervention namely psychoeducation. Outcome measures will be collected at baseline. Ethics approval has been obtained by Parul University-IECHR, (Approval Number- PU-IECHR/PIMSR/00/081734/370).

Study Participants

Stroke survivors who survived the episode of stroke will be screened for depression, anxiety and emotional resilience. The eligibility of participants to be a part of the study will be determined by the following criteria. Inclusion Criteria. Exclusion Criteria.

Recruitment of Study Subjects or Participants

Eligible stroke patients after screening will be recruited. Participants will be contacted directly and information regarding the research will be explained.

Sample Size Allocation

Sample size estimation was done using PAAS 11.0 software (PASS, UT, USA) taking $\beta = 0.1$, power= 90% with the level of significance at 0.05, with an assumed overall dropout rate of 10% of study participants. Final sample of 140 was computed. Patients will be screened unless each of the group (experimental and control) will have 70 participants each. Allocation of the participants in the group will be non-randomised. While assuming the dropout rate every attempt will be made to retain the participants by delivery adequate information to the patient, maintaining good interpersonal relationship with the participants.

Procedure

Participants will be recruited from the selected hospital. The eligibility of the participants will be confirmed on the basis of inclusion and exclusion criteria. The participants will be explained the study it's nature, course along with risks and benefits. After receiving the willingness informed consent will be obtained and baseline assessment will start and the participant will be allocated either of the 2 groups. The therapy sessions will be scheduled with the participants. The intervention planned for the targeted audience is bundled psychotherapeutic intervention in which Cognitive Behavior therapy will be paired up with problem solving therapy which will be delivered to the stroke survivors in 8 sessions in addition to which psycho education programme will also be delivered catering to the needs of the study participants. After the intervention the post-test will be determined for both the groups.

Outcome Measures

The outcome measures of the study can be understood in terms of primary outcome sand secondary outcomes. The primary outcomes of the study will be measured by Hamilton Depression Rating Scale, Hamilton Anxiety Rating Scale and Connor Davidson Resilience Scale to evaluate the efficacy of planned packaged intervention. The secondary outcome of the study will be measured by using the inferential statistics to understand the baseline characteristics and it's part in the onset and course of the problem to be studied.

Tools for Data Collection

Socio-Demographic Questionnaire: - To measure socio-demographic variables of stroke survivors. Post-Stroke Depression: - In the study post stroke depression is persistent negative changes in mood triggered by stroke that meets the criteria of DSM-V; APA 2013, quantifiable by Hamilton Depression Rating Scale with score < 25. Post- Stroke anxiety is manifestation of Generalized anxiety symptoms scored >17 secondary to stroke that meets the criteria of DSM-V; APA 2013, quantifiable by Hamilton Anxiety Rating Scale with score > 17. Resilience Scale: - The Connor-Davidson Resilience Scale (CD-RISC) will be used as a tool for data collection to assess the emotional resilience of stroke survivors participating in the study. Emotional resilience refers to an individual's ability to cope with stress, adapt to adverse situations, recover from emotional distress, and maintain psychological well-being despite challenging life events such as stroke. In the present study, the scale will be administered before and after the psychotherapeutic nursing intervention to determine the effectiveness of the intervention in improving emotional resilience among stroke survivors.

Statistical Analysis

The statistical analysis can be understood in various parts. First part is to determine the baseline characteristics using descriptive statistics. Second the effect of intervention will be determined by using t-test. In addition to this both the groups will be compared on primary outcome measures by using independent sample t test. Third the association of baseline characteristics will be determined with pre-scores

by using chi-square test. Fourth linear mixed models for repeated measures will also be used in between the 2 groups with both outcome measures as dependent variables.

RESULTS AND DISCUSSION

Recent evidence indicates that substantial percentage of stroke survivors are diagnosed with depression and anxiety which leads to poor recovery and psychiatric mortality. There is lack of evidence based psychological treatments for stroke patients. Results from similar study suggested improvement in depression and anxiety score post-intervention· The intervention planned will be checked for the feasibility if the intervention is found to be feasible, effective and acceptable the results from this study will enhance availability and foster dissemination of evidence-based treatment a well drafted psychotherapeutic intervention based on evidence supported by mental health professionals could serve as a cost-effective model of care(Cheung, Victor,2019 and Shi-Bin Wang, 2018).

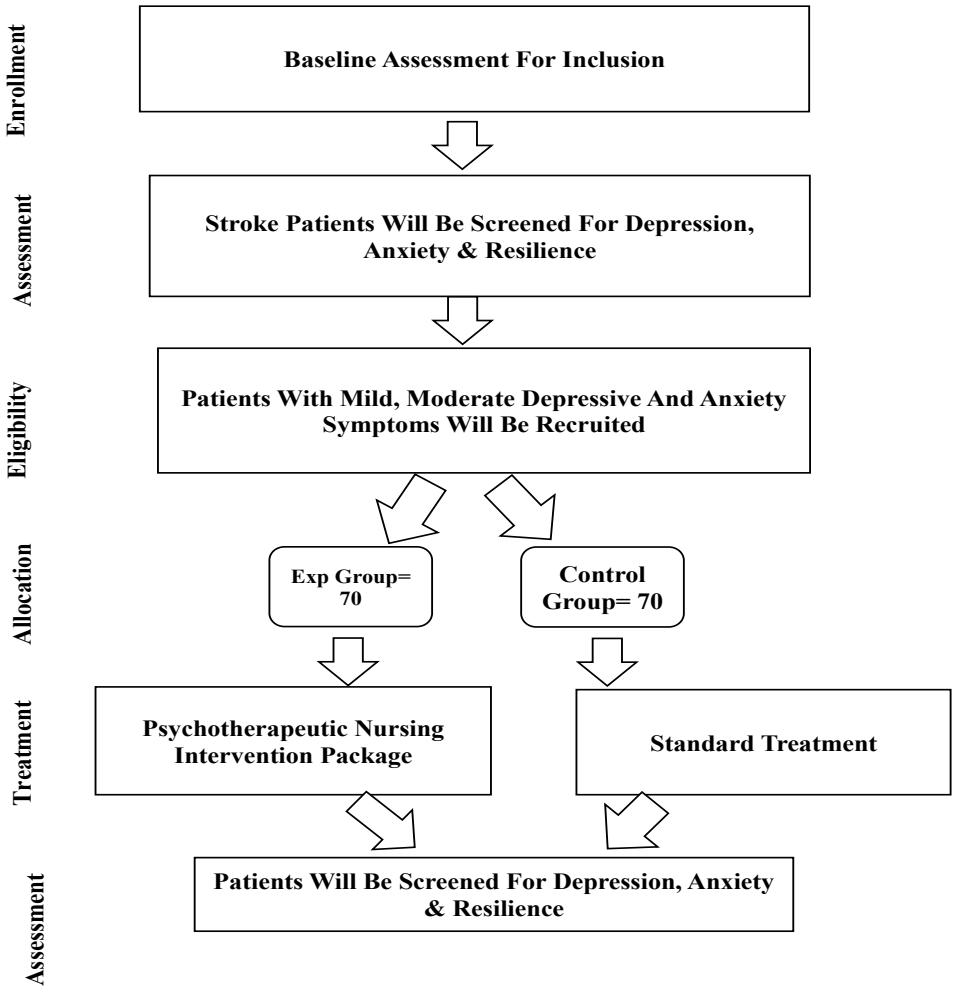

FIGURE 1 :-SCHEMATIC REPRESENTATION OF STUDY PROTOCOL

CONCLUSION

The designed psychotherapeutic nursing intervention protocol is expected to provide a structured and holistic approach for addressing post-stroke depression, anxiety, and resilience among stroke survivors. By integrating evidence-based psychotherapeutic strategies within nursing care, the protocol may enhance psychological well-being, improve coping abilities, promote resilience, and contribute to better overall recovery outcomes and quality of life following stroke.

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CONFLICT OF INTERESTS

The authors declare no conflict of interest

ETHICS APPROVAL

Ethical approval is received from PU-IECHR/PIMSR/00/081734/3703

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AI TOOL DECLARATION

The authors declares that no AI and related tools are used to write the scientific content of this manuscript.

DATA AVAILABILITY

Data will be available on request

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