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Research Protocol

Physiotherapy Section

Effect of Benson's Relaxation versus Mitchell's Relaxation along with Conventional Physiotherapy Exercise as an Adjunct to Medications to Stabilise Blood Pressure, Anxiety and Quality of Life in Preeclampsia: Research Protocol for a Randomised Controlled Trial

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ABSTRACT

Introduction: Preeclampsia, a hypertensive disorder of pregnancy, is a leading cause of maternal and foetal morbidity and mortality worldwide. It involves managing blood pressure, reducing anxiety and enhancing quality of life. This study will recruit participants diagnosed with preeclampsia, randomly allocating them into two groups. The conventional group will receive a routine exercise protocol along with Mitchell's relaxation technique, whereas the intervention group will receive Benson's relaxation technique along with routine exercises. Blood pressure will be measured using a digital sphygmomanometer, anxiety will be assessed using the Beck Anxiety Inventory and quality of life will be evaluated using the Health-Related Quality of Life questionnaire. The protocol will be administered over four weeks, with an interim assessment conducted at the second week and a post-assessment completed after the fourth week.

Need of the study: The preeclampsia population requires constant monitoring and care, as the vitals of affected women can be unstable. This group is at a higher risk for stroke and heart disease. Preeclampsia can impact foetal growth, leading to mental retardation, placental abruption and preterm birth. There is a lack of information regarding appropriate physiotherapy protocols for this population.

Aim: The study aims to compare the effectiveness of Benson's and Mitchell's relaxation techniques, combined with conventional physiotherapy exercises, to determine which approach yields better outcomes.

Materials and Methods: This randomised control trial will be conducted at Acharya Vinoba Bhave Rural Hospital and the Department of Community Physiotherapy of Ravi Nair Physiotherapy College in Sawangi Meghe, Wardha, Maharashtra, India, from February 2024 to August 2025. A total of 60 patients diagnosed with preeclampsia will be divided into two groups. Group A will receive conventional therapy, while the experimental group (Group B) will receive Benson's relaxation. After dividing patients into the two groups, each Group A and B will receive Mitchell's relaxation and Benson's relaxation, respectively, for 30 minutes, along with breathing exercises. Patients will receive these interventions five days a week. All relaxation techniques will be combined with conventional physiotherapy exercises in both groups.

Keywords: Antenatal care, Hypertension, Pregnancy-induced hypertension, Vitals

INTRODUCTION

New-onset proteinuria and new-onset hypertension, which frequently manifest after 20 weeks of gestation, are the hallmarks of preeclampsia-a widely recognised hypertensive condition during pregnancy. Diagnostic standards include: Proteinuria, defined as 0.3 g of urine excreted in 24 hours without signs of a urinary tract infection, typically correlating to 30 mg/dL (1+ reading on a dipstick) in a random urine determination (Report of the National High Blood Pressure Education Program Working Group on High Blood Pressure in Pregnancy) [1]. Diastolic blood pressure measurements are 90 mmHg and systolic blood pressure measurements are 140 mmHg.

The illness is associated with oedema, headaches, vision abnormalities and epigastric discomfort. Severe preeclampsia can lead to complications such as preterm birth, renal failure, subcapsular hepatic haematoma, placental abruption and even foetal or maternal mortality, with or without HELLP syndrome (ACOG 2002) [2]. Preeclampsia, also known as Pregnancy-induced Hypertension (PIH), is a medical condition that causes extreme distress and anxiety. It is characterised by a continuous rise in blood pressure to 140/90 mmHg or higher on two distinct occasions, separated by atleast four hours, after the 20th week of pregnancy or within the first 24 hours post-delivery in a woman who had previously been normotensive.

Its aetiology remains unclear, with pregnant teenagers and women over 40 years being more susceptible to it [3]. More seriously, PIH can impair foetal development and lead to serious prenatal and postnatal complications for the baby, in addition to endangering the mother's health and wellbeing [4]. Preeclampsia, which is defined as de novo hypertension and proteinuria in pregnancy, has not yet been fully understood pathophysiologically. Dr. Leon Chesley, a pioneer in the study of pregnancy-related hypertension, categorised the most likely causal factors into four main groups more than 30 years ago: nutritional, renal, immunologic and placental [5]. The World Health

Organisation (WHO) (2014) states that PIH ranks third among the causes of maternal death.

Research indicates that it affects approximately 5% to 8% of expectant mothers globally, complicates 6% to 8% of pregnancies and impacts up to 15% of pregnant women in referral centers [6]. Since established medical treatments exist to prevent or address complications, the majority of maternal fatalities are avoidable [7]. In the industrialised world, preeclampsia is treated with parenteral magnesium sulphate, prenatal aspirin therapy for high-risk mothers, perinatal blood pressure control and monitoring, betamethasone for patients under 34 weeks and close monitoring of postpartum blood pressures [5]. The only proven treatment remains timely delivery of the foetus and placenta.

Postpartum preeclampsia is becoming increasingly common, prompting continued surveillance even for individuals who showed no prenatal signs of the condition. Preeclampsia without severe features can be managed expectantly in the absence of labour, ruptured membranes, vaginal bleeding, or abnormal antepartum tests by utilising twice-weekly maternal and foetal monitoring until 37 weeks. With appropriate resources and strict inclusion criteria, expectant management may be attempted for women with severe preeclampsia before 34 weeks. Delivery is recommended whenever there is a deterioration in maternal or foetal condition, with special attention being given to the declining health of both mother and foetus.

Currently, American College of Obstetricians [5] and Gynecologists (ACOG) does not recommend pharmacological therapy for mild to moderate hypertension (systolic <160 mmHg or diastolic <110 mmHg) in preeclamptic patients, as it may increase the risk of foetal growth restriction and does not seem to reduce the chance of the illness progressing. Most signs and symptoms can be resolved before birth; however, preeclampsia can persist after delivery and, in certain cases, can arise de novo during the postpartum period [8].

Therapeutic relaxation techniques assist individuals in physically and mentally lessening their stress and anxiety [9]. Although relaxation methods have long been a mainstay of psychotherapy, they can also be utilised as adjunctive therapies in various healthcare settings to treat patients with a range of conditions, including but not limited to pain, stress, anxiety and depression [10]. Psychophysiological techniques known as relaxation promote physical and mental relaxation, which reduces stress [11]. These methods effectively alleviate discomfort and anxiety and are frequently used in physical therapy [12]. Despite being a widely accepted and often utilised concept, a clear definition of therapeutic relaxation remains problematic [13].

Mitchell's approach involves using a silent, solitary auditory relaxation technique. It suggests total engagement and autonomy, highlights the mind-body psychoneuroimmunological link and employs deep breathing, guided imagery and relaxation techniques. It is hypothesised that the posture associated with stress induces muscular dystonic patterns and stiffness, heightens muscle tension and alters the neurological and endocrine systems [14].

Benson's relaxation method, developed by Herbert Benson in 1970, provides a straightforward way to relieve stress [15]. This technique is known to reduce pain intensity and improve overall quality of life, including sleep quality. Simultaneously, it diminishes anxiety and mood swings while promoting physical activity [16]. Crucially, Benson's relaxation method has no negative effects on individuals, is easy to apply and offers multiple benefits [17].

Primary Objective

- To determine the effect of Benson's relaxation exercises, along with conventional physiotherapy, on vitals, anxiety and quality of life in preeclampsia.
- To determine the effect of Mitchell's relaxation exercises, along with conventional physiotherapy, on vitals, anxiety and quality of life in preeclampsia.

Secondary Objective

- To compare both Benson's and Mitchell's relaxation techniques and determine which provides better results.

Hypothesis

Alternate Hypothesis:

- H_0: Benson's relaxation will significantly improve vitals, anxiety and quality of life when provided with conventional physiotherapy in preeclampsia, compared to Mitchell's relaxation.
- H_1: There will be a significant difference between Benson's and Mitchell's relaxation exercises when given with conventional physiotherapy and the outcome results may show greater differences.

Null Hypothesis:

- N_0: Benson's relaxation will not improve vitals, anxiety and quality of life in preeclampsia patients.
- N_1: There will be no significant difference between Benson's and Mitchell's relaxation exercises; the outcome results may show no difference.

REVIEW OF LITERATURE

Bell JA and Saltikov JB conducted a study comparing the effectiveness of Mitchell's relaxation techniques with diaphragmatic breathing versus diaphragmatic breathing techniques alone in a supine position [18]. After intervention, a significant reduction in heart rate was observed in both groups ($p<0.05$ for group 1 and $p<0.01$ for group 2), although no differences were found between the two groups (not significant). Both treatment groups exhibited a significant reduction in heart rate. It may be more physiologically justifiable to use diaphragmatic breathing rather than Mitchell's complete technique. The present study is among the first to suggest that diaphragmatic breathing can be used alone and need not be incorporated into generalised relaxation procedures. Further research is recommended.

Mustafa R et al., conducted a comprehensive review covering all aspects of pregnancy-induced hypertension. They also reviewed the types of antihypertensives that are safe for use in pregnancy at different stages [4].

Rambod M et al., conducted a study involving a total of 80 haemodialysis patients, providing audiotapes of Benson's relaxation technique for 20 minutes over eight weeks [19]. The findings indicated that Benson's relaxation technique might relieve pain intensity and improve the quality of life in haemodialysis patients. Therefore, Benson's relaxation technique could be used as part of the care practice for alleviating pain intensity and enhancing the quality of life in haemodialysis patients.

Ganesh B et al., conducted a study involving 34 individuals with dysmenorrhoea, in which Mitchell's relaxation showed promising effects in reducing pain and stress levels. Therefore, it should be implemented for menstrual wellbeing [20].

Zenouzi A et al., conducted a Randomised Controlled Trial (RCT) in which Benson's relaxation was provided to pregnant women to reduce stress, anxiety and depression. The Depression Anxiety Stress Scale-21 (DASS-21) scale was used as an outcome measure and the scores effectively reduced [21].

Vicente Bertagnolli T et al., conducted an RCT involving 24 eligible pregnant women recruited from the high-risk obstetric ward [22]. The participants were women with a gestational age of 24 to 38 weeks, who were hospitalised for maternal and obstetric clinical control. Their results demonstrated that the physiotherapeutic protocol offered to pregnant women diagnosed with preeclampsia

was feasible and safe for both the mother and the foetus, providing a clinical reduction of anxiety in both groups, as well as a clinical reduction in pain for pregnant women in the intervention group.

Raipure A and Patil S conducted an RCT comparing the efficacy of Mitchell's and Benson's relaxation in patients with premenstrual syndrome to improve quality of life. They concluded that Benson's relaxation produced better results and recommended it for daily practice [23].

MATERIALS AND METHODS

The study is a randomised control trial and will be conducted at Acharya Vinoba Bhave Rural Hospital and the Department of Community Physiotherapy of Ravi Nair Physiotherapy College in Sawangi Meghe, Maharastra, India, from February 2024 to August 2025. It is a single-centric, two-arm parallel open-label equivalence, comparative study. All participants will provide written informed consent for the present study to be carried out. Ethical approval was obtained from the Institutional Ethics Committee DMIHER (DU)/IEC/2024/179 and the study has been registered on clinicaltrials.gov with the Clinical Trials Registry-India (CTRI) Reference Number CTRI/2024/05/066854.

Once approval is received from the ethics committee, the study will begin by obtaining written consent from the participants. Individuals meeting the necessary criteria will be randomly selected using opaque sequentially numbered envelopes and assigned to either Group A or Group B. Baseline findings will be recorded using the specified outcome measures, including a digital sphygmomanometer for blood pressure, the Beck Anxiety Inventory for anxiety and Health-Related Quality of Life Scale (HRQOL) for quality of life.

The study will be conducted under the guidance of the guide, Head of Department (HOD) and chief advisor of the research cell.

Inclusion criteria: The inclusion criteria are ages ranging from 18 to 45 years, with blood pressure greater than Systolic 140 mmHg/Diastolic 80 mmHg. Counselling will be provided by a psychologist pre- and post-treatment and participants should have low scores on the Beck Anxiety Inventory Questionnaire.

Exclusion criteria: The exclusion criteria include immunocompromised conditions such as Acquired Immunodeficiency Syndrome (AIDS), neurological impairments, cognitive impairments, musculoskeletal issues, neurological conditions, or any cardio-respiratory complications, as well as subjects on anti-anxiety drugs.

Participant timeline: Pre- and post-baseline data will be collected, with predata gathered at the start of the first week and post-data collected at the end of the fourth week, following an intervention lasting four weeks. Another recording of post-intervention data will occur on the final day of the fourth week. In [Table/Fig-1], the Consolidated Standards of Reporting Trials (CONSORT) flowchart is mentioned.

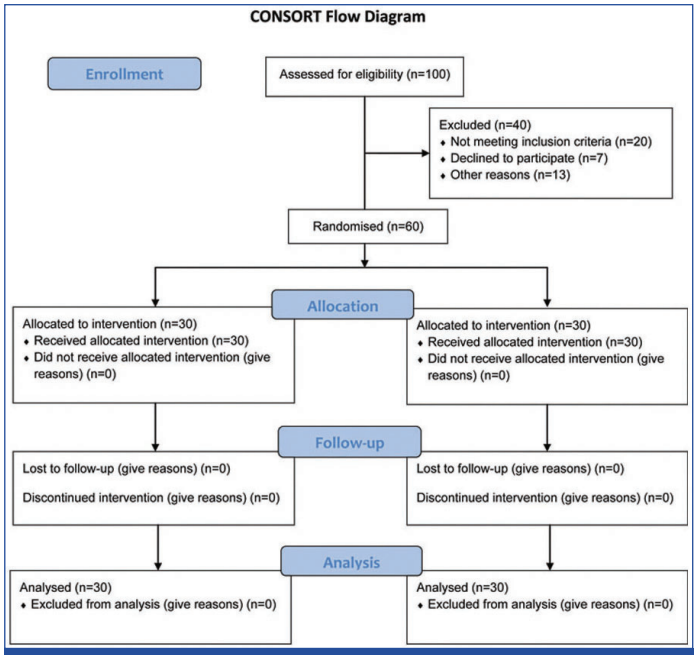
Sample size calculation: At a 5% level of significance ($Z\alpha$=1.96) and an 80% power ($Z\beta$=0.84), with a ratio allocation (Group 2/Group 1) of 1, the sample size is determined to be 26 per group. Considering a 15% dropout rate (total=4), a total of 30 samples will be required per group.

Randomisation sequence: This process involves the allocation of patients based on randomly generated numbers. The patient will select an envelope containing numbers and their assignment to the type of intervention will depend on the number drawn.

Allocation: Simple random sampling will be used, with computer-generated random numbers to randomise the study subjects.

Implementation: The random number sequence will be generated by a blinded person from a non healthcare background. The study's principal investigator will enroll and assign participants to the interventions.

Blinding: Assessors will be blinded to the intervention.



[Table/Fig-1]: CONSORT flow of the study.

Data collection methods: Assessment and collection of outcomes will occur in the preintervention stage after participants have been assigned to the intervention groups. Post-intervention data will be collected on the same day after the completion of four weeks of intervention.

Data management: The frequency percentage will be used for qualitative data, while the mean and standard deviation will summarise quantitative data.

Study Procedure

After obtaining ethical clearance from the Institutional Ethical Committee, patients diagnosed with preeclampsia who have been counselled by the doctor and psychologist and who are willing and meet the inclusion criteria, will be identified. The treatment will be an adjunct to pharmacological therapy. Pretreatment and post-treatment data will be recorded using the specified outcome measures.

After dividing patients into two groups, Group A will receive Mitchell's relaxation, while Group B will receive Benson's relaxation, each for 30 minutes along with breathing exercises. Patients will undergo these interventions five days a week. All relaxation techniques will be combined with conventional physiotherapy exercises in both groups.

Conventional physiotherapy exercises will include:

- Respiratory exercises (diaphragmatic breathing)
- Flexion, extension and lateral rotation of the head
- Circumduction of the shoulders (forward and backward movements)
- Flexion and extension of the elbows and wrists
- Hand opening and closing
- Dorsiflexion and plantar flexion
- Circular movements of the ankles
- Internal and external rotation of the hip joint (coxofemoral joint)
- Flexion and extension of the knees while sliding on the bed

Follow-up of the patients will be conducted daily.

Control group: Each day, subjects in both groups will receive 30 minutes of Mitchell's relaxation exercises in addition to conventional physiotherapy exercises. Exercises used in conventional physiotherapy will include breathing exercises (diaphragmatic breathing), head flexion, extension and lateral rotation, shoulder circumduction (forward and backward movements), elbow and wrist flexion and extension and

hand opening and closing. Patients will also perform dorsiflexion, plantar flexion, ankle rotations, internal and external rotation of the hip joint and knee flexion and extension while gliding on a bed. Daily follow-up with patients will be conducted.

Mitchell's physiological relaxation technique combines a series of isotonic contractions centered on reciprocal inhibition with diaphragmatic breathing exercises.

Experimental group: After determining whether patients are at risk of preeclampsia, Benson's relaxation will be administered for 30 minutes. This technique is divided into five sections:

1. A calm environment: Choose a spot away from distractions.
2. Comfortable position: It's crucial to assume a comfortable position, whether standing, sitting, walking, or lying down.
3. Appropriate acceptance: Ensure that every muscle in the body is relaxed, starting from the soles of the feet and ending with the facial muscles.
4. Focus: Maintain awareness of breathing patterns, concentrating on inhaling through the nose and exhaling through the mouth.
5. Relaxation: Keep a carefree demeanor throughout the process.

The techniques work by decreasing endogenous catecholamine levels and the activity of the sympathetic nervous system.

Outcome Measures:

- Health-Related Quality of Life Scale (HRQOL): The SF-36 is a useful tool for assessment and a shorter version, the SF-12, has recently been developed, offering greater efficiency. It provides a more concise view of overall health.
- Beck Anxiety Inventory: This tool is used to assess the intensity of anxiety. It is a widely used self-report instrument consisting of 21 items, with scores ranging from 0 to 63 [24].
- Digital Sphygmomanometer: This valid and reliable device measures blood pressure pre- and post-intervention. It is readily available and known for producing accurate results. The Accusure brand digital sphygmomanometer will be used.

STATISTICAL ANALYSIS

All data will be summarised with baseline characteristics. Demographic variables will be described using frequency and percentage for categorical data and mean and standard deviation for continuous data. Outcome variables will be analysed over continuous variables and summarised with the minimum, maximum, mean, standard deviation, standard error and 95% confidence interval for parametric data. Continuous outcome variables will be tested for normality using the Kolmogorov-Smirnov test at a 5% level of significance ($p \leq 0.05$). If the null hypothesis is rejected, data will be considered normal; otherwise, a non parametric test will be used to determine significance. A t-test will be used to assess the significance of differences at a 5% level ($p \leq 0.05$) between Mitchell's relaxation along with conventional physiotherapy (control group) and Benson's Relaxation along with conventional physiotherapy (experimental group). Non normal data will be summarised by mean, median and lower and upper quartiles and significance will be assessed using the Wilcoxon rank-sum test. Categorical variables will be summarised by frequency (N) and percentage (%) and categorical variables, such as stunted and non stunted, will be analysed using Fisher's-exact test to identify significant associations with different risk factors. All confounding variables will be analysed using multivariate analysis.

Methods: Monitoring

Data monitoring: The Data Monitoring Committee of Ravi Nair Physiotherapy College is responsible for overseeing the data.

Harms: The physician in charge will be promptly informed of all adverse events, whether inadvertent or requested, as well as any unexpected outcomes from trial interventions or trial conduct. Reports will also be submitted to the ethical committee.

Ethics and Dissemination

Research ethics approval: The study has been presented to and approved by the IEC.

Consent and assent: Each participant included in the study will be informed about the research and asked to provide their informed consent and assent.

Confidentiality: All personal data about the research participants will be kept confidential. Patient information will only be used with consent obtained from the individuals.

Declaration of interests: To clarify, there are no conflicts of interest or financial interests.

Access to data: The Principal Investigator (PI) is responsible for the storage and maintenance of all data collected during and after the study. The final trial dataset will be made available to the PI upon formal request for research and publishing purposes only and access will be granted with data anonymisation.

Ancillary and post-trial care: In accordance with the policies of Ravi Nair Physiotherapy College and DMIHER, care will be provided to research subjects if any circumstances arise that result in injury from trial participation, as determined by the PI.

Statistical methods: Demographic data (age and gender) will be analysed using descriptive statistics. Descriptive statistics, including mean, standard deviation, n (%), Chi-square test and independent t-test, will be used to check the homogeneity of descriptive statistics. Inferential statistics between the two groups will be analysed using an unpaired t-test, with group comparisons analysed using the t-test and Statistical Package for the Social Sciences (SPSS) version 21.0. A p-value of less than 0.05 will be considered significant for the study.

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