International Journal of Clinical Trials
Venkadalakshmi V et al. Int J Clin Trials. 2024 Feb;11(1):66-72
http://www.ijclinicaltrials.com
pISSN 2349-3240 | eISSN 2349-3259

DOI: https://dx.doi.org/10.18203/2349-3259.ijct20240044

Protocol

The effectiveness of extended postpartum comprehensive health care bundle selected outcomes of women with preeclampsia at 6 months: protocol of a randomized controlled trial

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Received: 20 October 2023
Accepted: 14 November 2023

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ABSTRACT

Background: Women who have experienced pre-eclampsia (PE) may also face additional health problems in later life, as the condition is associated with an increased risk of death from 2-fold increased risk of long-term cardiovascular disease (CVD), hypertension, stroke, an approximate 5-12-fold increased risk of end-stage renal disease (ESRD), metabolic syndrome, and diabetes.
Methods: Method was randomized controlled trial. Women with PE who delivered in PGIMER will be enrolled and will be allocated into experimental ad control group using a computer random table with allocation concealment. Enrolment will be done at the time of discharge; baseline assessment will be done 6 weeks and the intervention bundle will be implemented to the women in experimental group. The women in control group will receive routine care. Women in both the groups will be followed up at 6 months.
Conclusions: This study aims to determine the effectiveness of "extended postpartum comprehensive health care bundle (EP CHC bundle)" on selected outcomes of women with preeclampsia at 6 months. The comprehensive health care bundle will be designed with the inputs from all stakeholders, has the potential to suit the dynamic nature of management of women with preeclampsia after delivery.
CTRI registration number: CTRI/2021/04/032749 ON 12/4/2021

Keywords: EP CHC bundle, Preeclampsia, Postpartum women cardiovascular risk in women

INTRODUCTION

Pre-eclampsia (PE) Is the most common hypertensive disorder reported during pregnancy, which remains one of the top five causes of maternal and perinatal mortality worldwide, it is also associated with long term disability, early cardiovascular morbidity and related complications.[1-8] There is growing consensus that associated CVD risk persists into later life, far beyond the affected pregnancy period. In meta-analysis with 198,252 pre-eclamptic women, it was concluded that in comparison to women with normotensive pregnancies, women with PE had 3.7-fold (95% CI: 2.70-5.05) relative risk for developing hypertension 14 years after

pregnancy, a 2.16 (95% CI: 1.86-2.52) relative risk for IHD after 12 years, a 1.81 (95% CI: 1.45-2.27) relative risk of stroke after 10 years and a 1.79 (95% CI: 1.37-2.33) relative risk for venous thromboembolism after 5 years.[9-12] Earlier occurrence of PE in pregnancy is associated with poorer outcomes; in addition, the severity of PE is correlated with severity of CVD later in life. Interventions aiming to prevent long-term adverse events need to be initiated since the time of diagnosis of PE, but is lacking in practice.[13-15] Postpartum lifestyle interventions i. e., comprehensive health care bundle which emphasises on diet, exercise, sleep, stress management, and cessation of smoking and alcohol tailored specifically for women following a hypertensive disorder of pregnancy will be the best solution to prevent long term complications. This may act as an effective primary prevention strategy.[14-20]

Objectives

Objective of current study is to compare lifestyle pattern, cardiovascular risk, quality of life and complications of women with PE between experimental (who followed comprehensive postpartum health care protocol) and control group (routine care) at 6 months after delivery.

Null hypothesis (Ho)

Ho (1) There will be no significant difference in life style pattern (diet, exercise, sleep and stress and quitting of alcohol, smoking, and any illicit drugs), quality life, cardiovascular risks (Cardiovascular risk score, Selected CVD risk factors), reported complications of women with PE between the experimental group (who followed a comprehensive postpartum health care bundle) and the controlled group (routine care) at 6th month after delivery.

METHODS

Table 1: Schematic representation of study design.

Control group	O1c	O2c	--	O3c
Experimental	O1e	O2e	X	O3e

O1c: Enrolment before discharge of control group, O1e: Enrolment before discharge of experimental group, O2c: Baseline assessment at 6 weeks of control group, O2e: Baseline assessment at 6 weeks of experimental group, X: intervention of PE EP CHC bundle at 6 weeks, O3c: Post intervention assessment of control group at 6th month and O3e: Post intervention assessment of experimental group at 6th month.

Design

A randomized control study with allocation concealment will be conducted to assess the effectiveness of PE-EPCHC bundle on various outcome variables at six months. Consolidated standards of reporting trials (CONSORT) statement will be followed to execute the randomized controlled trial (Figure 1). Standard protocol Items: recommendations for interventional trials (SPIRIT) statement will be used to construct and present the randomized controlled trial study protocol.

Intervention

The intervention in the present study is a PE-EPHC bundle for women with preeclampsia that will be given/implemented/delivered to the postnatal women at six weeks through a nurse-led counseling, booklet with illustrations, demonstration of selected physical activity/exercises and videos of the exercises sent on WhatsApp. The various components of PE-EPHC bundle includes information/training on lifestyle modification, with certain modification on diet, exercise, sleep, stress management, cessation of smoking and alcohol. To reinforce the intervention, remainder phone call or tailored text messages will be given at 10 and 14th week. Participants will be asked to maintain a compliance chart on diet, exercises, sleeping pattern, stress reduction activity and quitting of smoking and alcohol if any.

PE-EPHC bundle with the components of counseling, booklet, and videos (Exercise) which includes the domains of diet, exercise, sleep, stress and substance abuse is developed through extensive review of literature and evidence based guidelines taken from WHO, AHA, ICMR, ISSHP, FIGO, NICE, NHLBI and the opinion from the experts in the field of nursing. Physiotherapy, dietary, obstetrics, psychiatry, psychology, cardiology for postpartum care, PE, NCD/CVD prevention and lifestyle modification was sought before framing the bundle.

Validation of intervention

The PE-EPHC bundle was validated using Delphi rounds till consensus arrived. Delphi experts chosen from dept. of obstetrics, nursing, dietetics and physiotherapy and psychology. Feedback was taken from patients about each component on its feasibility and legibility/comprehension. The scale CVI of each component is maintained >0.8

Routine care

On the other hand control group will receive routine care from the health care providers as they discharged with antihypertensive medication, followed up at 1st, 2nd and 6th week postnatally in obstetric department and then referred to the internal medicine if blood pressure still not controlled, or symptoms persist or arise

Participants

Primiparous women with PE who delivered 34 POG onwards in obstetric units, having healthy live singleton baby and willing to participate in the study, those who are willing to follow up in PGIMER and those who are able speak and/or read English, Hindi and Panjabi and Those who are having and are able to operate a smartphone will be enrolled. Primiparous women with PE who has a

history of chronic diseases, postpartum psychosis, and thromboembolism and who developed severe postnatal complications during the hospital stay such as sepsis, stroke, ARDS, or got intubated/became unconscious will be excluded from the study.

Sample size and sampling technique

Sample size was calculated using www.openepi.com, according to the RCT by Rich-Edwards et al based on the effect size of outcome variable (life style pattern). Mean difference of physical inactivity in experimental group was 16.5±10.7 and in control group it was 22.7±16.5. Number of study participants required for study with 95% confidence level, 80% of test power was estimated at 79 in each group. Considering 20% attrition, the sample size for the study will be 95, hence we intend to take 100 in each group. Using total enumeration sampling technique, 200 primiparous mothers who delivered in obstetric units and visiting to obstetric OPDs during August 2022 to September 2023 will be enrolled and randomly allocated to experimental and control group.

Randomization and allocation concealment

Participants will be allocated consecutively into experimental and control group using a computer random table with allocation concealment using non-transparent sealed envelope method. The intervention bundle will be implemented to the women in experimental group. The women in control group will receive routine care. Women in both the groups will be followed up at 6 months.

Variables under the study

Independent variable of the study is PE-EPCHC bundle. Outcome variables of the study that will be measured at six months are lifestyle pattern (Diet, Physical activity, Sleep, Substance abuse) quality of life, cardiovascular risk (CVD risk score (Lipid profile, BP etc), Anthropometric measures (BMI, TSF, WHR, WC, HC), Echo changes) Complications developed after 6 weeks of delivery. Extraneous variables of the study include socio-demographic variables of the patient, severity of PE, availability of family and social support.

Tools and techniques

Depending on the study variables, the tools were selected or developed after extensive review of literature and suggestions from the experts. The tools used in the present study is enlisted with its purpose, validity and reliability in Table 2.

Table 2: Tool for data collection and its validity and reliability.

Tool	Purpose	Validity and reliability
Patient proforma	To assess the socio- demographic profile of women with history of preeclampsia	Validity >0.8
Socio-demographic profile clinical profile	To draw clinical profile the of women with history of preeclampsia	
komPAN dietary habits questionnaire	To assess the pro and non-healthy dietary index and 24 hour dietary recall	Reliability 0 .6 (Turconi et al, 2003)
WHO the global physical activity questionnaire	To assess the physical activity in METs	Reliability: 0.53 to 0.83 (Bull et al, 2009)
The Pittsburgh sleep quality index (PSQI)	To assess the sleeping pattern	Reliability: 0.736 (Buysse et al 1989)
Cohen perceived stress scale	To assess the level of perceived stress	Reliability: 0.79 (Andreou, 2011)
WHO ASSIST	To assess the substance use	Average test-retest reliability: 0.58-0.9
WHO BREFF QOL assessment scale	To assess the quality of life	Reliability: ≥0.7
QRISK3 cardio vascular disease assessment scale	To assess the risk of cardio vascular disease	R2 of 64.0% (63.8 to 64.4%); D statistic of 2.735 (2.716 to 2.753); and ROC statistic of 0.894 (0.893 to 0.896)
Echo machine	To assess ECHO	Calibrated
Sphygmomanometer	To measure Office BP	Calibrated
HbA1c analyser	To assess HbA1c	Calibrated
Au480 Beckman coulter device	To assess lipid profile	Calibrated
Weighing scale and height scale	To measure BMI	Calibrated
Measuring tape	To measure waist hip ratio	Calibrated
Mid arm circumference tape	To measure mid arm circumference	Calibrated

Continued.

Tool	Purpose	Validity and reliability
Vernier caliper	To measure triceps skin fold	Calibrated
Uristix reagent	To measure urine protein	Calibrated
Complications check list	To assess the developed complications	Validity >0.8
PE-EPCHC bundle	To modify the lifestyle behaviour	CVI of each component: >0.8. Suitability assessment of materials (SAM), established 'superior for the content'.
Video on physical activity/ exercise and progressive muscle relaxation therapy (PMR)	To teach exercise and stress management	Validity >0.8

Data collection procedure

Data will be collected from obstetric and internal medicine (Hypertensive clinic) units of PGIMER, Chandigarh at discharge and are advised for routine follow up at six weeks in OB OPD. Subjects who meet the inclusion criteria will be enrolled in the study. Written informed consent will be taken from the study subjects. Subjects will be randomly allocated into the experimental and control group using computer generated random numbers with allocation concealment. Sociodemographic and clinical profile will be collected at the time of discharge. and follow-up advice will be given at the time of discharge. During the follow up at 6th week in OPD, blood pressure, anthropometric measurements, urine protein and ECHO will be assessed. PE-EPCHC bundle will be given to the women in experimental group where they are counselled by the nurse cum researcher on life style modification and trained to do exercise by physiotherapist. Booklet containing the components on diet, exercise, sleep, stress reduction and quitting of substance abuse will be given to them. Video on physical activity/exercise-stress management and PMR will be send through WhatsApp and compliance chart also given to them. Reinforcement on life style modification at 10th and 14th week and reminder text messages will be given monthly by researcher to the women in experimental group. Control group will receive the routine follow up and advice from obstetrician. At 6th month postnatally women in both the groups will be reviewed in OPD where the researcher with the help of appropriate tools/techniques will assess all the outcome variables including dietary habits, physical activity, sleep pattern, stress level, consumption of smoking and alcohol and drugs, blood pressure, anthropometric measurements, lipid profile, HbA1C, ECHO, quality of life, development of complications and CVD risk assessment.

Feasibility evaluation-pilot study

Pilot study will be conducted in labour room and obstetric and internal medicine (Hypertensive clinic) OPDs to test the feasibility of the developed tool and intervention bundle.

Plan for data analysis

Descriptive data will be analysed using SPSS 23.0 (IBM, Armonk, New York). All data will be presented in terms of means, frequency, Standard deviation and confidence interval. A two-sided p=0.05 will be considered statistically significant. Per-protocol and intention-to-treat analysis will be done to compare outcomes at baseline, 6 months. All analysis will be done after adjusting for the confounding variables and socio-demographic variables at baseline between the control and experiment group. Chi-square test and Mann Whitney U test will be will be used to compare the non-parametric variables between the control and experimental group. Independent t test will be used to compare parametric variables between the control and experimental group. The missing values will be replaced using mean.

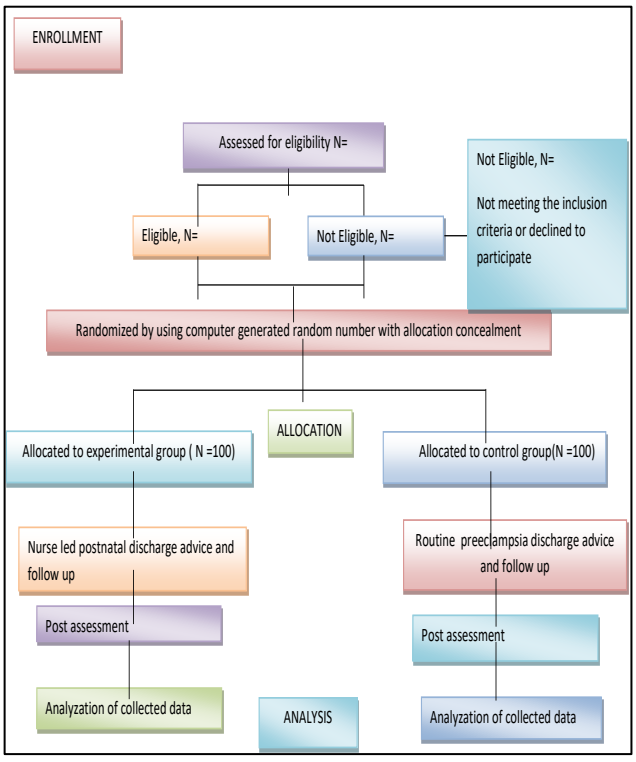

Figure 1: Consort diagram of the study.

Ethical considerations and dissemination

All relevant ethical guidelines will be followed at each step of the study. This study will involve the women with preeclampsia after delivery. The researcher will aim at administering comprehensive health care bundle to them. There will be no interference in the routine treatment plan of the postnatal women. There will be strict adherence to the principles of the declaration of Helsinki (2013, 7th edition, Fortaleza). The trial has being registered with the clinical trial registry of India (CTRI/2021/04/032749 ON 12/4/2021). The ethical approval of the study has been taken from the institute ethics committee, PGIMER, Chandigarh, India (Ethical clearance number: NK/6983/PhD/790), which is an independent body. All participants will be informed about the participation in the research, objectives of the study and duration of their involvement in advance and a participant information sheet will be given. Informed written consent will be taken from the participants. Full autonomy will be provided to the participants for withdrawing from the study at any time without any adverse effects on their subsequent care. Prior permission is obtained from the competent authority of the department of obstetrics and gynaecology and internal medicine. Confidentiality and anonymity of the participants will be ensured while data collection and reporting the results of the study.

DISCUSSION

Women are under-represented in clinical trials which may end up with the lack of data to make accurate clinical decisions on 51% of the world's population on pregnancy related disorders and future cardiometabolic disorders risk association.[21-25] Further research into the one of the pregnancy-specific risk factors i.e. preeclampsia effects would not only improve our understanding of the etiology of cardiometabolic disorders, but could also inform health policy makers and clinical guideline committees in tailoring sex-specific interventions for the treatment and management of these risk factors. That can be identified during reproductive life that may improve current risk assessment strategies for primary prevention of CVD.[26-30] A focus on primary prevention of CVD is necessary to reduce CVD mortality and the overall CVD burden among these specific papulations.

Weight retention trend in the first-year post-partum became a leading factor to adverse cardiometabolic profile to emerges as early as one year postpartum in women who do not lose weight between 3 and 12 months after delivery.[31-36] In Indian setting after delivery, maternal capacity for restoring normal weight regulation is enhanced by breastfeeding, but may be disrupted by lifestyle factors, including lack of time for exercise; traditional dietary changes, limited sleep duration because of their newborn baby, stress and substance abuse.[37,38]

Currently, postpartum lifestyle interventions tailored specifically for women following a hypertensive disorder of pregnancy are lacking although those demonstrated to be effective or their history is not taken into account of assessing the future CVD risk and other complications. Only 9% of internists and 38% of obstetrician-gynaecologists were providing cardiovascular risk-reduction counselling to women with a history of preeclampsia. Although the majority of obstetrician-gynaecologists were aware of higher CVD risk after PE, weaknesses exist in the follow up care and counselling of these patients.[20,39,40]

Nurse led assessment such as biophysical, biochemical and physiological and intervention, comprehensive health care bundle to post preeclamptic women would help to impart knowledge to women regarding her future risk and to identify early development of complication which will further facilitates women to step into obstetricians' and physicians' office early to get managed appropriately. This role of nurse would reduce the burden on time and energy on obstetricians and physicians especially when there is less obstetricians available during the follow-up. The women tent to visit health care facility regularly during her pregnancy and up to 6 weeks postpartum as per the WHO recommendations. This is the golden opportunity to catch-up and initiate interventions to the postnatal women with history of preeclampsia.

The present study is being planned at a tertiary-level obstetric units and internal medicine-hypertensive clinic in India. The investigator, VL, will be solely responsible for the administration of the interventions to the experimental group.

CONCLUSION

This study aims to determine the effectiveness of "EP CHC bundle" on selected outcomes of women with preeclampsia at six months. The comprehensive health care bundle will be designed with the inputs from all stakeholders, has the potential to suit the dynamic nature of management of women with preeclampsia after delivery.

ACKNOWLEDGEMENTS

The authors would like to thank the postgraduate institute of medical education and research, Chandigarh for supporting this research.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Venkadalakshmi V, Dhandapani M, Gainder S, Suri V, Das K, Vejeyvergiya R, Gosh A et al. The effectiveness of extended postpartum comprehensive health care bundle selected outcomes of women with preeclampsia at 6 months: protocol of a randomized controlled trial. Int J Clin Trials 2024;11(1):66-72.