

Research Article

Effect of Relaxation Therapy on Mild Pregnancy Induced Hypertension

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ABSTRACT

The study analyses the Effectiveness of relaxation therapy on the level of stress and physiological parameters among the antenatal mothers with mild pregnancy induced hypertension. Quasi experimental approach was adopted in the study to evaluate the effectiveness of relaxation therapy on the level of stress and physiological parameters. One group pre-test post-test research design was selected for the study. Determining an objective cause and effect relationship between relaxation therapy and level of stress and physiological parameters were a challenging effort. Since the difference in mean post therapy score is evident, however minor it may be, its implication is far reaching. It was an enriching professional experience for the investigator. As this study has opened up a new zone for independent nursing practice, its potentiality requires further exploration.

Keywords: stress; relaxation therapy; physiological parameters.

The relationship between hypertension in pregnancy and poor maternal and fetal outcome had long been recognized and the thrust of prenatal care is laid on improving the pregnancy outcome associated with pregnancy induced hypertension.¹ Hypertensive disorders of pregnancy if unchecked will result in eclampsia with generalized convulsions. The majority of the studies indicated that primiparae, of all age group showed a high rate of pregnancy induced hypertension and it was five times higher among the mothers above 30.² Pregnancy invariably involves a situational stress. When complications develop, threatening the lives of the expectant mother and her fetus the client and the family face a far greater situational stress. Studies have demonstrated that platelet activation in women with pre-eclampsia increases plasma catecholamine levels compared with normal pregnancy. High levels of stress over a prolonged period certainly have lifelong impact on the development of the child.³

It is acknowledged that techniques of relaxation and deep breathing go a long way in preparing pregnant women to cope with challenges and discomforts associated with child birth. Practicing relaxation and breathing

techniques also have a positive effect on the fetus. Several studies are being conducted on the impact of relaxation techniques on hypertension. The results revealed that all relaxation therapies were effective in reducing blood pressure, especially progressive muscle relaxation compared to cognitive imagery relaxation.⁴ The rate of maternal mortality due to hypertensive disorder during pregnancy is high, even where maternity services are highly improved. In India hospital facilities are less, even though there is high prevalence of pregnancy induced hypertension. The medical management of such case with drugs has its own disadvantages. For instance, anti hypertensive drugs will cause fetal complications like intrauterine growth retardation .So if such cases of hypertension are managed by non pharmacological measures it will be helpful for the mother and the fetus, especially the treatment of mild cases of pregnancy induced hypertension. It has been recommended that mild cases of pregnancy induced hypertension can be managed on an ambulatory basis by blood pressure monitoring, daily albumin checking, daily fetal movement counting (DFMC) and rest and relaxation at home.⁵ During her clinical experience, the investigator, identified

the majority of the women with pregnancy induced hypertension were overly worried about their high risk condition and poor health of the babies. This was devastated by the long hospital stays, finally ending in poor prognosis of the disease condition. Moreover, they showed symptoms like sleep disturbances, poor appetite and mood fluctuations. Although research has revealed the positive effects of relaxation techniques on women with pregnancy induced hypertension during the intra-partum period, little is known about the combined effect of progressive muscle relaxation, guided imagery and deep breathing exercises on the antenatal period. Hence the investigator recognized the need for a detailed study on the effect of relaxation therapy like guided imagery, progressive muscle relaxation and deep breathing – all simple, non intrusive and inexpensive methods which positively influence the outcome of pregnancy in women with pregnancy induced hypertension.

Objectives

To assess the level of stress and physiological parameters among antenatal mothers with mild pregnancy induced hypertension. The study also aims to find out the effect of Relaxation Therapy on the level of stress and physiological parameter among antenatal

mother with mild pregnancy induced hypertension.

Methodology

Research approach

A quasi- experimental approach was adopted. A quasi experiment involves the manipulation of an independent variable and it lacks randomization or a control group.^{6,7} Research design is the overall plan for obtaining answer to the research questions for testing the research hypotheses⁸. The design selected for this study was one group pretest post test design. All subjects were given a pretest, those in the experimental group were instructed to practice relaxation techniques. Then groups were asked to take a post test. The pretest was carried out on two days for assessing demographic data, physiological parameters and stress. Teaching section of Relaxation therapy was carried out for a period of two weeks, six days a week in the morning, between 10am to 11 am. The ethical committee has given sanction for the present study as per order: ACNYS/OP/2007/OC/242 dated on 31/07/2007. The research design adopted for the study is shown in the Table no: 1

Table 1: Diagrammatic representation of study design

Pre test	Intervention	Post test
Pre therapy assessment of stress level (O_1)	Relaxation Therapy (X)	Post therapy assessment (O_2)
Pre therapy assessment of physiological parameters like BP, Proteinuria, edema (O_1)	Relaxation Therapy (X)	Post therapy assessment (O_2)

Variables

A variable is something that varies or differs from one person to another.

1. Dependent Variables: Level of stress, Physiological parameters.
2. Independent Variable: Relaxation techniques, which include deep breathing, progressive muscle relaxation and guided imagery.
3. Extraneous Variables: Age, education, monthly income, location of the home, obstetrical score, religion, occupation & diet.

Setting of the study

The study was conducted at government hospital and A.J Hospital, Mangalore. The reason for the selection of these hospitals was

the availability of the required number of antenatal mothers with mild PIH.

Population

The population selected for the study comprised of 30 antenatal mothers with mild pregnancy induced hypertension.

Sample and sampling technique

The sample size consisted of 30 antenatal mothers with mild pregnancy induced hypertension. The sampling technique used was non probability, purposive sampling technique.

Sampling criteria

The samples were selected on the following criteria.

Inclusion criteria

- 1) Antenatal mothers with mild pregnancy induced hypertension
- 2) Antenatal mothers between 30-38 weeks of gestation
- 3) Antenatal mothers who know to read & write Kannada.

Exclusion criteria

- 1) Antenatal mothers with complications like diabetes, bleeding disorders, multiple pregnancy, renal and heart diseases.
- 2) Antenatal mothers, who do not speak, read or write Kannada.
- 3) Antenatal mothers less than 30 weeks of gestation
- 4) Antenatal mothers who are not cooperative.

Data collection instrument

"Data collection is the gathering of information needed to address the research problem⁸." The present study was planned primarily to determine the effectiveness of relaxation therapy on level of stress & physiological parameters of antenatal mothers with mild pregnancy induced hypertension, by using observation checklist and rating scale. Data collection was done by demographic data, assessing physiological parameters by using observation checklist before and after therapy and assessing stress by rating scale before and after relaxation therapy.

Selection and development of the tool

The investigator developed the tool after consulting the subject experts and reviewing the literature on relevant topics. The tool selected for the study were, demographic proforma, observation checklist, rating scale & relaxation therapy was developed.

Content validity of the tool

The prepared tool with the problem statement, objectives & criterion checklist was given to 9 experts to ensure content validity. Six experts were from the field of obstetrics and gynecological nursing specialty and two experts from obstetrics and gynecological specialty (doctors). The criterion checklist contained three columns of Agree, Disagree and Remarks / suggestion by the experts. Out of 39 items in the tool, 100% agreement for 36 items, 87.5% agreement for 2 items, 1 item was modified on the basis of expert opinion. Tools were translated to Kannada. The investigator had undergone 15 days Yoga and Relaxation Therapy training under Alva's yoga and naturopathy clinic.

Pre testing of the tool

After obtaining the permission from the medical superintendent and the obstetrician of Prabhu General Hospital, Moodbidri, the tool was pre-tested on a sample of 5 patients. The main purpose of pre-testing was to find out the clarity of the item. The respondents found the language of the rating scale were simple and understandable. The average time taken for pre-testing the tool was 30 minutes and was acceptable to the subject.

Reliability of tool

To ensure the reliability, the tool was administered to 10 antenatal mothers with mild pregnancy induced hypertension, admitted in Prabhu General Hospital, Moodbidri, after obtaining permission from the medical superintendent. The reliability coefficient of the tool was found using split half method following Spearman Brown Prophecy Formula. The reliability of the tool was found to be $r = 0.92$, which was statistically significant, this indicates that the tool was reliable.

Description of the final tool

The following tools were developed to collect data for evaluating the effect of relaxation techniques on women with mild PIH. **Tool – I** – Socio-demographic data collected by using a semi structured Interview schedule. **Tool – II** – An observation check list to assess the various signs and symptoms of clients with pregnancy induced hypertension. **Tool – III** – A stress inventory to assess the level of stress. **Tool – IV** – Relaxation techniques.

Pilot Study

After obtaining the written permission from the medical superintendent of Prabhu hospital, Moodbidri, and Alva's Health Centre, Moodbidri, a pilot study was conducted on 15-07-2007 to 06-08-2007 among 10 antenatal mothers. The objectives of the study were explained to each subject. Assessing the level of stress and physiological parameters by using check list & rating scale, relaxation therapy was administered to the subjects and reassessed the parameters and stress. The tool was found feasible and practicable. No change was made after the pilot study. The data was analyzed using descriptive & inferential statistics. The investigator decided to carry out the actual data collection after the pilot study.

Data collection process

The Data was collected from government hospital and A.J. Hospital, Mangalore. A formal letter was sent to the medical superintendent of the hospital and a written

permission was obtained to conduct the study. The consent was taken prior to the study from the subject and the nature of study was explained to the participants. The subjects were made comfortable and relaxation therapy was administered after assessing pre-therapy stress and physiological parameters, by means of observation check list & rating scale. The relaxation therapy was administered for 30 minutes daily for 2 weeks followed by assessment of post therapy scores. The clients were co-operative, excited and interested to do and practice the relaxation techniques; the data was thus collected and compiled for data analysis.

Plan for data analysis

The investigator planned to analyze the data by using both descriptive and inferential statistics.

RESULTS AND DISCUSSION

Organization of the study findings

The data collected from antenatal mothers with mild PIH is organized and presented under the following headings: **Section I:** Sample characteristics; **Section II:** To test the effectiveness of therapy. a) Effect of therapy on stress. b) Effect of therapy on physiological parameters. **Section III:** To assess the correlation between physiological parameters and stress scores. **Section IV:** To assess the association between pre-therapy scores of the level of stress and the selected variables such as age, obstetrical score, diet, occupation & religion.

Section I

The sample characteristics of 30 antenatal mothers with mild PIH were described in terms of frequency and percentage. The data are presented in Table 2 & 3.

Table 2: Frequency and percentage distribution of antenatal mothers with mild PIH based on their sample characteristics N =30

Demographic Characteristics	Frequency	Percentage
Age		
18 – 26 years	11	36.7%
27 – 35 years	10	33.3%
36 and above	9	30.0%
Monthly Income		
1500 – 3000	-	-
3001 – 4500	3	10%
4501 – 6000	20	66.7%
6001 – above	7	23.3%
Educational Status		
No formal Schooling	1	3.5%
Primary School	5	16.7%
High School	14	46.7%
College	9	30%
Professional	1	3.3%
Location of the home		
Rural	16	53.3%
Urban	14	46.7%
Obstetrical Score		
Gravida		
G ₁	9	30%
G ₂	17	56.7%
G ₃	4	13.3%
Para		
P ₀	9	30%
P ₁	17	56.7%
P ₂	4	13.3%
Abortion		
A ₀	28	93.3%
A ₁	2	6.7%
Religion		
Hindu	19	63.3%
Muslim	8	26.7%
Christian	3	10%

Table 3: Frequency and percentage distribution of antenatal mothers with mild PIH based on their sample characteristics N =30

Demographic Characteristics	Frequency	Percentage
Occupation		
House wife	26	86.7%
Laborer	-	-
Government Service	1	3.3%
Professional	3	10%
Private Service	-	-
Any other	-	-
Diet		
Vegetarian	15	50%
Non Vegetarian	-	-
Mixed	15	50%
History of PIH		
Yes	1	3.3%
If Yes, specify	2	6.7%
No	27	90%
Medical Treatment		
Yes	1	3.3%
If Yes, specify	-	-
No	29	96.7%
PIH in previous pregnancy		
Yes	1	3.3%
If Yes, specify	3	10%
No	26	86%

The findings of the study demonstrated that, among the subjects, majority were in the age group 18 to 26 years, majority had the income of 4501 to 6000, majority were Hindus, housewives, subjects from rural background, with high school education. 50% of subjects were vegetarians and 50% were mixed groups. Majority did not have previous history of PIH, had not undergone medical treatment for hypertension and PIH in previous pregnancy.

Section II

(a) Effect of therapy on stress

The data on the level of stress were analyzed in terms of mean, minimum score, maximum score, standard deviation and 't' value & were presented in Table 4. Table 3 shows that, the mean of pre-relaxation score (17.40) was significantly higher than the mean of post relaxation score (7.17). Hence, the null hypothesis was rejected and research hypothesis was accepted.

Table 4: Minimum score, maximum score, mean, standard deviation and 't' value of level of stress score

Stress Score	Minimum Score	Maximum Score	Mean	Standard Deviation	t value	Remarks
Pre relaxation Score	13	50	17.4	7.872	$t_{(29)} = 12.497$ $P = 0.000$	Highly significant (HS)
Post Relaxation Score	2	26	7.17	4.587		

$t_{(29)}=12.49$ table value $t_{(29)}=2.045$, $P<0.05$. Highly Significant.

b) Effect of therapy on physiological parameters

The data on physiological parameters were analyzed in terms of mean, minimum score, maximum score and standard deviation, were presented in Table 5&6. The data presented in table 4 shows that, the mean pre-therapy scores of diastolic BP (91.00) & Systolic BP

(141.67) was significantly higher than the mean of post therapy scores of diastolic BP (88.03) & systolic BP (137.80). Hence, the null-hypothesis was rejected and the research hypothesis was accepted.

Table 5: Minimum score, maximum score, mean standard deviation and 't' value of physiological parameter (SBP & DBP) N= 30

Physiological Parameter	Minimum Score	Maximum Score	Mean	Standard Deviation	t value	Remarks
Pre-diastolic BP Post diastolic BP	80 70	100 90	91.00 88.03	5.477 6.078	$t_{(29)} = 5.661$ $P = 0.000$	HS (Highly Significant)
Pre systolic BP Post systolic BP	130 120	150 140	141.67 137.80	8.743 8.313	$t_{(29)} = 4.331$ $P = 0.000$	HS (Highly Significant)

$t_{(29)}=5.661$, Table value $t_{(29)}=2.045$, $P<0.05$. Highly Significant

Table 6: Minimum score, maximum score, mean, standard deviation and Wilcoxon signed Rank test (Z test) of physiological parameters N=30

Physiological Parameters	Minimum Score	Maximum Score	Mean	Standard Deviation	Z value & P Value	Remarks
Pre Weight Post Weight	1 1	3 3	2.13 1.9	0.73 0.607	$Z = -2.646$ $P = .008$	HS(Highly Significant)
Pre Proteinuria Post Proteinuria	4 4	4 4	4 4	.000 .000	$Z = -.00$ $P = 1.000$	NS(Not Significant)
Pre Pitting Edema Post Pitting Edema	4 4	4 4	4 4	.000 .000	$Z = -.00$ $P = 1.000$	NS
Pre Headache Post Headache	1 1	4 4	2.20 3.07	.997 .828	$Z = -4.564$ $P = .000$	HS
Pre Edema Post Edema	1 2	5 5	3.47 4.10	1.167 .712	$Z = -3.126$ $P = .002$	HS
Pre Epigastric Pain Post Epigastric Pain	1 1	3 3	2.53 2.70	.776 .651	$Z = -2.236$ $P = .025$	Significant
Pre Sleep Post Sleep	3 3	3 3	2.03 2.47	.7890 .681	$Z = -2.969$ $P = .003$	HS

Z table value=1.96, Z cal=2.646, $P<0.01$. Highly Significant.

The data presented in Table 5 shows that, the mean of pre-therapy scores were weight (2.13), proteinuria (4) pitting edema (4), headache (2.20), edema (3.47) epigastric pain (2.53) sleep (2.03) and the mean of post therapy scores were, weight (1.90), proteinuria (4), pitting edema (4) headache (3.07) edema (4.10) epigastric pain (2.70) & sleep (2.47). There was a significant positive change in mean of pre-therapy scores & post therapy

scores of weight, headache, edema, epigastric pain and sleep and there was no significant difference in the mean of pre therapy scores and post therapy scores of proteinuria and pitting edema.

Section III In order to find the correlation between of physiological parameters and stress score, the following null hypothesis was tested.

Table 7: Correlation test on the significant correlation between physiological parameters and stress score, N=30

Physiological Parameters	Pre Relaxation Score	Remarks
Pre Diastolic BP	Pearson Correlation Coefficient = -.060 P = .73	No Significant Correlation
Post Diastolic BP	Pearson Correlation Coefficient = -.061 P = .995	No Significant Correlation
Pre Systolic BP	Pearson Correlation Coefficient = -.104 P = .583	No Significant Correlation
Post Systolic BP	Pearson Correlation Coefficient = -.068 P = .723	No Significant Correlation
Pre Weight	Spearman Coefficient = -.019 P = .922	No Significant Correlation
Post Weight	Spearman Coefficient = -.284 P = .128	Weak Correlation
Pre Proteinuria	r=0	No correlation
Post Proteinuria	r=0	No correlation
Pre Pitting Edema	r=0	No correlation
Post Pitting Edema	r=0	No correlation
Pre Headache	Spearman Coefficient = -.137 P = .471	No Significant Correlation
Post Headache	Spearman Coefficient = -.128 P = .500	No Significant Correlation

Table 8: Correlation test on the significant correlation between physiological parameters and stress score

Physiological Parameters	Pre-Relaxation Score	Remarks
Pre Edema	Spearman Coefficient = -.109 P = .568	No Significant Correlation
Post Edema	Spearman Coefficient = .071 P = .710	No Significant Correlation
Pre Epigastric Pain	Spearman Coefficient = -.317 P = .088	Moderate Correlation
Post Epigastric Pain	Spearman Coefficient = -.019 P = .919	No Significant Correlation
Pre Sleep	Spearman Coefficient = -.033 P = .863	No Significant Correlation
Post Sleep	Spearman Coefficient = -.279 P = .136	Weak Correlation

The data presented in Table 7 and 8 shows that, the r value for pre-therapy scores were, diastolic BP ($r = -.060$), systolic BP ($r = -.104$), weight ($r = -.019$), proteinuria ($r = 0$), pitting edema ($r = 0$), headache ($r = .137$), edema ($r = .109$), epigastric pain ($r = .317$) sleep ($r = .33$). There was no significant correlation between pre-therapy scores of diastolic BP, systolic BP, weight, edema, headache and sleep & pre relaxation score ($r < .3$). There was moderate correlation between pre-therapy scores of epigastric pain

and pre- relaxation score ($r = .3-.5$). Hence, the null hypothesis was accepted and research hypothesis was rejected. The findings of the study revealed that the mean pre-relaxation score (17.40) on level of stress was significantly higher than the mean of post relaxation scores (7.17). This shows that, relaxation therapy had reduced level of stress in antenatal mothers with mild pregnancy induced hypertension. The findings of the present study is congruent with the study conducted in the United States, on effect of progressive muscle relaxation attention control

and silence on stress response, the findings suggested that cognitive cues provided by stress management techniques contributed to relaxation.

Section IV

In order to find the association between pre-therapy scores of the level of stress and the

selected variables such as age, obstetrical score, diet, occupation and religion, the following null hypothesis was tested. Chi-Square test of association was computed (Table: 9 and 10) to determine the association between pre-therapy scores of the level of stress & the selected variables such as age, obstetrical score, diet, occupation & religion.

Table 9: Chi-square test to determine the significant association between Stress, and selected variables N = 30

Demographic Characteristics	Pre – Relaxation Score		Total	χ^2 (d.f)	Remarks
	No Stress	Mild Stress			
Age					
18-26 years	7	4	11	$\chi^2_{(1)}$ = 0.142 P = .838	Not Significant
27-35 years	6	4	10		
36 and above	4	5	9		
Monthly Income					
1500 - 3000				$\chi^2_{(1)}$ = 0.165 P = 0.684	Not Significant
3001 - 4500	3	0	3		
4501 - 6000	11	9	20		
6001 - above	3	4	7		
Education					
No Formal Schooling	0	1	1	$\chi^2_{(1)}$ = 1.086 P = 0.297	NS
Primary School	3	2	5		
High School	7	7	14		
College	7	2	9		
Professional	0	1	1		
Location of the Home					
Rural	8	8	16	$\chi^2_{(1)}$ = 0.624 P = 0.431	NS
Urban	9	5	14		
Obstetrical Score					
Gravida				$\chi^2_{(1)}$ = 0.524 P = 0.469	NS
G1	6	3	9		
G2	9	8	17		
G3	2	2	4		
Para P0					
P1	6	3	9	$\chi^2_{(1)}$ = 4.180 P = 0.041	NS
P2	9	8	17		
	2	2	4		
Abortion A₀					
A ₁	16	12	28	$\chi^2_{(1)}$ = 0.0001 P = 0.687	NS
	1	1	2		
Religion					
Hindu	10	9	19	$\chi^2_{(1)}$ = 0.344 P = 0.558	NS
Muslim	4	4	8		
Christian	3	0	3		
Diet					
Vegetarian	8	7	15	$\chi^2_{(1)}$ = 0.136 P = 0.716	NS
Non Vegetarian					
Mixed	9	6	15		

Table 10: Chi-square test to determine the significant association between Stress, and selected variables N=30

Demographic Characteristics	Pre – Relaxation Score		Total	χ^2 (d.f)	Remarks
	No Stress	Mild Stress			
Occupation					
Housewife	15	11	26	$\chi^2_{(1)}$ =0.084 P = 0.773	NS
Labourer	1	0	1		
Government .Service Professional	1	2	3		
History of PIH					
Yes	0	1	1	$\chi^2_{(1)}$ =0.136 P =0.713	NS
If yes, Specify	2	0	2		
No	15	12	27		
Medical Treatment					
Yes				$\chi^2_{(1)}$ =0.0002 P =0.99	NS
If yes, Specify	1	0	1		
No	16	13	29		
PIH in Previous Pregnancy					
Yes	0	1	1	$\chi^2_{(1)}$ =0.632 P =0.427	NS
If yes, Specify	3	0	3		
No	14	12	26		

$\chi^2_{(1)} = 0.084$, Table value $\chi^2_{(1)} = 3.84$, $P > 0.05$. Not Significant.

The data presented in the Table 9 and 10 shows that, there was no significant association between pre therapy scores of level of stress and the selected variables, age ($\chi^2_{(1)} = 0.042$, $P = 0.835$), income ($\chi^2_{(1)} = 0.165$, $P = 0.684$), education ($\chi^2_{(1)} = 1.086$, $P = 0.297$), location ($\chi^2_{(1)} = 0.621$, $P = 0.431$) obstetrical score (gravida ($\chi^2_{(1)} = 0.524$, $P = 0.469$), para ($\chi^2_{(1)} = 4.180$, $P = 0.041$), abortion ($\chi^2_{(1)} = 0.0001$, $P = 0.687$), religion ($\chi^2_{(1)} = 0.344$, $P = 0.558$), occupation ($\chi^2_{(1)} = 0.084$, $P = 0.773$), diet ($\chi^2_{(1)} = 0.136$, $P = 0.136$), history of PIH ($\chi^2_{(1)} = 0.136$, $P = 0.713$), medical treatment ($\chi^2_{(1)} = 0.0002$, $P = 0.99$) PIH in previous pregnancy ($\chi^2_{(1)} = 0.632$, $P = 0.427$). Here $\chi^2_{(1)} < 3.84$, $P > 0.05$, hence the null hypothesis was accepted and research hypothesis was rejected. Therefore it was interpreted that there was no significant association between pre-therapy scores of level of stress and selected variables. The study findings revealed that, there was no significant correlation ($r < .3$) between pre-therapy scores of physiological parameters and pre-relaxation scores. There was moderate correlation between pre-therapy scores of epigastric pain ($r = .317$) and pre-relaxation scores of stress. As there is an increasing incidence of hypertensive disorders of pregnancy, nurses should conduct researches on the development of intervention strategies of early detection and prevention of its sequela on the mother and the fetus. Hence research in this area should be promoted by providing funds, personnels and materials.

Limitations

As the study is limited to 30 samples, and sampling technique being non probability purposive, generalization of the finding is

limited. The changes in the physiological status after administering the post test are not taken into account. Relaxation therapy was practiced only for a duration of 1 ½ weeks due to high attrition rate of the sample. Being quasi experimental, one group pretest and post test design and its internal validity is open to question. The investigator could not control the effect of antihypertensive drugs due to ethical reasons.

Recommendations

A similar study can be replicated on a larger sample using probability sampling techniques. A study can be conducted by using relaxation therapies for a longer period of time. A similar study can be replicated in another setting. Another study can be conducted to monitor the effect of relaxation therapies during the intra-natal period on women with pregnancy induced hypertension. A comparative study can be done to evaluate the effect of relaxation therapy in two groups without the treatment of drugs.

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