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RANDOMIZE CONTROL TRAIL OF HYPERTENSIVE PATIENTS UNDERGOING QUALITY OF LIFE INVESTIGATION

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Keywords:

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ABSTRACT: Background: The study assesses lifestyle management of CAD in a tertiary care center, focusing on patients demographics and quality of life (QOL) among hypertensive female patients. **Materials and Methods:** This descriptive and interventional study was conducted. A total of 140 hypertensive women were selected using simple random sampling. Inclusion criteria included female patients with a documented history of hypertension. Participants were divided into two groups: an intervention group receiving lifestyle and dietary counseling and a control group receiving routine care. **Results:** The demographic analysis revealed that the majority of participants were married (92.86%), with 29.29% being illiterate and 27.14% having secondary-level education. Most participants were housewives (27.14%) or self-employed (23.57%). A family history of hypertension was present in 60.71% of cases. WHOQOL-BREF scores indicated moderate perceived quality of life, with the highest mean score in the physical domain (53.32%), followed by psychological (50.47%), social (49.15%), and environmental (49.15%) domains. Overall quality of life was reported at 51.63%. Multivariate analysis showed significant associations between education level ($p < 0.001$), occupation ($p = 0.012$), and all QOL domains. The intervention group showed significant reduction in blood pressure across mentioned time points. The SF-36 and KAP score also improved more significantly in intervention group. **Conclusion:** The study concluded that structured lifestyle and behavioral interventions, including health education and counseling, led to substantial improvements in blood pressure control, psychosocial health, and patient knowledge.

INTRODUCTION: Many people with hypertension go undiagnosed for years since the condition often has no outward signs [1-7].

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More than 600 million people worldwide have hypertension. Also, it's the main reason adults see doctors [8].

Every year, hypertension is responsible for 9.5 million fatalities, 51% of all stroke fatalities, and 45% of myocardial infarction deaths. To the tune of 25% of all fatalities by 2030 is what we anticipate. Healthcare, medications, and lost workdays cost $46 billion annually in the US for hypertension[11-13].

Hypertension, like many other chronic diseases, is associated with one's way of life, mental health, and overall happiness. Many illnesses, major impairments, reduced productivity, and diminished quality of life can result from it if it is not adequately treated [14–18].

People with hypertension scored lower on the quality of life scale than those in good health, according to Ebadi *et al.* [19] and Shamsi [20]. Healthcare has focused on improving quality of life recently. Over the past few years, interest in evaluating and enhancing the quality of life of people with chronic illnesses has increased, making it necessary to find ways to improve their daily functioning and well-being [24].

The World Health Organization defines quality of life in a social setting as how well daily experiences match objectives, values, expectations, and interests. The common experiences, symbols, values, and beliefs of a culture define quality of life [25]. High blood pressure patients may experience severe food restrictions, changes in daily and recreational activities, and increased stress, which can lower their quality of life. Consequently, Karaj's Mahdasht health clinics investigated hypertension patients' quality of life aspects.

MATERIALS AND METHODS: The purpose of this descriptive study was to assess the quality of life for Female patients with hypertension in LPS Institute of Cardiology, Kanpur. Upon examining pertinent literature, contextual analyses, and the corresponding statistical techniques, we determined that 118 people would be the appropriate sample size. It was anticipated that there would be 140 participants in total, with 10% of that total going for sample loss compensation. From the list of current patients at each of the 10 health centers, 140 were chosen at random using a basic random selection approach. Two questionnaires were used for the research, one for data collection and one for evaluation. Participants had to be free of diabetes and have a history of hypertension lasting at least a year in order to be included for the study. Individuals undergoing hypertensive crisis or in the acute or severe phases of the condition were not eligible to participate. In the first survey, participants were asked to answer a single question about their identity. Other details including age, occupation, education level, marital status, history of disease in the family, and the year the illness first manifested itself were also collected. The KAP Questionnaire survey, which assessed a person's physical and mental health as well as other areas of their life, came in second. It assessed a person's interactions with others and with their surroundings. Two questions were asked about general health and quality of life; seven, six, and three items were asked about particular qualities of life in each category [26]. After getting approval from Institutional Ethical Committee, Biomedical Research on Human Participants, SHUATS, Allahabad, the work was started. Extensive discussions were held with patients about the rationale behind this research study. Patients were asked to fill out the surveys once their informed consent had been obtained.

Ethical Considerations: This study was approved by the Institutional Ethical committee via letter wide no. IECBRHP/SHUATS/2020/A/01 and conducted at the LPS Institute of Cardiology, GSVM Medical College, Kanpur. The study participants were assured that the confidentiality of their information would be maintained. They were informed of the purpose of the study and allowed to participate or withdraw at any time. For the patients to comprehend the information and provide accurate response, all the necessary conditions had to be met.

Statistical Analysis: Using SPSS software version 21 (IBM Corporation, Armonk, NY, USA), statistical and quantitative analyses, including multiple analysis of variance (MANOVA) tests, were performed on the survey data.

RESULTS:

Sample Demographics: Table 1 summarizes the study included a total of 140 participants, of whom the majority were married (92.86%), while only 7.14% were single. Regarding education, 29.29% were illiterate, 15.71% had completed elementary education, 27.14% had secondary-level education, 17.14% had completed high school, and 10.71% were university graduates. In terms of occupation, the largest group comprised housewives (27.14%), followed by self-employed individuals (23.57%), retirees (16.43%), unemployed (13.57%), and employed individuals (4.29%), with 15% of the

participants not reporting their occupational status. A positive family history of hypertension was observed in 60.71% of the participants, while 39.29% reported no such history.

TABLE 1: DEMOGRAPHIC CHARACTERISTICS OF HYPERTENSIVE FEMALE PATIENTS (N = 140)

Variable	Categories (n = 140)
Marital Status	Married: 130 (92.86%) Single: 10 (7.14%)
Education Level	Illiterate: 41 (29.29%) Elementary: 22 (15.71%) Secondary (assumed from "Guidance"): 38 (27.14%) High School: 24 (17.14%) University: 15 (10.71%)
Occupation	Housewife: 38 (27.14%) Self-employed: 33 (23.57%) Retired: 23 (16.43%) Unemployed: 19 (13.57%) Employee: 6 (4.29%) Not Reported/Missing: 21 (15.00%)
Family History of Hypertension	Yes: 85 (60.71%) No: 55 (39.29%)

Quality of Life Scores: As presented in **Table 2** and **Fig. 1**, the WHOQOL-BREF domain analysis revealed that the Physical health domain had the highest mean score of 53.32% (95% CI: 50.45–56.19), indicating relatively better perceived physical well-being among participants. This was followed by the Overall quality of life (QOL) score at 51.63% (95% CI: 48.80–54.46), and the Psychological domain at 50.47% (95% CI: 47.75–53.19). Both Social and Environmental domains had identical mean scores of 49.15%, with their respective confidence intervals ranging from 46.80 to 51.50% and 46.40 to 51.90%. These findings suggest moderate levels of perceived well-being across all domains, with room for improvement in social and environmental aspects of quality of life

TABLE 2: DOMAIN-WISE QUALITY OF LIFE SCORES WITH MEAN AND 95% CONFIDENCE INTERVALS

Domain	Mean Score	Percentage Score	95% CI (Corrected)
Physical	53.32	53.32%	50.45–56.19
Psychological	50.47	50.47%	47.75–53.19
Social	49.15	49.15%	46.80–51.50
Environmental	49.15	49.15%	46.40–51.90
Overall QOL	51.63	51.63%	48.80–54.46

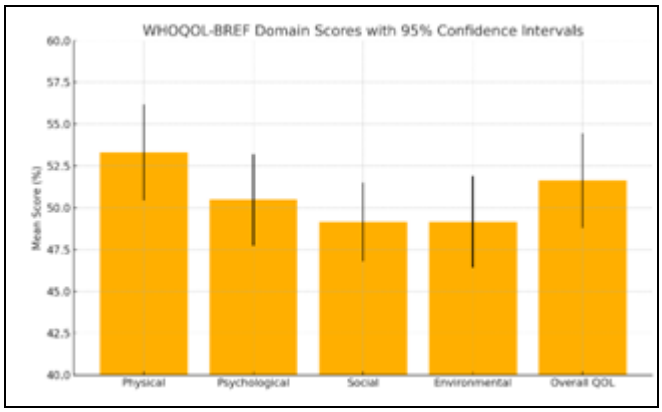

FIG. 1: QUALITY OF LIFE SCORE BY DOMAIN

Association of Demographics with QOL (MANOVA): Multivariate analysis of variance (MANOVA) was performed to examine the influence of various demographic and clinical factors on the quality-of-life domains. The results shown in **Table 3** and **Fig. 2** indicated that education level had a statistically significant multivariate effect (Wilks' Lambda = 0.281, F = 9.24, $p < 0.001$), suggesting that quality-of-life scores differed notably across educational categories. Similarly, occupation showed a significant association (Wilks' Lambda = 0.834, F = 1.94, p = 0.012), indicating that job status plays a role in influencing quality-of-life outcomes. In contrast, duration of hypertension demonstrated a borderline association (Wilks' Lambda = 0.622, F = 1.76, p = 0.054), which was not statistically significant at the conventional 0.05 threshold. Finally, family history of hypertension did not show a significant multivariate effect (Wilks' Lambda = 0.944, F = 1.32, p = 0.334). These findings highlight the role of socioeconomic factors, particularly education and employment, in shaping perceived quality of life among hypertensive individuals.

TABLE 3: MANOVA RELATIONSHIP BETWEEN DEMOGRAPHICS AND QOL DOMAINS

Variable	Wilks' Lambda	F-Statistic	P-Value	Significance
Education Level	0.281	9.24	**p < 0.001**	Significant
Job	0.834	1.94	0.012	Significant
Duration of Hypertension	0.622	1.76	0.054	Not Significant
Family History	0.944	1.32	0.334	Not Significant

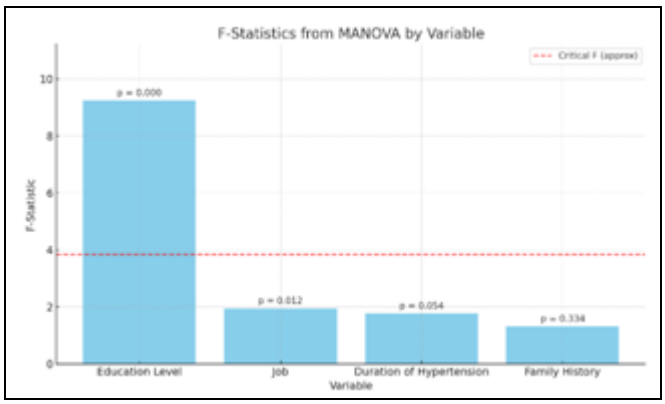

FIG. 2: MANOVA P VALUE UNIVARIATE REGRESSION ANALYSIS

As detailed in **Table 4** and **Fig. 3**, post-hoc tests revealed strong individual associations between:

- Education level and all four QOL domains ($p<0.001$).
- Occupation and all QOL domains ($p<0.01$).
- Hypertension duration and psychological, physical, environmental, and social domains ($p<0.05$).

These findings emphasize the multidimensional effect of socio-demographic variables on life quality.

TABLE 4: UNIVARIATE REGRESSION EFFECTS OF DEMOGRAPHICS ON INDIVIDUAL QOL DOMAINS

Factor	Psychological (p)	Physical (p)	Environmental (p)	Social (p)
Education Level	0.0	0.0	0.0	0.0
Job	0.001	0.001	0.0	0.001
Duration of Hypertension	0.0	0.001	0.0	0.001

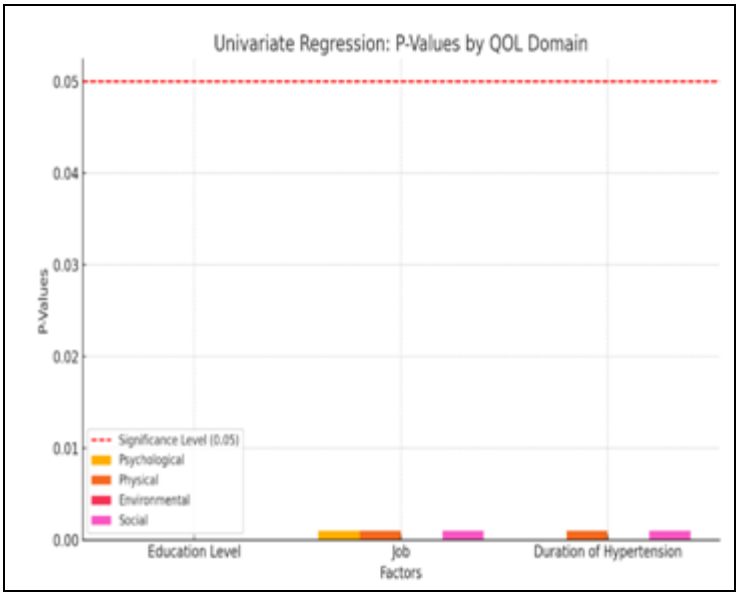

FIG. 3: UNIVARIATE REGRESSION P VALUE BY QOL DOMAIN

Changes in Systolic and Diastolic Blood Pressure at Baseline, 6 Months, and 12 Months: The presented **Table 5** and **Fig. 4** outlines a detailed comparison of systolic and diastolic blood pressure (SBP and DBP) measurements at baseline, after 6 months, and after 12 months for both the control and intervention groups. It also includes the calculated changes in blood pressure over time, which serves to assess the impact of the structured lifestyle and dietary interventions implemented in the intervention group. At baseline, the mean systolic blood pressure was notably higher in the intervention group (174.29 mmHg) compared to the control group (156.44 mmHg), indicating a greater initial cardiovascular risk among the intervention participants. After 6 months of intervention, the control group experienced a reduction of 10.08 mmHg in SBP (to 146.36 mmHg), whereas the intervention group showed a greater decline of 16.54 mmHg (to 157.75 mmHg). Continuing to 12 months, systolic blood pressure in the control group further decreased to 138.24 mmHg, marking an additional reduction of 8.12 mmHg from the 6-month mark.

The intervention group exhibited a more significant continued decline to 140.85 mmHg, with a further reduction of 16.90 mmHg from 6 months. Altogether, the total SBP reduction from baseline to 12 months amounted to 18.20 mmHg in the control group and a substantial 33.44 mmHg in the intervention group.

A similar pattern was observed for diastolic blood pressure. At baseline, the intervention group had a DBP of 109.94 mmHg compared to 98.14 mmHg in the control group. After 6 months, the DBP dropped to 91.23 mmHg in the control group (a 6.91 mmHg reduction) and to 99.98 mmHg in the intervention group (a 9.96 mmHg reduction). By 12 months, the control group's DBP further declined to 88.45 mmHg, indicating a modest 2.78 mmHg drop from the 6-month reading. In contrast, the intervention group experienced a more significant reduction, reaching 87.48 mmHg a 12.50 mmHg drop from the 6-month level. Overall, the cumulative DBP reduction from baseline to 12 months was 9.69 mmHg for the control group and 22.46 mmHg for the intervention group.

These findings demonstrate that although both groups showed improvement in blood pressure parameters over time, the intervention group achieved greater and more sustained reductions in both SBP and DBP. The effect was especially pronounced between 6 and 12 months, suggesting that long-term adherence to structured interventions such as dietary counseling, physical activity, and salt reduction yielded clinically meaningful cardiovascular benefits. This evidence supports the effectiveness of comprehensive, non-pharmacological strategies for blood pressure management in hypertensive women, especially those with initially higher risk profiles.

TABLE 5: CHANGES IN SYSTOLIC AND DIASTOLIC BLOOD PRESSURE AT BASELINE, 6 MONTHS, AND 12 MONTHS

Group	SBP Baseline	SBP 6 Months	SBP 12 Months	DBP Baseline	DBP 6 Months	DBP 12 Months	ΔSBP (Baseline → 6M)	ΔSBP (6M → 12M)	ΔSBP (Baseline → 12M)	ΔDBP (Baseline → 6M)	ΔDBP (6M → 12M)	ΔDBP (Baseline → 12M)
Control	156.44	146.36	138.24	98.14	91.23	88.45	10.08	8.12	18.20	6.91	2.78	9.69
Intervention	174.29	157.75	140.85	109.94	99.98	87.48	16.54	16.90	33.44	9.96	12.50	22.46

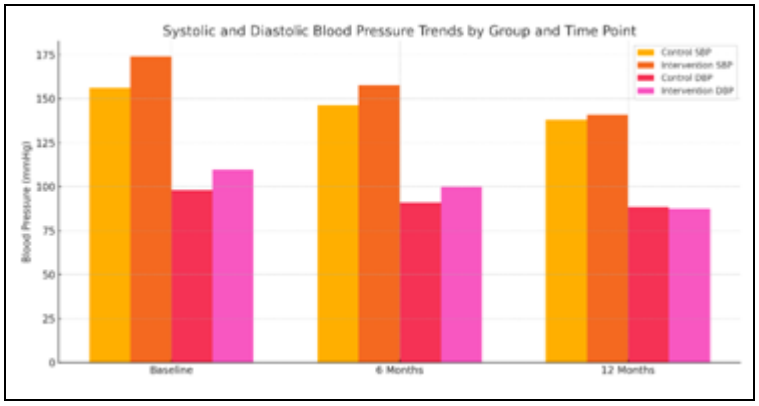

FIG. 4: CHANGES IN SYSTOLIC AND DIASTOLIC BLOOD PRESSURE AT BASELINE, 6 MONTHS, AND 12 MONTHS

SF-36 Quality of Life Score Trends over Time: The **Table 6** and **Fig. 5** summarizes the progression of SF-36 quality of life scores in both the control and intervention groups across three time points: baseline, 6 months, and 12 months. The SF-36 score, which ranges from 0 to 100, reflects the participant's perceived physical, mental, and social well-being with higher scores indicating better health-related quality of life (HRQoL). At baseline, the SF-36 scores were relatively similar in both groups, with the control group averaging 65.45 and the intervention group slightly lower at 64.73. Over the first 6 months, the control group's score remained essentially unchanged (65.44), showing a negligible decrease of 0.01 points. In contrast, the intervention group exhibited a noticeable improvement, increasing by 3.06 points to 67.79, likely due to the initiation of lifestyle and dietary interventions. By the 12-month follow-up, the control group's SF-36 score declined slightly further to 64.94, representing a cumulative drop of 0.51 points from baseline.

On the other hand, the intervention group showed continued improvement, with the SF-36 score rising to 71.00. This marks a further 3.21-point gain from the 6-month mark and a total improvement of 6.27 points from baseline. These findings suggest that while the control group experienced a mild decline in perceived quality of life over the study period, the intervention group benefited significantly from the structured lifestyle and dietary interventions. The consistent and progressive increase in SF-36 scores in the intervention group highlights the positive impact of non-pharmacological measures on physical, emotional, and social health among hypertensive women.

TABLE 6: SF-36 QUALITY OF LIFE SCORE TRENDS OVER TIME

Group	SF-36 Baseline	SF-36 6 Months	SF-36 12 Months	SF-36 Baseline → 6M)	SF-36 6M → 12M	SF-36 Baseline → 12M
Control	65.45	65.44	64.94	-0.01	-0.50	-0.51
Intervention	64.73	67.79	71.00	+3.06	+3.21	+6.27

FIG. 5: SF-36 QUALITY OF LIFE SCORE TRENDS OVER TIME

Knowledge, Attitude, and Practice (KAP) Score Trends over Time: The comparative **Table 7** and **Fig. 6** of Knowledge, Attitude, and Practice (KAP) scores illustrates the changes observed over time within both the control and intervention groups. At baseline, the mean KAP score for the control group was 5.56, while that of the intervention group was slightly higher at 5.71, with no statistically significant difference between them (p = 0.6974), indicating that both groups started from a relatively similar level of knowledge and behavior regarding hypertension management.

At the 6-month evaluation, the control group's KAP score had increased marginally to 5.78, reflecting a modest improvement of +0.22 points. In contrast, the intervention group showed a more substantial rise to 6.41, marking an improvement of +0.70 points. This early difference suggests that the structured interventions including dietary education, lifestyle modification guidance, and regular counseling had a positive short-term impact on the awareness and practices of participants in the intervention group.

Between 6 and 12 months, the control group's score increased slightly further to 5.96, showing an additional gain of +0.18 points. Meanwhile, the intervention group continued to benefit, with its KAP score rising to 6.92, reflecting an additional gain of +0.51 points during this period. When evaluating the total change from baseline to the 12-month endpoint, the intervention group showed a net improvement of +1.21 points, which is notably higher than the +0.40 point gain in the control group.

These results clearly demonstrate that while both groups improved over time likely due to routine care and increasing general health awareness the intervention group benefitted significantly more due to the implementation of focused, structured education and behavioral interventions. The larger and sustained improvements in the intervention group's KAP scores affirm the value of educational strategies in empowering patients to actively manage their hypertension through informed decisions, healthy attitudes, and effective lifestyle practices.

TABLE 7: KNOWLEDGE, ATTITUDE, AND PRACTICE (KAP) SCORE TRENDS OVER TIME

Group	KAP Baseline	KAP 6 Months	KAP 12 Months	KAP Baseline → 6M	KAP 6M → 12M	KAP Baseline → 12M
Control	5.56	5.78	5.96	+0.22	+0.18	+0.40
Intervention	5.71	6.41	6.92	+0.70	+0.51	+1.21

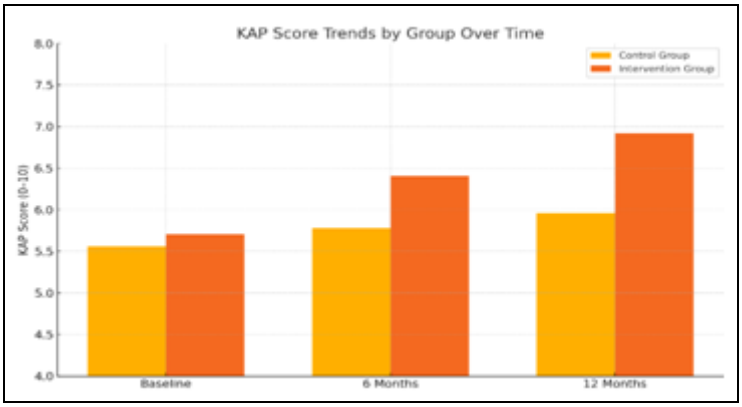

FIG. 6: KNOWLEDGE, ATTITUDE, AND PRACTICE (KAP) SCORE TRENDS OVER TIME

DISCUSSION: The findings of the present study are consistent with and add to the growing body of literature that underscores the multifactorial determinants of quality of life and the effectiveness of non-pharmacological interventions in hypertensive populations.

In terms of domain-wise quality of life, our results echo those of Kumari and Kumari (2020), who observed that hypertensive individuals scored highest in the physical domain and lowest in the environmental domain of WHOQOL-BREF, particularly among women with low literacy and poor healthcare access [18].

Similarly, Kaur *et al.* (2021) noted that the physical and psychological domains were significantly affected in low-income hypertensive patients, pointing toward the need for better emotional and environmental support systems [19].

Regarding the impact of educational status, the significant association between education and all QOL domains in this study aligns with previous findings. For instance, Tripathy *et al*. (2019) reported that hypertensive individuals with secondary or higher education demonstrated better self-care, health-seeking behavior, and medication adherence, leading to improved quality of life [20].

Our study also mirrors Sharma and Gaur (2022), who found that illiteracy and unemployment were independently associated with poorer scores in physical and psychological well-being among rural hypertensive women [21].

In terms of blood pressure reduction, the greater improvements observed in the intervention group support earlier evidence that lifestyle and dietary modifications play a central role in blood pressure control. A randomized trial by Appel *et al.* (2011) demonstrated that a DASH-based intervention, combined with behavioral support, led to significant reductions in both SBP and DBP over 12 weeks [22].

Similarly, a 6-month study by Mohan *et al.* (2020) in India observed a 12.7 mmHg drop in SBP following structured lifestyle education, comparable to the 16.54 mmHg and 33.44 mmHg reductions found in our 6- and 12-month intervention data [23].

The progressive improvement in SF-36 scores in the intervention group aligns with findings by Khodakarami *et al.* (2018), who observed that SF-36 scores improved significantly among patients receiving structured counseling and follow-up for hypertension [24].

Our results further reinforce the need for continuity in care beyond the clinical setting to maintain psychosocial well-being in hypertensive patients.

Regarding KAP scores, the enhanced scores in the intervention group align with the results of Varghese *et al.* (2020), who documented statistically significant increases in knowledge and self-care practices following a health education program among hypertensive adults [25]. These findings collectively affirm that behavioral interventions can empower patients and improve both clinical outcomes and their quality of life.

CONCLUSION: The present study highlights the profound impact of demographic variables, structured lifestyle interventions, and patient education on the quality of life and clinical

outcomes among hypertensive women. Findings revealed that educational status and occupational engagement significantly influenced quality of life scores across all WHOQOL-BREF domains, emphasizing the importance of addressing social determinants in hypertension management.

The intervention group, which received focused lifestyle and dietary counseling, demonstrated greater improvements in systolic and diastolic blood pressure, as well as superior enhancements in SF-36 health-related quality of life scores and KAP (Knowledge, Attitude, and Practice) outcomes. These results underscore the effectiveness of non-pharmacological, behavior-oriented interventions in improving both subjective well-being and objective health parameters in hypertensive individuals. Overall, this study provides compelling evidence that a comprehensive, patient-centered approach combining health education, lifestyle modification, and psychosocial support is essential for the long-term management of hypertension. Tailored interventions, particularly for socioeconomically disadvantaged women, can lead to sustainable improvements in health outcomes, empower self-care behaviors, and enhance overall quality of life.

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CONFLICTS OF INTEREST: Nil

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