Investigating the Effect of the Orem-based Self-Care Education Model on Improving the Quality of Life and Health-Promoting Lifestyle in Hypertensive Patients: a randomized controlled clinical trial

Abstract

Aim: Hypertension remains a significant global health challenge, ranking among the most prevalent and enduring non-communicable chronic diseases.

Methods: This randomized controlled clinical trial was conducted to evaluate the effectiveness of a educational intervention, explicitly developed on the basis of Orem's self-care theoretical framework. Participants were randomly assigned to either an intervention group, which received the Orem-based educational program, or a control group that received standard care.

Finding: A total of 80 adults with hypertension, with a mean age of 44.16 ± 4.60 years, were enrolled in the study. Baseline assessments indicated no statistically significant differences between the control and intervention groups in terms of quality of life, lifestyle behaviors, or self-care capacity. However, follow-up evaluations conducted immediately after the intervention, as well as at one-month and three-month intervals, revealed statistically significant improvements across all measured outcomes in the intervention group.

Conclusion: The implementation of an Orem-based self-care educational intervention led to meaningful short-term improvements in quality of life, health-promoting behaviors among individuals managing hypertension. These findings advocate for the integration of similar evidence-based approaches into clinical practice and healthcare policy to support sustainable health outcomes for individuals living with chronic illnesses such as hypertension.

Keywords: Hypertension; Quality of Life; Self-Care; Educational Intervention

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Introduction

Hypertension is the major modifiable risk factor for heart disease, stroke and kidney failure and it is the leading cause of death and the second leading cause of lost disability adjusted life-years worldwide (1). Globally, the prevalence and total burden of hypertension are growing, particularly in countries with low and middle incomes (2). It was predicted that around 29.0% of women and 26.0% of men would have hypertension by 2025 (3). The global burden of hypertension was projected to exceed 1.6 billion by 2025 (4). The escalating prevalence of hypertension (HTN) constitutes a critical threat to global public health, with current estimates attributing approximately 17 million deaths annually to this condition. In Iran, national statistics indicate that nearly 46% of the population is affected by hypertension, underscoring its considerable burden on the healthcare system and the population at large (5-6). As a leading contributor to approximately 45% of cardiovascular-related deaths and more than half of all cerebrovascular fatalities, HTN continues to exert profound clinical consequences. These outcomes are largely attributable to its asymptomatic presentation and insidious progression, characteristics that have earned it the designation "silent killer" (7-8).

The World Health Organization defines quality of life (QoL) as an individual's perception of their position in life, situated within the context of their cultural values, belief systems, personal goals, physical health, psychological state, social relationships, and environmental circumstances (9-10). In the context of nursing practice, the promotion of QoL is not merely an aspirational goal but a fundamental component of patient-centered care. Achieving this outcome necessitates a multifaceted approach that extends beyond pharmacological treatment and emphasizes active patient involvement in self-care and long-term disease management (11).

Self-care education equips individuals with the requisite knowledge and practical skills to assume responsibility for their own health, thereby fostering autonomy, preserving functional capacity, and attenuating the progression of chronic diseases (12). Among the various theoretical frameworks guiding such interventions, Orem's self-care theory remains one of the most comprehensive and contextually adaptable models. This framework provides a systematic approach to identifying self-

care deficits, assessing patient needs, and delivering tailored support, particularly for individuals managing long-term conditions such as HTN (13).

Orem's self-care model has been designed to promote care based on the conditions and needs of individuals when they experience a deviation from normal health and underscores the role of caregiving in the form of a wholly compensatory system, partly compensatory system, and supportive-educative system. In the wholly compensatory system, the nurse is in charge of the patient's entire care plan to compensate the patient's inability to perform self-care. In the partly compensatory system, both the nurse and the patient participate in self-care. The supportive-educative system comes in when the patient is ready to learn to perform an activity, but is not able to do it without support and education—in this situation, the nurse mostly plays the role of an educator and advisor (14-15). In the present study, the researchers used the supportive-educative system defined by Orem's self-care model.

Given the high prevalence of hypertension and its well-established association with life-threatening complications, including myocardial infarction and cerebrovascular accidents, the development and implementation of evidence-based, patient-centered educational strategies are of paramount importance. Most of the studies in this field have been conducted descriptively, and the few available experimental studies have not used Orem's self-care model. Although previous studies have shown the impact of educational interventions using different models, including Pender's Health Promotion Model and Health Belief Model, to promote the hypertensive patients, quality of life and self-care behaviors (16-17), few studies have investigated the effect of an educational program using Orem's self-care model in hypertensive patients had been done. Thus, due to the importance of the subject and since few studies have been carried out in this area, it is recommended that the present study should be carried out in different countries to develop knowledge translation in patient education. Accordingly, the present study was designed to find out the impact of an educational program using Orem's self-care model on the improving the quality of life and health-promoting lifestyle in Hypertensive patients in the south of Iran.

Methods

Study Design

A prospective, open-label randomized controlled trial (RCT) was conducted to rigorously evaluate the effectiveness of a structured educational intervention grounded in Orem's self-care theory. The study was implemented at two tertiary cardiovascular referral centers located in southern Iran and spanned an eight-month period, from August 2022 to April 2023. Owing to the inherently interactive nature of the intervention, blinding of participants and providers was not feasible and therefore was not employed.

Eligibility Criteria

Inclusion and exclusion criteria were precisely defined to ensure methodological rigor in participant selection. Eligible participants were adults aged between 30 and 55 years with a confirmed clinical diagnosis of hypertension who provided written informed consent. Individuals were excluded if they experienced acute clinical deterioration during the study period or voluntarily withdrew their participation at any stage. Such exclusions were applied to preserve the internal validity of the study and to ensure the integrity of the final analysis.

Sample Size Determination

The sample size was calculated based on statistical parameters reported by Jamshidi et al. (18), utilizing assumptions appropriate for comparing mean values across two related groups. Assuming a two-tailed significance level (α) of 0.05 and a statistical power (1−β) of 90%, the minimum required sample size for each group was determined to be 28 participants. To account for potential attrition and to enhance the statistical power of the analysis, the sample size was deliberately increased, resulting in the allocation of 40 participants to each group. This adjustment was made to strengthen analytical robustness and to improve the generalizability of the study findings.

$$n = \frac{(z_{1-\frac{\alpha}{2}} + z_{1-\beta})^2 \sigma^2}{(\mu - \mu_0)^2}$$

Randomization Process

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From an initial cohort of 94 individuals diagnosed with hypertension, participants were recruited using a non-random convenience sampling method. Following an eligibility assessment based on predefined inclusion criteria, 14 individuals were excluded due to non-compliance with the study's entry requirements. The final sample comprised 80 participants, who were then randomly assigned to two equal groups: the experimental arm (n = 40) and the control arm (n = 40).

Random allocation was carried out through a straightforward yet rigorously controlled concealment procedure. Eighty identical cards, with half labeled "A" and the other half labeled "B," were thoroughly shuffled and placed in a sealed, opaque container to mitigate selection bias. Each eligible participant was instructed to draw a card blindly. Those who selected "A" were assigned to the intervention group, while those who drew "B" were allocated to the control group. A detailed account of participant recruitment, allocation, retention, and follow-up is visually presented in the CONSORT flowchart (**Fig.1**) .

Study Procedure

Prior to the commencement of the study, full ethical approval was obtained from the Institutional Review Board (IRB) of the affiliated academic institution. Following protocol approval, a formal authorization letter was issued by the Office of the Vice-Chancellor for Research. Upon arrival at the clinical site, the principal investigator provided prospective participants with a clear and comprehensive explanation of the study's objectives, scope, and procedures. Both verbal and written informed consent were obtained from individuals who agreed to participate.

The educational intervention, meticulously designed in alignment with Dorothea Orem's self-care theoretical framework, consisted of six structured instructional sessions, each lasting approximately two hours. To preserve group integrity and prevent cross-contamination, sessions were conducted separately for the two groups. Each session accommodated approximately 20 participants, ensuring an optimal facilitator-to-participant ratio conducive to meaningful interaction. The instructional approach incorporated didactic lectures, interactive discussions, and the distribution of printed educational materials. In response to the ongoing COVID-19 pandemic, all sessions strictly adhered to public health guidelines, including physical distancing and routine sanitization.

The educational content was closely aligned with the central tenets of Orem's model and tailored to address the complex self-care needs of adults managing hypertension. Curriculum topics included the physiological mechanisms underlying blood pressure regulation, etiological factors contributing to hypertension, and the systemic consequences of uncontrolled blood pressure. Instruction emphasized the development of self-management competencies across several key domains: initiation of regular physical activity, adherence to dietary recommendations, weight management, stress regulation, and engagement in mind-body practices such as diaphragmatic breathing, yoga, and meditation. Additional content focused on risk-reduction behaviors, including smoking cessation, abstinence from alcohol, adherence to prescribed pharmacologic treatments, accurate self-monitoring of blood pressure, and maintenance of routine medical follow-ups.

Each of the six sessions addressed a distinct thematic focus:

- **Session 1** provided an overview of blood pressure physiology, definitions of hypertension, and associated health risks.
- **Session 2** explored modifiable and non-modifiable risk factors, along with the long-term complications of poorly controlled hypertension.
- **Session 3** introduced the concept of self-care and outlined empirically supported strategies for chronic disease management.
- **Session 4** focused on behavioral lifestyle modifications, including exercise planning, nutritional practices, body weight regulation, and stress coping techniques.
- **Session 5** examined integrative therapies such as controlled breathing, yoga, and meditation, and addressed the health risks linked to tobacco and alcohol use.
- **Session 6** featured a hands-on demonstration of home blood pressure monitoring techniques and reinforced the importance of ongoing clinical engagement and medication adherence.

Participants in the intervention group attended all six sessions and had continuous access to expert facilitators who addressed individual questions to ensure thorough comprehension of the material. Printed pamphlets were also provided as supplementary educational resources. In contrast, the control group did not receive any instructional content during the intervention period. However, in accordance with ethical considerations, control participants were given the same informational pamphlets upon study completion.

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Data collection was conducted at four distinct time points: prior to the intervention (baseline), immediately after the final session, one month following the intervention, and again at the three-month follow-up. At each interval, participants completed validated self-report instruments under direct supervision by trained research personnel, and blood pressure measurements were performed using standardized clinical procedures. All data were subsequently entered and analyzed using SPSS software to detect statistically significant differences and trends across measured outcomes.

Instrumentation

A comprehensive battery of empirically validated instruments was employed to facilitate multidimensional data collection. These included a demographic data form, the Short Form-36 Health Survey (SF-36), the Health-Promoting Lifestyle Profile (HPLP), and the Hypertension Self-Care Profile (HTN-SCP), each selected for its established psychometric reliability and direct relevance to the study objectives.

The demographic questionnaire comprised thirteen systematically constructed items designed to capture essential sociodemographic and clinical variables. Collected data included chronological age, gender identity, educational attainment, occupational status, marital condition, smoking behavior, systolic and diastolic blood pressure readings, body mass index (BMI), presence of comorbidities, duration since hypertension diagnosis, and history of medical consultations related to hypertensive care.

To assess participants' perceived health-related quality of life, the study employed the SF-36, originally developed by Ware and Sherbourne in 1992 (19). The Persian-language version, previously translated and psychometrically validated by Montazeri et al. (20), was utilized. This 36-item instrument encompasses eight multidimensional domains: physical functioning, role limitations due to physical health, role limitations due to emotional problems, vitality, mental health, social functioning, bodily pain, and general health perceptions. Each domain is scored on a scale from 0 to 100, with higher scores reflecting better perceived health status and overall quality of life.

Lifestyle behaviors associated with sustained health promotion were evaluated using the Health-Promoting Lifestyle Profile (HPLP), originally developed by Walker and colleagues (21). This instrument measures six critical dimensions of health behavior: nutrition, physical activity, health responsibility, interpersonal relations, stress management, and self-actualization. Its Persian version, psychometrically validated by Zaidi et al. in 2013 (22), comprises 52 items rated on a four-point Likert scale ranging from 1 (never) to 4 (routinely). Cumulative scores indicate the extent to which individuals engage in behaviors conducive to health promotion.

Hypertension-specific self-care competencies were assessed using the Hypertension Self-Care Profile (HTN-SCP), developed by Han et al. in 2014 (23). Although initially validated among Korean American populations, the instrument was later culturally adapted and validated for use among Iranian adults by Ghanei and colleagues in 2017 (24). The HTN-SCP consists of 20 items spanning four principal domains: adherence to dietary and exercise recommendations, compliance with prescribed medications, ability to interpret nutritional labels, and general self-management of hypertension. Each item employs a four-point response scale, with higher scores indicating greater adherence to recommended self-care behaviors.

Statistical Analysis

Data management and statistical analyses were conducted using IBM SPSS Statistics, version 22. Descriptive statistics were used to summarize demographic characteristics and outcome variables. Between-group differences were assessed using independent sample t-tests for continuous variables and chi-square tests for categorical variables. To examine within-group changes over time, repeated measures analysis of variance (ANOVA) was employed, allowing for the longitudinal evaluation of intervention effects across multiple time points.

Ethical considerations

Prior to participation, all individuals were comprehensively informed about the study's objectives, methodological procedures, and data usage protocols. Written informed consent was subsequently obtained. Participant confidentiality and anonymity were rigorously preserved throughout the data collection, management, and analysis phases. The study protocol received ethical clearance from the Research Ethics Committee of Fasa University of Medical Sciences (Approval No. IR.FUMS.REC.1400.153), and all procedures adhered strictly to institutional ethical guidelines and the principles outlined in the Declaration of Helsinki. In cases involving legally dependent

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individuals, informed consent was additionally obtained from authorized legal guardians or representatives.

Results

The final analytical sample comprised 80 adult participants with a confirmed diagnosis of hypertension, with a mean age of 44.16 years (±4.60 SD). Baseline demographic characteristics showed no statistically significant differences between the experimental and control groups, thereby confirming the initial comparability of the cohorts (see Table1). Similarly, pre-intervention quality of life scores did not exhibit any meaningful intergroup differences.

Post-intervention assessments, however, revealed statistically significant improvements in quality of life among participants in the educational intervention group. These enhancements were sustained at both the one-month and three-month follow-up assessments when compared with the control group ($P < 0.001$) (Table 2). Although no significant differences in health-promoting lifestyle behaviors were observed at baseline, the intervention group demonstrated substantial and statistically significant improvements across all post-intervention time points ($P < 0.001$) (Table 3).

A similar pattern emerged in the domain of self-care efficacy. Baseline scores did not differ significantly between the two groups; however, participants in the intervention group exhibited marked improvements following the intervention. These gains remained statistically robust at both follow-up intervals ($P < 0.001$) (Table 4).

With regard to blood pressure outcomes, baseline systolic and diastolic values were statistically comparable between the groups. Notably, the intervention group experienced a significant reduction in systolic blood pressure immediately post-intervention and at the one-month follow-up. Although this reduction diminished slightly by the three-month evaluation, diastolic blood pressure levels in the intervention group continued to demonstrate statistically significant and clinically meaningful reductions across all follow-up time points ($P < 0.001$) (Table 5).

Discussion

This study systematically evaluated the effectiveness of a theory-driven self-care educational intervention, grounded in Orem's conceptual model, in enhancing quality of life and fostering health-promoting behaviors among individuals diagnosed with hypertension. The equivalence of baseline characteristics across study arms served to strengthen the internal validity of the observed outcomes.

Following the implementation of the six-session instructional program, participants in the intervention group exhibited statistically significant improvements in both subjective well-being and self-regulatory health behaviors. While reductions in systolic blood pressure were apparent immediately post-intervention and at the one-month follow-up, this trend attenuated somewhat by the third month, suggesting a potential need for periodic reinforcement. In contrast, diastolic pressure reductions remained stable and statistically significant throughout the follow-up period, indicating a more durable physiological response to the intervention.

These findings are congruent with those of Bayrami et al. (2016), who reported a strong association between active self-care engagement and improved quality of life among individuals with chronic conditions. The current study extends this line of inquiry by providing additional empirical support for the efficacy of structured educational programs, particularly when underpinned by a well-established nursing theory. The results confirm that theoretically guided interventions can produce sustained improvements in both behavioral and clinical outcomes in hypertensive populations (25).

A substantial body of empirical research has underscored the critical role of lifestyle modification in optimizing clinical outcomes among individuals with chronic diseases. In a descriptive-comparative study, Zarei et al. (2021) demonstrated a clear and direct relationship between positive behavioral changes and enhanced health indices (26). Consistent with this body of evidence, the present study documented significant improvements across multiple lifestyle dimensions following the implementation of a targeted self-care training program. Concurrent reductions in systolic and diastolic blood pressure provided further validation of the intervention's effectiveness in mitigating cardiovascular risk.

Similar conclusions were drawn by Kohneforoodi et al. (2019), who found that adherence to self-care practices significantly predicted higher levels of self-efficacy, a recognized psychosocial determinant

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of successful hypertension prevention and management (27). Their endorsement of individualized, behaviorally oriented interventions is reflected in the current study's application of Orem's theoretical framework, which informed the design of a personalized educational strategy. This model-based approach yielded measurable benefits in both cognitive-behavioral and physiological domains, thereby reinforcing its practical relevance and applicability in clinical settings.

Further empirical support for comprehensive self-management strategies was offered by Arabshahi and colleagues (2019), whose descriptive-analytic study identified a notable adherence gap, particularly regarding sodium restriction, despite relatively high compliance with medication use and physical activity guidelines. Approximately 25% of patients were unable to effectively limit dietary sodium intake (28). In alignment with these findings, the present intervention adopted a holistic perspective by integrating key components of hypertension management, including nutritional modification, pharmacologic adherence, and physical activity promotion. This multidimensional approach contributed to significant and sustained reductions in both systolic and diastolic blood pressure, underscoring the necessity of comprehensive self-care education.

In a cross-national investigation conducted across three healthcare institutions in Sri Lanka, Pirasat et al. (2019) identified widespread deficits in patient awareness concerning diagnostic criteria, treatment goals, and personal blood pressure targets, despite a general understanding of hypertension risk factors (29). Although medication adherence was rated as satisfactory, memory lapses frequently emerged as a principal barrier to consistent therapeutic compliance. In response, the authors advocated for the implementation of individualized educational interventions. Echoing this recommendation, the current study incorporated modular instruction covering key topics such as the pathophysiology of hypertension, potential complications, pharmacologic adherence, and the importance of regular medical follow-up. The observed improvements in patient-reported outcomes following the intervention provide compelling evidence for the efficacy of this educational model.

Katata et al. (2020) identified a constellation of risk factors associated with suboptimal self-care engagement, including advanced disease severity, the presence of comorbid respiratory conditions, limited formal education, and the absence of prior instruction in self-management strategies (30). These findings highlight the importance of tailoring health education to reflect the sociodemographic and clinical profiles of target populations. Within this context, the present study's implementation of a theory-informed, demographically sensitive intervention significantly enhanced participants' self-care capabilities, thereby demonstrating its effectiveness in addressing diverse patient needs.

The critical importance of non-pharmacologic strategies in the management of hypertension was reaffirmed by Carey et al. (2022), whose comprehensive guideline review positioned lifestyle modification as the cornerstone of effective blood pressure control (31). Their recommendations highlighted several key behavioral targets, including dietary moderation—specifically, sodium reduction and potassium enrichment—balanced nutritional intake, routine physical activity, and responsible alcohol consumption. The empirical findings of the present study align closely with these best-practice recommendations. Participants in the intervention group demonstrated improved adherence to prescribed lifestyle modifications, which corresponded with statistically significant reductions in both systolic and diastolic blood pressure. These results suggest a synergistic relationship between enhancements in quality of life and positive lifestyle behavioral changes, collectively contributing to sustained blood pressure regulation.

Limitations

The participants were recruited from a single center in southern Iran, which may limit the generalizability of the findings. Another limitation of this study was the small sample size. It is recommended to use a larger population size in similar research. Aa another limitation of the study, lack of blinding and non-equivalent intervention intensity between groups and the short time period between the intervention and assessment of the patients' outcomes can be mentioned. It is further suggested that longitudinal and prospective cohort studies. Data were collected using self-reported measures such as self-efficacy and life satisfaction scores. Potential response bias may have resulted from participants' responses that they perceived as socially acceptable or that did not accurately represent their genuine emotions and experiences.

Conclusion

This study offers compelling evidence that an educational intervention grounded in Orem's self-care theory can significantly enhance the quality of life, health-promoting behaviors, and blood pressure control of individuals with hypertension during the initial post-intervention period. However, the observed diminution of effects over time underscores the necessity of implementing sustained

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reinforcement strategies. It is therefore recommended that periodic booster sessions or continuous support mechanisms be instituted to maintain behavioral momentum, facilitate enduring lifestyle adjustments, and promote long-term hemodynamic stability.

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