



Intervention based on the family health nurse model on hypertension in the elderly: Protocol for a randomized clinical trial

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Abstract:

BACKGROUND: This demographic is disproportionately affected by various health challenges, making them the primary users of healthcare resources, with hypertension being a prevalent chronic condition among them. Effective management of blood pressure can lead to a notable decrease in expenditures associated with advanced medical treatments. Among the various family-centered strategies, the family health nurse (FHN) model, proposed by the World Health Organization in 1998, stands out.

MATERIALS AND METHODS: This randomized controlled clinical trial was carried out from September to March 2023 at selected healthcare institutions in Isfahan City. A random number table was used to identify 78 eligible participants for the study. The intervention group received strategies rooted in the FHN model, including personalized and family education, establishment of self-help groups, and both internal and external support follow-ups to enhance hypertension self-management. In contrast, the control group received standard care. The efficacy of the intervention was assessed using the Stanford University Chronic Disease Self-Management Questionnaire, comprising 38 questions across 8 dimensions, administered at three intervals: before the intervention, immediately post-intervention, and 3 months later, alongside blood pressure measurements.

CONCLUSION: Considering that social factors, including the family, are determinants of health, determining the effectiveness of the FHN model on the control and prevention of hypertension can provide a suitable framework for providing family-oriented services to the elderly with hypertension and improving their health. By carrying out the necessary tests, information will be gathered. Software called SPSS 22 (Version 18, Isfahan, Iran) will be used for data analysis.

Keywords:

Elderly, family nurse, hypertension, model, self-management

Introduction

Aging is a widespread global phenomenon, with significant growth in the elderly population observed since the early 20th century. This growth is driven by increased life expectancy, improvements in health and preventive care, advancements in pharmaceuticals,

greater access to information, and better education on healthcare. This upward trend is also evident in Iran.^[1] The global elderly population reached 1 billion in 2019 and is projected to rise to 1.4 billion by 2030.^[2] In Iran, statistics from 2021 indicate a total of 9,528,000 elderly individuals, with 719,000 residing in Isfahan.^[3] Furthermore, the elderly are the most frequent users of healthcare services due to various health

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challenges. Non-communicable diseases such as obesity, diabetes, hypertension, cardiovascular issues, kidney dysfunctions, arthritis, respiratory ailments, and cancers are prevalent among this age group and are primary contributors to mortality.^[4-6] Hypertension, a widespread condition among the elderly, poses numerous health risks. As defined by the Centers for Disease Control and Prevention in the United States in 2021, hypertension is characterized by readings exceeding 140/90.^[7] Between 1990 and 2019, the global incidence of high blood pressure among individuals aged 30–79 has doubled. In 2018, the prevalence of hypertension among adult Iranians (aged over 50) reached 42%, with figures of 47% in women and 38% in men.^[8] In Isfahan province, the prevalence of hypertension among the elderly is noted to be 55.79%.^[9]

High blood pressure is the most common reason for outpatient visits to the doctor and is the most recognizable and treatable risk factor for many brain and heart disorders.^[10] Blood pressure control can significantly reduce treatment and medical care costs at both the pre-hospital and hospital levels, including through non-pharmacological and pharmaceutical approaches. These treatments can also delay or prevent the complications associated with high blood pressure. One essential approach to blood pressure control is hypertension management training, which enhances problem-solving skills in individuals with high blood pressure.^[11]

Self-management of high blood pressure includes following a healthy diet, engaging in regular physical activity, managing stress, attending doctor's appointments, consistently taking prescribed high blood pressure medications, maintaining social relationships, and adhering to these practices, all of which are associated with improved blood pressure control.^[12,13] Disease self-management is one of the responsibilities of nurses in designing and implementing health promotion programs. Interventions involving family participation in disease control, especially for chronic diseases, help manage disease complications.^[14,15] High blood pressure affects not only the individual but also involves family members in controlling the contributing factors.^[16] In other words, the "family" has been identified as an important influencing or neutralizing factor among family members when dealing with a disease or a larger system, such as the healthcare system.^[17] In healthcare, including nursing care, several family-oriented theories and models can serve as suitable frameworks for providing nursing care and services. One such model is the family health nurse (FHN) model, introduced by the World Health Organization in 1998, which was later localized by Kishori *et al.* in their 2011 study.^[18-21]

The adapted model includes three strategies:

1. Empowering families to encourage their participation
2. Producing and providing appropriate services based on the actual health needs of families, considering the contextual, functional, and structural aspects of families
3. Coordinating the integration and use of all governmental and non-governmental resources to produce affordable, timely, and accessible health services.^[18]

Research gap

In countries with advanced development, the role of the FHN within the healthcare system is clearly defined.^[21,22] However, there is a lack of literature explaining the role and function of FHNs within the Iranian healthcare context.^[23] Currently, there is a noticeable absence of research investigating the impact of the Family Health Nursing model on managing hypertension among the elderly. This highlights a significant gap in understanding the involvement of FHNs within the health system.^[24] Given the lack of prior studies on FHNs in our country, along with the widespread prevalence of hypertension and its effects on individuals and families, this research, entitled "The Impact of Implementation of Family Nursing Model on High Blood Pressure in the Elderly," is warranted.

Materials and Methods

Study design and setting

This investigation will utilize a clinical trial methodology, incorporating both experimental and control groups (randomized controlled clinical trial). The study is conducted within the context of Isfahan's Medical University, registered under IR. IRCT20190806060444449N2, and will involve 76 participants aged between 60 and 74 years. Data collection is set to occur at Kerdabad Health Services, Bonakdar Health Services, and Isfahan Medical University. This clinical trial will unfold across three phases, examining how the independent effects of the family health nursing model influence the dependent variable: self-management practices among the elderly suffering from hypertension.

Study participants and sampling

The sampling was conducted in three randomized stages. In the first phase, participants were randomly selected between two centers, labeled as Center One and Center Two in Isfahan, using a coin toss. The second stage involved randomly selecting from the participants in Center One. In the third step, participants were selected from the chosen centers using a systematic method that adhered to the study's entry criteria through the Apple system.

To determine the sample size, the total number of individuals in the research community was divided by the required sample size, resulting in a value referred to as k . A random number below ten was then selected, which we called N . Subsequently, participants were chosen based on the formula $k + N$, $k + 2N$, and $k + 3N$, continuing until the last subject was selected.

Based on the formula

$$n = \frac{2(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta})^2 (SD)^2}{(d)^2}$$

Assuming the variances were the same, a study was conducted with 95% confidence and 80% test power, involving 76 people in total (38 in the test group and 38 in the control group). The study was conducted within the corporation. The sample method used was a random examination, adhering to the entry requirements of the study. The study participants consist of elderly individuals who have been referred to health centers with a blood pressure reading higher than 140/90. This group includes Persian-speaking seniors aged 60–74, all of whom have an active health record at the selected health centers in Isfahan City. These individuals have been diagnosed with high blood pressure by a physician for at least 6 months, consent to participate in the study, and also have type 2 diabetes. Participants with thyroid disorders or mental health conditions were excluded from the study [Figure 1].

Data collection tool and technique

The meeting was held in one of the center's rooms with permission from the center. The method of data collection in this study is through questioning. The data collection tool is a two-part questionnaire for elderly individuals with hypertension. The first part of the questionnaire includes demographic and underlying information (age, sex, marital status, height, weight, waist circumference, education, number of children, employment status, religion, duration of hypertension, other chronic illnesses, and income). The second part of the questionnaire is the Self-Management in Chronic Diseases tool from Stanford University, developed by Professor Larry at Stanford University, which covers eight dimensions. The dimensions of stress and fatigue are scored from zero to ten using a visual chart. For the physical activity dimension, the level of physical activity is scored with six items ranging from 0 to 4. This is followed by an assessment of compliance with drug treatment, which evaluates the individual's condition with four items and two yes/no options for the past two weeks. Finally, the effect of the disease on social communication is measured daily with four items scored from 0 to 4. The next section addresses the recent state of health, which includes seven

questions using an 11-point Likert scale. Communication with the doctor and other healthcare workers is assessed using three items on a Likert scale ranging from 0 to 5, examining five aspects. In the aforementioned questionnaire, the nutritional behavior of the patients was not evaluated. Therefore, a researcher-developed questionnaire was utilized, drawing on other existing questionnaires to assess adherence to the diet of patients with high blood pressure based on the DASH regimen. This questionnaire consists of 11 items with a 5-point Likert scale. It was validated and verified by Shahrbanu Daniali in Isfahan City in 2015 with a sample of 500 patients with high blood pressure.

The study process will consist of three stages: pre-intervention, intervention, and evaluation.

Pre-intervention stage

After obtaining permission from the university's research vice-chancellor and receiving the project's ethics code, the researcher visited the aforementioned health centers. After introducing himself, explaining the research objectives, and obtaining permission from the center's director, he organized a meeting to familiarize himself with the center's personnel. During this meeting, he explained the project's objectives and sought their support to encourage participation in the project. With the assistance of healthcare workers, the researcher compiled a list of elderly individuals with high blood pressure who have files at the center, are registered, and meet the inclusion criteria. Then, during a phone call, he introduced himself and explained the research mission, inviting them to visit the center.

The steps before the home visit are as follows

After attending the specified centers, the researcher thoroughly explains the purpose of the study to the participants, emphasizing that their participation is voluntary. This study requires at least two home visits, and all information will be kept completely confidential and accessible only to the researcher. If the participant agrees, they are asked to complete and sign the informed consent form. Once the consent form is signed, the researcher measures the participant's weight, height, waist circumference, and blood pressure using a scale, measuring tape, and sphygmomanometer. After calculating the body mass index, demographic information is recorded in the questionnaire. Additionally, during this session, which serves as a pre-intervention session, the participant completes Stanford's chronic disease self-management questionnaire. The researcher assists those who are unable to fill out the questionnaire.

Home visit

We arranged home visits to take place over at least two sessions.

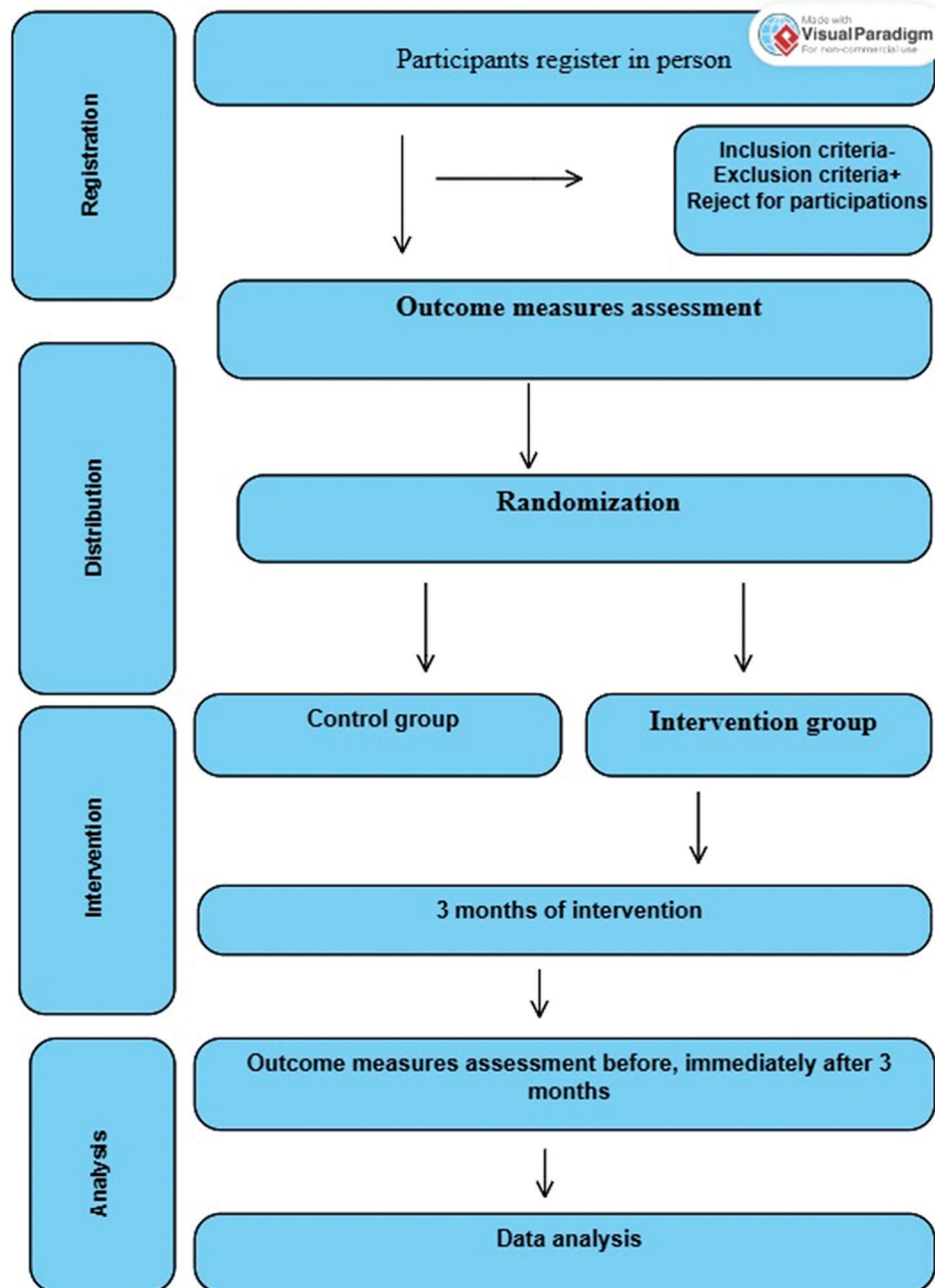


Figure 1: The diagram demonstrating randomized controlled trial protocol

First home visit

Before visiting the home, coordinate the home visit time with the client through a phone call while organizing the research team. Upon arrival, the researcher is introduced to effective communication with family members, and the necessity of individual and family participation at different stages is explained. Then, with the help of family members and the client, the Family Health Ambassador (FHA) is selected. The selection criteria for an FHA include:

- Being literate
- Living with the patient or being a close relative of the patient

- Have the ability to care for the patient if necessary.

During the first home visit, the researcher evaluated the family's economic status by observing the type of dwelling and the furniture present. In collaboration with the referrer, an Ecomap and genogram of the family were created to assess their relationships with the surrounding environment. Finally, based on these evaluations, the researcher, along with the client and family members, discussed the family's limitations and strengths. They were informed that after analyzing the information, a list of problems would be prepared with their input, using

a decision matrix, and prioritized in the next meeting. The duration of the home visit ranges from 20 minutes to 1 hour. The number of sessions is determined by the family's needs, with a minimum of two visits mandated for necessary assessments to identify the family's strengths and weaknesses before scheduling the next session. Additionally, following the home assessment, the researcher noted the nursing diagnosis related to the older adult and placed it in the family folder, which would later be followed up within the relevant department (including visits from a doctor, nutritionist, psychiatrist, and health care provider). There will also be external follow-ups conducted in cooperation with the head of the health center.

Second home visit

During this session, the researcher, with input from the individual and their family, develops a list of problems based on findings from the previous visit and the patient's statements. These problems are prioritized according to several criteria: severity or importance, prevalence and frequency, feasibility, and the impact of potential interventions. Each problem is scored on a scale from 1 to 5 regarding these criteria, with the highest-scoring problems receiving priority.

Following this, the researcher identifies factors influencing these problems, considering both the family's capabilities and obstacles through interviews with family members. Then, based on the identified factors, the researcher collaborates with the client and family to establish goals and create an operational plan, which includes methods of implementation, timelines, and evaluation strategies. The investigator will reach an agreement with the patient and the FHA regarding the evaluation methods of the planned interventions.

The patient and the FHA will be encouraged to implement these programs at home, such as a physical activity regimen, nutritional guidance, medication management, and other strategies from the effective monitoring model of family health. They will also be asked to participate in training sessions and self-help group meetings, as well as facilitate case referrals under the care and supervision of the FHA.

Ethical consideration

This paper is based on a master's thesis approved by the Research Ethics Committee of Isfahan University of Medical Sciences (IR.MUI.NUREMA.REC.1402.056). We are grateful to the Vice Chancellor for Research and Technology for their financial support (3402138).

Performance in the health center

Training sessions

Based on the educational needs identified for the families, the researcher, in agreement with the client

and the FHA, will provide training in various topics, including the disease process of hypertension, its symptoms and complications, prevention and treatment strategies, nutrition for hypertension, physical activity for the elderly with hypertension, blood pressure monitoring, stress management, and self-esteem enhancement. Training will be delivered through lectures and question-and-answer sessions in a group discussion format.

Given that there are two sample centers, the training classes will be conducted over eight sessions, with four sessions held at each center, lasting 30–45 minutes each. In-person training will take place once a week for four consecutive weeks in the health center's meeting hall.

First training session

During this session, the course of the disease and its treatment were covered through a lecture on blood pressure, including its causes, risk factors, and signs and symptoms in hypertensive patients, presented via PowerPoint. The session also included information on arranging referrals to doctors, monitoring blood pressure using various digital, manual, and mercury devices, and the correct use of medications, focusing on timing and avoiding drugs that interfere with high blood pressure medications, such as Choman Plavix and ASA. Solutions for preventing forgetfulness in taking medications were also provided.

Second training session

In this meeting, participants were introduced to different food groups, food units, the recommended number of daily meals and snacks, the components of a healthy plate, the food pyramid, and the permissible amount of salt consumption. The training was delivered through PowerPoint presentations and lectures by the center's nutrition expert and researcher during group discussions and face-to-face sessions. Additionally, recommendations for improving the diet of the elderly were provided, emphasizing adequate fluid intake, more frequent but smaller meals, the importance of maintaining a healthy weight ratio, cooking methods such as steaming and grilling, and avoiding fast food, canned food, and salty foods.

The third training session

During this session, the benefits and effects of exercise on blood pressure, obstacles to physical activity, and examples of exercise programs were explained. Additionally, a speech with motion graphics lasting 5 minutes and 50 seconds was presented to demonstrate proper physical activity. Key topics discussed included the importance and necessity of exercise, its effects and consequences, appropriate clothing, and the ideal environment for exercising. The researcher taught the

components of a sports activity, including warming up, stretching, engaging in the main activity, and cooling down, by demonstrating various movements. Participants were advised on basic walking techniques, such as wearing suitable clothing, choosing a smooth path, having a companion, effective breathing, and following a personalized exercise program tailored to individual conditions and challenges. They were also provided with individual advice and encouraged to be patient with lifestyle changes.

The fourth training session

In the fourth training session, the researcher and a mental health center expert used a PowerPoint presentation to explain disorders such as stress and the necessary measures to manage it. Topics covered included time management, financial management, engaging in favorite activities, deep breathing techniques, self-awareness skills, and solutions for enhancing self-awareness. Strategies to strengthen self-esteem were also taught to help control and prevent depression by addressing seclusion and isolation among the elderly.

Peer groups

Peer groups align with the strategy of producing and providing services based on needs, increasing self-esteem, and sharing everyday experiences through social participation. To identify the health-related needs of families, the researcher forms peer groups with the participation of clients and health ambassadors. Peer group meetings are held in groups of 5–7 people with FHA, based on arrangements made at the center with the presence of families. The purpose of these group discussions is to enhance knowledge and learning, develop positive interpersonal relationships, foster empathy, and provide emotional support by sharing experiences, information, and strategies for dealing with everyday problems with other peer group members.

Referral follow-up

One of the dominant approaches in this model is the sociological approach. Based on this approach, the health-related needs of individuals and families are evaluated comprehensively, considering various aspects of health, including psychological, social, spiritual, emotional, and environmental factors. If necessary, the researcher refers the client to a doctor and follows up with other referrals (such as a nutritionist, psychiatrist, physiotherapist, etc.) through phone calls with the client.

Immediately after the end of the intervention

Immediately after the end of the intervention, the participants will be asked to go to the health center to complete anthropometric information (body mass index, waist circumference, etc.), and they will also be asked to fill out the chronic disease self-management form

again. We will help the elderly with vision and hearing problems due to old age complete the questionnaire.

Three months later after the end of the intervention

Three months after the completion of the research intervention, the clients of the test and control groups will be contacted again, and they will be asked to return to the center for monthly care after the presentation of weight (body mass index), waist circumference, and blood pressure. The patient's blood pressure is measured and recorded in the monthly care form and household folder. In the end, the cooperation of the control group in this research is appreciated, and a booklet prepared for them will be presented as a memorial.

Statistical analysis method

Data analysis will be done using SPSS 22 software version 18 (IBM Company, Armonk, NY, USA). MANCOVA, ANCOVA, and independent sample *t*-tests are used to compare nominal, ordinal, and numerical variables. In addition, a paired sample *t*-test is used for intragroup comparison. Significant *P* values are those less than 0.05.

Discussion

This paper describes the FHN Model intervention to investigate its effects on hypertension in the elderly. Due to the increasing prevalence of hypertension, our effective results might be used to improve the condition of these patients. The model has been designed to be effective on all aspects of DSMES, which have rarely been addressed. Moreover, the educational content includes parts and components that can be continuously upgraded. Finally, all parts of the program can be used for all seniors with high blood pressure. Various studies have discussed the importance of timely intervention and treatment of hypertensive patients. High blood pressure can be controlled with medication and by following a healthy lifestyle. Studies have shown that the health system has been ineffective in controlling this disease in elderly people, which can be attributed to the neglect of the role of the family and inadequate follow-up of elderly patients covered by health service centers.

Conclusion

The family health nurse model will be presented to the elderly using the following three strategies:

- 1- Empowering families to encourage their participation.
- 2- Producing and providing appropriate services based on the actual health needs of families, while considering the contextual, functional, and structural aspects of families.
- 3- Coordinating the integration and utilization of all government and non-government resources to produce affordable, timely, and accessible health services.

These strategies will be implemented during three phases: before the study (sampling and follow-up of pre-study arrangements), during the study (follow-up within the center through training sessions and forming a peer group, and outside the center through home visits), and after the study (pre-study assessment, immediately after the study, and three months post-study) [Figure 2].

Policy implication

Considering the role of the family as a major influencing factor alongside the recipient of care, it is necessary to investigate methods that can effectively improve the current situation. In this regard, by examining the localized model of the FHN, whose positive effects have been measured in different societies outside of Iran, it is hoped that the results of this study can serve as a suitable model for providing family-oriented services to improve the blood pressure of elderly people with hypertension in Iran.

Limitations and recommendations

One of the strengths of this study is the implementation of the FHN model for the first time in Iran, alongside three approaches: home visits, training sessions at the center, and the formation of peer groups. This study

also highlights the importance of educating men and women on disease management. However, a limitation is the lack of prior studies on the impact of the FHN in Iran, which affected the analysis of our results. Further research is necessary.

The mental and psychological conditions of the patients in this study may have influenced their responses to the research questions. Stress and anxiety can affect systolic and diastolic blood pressure fluctuations, and since data were obtained through self-reporting questionnaires, there may be biases in the responses. Additionally, only two home visit sessions were conducted due to restrictions.

In group meetings, factors such as introversion and illiteracy among many elderly participants, both men and women, led to brief interactions. This was somewhat mitigated by the researcher's management and motivation during the meetings.

This study was conducted with a limited number of hypertension patients from two health centers, so the results may not be generalizable to the entire population of hypertension patients. Future studies should involve

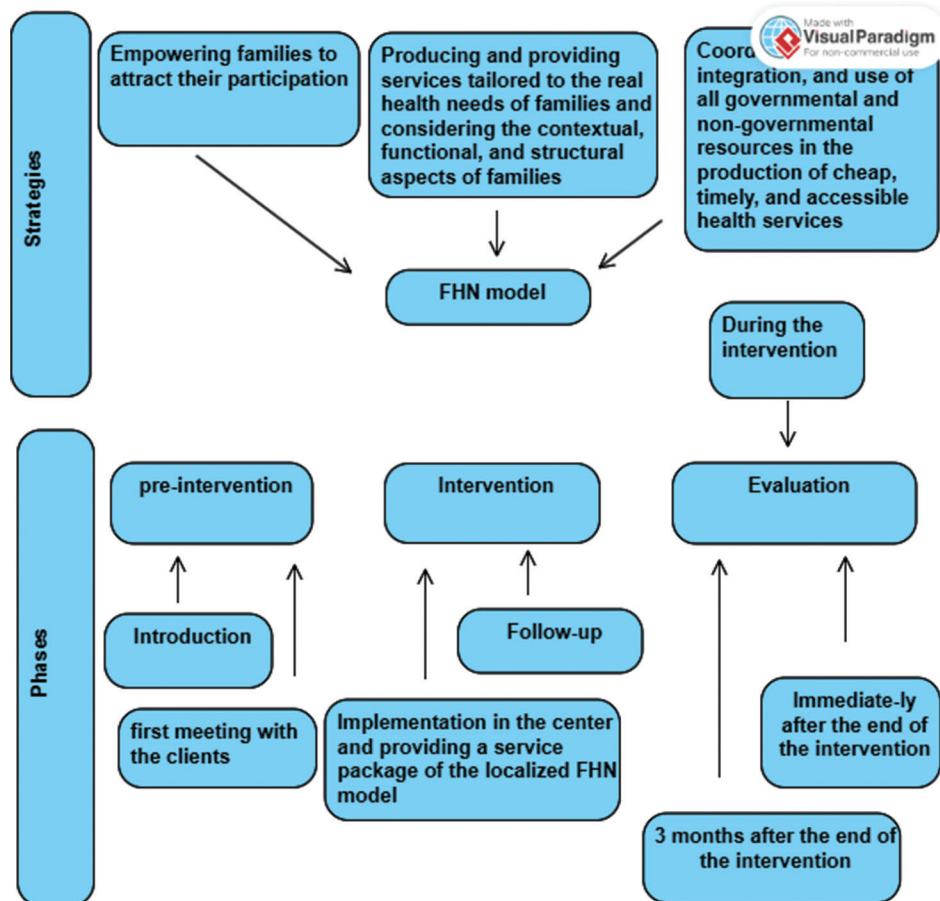


Figure 2: Family health nurse model

a larger population and more health centers to enhance the applicability of the findings.

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Conflicts of interest

There are no conflicts of interest.

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