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Intervention based on the family health nurse model on the anthropometric and glycemic indicators of middle-aged prediabetics: Protocol for a randomized clinical trial (RCT)

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Abstract:

BACKGROUND: Diabetes and prediabetes are some of the most prevalent and expensive diseases. The role and support of the family are some of the most helpful variables in managing and preventing diabetes and prediabetes. The aim of this study is to examine the intervention based on the family health nurse model on the anthropometric and glycemic indicators of middle-aged prediabetics.

MATERIALS AND METHODS: This randomized clinical trial study will be conducted from January to March 2024 in selected healthcare facilities in Isfahan City. Using a table of random numbers, 72 eligible people will be randomly selected from the intervention and control centers to participate in the study. After getting written consent, a list of the families' health-related issues, resources, and challenges will be gathered by visiting the clients' homes. Then, family health nurse model-based interventions are put into place for them. By carrying out the necessary tests, information will be gathered. Software called SPSS 26 will be used for data analysis.

CONCLUSION: Determining the effectiveness of the Family Health Nurse (FHN) model on the control and prevention of diabetes can offer a suitable framework for providing family-oriented services to middle-aged people with prediabetes and improving their health by considering social factors, such as family.

Keywords:

Anthropometry, diabetes mellitus, family nursing, glycemic index, prediabetic state

Introduction

Globally, chronic illnesses are now the leading cause of death and disability.[1] Diabetes is one of the most challenging and severe chronic illnesses that can be controlled and reversed in prediabetes.[2,3] We can avoid long-term conditions if proper measures are taken during this critical period.[4] Prediabetes indicates an increase in blood sugar of 100–125 mg/dL and is more common than diabetes.[5] People with prediabetes are more likely to develop diabetes and cardiovascular diseases than people with regular blood sugar, making them desirable for diabetes prevention plans.[6-8] Studies have shown that diabetes is responsible for 6.7 million deaths in 2021, resulting in $966 billion in health costs.[9]

When a family member is diagnosed with a chronic illness, the whole family is affected, so it can be difficult for the family to balance

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the individual wishes and the needs of the entire family and the sick family members.[10] Therefore, the nature of this disease and its complications, in addition to imposing a heavy economic burden on the health system and the family, leads to a decrease in the quality of life of the patient and his family.[11] A newly diagnosed person first seeks information from his family and needs emotional support.[12,13]

Studies have used various methods to control and treat prediabetes, including lifestyle change interventions, nutrition modification, and increased physical activity. However, considering the role of the family in the treatment of prediabetes, family-oriented interventions in health promotion are of particular importance.[12,13]

In healthcare, including nursing care, some family-oriented theories and models can be used as a suitable framework for providing nursing care and services.[10] One of these models is the FHN model. In 1998, the WHO introduced the FHN model.[14] The role and performance of family-centered models have been proven, and the implementation of FHN in the healthcare system in developed countries has been defined.[15] However, in Iran's current health system, there is no defined role and function for FHN, and nursing care is treatment-oriented and concentrated in medical centers. Keshvari *et al*.[16] adopted this model in their study in 2010, but intervention based on this model has yet to be done.

The adapted model has three strategies:
1. Empowering families to attract their participation.
2. Producing and providing services that are appropriate or based on the actual health needs of families and according to the background, functional, and structural aspects of families.
3. Coordination integration and use of all governmental and nongovernmental resources in producing cheap, timely, and accessible health services.[16]

Therefore, considering the high prevalence of prediabetes and diabetes and its impact on the individual and family, as well as FHN's focus on the family as the central unit of society and the importance of changing behavior, lead to a healthy lifestyle. This study will be conducted with the aim of "investigating the intervention based on the family health nurse model on anthropometric and glycemic indicators of middle age in the pre-diabetes stage."

Materials and Methods

Study design and setting

This study will be a case-control randomized clinical trial [Figure 1]. After receiving the introduction letter from the Research Vice-Chancellor of the University of Medical Sciences, the researcher referred to the Health Vice-Chancellor among the centers where social medicine is located, one center will be selected as an intervention center, and a homogeneous center (in terms of demographic, cultural and economic characteristics) will be chosen as a control center.

Study participants and sampling

The participants include middle-aged men and women with an electronic health profile in the SIB[1]. Systems in selected healthcare centers who have recently been diagnosed with prediabetes by a doctor after performing a Hemoglobin A1C (HbA1c) test and are willing to participate in the study. Exclusion criteria are unwillingness to continue participating in the research and development of diabetes.

In this study, using the following formula, with 95% confidence, 80% test power, and 10% dropout, the required number of samples was 72 people (36 people in the test group and 36 people in the control group).

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

$Z\ (1-\alpha/2)$ = 95% confidence coefficient is equal to 1.96.

$Z\ (1-\beta)$ = 80% test power factor is equal to 0.84.

S1 = standard deviation in the control group

S2 = standard deviation in the intervention group

Assuming equal variances

S1 = S2

d is the minimum difference in the average hemoglobin a1c that makes the difference meaningful, which we considered 0.12 in this study.

For the random sampling method, a list of all the people who meet the criteria for entering the research in the intervention and control center is prepared and numbered in order. The samples will be selected using a random number table.

Data collection tool and technique

Demographic information form, sphygmomanometer, tape, scale, and blood test are used to collect data.

1 The Sib system has been installed in medical universities since the beginning of October 2015; any registration, collection, and information reporting will be done only through the Sib system. All information about healthcare services needed in community and health centers are entered and recorded in this system.

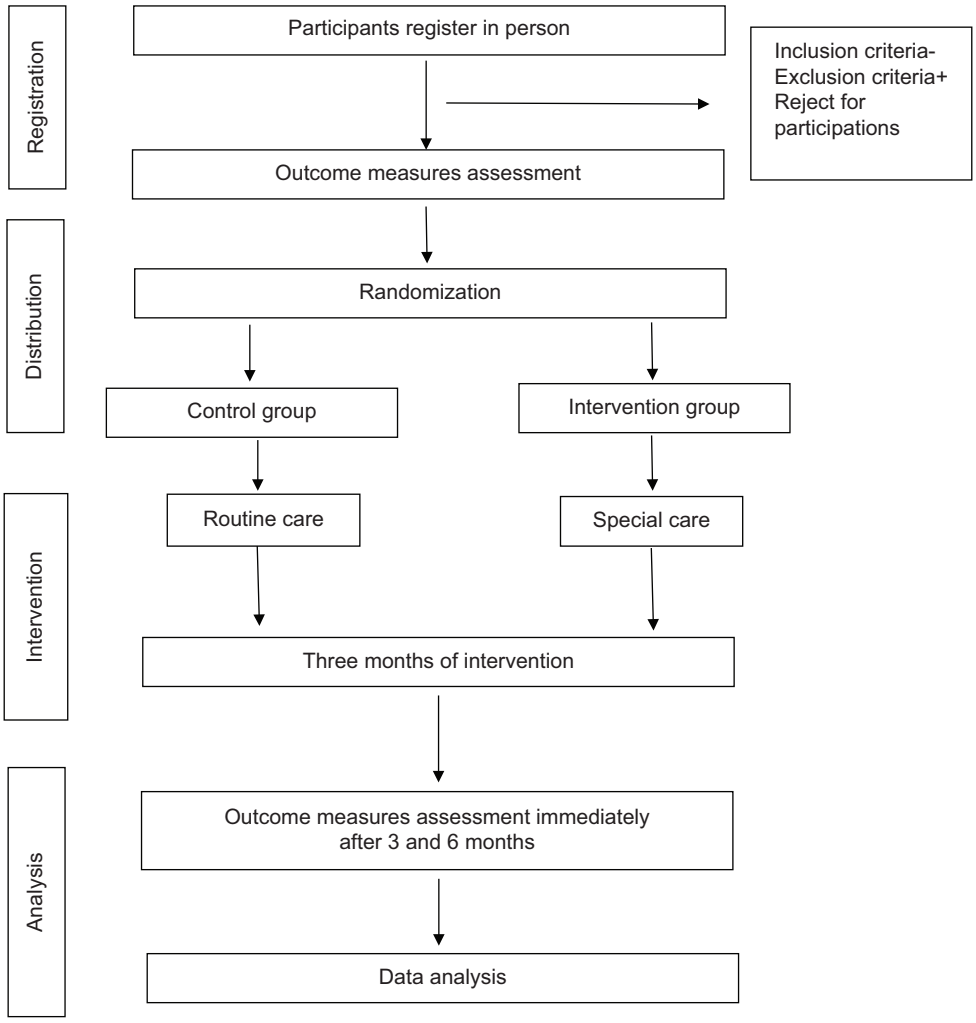

Figure 1: The diagram demonstrating randomized controlled trial protocol

A calibrated sphygmomanometer is used to measure blood pressure. A standard tape measures height, waist, and wrist circumference. The measurement tool is the same for all samples to check validity and reliability. One person makes measurements under the same conditions for everyone. All samples are sent to a laboratory, and the same laboratory conditions are used to measure blood factors.

The present study will be conducted with the clinical trial method in two control and case groups to determine the effect of the intervention based on the FHN model on blood sugar and anthropometric indicators in middle-aged people with prediabetes. The intervention method will be in three stages: before, intervention, and evaluation [Figure 2].

1. Preintervention:

After obtaining permission, the researcher will refer to comprehensive health service centers. The research team visited the mentioned centers, and after introducing themselves, explaining the research objectives, and obtaining permission from the director of the center, with his coordination, we held a meeting to familiarize themselves with the center's personnel. In this meeting, the project's goals will be explained to them, and their support will be sought to attract participation. With the help of healthcare providers, the researcher extracts the list of prediabetic people with a profile in the center whose details are registered in the Sib system and who meet the study entry criteria. Then, using a simple random sampling method, study participants will be selected and invited to participate in the study by telephone. The study's objectives are explained during the meeting with the participants in the center. This study includes home visits and the need for participants to visit the health center several times. Therefore, the time of their presence at the center is determined based on their opinion. A suitable space will be determined to communicate with the clients and complete the forms and measurements.

1-1. First visit with clients

According to the first strategy of the adapted FHN model, the research team introduces themselves and

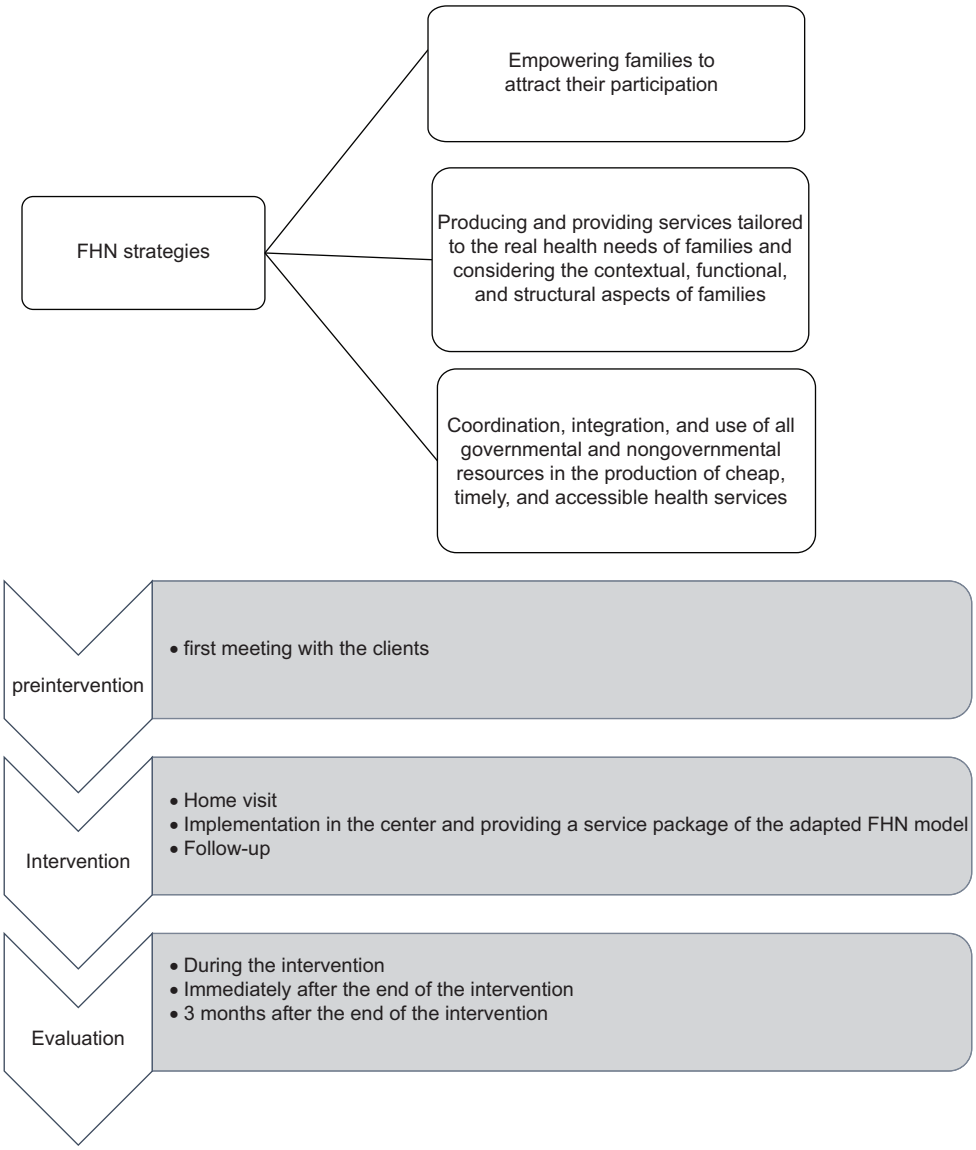

Figure 2: FHN strategies and stages

welcomes the client after the client visits the center. First, the researcher thoroughly explains the purpose of the study to the client. It is explained to them that participation in this project is voluntary. They can withdraw from the study at any time, and their refusal to participate or unwillingness to continue cooperation will not affect the quality and quantity of their care. They are told that the study will require two to five home visits. The information will be completely confidential and only available to the researcher. The client is asked to complete and sign the informed consent. Then, the patient's weight, height, waist circumference, and blood pressure are measured by the researcher, and after calculating the body mass index (BMI), the demographic information is recorded in the demographic. To measure the level of HbA1c, Low-density lipoprotein (LDL), and High-density lipoprotein (HDL), a blood sample is taken from the patient and sent to the laboratory. After the initial evaluation of the client, the researcher receives the client's exact address, the home phone number, and the mobile phone available for the home visit and coordinates with him regarding the first home visit.

2. Intervention:

2-1. Home visit:

According to the second strategy of the adapted FHN model, home visits are arranged in two to five sessions.

First home visit:

Before visiting the home, the research team coordinates the home visit time with the client through a phone call, and he goes to the client's home, introduces himself, and communicates sincerely with the family. In this meeting, the purpose of the research and the necessity of individual and family participation in the various

stages of needs assessment and planning for the family and the individual will be explained. The Family Health Ambassador (FHA) is selected with the help of family members and the client to create the necessary coordination to follow the formulated health goals. The selection criteria for an FHA include living with the patient or being a close relative and being able to care for the patient if necessary. In the home visit program, the economic status is assessed by observing the type of building and home furniture, and at this stage, with the help of the client and family, Ecomap and the family's genogram are drawn to check the family's relationship with the surrounding environment. Individuals and family genetic history and family structure and relationships will be examined.

Finally, according to the evaluations made by the researcher, together with the client and family members, he examined the limitations and abilities of the family, and they were told that after analyzing the information, with their help, the list of problems is defined and prioritized according to the decision matrix in the next meeting. The duration of the home visit will be 20 min to an hour. Also, at the end of each session, the next session will be coordinated with the family. Based on the family's needs, the number of home visit sessions is different, and for each family, between two and five home visit sessions will be held.

Second home visit:

In this meeting, the researchers, with the help of the individual and the family, extract a list of problems based on the findings of the previous visit and their statements. Furthermore, based on the following criteria (severity, prevalence and frequency, feasibility, importance, and effect of intervention) they prioritize the problems. In this way, each problem is scored from 1 to 5 in terms of the mentioned items, and the problem that gets the highest score is given priority. After that, the researcher identifies the factors affecting the problems (family abilities and obstacles) through interviews with the family. After that, in line with the identified factors, with the help of the client and the family, he formulates a goal setting and an action plan (implementation method, schedule, and evaluation). The researcher will agree with the patient and FHA on the method of evaluation of the regulated programs.

2-2. Implementation in the healthcare center:
The following actions are taken according to the second and third strategies of the adapted FHN model.

Training sessions

According to the extracted educational needs of the families, the researcher, based on the agreement with the client and FHA in the fields of (prediabetes disease process, symptoms and complications, prevention and treatment, nutrition in prediabetic patients, physical activity in prediabetic patients, blood sugar monitoring), training will be provided by lecture and discussion group.

Peer groups

To identify the health-related needs of families, the researcher forms peer groups with the participation of clients and FHAs. Peer group meetings are held in groups of five to seven people with FHAs based on arrangements made in the center. Peer groups are held to increase self-esteem and share everyday experiences, developing positive interpersonal relationships, empathy, and emotional support through sharing experiences, information, and ways to deal with everyday problems with other peer group members.

Follow-up referrals

Based on the extracted health needs, If necessary, the researcher introduces the client to the various healthcare providers, including physicians, nutritionists, psychiatrists, endocrinologists, physiotherapists, etc., and follow-up referral outcomes through phone calls with the client.

3. Evaluation:
After the end of the intervention:

Immediately after the end of the intervention, the participants are asked to go to the health center to complete anthropometric information (BMI, waist circumference, etc.).

Three months later

After three months, the clients will be contacted again and asked to return to the center for tests. The patient's blood sample is taken to test HbA1C, LDL, and HDL, and the patient's weight (BMI), waist circumference, and blood pressure are measured and recorded. In the end, the cooperation of the applicants in this research is appreciated, and a booklet including all educational files presented to the intervention group is provided. It will be presented to the control group as a memorial.

Ethical consideration

This study has been registered under clinical trial registration number IRCT20230516058206N1 in the Iranian Clinical Trials Registry (WHO subgroup). Isfahan University of Medical Sciences approved the project's ethical guidelines and national norms and standards (IR.MUI.NUREMA.REC.1402.054). Before recruitment, each participant will be informed about the study objectives,

assured about the privacy of the study data, and will be asked to sign a written informed consent. Both participating in the study and stopping it are optional.

Data analysis

Data analysis will be done using SPSS version 22. MANCOVA, ANCOVA, and independent *t*-tests compare nominal, ordinal, and numerical variables. In addition, a paired *t*-test is used for intragroup comparison. Significant *P* values are those less than 0.05.

Discussion

Various studies have discussed the importance of timely intervention and treatment of prediabetic patients. Since these patients have a chance of not getting diabetes if treated on time, it places these people among the appropriate intervention groups. Studies have shown that the healthcare system has been unsuccessful in controlling these patients, which can be attributed to the lack of a systematic plan to implement interventions for this group and ignoring other dimensions of health, including the social dimension, such as family. Considering the role of the family as the primary recipient of care in the adapted FHN model, it is hoped that the results of the FHN model can be a suitable model for providing family-oriented services to improve the blood sugar control of middle-aged people with prediabetes.

Limitations and recommendations

Since this study has not been implemented yet, the possible limitations are not clear.

Conclusion

Determining the effectiveness of the FHN model on the control and prevention of diabetes can offer a suitable framework for providing family-oriented services to middle-aged people with prediabetes and improving their health by considering social factors, such as family.

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Conflicts of interest

There are no conflicts of interest.

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