Original Article

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Quick Response Code:

Website: www.jehp.net

DOI: 10.4103/jehp.jehp_1706_21

Home health care of Iranian elderly with dementia: Study protocol for guideline adaptation

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Received: 23-11-2021
Accepted: 09-04-2022
Published: 31-01-2023

Abstract:

BACKGROUND: Advanced stages of dementia interfere with elderly self-care. Consequently, they need caregivers who take responsibility for their care in the long-term. Restrictions to the caregiver's access to information, resources, and organizational support have created problems in their caregiver role, which is why the World Health Organization (WHO) emphasizes caring for caregivers by providing evidence-based information and training programs. As there is no clinical practice guideline for home care in the Islamic Republic of Iran, this study aims to develop a home health care guideline for the elderly with dementia.

MATERIALS AND METHODS: The ADAPTE process provided by the Guidelines International Network was considered as the basis. In order to identify the care needs of Iranian patients with dementia, semi-structured interviews were added to this guideline.

DISCUSSION: The identification and implementation of the perspectives of patients and caregivers during the process of guidelines adaptation increase the applicability of the guidelines. Improved quality of life for the patients in their place of residence is one of the expected consequences of this guideline's implementation. The developed guidelines will be used at home health care centers, and dementia and Alzheimer's associations in Iran.

Keywords:

Dementia, Alzheimer, Home Health Care, Caregivers, clinical practice guidelines, Adaptation, Islamic Republic of Iran

Background

According to the World Health Organization (WHO), the world is rapidly aging.[1] The global dementia epidemic is one of the consequences of an aging population. According to statistics released by Alzheimer's Disease International (ADI), every three seconds, someone in the world develops dementia. As the global population ages, the number of people living with dementia is expected to triple from 50 million in 2018 to 152 million by 2050.[2] The growing trend of dementia is not steady around the world. The highest prevalence of the disease is in Asia (48%), which will increase to 59% in 2050.[3] Age standardized dementia prevalence rate in Iran, based on the WHO standard population, is 8.1%. The prevalence increases with the population's age, starting at 3.7% in the age group of 60–64 years and reaching 13.0% in the age group ≥80 years. It means that with every one year of increase in age, there is an increase of about 6% in the prevalence of dementia.[4] An elderly person with dementia is a vulnerable person as the disease disturbs self-care through creating a progressive effect on memory and cognition. Thus, these patients become more and more dependent on their caregiver[5] and need caregivers who will be responsible for their care in the long term.

Given that most patients are cared for in their homes,[6,7] the WHO has identified

How to cite this article: Irajpour A, Maleki F, Shati M, Najafii MR. Home health care of Iranian elderly with dementia: Study protocol for guideline adaptation. J Edu Health Promot 2023;12:8.

home health care (HHC) as a way to improve the quality of life of these patients.[8] Having a key role in supporting patients and their family, HHC refers to a type of health care service[9] that is provided in the residence of the patient and involves the participation of the client and their families.[10] In HHC, there is a demand for the use of specialized services for patients and family members.[9] In this regard, clinical practice guidelines help the health team to provide more effective care.[11]

Care guidelines are statements that prevent non-standard actions while explaining the implementation stages.[12] Additionally, they play a key role in reducing preventable errors and costs, increasing the health of society, increasing productivity, reducing diversity of care, establishing coordination and agreement among health care workers, promoting efficient use of resources, and focusing on quality control processes.[11,13] In order to develop guidelines, expert support, rich support for epidemiological studies, clinical trials, review studies and meta-analysis of the intended population are required.[12] Thus, the adaptation of guidelines is considered in societies where rich sources of information and expertise are not available.[14] Adaptation of guidelines is a systematic approach. In this process, the existing guidelines are modified to be used in the intended cultural and organizational context.[12] As such, they become more applicable within the socio-cultural context.[15]

To our knowledge, there is no HHC guideline for the elderly diagnosed with dementia in Iran. Thus the aim of this study is to design and develop an adaptable and applicable HHC guideline in the health system of the country in order to provide effective care to these patients. As the WHO has emphasized the need for coherent planning and informed approach of governments and sectors in coping with the disease,[1] the present study will be helpful in achieving the global goal.

Materials and Method

The present study was based on the second version of the ADAPTE process provided by the Guidelines International Network (GIN).[16] According to this instruction, in order to adapt a HHC guideline for the elderly with dementia, three phases of setup, adaptation, and finalization of the guidelines will be performed. In the adaptation phase, in order to identify the care needs of Iranian patients with dementia, semi-structured interviews will be added to the stages of this phase as a complementary part [Table 1].

Phase one: Setup

In this phase, the possibility of the adaptation process is evaluated and the required resources, facilities, and skills are determined. This phase is completed by setting the adaptation process program.[16] In the present study, in order to determine the feasibility of the adaptation process, the researchers searched guideline databases including National Guideline Clearinghouse (NGC), Guidelines International Network (GIN), National Institute for Clinical Excellence (NICE), and Scottish Intercollegiate Guidelines Network (SIGN)) for the presence of guidelines related to the research topic. Finding several clinical practice guidelines (CPGs) related to the research topic ensured that the adaptation process is possible. Moreover, the Elderly Health Office of Iran's Ministry of Health, and Medical Education (MOHME) approved the adaptation plan, and Isfahan University of Medical Sciences funded it. The adaptation process program was prepared as the PhD proposal of nursing and was registered under the number of IR.MUI.RESEARCH.REC.1399.212 in the ethics committee of Isfahan University of Medical Sciences.

Table 1: The phases and steps of the study

Phase	Step
Setup	Establish an organizing committee
	Select a guideline topic
	Check whether adaptation is feasible
	Identify necessary resources and skills
	Write adaptation plan
Adaptation	Determine the scope and purpose
	Search and screen retrieved guidelines
	Determine the care needs of the elderly with dementia
	Assess guidelines
	Select between guidelines and recommendations
	Prepare draft adapted guideline based on care needs and guidelines
Finalization	External review of the adapted guideline
	Produce final guideline
	External review of the guideline

Phase two: Adaptation

Based on the ADAPTE process, in this phase, the scope and purpose are identified and guidelines related to the intended subject are searched and screened. Finally, the draft of the guideline is written.[16]

The research questions in the present study were determined and answered based on the Population, Intervention, Professions, Outcomes and Health care system (PIPOH) method. The target population is the Iranian elderly with moderate-to-severe dementia because in these two stages of the disease, patients become dependent or partially dependent on self-care. The intended guideline will be designed and developed in the area of care for the elderly with dementia living at home. The target users will include formal (nurses and nursing assistants) and informal caregivers (family members and home caregivers). Improving the quality

of life of the patient in their place of residence is one of the expected consequences for the implementation of this guideline.The developed guideline will be used at HHC centers, and dementia and Alzheimer's associations in Iran.

In order to search and screen the available evidence and guidelines, four databases (PubMed, Scopus, ProQuest and Scientific Information Database (SID)), online international guideline databases (NGC, GIN, NICE, SIGN, Ontario Guideline Advisory Committee (GAC), New Zealand Guidelines Groups, Clinical Practice Guideline (CPG), Standards, Options et Recommendations (SOR) and World Health Organization (WHO)), and websites of Alzheimer's Disease International (ADI) are searched. "Home health care", "caregiver", "clinical practice guideline", and "dementia" are keywords which are expanded with use of truncation symbols and through expansion of subject headings. Publication language is limited to English and Persian due to constraint of resources for translations. Publication dates are limited to 10 recent years.

The guidelines and evidence that are not fully accessible or that are in the areas of screening, diagnosis, evaluation, prevention of cognitive impairment, and care for families or caregivers of patients are excluded.

The retrieved guidelines are evaluated by specialists including neurologists, psychiatrists, nurses, and clinical psychologists using the Appraisal of Guidelines for Research & Evaluation (AGREE) Instrument. As each guideline should be critiqued by at least two, and in the optimal case, by four assessors to increase the reliability of the AGREE instrument,[17] this issue is considered in selecting the number of participants. The Persian version of AGREE instrument will be used with no statistical significant differences between the mean values obtained from the English and the translated versions of AGREE.[18]

After collecting the opinions of the assessors, the standard score of the AGREE instrument domains is calculated according to the instructions for its use.[17] The AGREE user's manual does not provide cutoff scores for high/low quality CPGs. According to previous studies, the guidelines will be classified into three categories of very good (most domains score above 60%), good (most domains score between 30% and 60%), and not good (most domains score less than 30%).[19,20] The guidelines that are categorized as "very good" will be the basic guidelines and whole guideline and all of its recommendations will be accepted. The guidelines categorized as "good" will be used as complementary in the development of the adapted guideline. The third category of guidelines will be excluded.[16]

The integration of qualitative research results with the guidelines during the adaptation process leads to a comprehensive view about the patient and their condition, and makes the guideline more applicable.[21] In this study, the recommendations and actions of the guideline draft were a combination of the basic and complementary guidelines, and were based on the needs of the elderly with dementia living at home. In order to identify the HHC needs of the elderly with dementia, a descriptive, exploratory, qualitative study will be conducted. Two participating groups including home caregivers of patients as well as health system staff involved in the process of the treatment and care of the elderly with dementia will be interviewed.

Interviews will be conducted with the caregivers who have been responsible for the care or physical and psychological support[22,23] of a moderate-to-severe dementia patient for at least four hours per week during the last six months.[24,25] Moreover, not being diagnosed with chronic mental illness, no use of drugs and psychotropic substances, having communication skills for the exchange of experiences and feelings, and willingness to participate in the study are among the inclusion criteria. Exclusion criteria consist of unwillingness to continue cooperation or the death of the care recipient person. Inter-professional team including nurses, neurologists, psychiatrists and psychologists, pharmacists, nutritionists, physiotherapists, speech therapists, and social workers participating in the treatment and care of dementia patients will be included in the study if they are willing and have the required time.

Using purposive sampling method, the selection of the participants in accordance with the objectives of the research will continue until data saturation is reached. After obtaining informed oral and written consent, in-depth semi-structured, face-to-face, and individual interviews will be conducted with the participants. The care needs of the elderly with dementia are different at different stages of the disease and at different times of day or night.[26] Thus, if the patients have different caregivers for day and night, both of them will be interviewed. The severity of the disease will be determined using the Clinical Dementia Rating (CDR) tool to identify the care needs of each stage.[27] As many studies have previously been conducted on the needs of patients with dementia[28,29] and as researchers seek a comprehensive understanding of the needs of the elderly with dementia in Iran, directional analysis will be used.[30] To this end, by performing a systematic review and using the keywords of dementia* AND need* in Scopus and ProQuest databases, the needs of patients with dementia will be identified and the initial classification matrix will be formed. Like other qualitative research, the data

analysis process takes place simultaneously with the data collection so that the results of the initial data analysis can guide subsequent interviews.[31]

In addition to interviews, observations are also made to describe the setting, activities, and interpretation of the data. A detailed description of the patient's situation and behavior is provided through field notes. The researcher writes down what they see, hear, think, or experience during the interview, and collects data accordingly as well.[32] At the end of this phase, according to the detected needs, the draft HHC guideline for Iranian elderly with dementia will be written using the basic and complementary guidelines and, if necessary, a systematic review will be performed.

Phase three: Finalization

In the finalization phase, the developed draft is validated after receiving feedback from stakeholders and the final document is developed.[16] For this purpose, RAND-UCLA Appropriateness Methodology (RAM) is used in this research. According to the instructions for using RAM, 9 to 15 health system employees from different specialties will be purposefully selected and invited to participate in two specialized in-absentia and in-person panels. The first panel will be in absentia. The draft of adapted guidelines will be emailed to experts, who will be asked to rate the actions and recommendations on criteria of usefulness, clarity, relevance, and implementation capability according to the RAM pattern, using a Likert scale from 1 to 9.[33,34]

After calculating the average scores of each assessor, the median scores of the experts for each recommendation are calculated. According median score ranges, each action will be classified into one of the following categories: inappropriate (1 to 3), uncertain (4 to 6), and appropriate (7 to 9). Another indicator that is calculated is the agreement level of the panel members. The more the agreement on the appropriateness of the action, the greater will be its power and certainty. The level of the agreement and disagreement is determined based on Table 2 provided by the Office of Standardization and Development of Clinical Guidelines in Iran. Decisions on actions are then made according to Table 3.[35]

Finally, recommendations which rate in uncertain category or experts will be disagreeing about them discuss in second panel. According to expert's opinions, these recommendations will correct or exclude. The final version of the adapted guideline will be approved by 10 health system employees who won't participate in the process of adaptation. The confirmers evaluate the guideline by using yjr AGREE reporting checklist.[36]

Table 2: Evaluations of the agreement of the experts

	Full agreement
	The number of experts whose mean is out of the median category
Number of panel members	
8-10	2 ≥
11-13	3 ≥
14-16	4 ≥

Rigor and trustworthiness

In order to ensure the rigor and trustworthiness of the data, the four criteria, namely, credibility, dependability, transferability and confirmability suggested by Lincoln and Guba will be considered.[37] To this end, the researcher increases the rigor and trustworthiness of the results through identifying their ideas and assumptions before starting the research, selecting health system specialists with maximum variation in terms of demographic characteristics and expertise, obtaining the consensus of the experts about the draft of the guideline, approval of the final version by experts outside the research, detailed registration of all activities and decision-making, and retention of the documents in all phases of the guidance development as well as detailed reporting. Moreover, the following measures will be performed in the qualitative part of the research: in-depth interviews with the participants in various sessions and different settings, the combination of various data collection methods (interview, observation, field notes, etc.), review of the transcripts and codes by the participants to verify the accuracy of the data and the extracted codes, and review of the data by the experts separately in order to ensure that the categories match the statements of the participants.

Discussion

Evidence-based clinical guidelines are prepared based on the systematic search of evidence and studies.[12] The connection between the produced evidence and the clinical field is made possible by providing valid

Table 3: How to decide on recommendations

Criterion / Decision	Category of median			Agreement	
	Inappropriate	Uncertain	Appropriate	Agree	Disagree
Confirm as final recommendation			*	*	
Exclude recommendation	*			*	
Decision in the second panel of experts		*		Agree or Disagree	
	Appropriate or Uncertain or Inappropriate				*

knowledge in accordance with the objectives, resources, and context. Clinical guidelines are tools that facilitate the transfer of knowledge to the functional realm. Paying attention to the viewpoint of the target users increases the applicability of the guidelines in the socio-cultural context.[21] Therefore, in the adaptation process of the present guideline, while taking into account the available evidence and knowledge, the care needs of the patient and the views of the caregiver will also be considered. The complexities of dementia and caring for people with this disease in the home environment[3] are such that the mere presence of stakeholders in expert panels cannot address all aspects that is mentioned in the ADAPTE toolkit. Accordingly, the identification and extraction of the care needs of the patient are added to the adaptation stages mentioned in the instructions of the GIN in order to pay special attention to the characteristics of the audience and the context. In this process, the researchers will try to find out the beliefs, values, and behavioral patterns of the target population by interacting with them. This effort will contribute to the better understanding of the context, meanings of behavior, and various cultural, social, economic, and political factors affecting HHC of the Iranian elderly with dementia.

The significance and priority of the need for a comprehensive scientific collection and design of valid actions to improve the care and quality of life of dementia patients at the international and national level,[1] together with the emphasis of the MOHME on the adaptation of clinical guidelines[14] made the researchers adapt the mentioned clinical guideline with the cooperation and support of the relevant organization. This guideline can be used in various areas of care for dementia patients such as HHC centers, the Iranian Dementia and Alzheimer's Association and NGOs, and can be used by formal and informal caregivers. It is hoped that the use of this guideline can play a more effective role in improving the care and quality of life of patients with dementia.

Declaration of patient consent

The authors certify that participants will obtained all appropriate consent forms.The participants will understand that their names and initials will not be published and due efforts will be made to conceal their identity.

Acknowledgements

This paper was extracted from PhD thesis. The authors would like to thank Isfahan University of Medical Sciences and MOHME for supporting this research.

Ethical approval for this study has been obtained by the ethics committee affiliated with Isfahan University of Medical Sciences, Isfahan, Iran (IR.MUI.RESEARCH.REC.1399.212).

Authors' contributions

The present study protocol is the research priority of the Elderly Health Office of Iran's Ministry of Health and Medical Education. Alireza Irajpour, Fatemeh Maleki, Mohsen Shati and Mohamad Reza Najafii were involved in the study design and developed the framework of the work. Fatemeh Maleki wrote the first draft of this manuscript. Alireza Irajpour, Mohsen Shati and Mohamad Reza Najafii reviewed and worked on the subsequent drafts of the protocol and manuscript. All authors approved the final manuscript.

Financial support and sponsorship

This study protocol is related to the dissertation proposal for Ph.D. in nursing "Design and development of a clinical home care guideline for the elderly with dementia", which has been reviewed and funded by Isfahan University of Medical Science (Grant no. 399122). The maximum budget that such studies could receive was allocated to it. The funding body just has provided financial support and had no role in the design of the study and writing of the manuscript. Additionally, the Elderly Health Office of Ministry of Health and Medical Education in I.R. Iran has promised to provide executive support to the project.

Conflicts of interest

There are no conflicts of interest.

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