




Protocol Study

Effects of a COPE-Based Intervention on Resilience and Health Outcomes in Caregivers of Elderly with Diabetes: A Protocol Study

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ABSTRACT

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Introduction: Caring for older adults with type 2 diabetes presents multiple physical and psychological challenges that can impact the quality of life of family caregivers. The Creativity, Optimism, Planning, Expert Information (COPE) model, with a focus on comprehensive education and support, have the potential to improve resilience, health literacy, and better illness perception. This study aims to evaluate the effectiveness of an intervention program based on the COPE model on resilience, health literacy, illness perception, and quality of life of family caregivers of elderly people with type 2 diabetes.

Methods: This study is a randomized controlled trial (RCT) protocol with a pre-test and post-test design. The target population consists of family caregivers of elderly people with type 2 diabetes referring to health centers affiliated with Shahrekord University of Medical Sciences. The sample size will be 45 participants in each group (intervention and control), totaling 90 participants. The study will be conducted in two phases: first, designing an educational-support program based on the COPE model through a review of literature and expert panel opinions; and second, implementing the program, which includes a pre-test, delivering the intervention (through in-person sessions, telephone follow-ups, and WhatsApp support), and conducting post-test assessments immediately and three months after the intervention. Data will be collected using a demographic questionnaire, the Connor-Davidson Resilience Scale, the TOFHLA Health Literacy Questionnaire, the Illness Perception Questionnaire, and the SF36 Quality of Life Questionnaire. Data analysis will be performed using SPSS-23 software.

Conclusion: This protocol outlines the methodology for a randomized controlled trial that will evaluate the efficacy of a COPE model-based intervention. If proven effective, this structured program can serve as a practical and replicable framework in healthcare systems to support family caregivers of elderly individuals with type 2 diabetes, potentially enhancing their resilience, health literacy, and overall quality of life.

Keywords: COPE Model, Resilience, Health Literacy, Illness Perception, Quality of Life, Aged

Introduction

Ageing has caused changes in various aspects of health, including physical, mental, and social well-being, and has led to the development of various chronic diseases, including diabetes (1). Today, the

diabetes epidemic is one of the most important causes of mortality and disability and one of the most escalating public health disabilities in the world (2). Since the health of chronically ill patients, such as

elderly diabetics, depends on the health of their caregivers, it is particularly important to consider the health of caregivers; the closer the relationship between the patient and the caregiver, the greater the challenges and difficulties that caregivers face (3).

Family members are the main group of non-professional caregivers (caregivers who have not received specialized training in caring for patients and whose care is limited to the home) (4). Family caregivers are partners, relatives, or friends who provide care over months to years that requires a significant amount of time and involves performing a wide range of physical, social, emotional, or financial tasks (5).

In the United States, a report by the National Alliance for Caregiving and American Association of Retired Persons estimated that approximately 53 million adults provided unpaid care to an adult or child in the year 2020 (6). In Iran, while national statistics on the precise number of caregivers are scarce, the high and growing prevalence of chronic diseases alongside rapid population aging strongly suggests a substantial and expanding population of family caregivers. This underscores the critical need for focused research and support initiatives for this group (7).

Resilience can be considered as a variety of individual abilities to maintain or restore relatively stable physical and psychological functioning when faced with stressful events and life adversities. Resilience is a dynamic mechanism that is affected over time by changes in factors such as living conditions, environment, and situational and contextual factors (3). Resilience helps individuals to more easily overcome the crisis of a diagnosis, reduces the impact of tasks resulting from medical care and treatment, and improves the psychosocial adjustment and well-being of caregivers during their patient's illness (8). It can be said that resilient individuals have a greater ability to adapt to environmental changes, self-healing, the ability to adapt to hardships, greater health and independence, a sense of well-being for themselves and others, and a higher quality of life (9, 10).

The importance of health literacy has been increasingly demonstrated in the levels of general literacy and care literacy of family caregivers. Health literacy includes the ability to understand prescription drug instructions, medical education brochures, the ability to benefit from the complex medical system, decision-making, and the ability to apply these skills in health-related situations. In addition, the level of health literacy of caregivers is also influential in understanding the disease (11). Correct understanding of the health status of elderly by family members can

also reduce the rate of death, complications, and consequences of the disease and improve the quality of life of themselves and the elderly (12).

Interventions aimed at improving resilience, health literacy, illness perception, and quality of life can provide a new and complementary approach for families dealing with chronic diseases such as heart failure. One of the family-centered educational support programs is the Creativity, Optimism, Planning, Expert Information (COPE) model. This model was first proposed by Houts et al., in 1996 based on a combination of stress and adaptation and family systemic resilience models. The COPE model is a combination of four main components: Creativity, Optimism, Planning, and Expert Information (13). This model has two main goals; the first goal is to increase the effectiveness and efficiency of care provided to the patient, and the second goal is to enhance the caregiver's sense of efficacy and satisfaction in caring for the family, especially their patient. In fact, this model emphasizes creative thinking to see problems in new ways, maintain an optimistic attitude, create plans to solve problems, and learn how to follow up on expert information (14, 15).

The nursing profession is in a position that has direct and indirect connections with other paramedical professions and all segments of society and can play a key role in providing comprehensive information on care and providing new health information to elderly and their families. In fact, one of the duties of nurses is to help families improve their abilities to deal with actual and potential problems, because the family is an essential member of care and continues the path of the nurse. In the last century, paying attention to family health has become an important issue in the medical profession, especially nurses. The health of family members leads to better patient care and greater benefits for the patient (16).

Despite the established efficacy of the COPE model in improving outcomes for caregivers of elderly with conditions such as heart failure and cancer (14, 17), a distinct research gap exists regarding its targeted application for family caregivers of the elderly with type 2 diabetes. While studies like Alaei et al. demonstrated its success in enhancing resilience in heart failure caregivers (14), the unique, long-term, and self-management-oriented challenges of diabetes care necessitate a specific investigation. The COPE model, provides a highly relevant framework to address these distinct needs (14, 17). To address this disparity, the present study will develop and evaluate the efficacy of a tailored COPE-based intervention, designed specifically to strengthen resilience, improve health literacy, foster adaptive illness perceptions, and enhance the quality of life for these family caregivers.

Method

Study design

This randomized controlled trial is a protocol design for a supportive educational intervention for caregivers of elderly people with type 2 diabetes.

Setting

This study will be a randomized controlled trial with a pre-test and post-test design. This study will be conducted at health centers affiliated with Shahrekord University of Medical Sciences, Iran. A total of 90 eligible family caregivers of elderly with type 2 diabetes will be randomly assigned to either an intervention or control group using computer-generated random numbers concealed in sealed envelopes, adhering to CONSORT guidelines. The intervention group (n = 45) will receive a COPE model-based program delivered through six sessions (two in-person and four telephone sessions) supplemented by WhatsApp follow-ups over one month, while the control group (n=45) will receive routine care, with the full educational package provided to them upon study completion for ethical considerations.

Sample size

The sample size was calculated using G*Power software (version 3.1.9.7). The calculation was based on the primary outcome of resilience score, using an independent t-test to compare the means between the two groups. According to the results of a similar study by Alaei et al., (14) which evaluated the effect of a COPE-based intervention on the resilience of family caregivers of elderly with heart failure, the effect size (Cohen's d) was estimated to be 0.85. With a type I error (α) of 0.05 and a test power ($1-\beta$) of 0.80, the minimum required sample size was calculated to be 44 participants per group. To account for a potential attrition rate of approximately 10%, the final sample size was set at 45 participants in each group (45 in the intervention group and 45 in the control group), resulting in a total of 90 participants. Participants

Participants are family caregivers of elderly people with type 2 diabetes who will visit health centers in Shahrekord, during the year 2025. The eligibility criteria for participants are presented in table 1.

Randomization

Participants will be allocated to intervention and control groups based on computer randomization

numbers. Allocated numbers will be kept in sealed envelopes. This trial will be conducted in accordance with the CONSORT statement.

Study procedure

Two phases have been considered in the design of this study. In the first phase of the study, an educational-support program will be designed. The educational-support program will be designed in a two-step process to ensure its validity and relevance. First, a preliminary program structure and content will be drafted based on the core components of the COPE model and a comprehensive review of literature on interventions for caregivers of elderly with diabetes. Subsequently, this preliminary draft will be presented to a panel of experts (including specialists in Health Education and Promotion, Geriatric Health, Nursing, and Physician) for content and face validity assessment. Their feedback on the relevance, feasibility, and clarity of the sessions, materials, and delivery methods will be collected using a structured checklist and incorporated into the final program. This iterative process ensures that the final intervention is both theoretically grounded in the COPE model and contextually tailored based on expert consensus. To follow up on the education, a virtual group, reminder messages, and phone calls will be considered for the participants. The second phase will include a pre-test, implementation of the educational intervention, and a post-test immediately and 3 months later in the intervention and control groups.

Phase I. Designing an educational-supportive program: The supportive-educational program for caregivers in the intervention group is designed as six training sessions based on the COPE model, as detailed in table 2.

The training sessions will be conducted by the researcher in six groups of five people, with two sessions in Shahrekord city health centers for 60 minutes and four sessions in the form of telephone calls for 30 minutes, along with follow-ups through groups on the WhatsApp platform, over a period of one month. The scheduling of these sessions will be agreed upon by the researcher with the caregivers. In these sessions, the three main problems of each caregiver in relation to patient care, such as the patient's activity level, strategies for improving resilience, and other issues, will be examined based on the COPE model. In the face-to-face sessions, lecture techniques, question and answer, educational images, and educational booklets will be used according to the needs of the elderly' caregivers.

Table 1. Participant eligibility criteria

Inclusion criteria	Exclusion criteria
<ol style="list-style-type: none"> 1. Willingness to participate in the study. 2. Caregiver aged over 18 and under 65 years. 3. Not being a member of the healthcare team (e.g., physician, nurse). 4. Ability to read and write in Persian. 	<ol style="list-style-type: none"> 1. Withdrawal from cooperation at any stage of the study. 2. Death of the care recipient during the study period. 3. Severity of the elderly person's illness that precludes continued participation. 4. Non-participation in at least one telephone or face-to-face session.
<ol style="list-style-type: none"> 5. Not participating in another similar study concurrently. 6. Not providing care for another person with a chronic illness concurrently. 7. Self-reporting of no known psychiatric disorder. 8. Designation as the primary caregiver by the patient. 9. The elderly care recipient has a diagnosis of type 2 diabetes. 	

Table 2. Educational content of the cope model-based supportive-educational program sessions

Session content	Session type
<ol style="list-style-type: none"> 1. Determining the caregivers' problem regarding care and care challenges in the elderly with diabetes 2. Prioritizing problems, explaining and reviewing the problem-solving process based on the components of the Cope model: four main components (creativity, optimism, planning, specialized information) 3. Applying the problem-solving process based on the Cope model to the problem, brainstorming by the researcher for the caregivers 4. Explaining the identified problem, choosing the appropriate solution using lecture techniques, questions and answers, educational images and educational booklets, choosing a person who can help him solve the problem (nurse, doctor and other people) 5. Developing a plan 6. Consulting to determine the time of the next session 	In-person sessions (60 minutes each session)
<ol style="list-style-type: none"> 1. Reviewing the amount of reading the booklet, which is collected by the researcher based on articles and references, and includes: familiarity with diabetes, signs and symptoms of the disease, factors controlling and exacerbating the disease, appropriate diet, amount of physical activity, side effects and drug interactions, how to properly and safely care for the elderly, explanation of the concepts of resilience, health literacy, perception of the disease and quality of life, factors affecting each of the above components, strategies for improving the components, the effects of implementing the developed program and studying the materials on caregivers and how to properly care for the patient, the need to follow up on specialized information from health care providers, etc. 2. Monitoring the amount of program implementation 3. Determining the problem that was the next priority 4. Encouraging the caregiver to study materials related to the next problem before the next session 5. Consulting to determine the time of the next session 	Telephone sessions (30 minutes each session)
Reviewing and responding to caregivers' questions and problems within one month	WhatsApp Follow-ups

Phase II. Implementation of educational intervention: In this phase, the finalized educational-support protocol will be evaluated through a randomized controlled trial. Participants will be randomly assigned to either the intervention group or the control group. The intervention group will receive

the COPE model-based program, while the control group will receive routine care. To uphold ethical standards, the control group will be offered the complete educational materials after the final post-test data collection is completed.



Assessment tools

Data will be collected using a demographic questionnaire (age, gender, education, marital status, occupation, and income), and validated scales, including the Persian version of abridged Connor-Davidson Resilience Scale 10 (CD-RISC-10), the Test of Functional Health Literacy in Adults (TOFHLA), the Illness Perception Questionnaire-Revised (IPQ-R), and the 36-Item Short Form Health Survey (SF-36).

The CD-RISC-10 (18) has 10 self-report items. The response to each item is assessed on a five-point Likert scale. (Not true at all), 1 (Rarely true), 2 (Sometimes true), 3 (Often true), 4 (True nearly all the time). The range of test scores is between 0 and 40. So that the higher the subject's score is, the higher the resilience. The validity and reliability of this scale have been confirmed by Rezaeipandari et al., (19).

The TOFHLA (20) consists of two sections: Numerical Comprehension and Reading Comprehension. The reading comprehension section assesses the patient's ability to read and understand text. These texts include instructions for preparing for an imaging test, patient rights and responsibilities in insurance forms, and a standard hospital consent form. The individual's score in this section is considered to be between 0-50. The numerical comprehension section assesses the patient's ability to understand and act on a doctor's advice that requires calculation. This section contains 10 explanations or health instructions regarding prescribed medications, when to see a doctor, steps for using financial assistance, and an example of a medical test result. The individual's score in this section is considered to be between 0-50. This section contains 17 questions. The total score of these two sections is obtained from the sum of the scores. A score of 0-59 is considered insufficient health literacy, a score of 60-74 is borderline health literacy, and 100-75 is considered adequate health literacy. The correlation coefficient of this questionnaire in studies was determined to be 89% and its Cronbach's alpha was determined to be 75% (21, 22). Its validity and reliability have also been evaluated in the Iranian population (23).

The IPQ-R (24) was first developed by Weinman et al., in 1996 and has been widely used to assess the perception of illness in people with different illnesses. In this questionnaire, the minimum score is 8 and the maximum is 80. This questionnaire has 9 parts: nature, time course (acute or chronic illness), disease outcome, disease controllability, treatability, continuity (related to the individual's overall perception of the illness), time course or periodicity of the illness, emotional representation (how much negative emotional reactions such as fear have been caused by the illness in the individual), and cause (psychological causes, internal causes, and environmental causes). The answers to the questions are marked on a 5-point Likert scale from "strongly agree" to "strongly disagree". Cronbach's alpha coefficient for different parts of the questionnaire has varied from 79% to 89%, and the test-retest reliability coefficient for different questions has been reported to

be 46% to 88% at an interval of 6 weeks. Also, the correlation coefficient between different parts of the questionnaire has been reported to be 46% to 88%. The discriminant validity of the questionnaire has been calculated and confirmed by examining 9 chronic diseases (25).

The SF-36 (26) is a widely used, generic measure of health-related quality of life that has been validated in diverse populations, including caregivers. It consists of 36 items that assess eight health domains: physical functioning (10 items), role limitations due to physical health (4 items), bodily pain (2 items), general health perceptions (5 items), vitality (4 items), social functioning (2 items), role limitations due to emotional problems (3 items), and mental health (5 items). An additional single item assesses perceived change in health. Each domain is scored on a scale from 0 to 100, where 0 indicates the worst possible health state and 100 indicates the best possible health state. The eight domain scores can also be summarized into two summary scores: the Physical Component Summary (PCS) and the Mental Component Summary (MCS). These scores are standardized to a mean of 50 and a standard deviation of 10 in the general population. The SF-36 has demonstrated excellent psychometric properties across numerous studies. It has high internal consistency (Cronbach's alpha typically > 0.80 for all domains), good test-retest reliability, and well-established construct validity. The Persian version of the SF-36 has been validated in the Iranian population and has shown good reliability and validity for use in both clinical and research settings (27).

Statistical analysis

Data analysis will be performed using SPSS software (version 23). The normality of the distribution for quantitative variables will be assessed using the Kolmogorov-Smirnov test. Descriptive statistics will be presented as mean (standard deviation) for quantitative variables and number (percentage) for qualitative variables. To address the study aim, an independent samples t-test will be used to compare the mean scores of resilience, health literacy, illness perception, and quality of life between the intervention and control groups at the post-test and three-month follow-up stages. Analysis of Covariance (ANCOVA) may be employed to adjust for baseline scores. The relationships between the main study variables (e.g., resilience, health literacy, and quality of life) will be examined using Pearson correlation analysis. A p-value of less than 0.05 will be considered statistically significant. Effect sizes will be reported for significant findings to illustrate the practical importance of the results.

Outcome measures

Resilience

The mean score of resilience in elderly caregivers will be measured using the CD-RISC-10 in the pre-test and post-test stages.

Health literacy

The mean score of health literacy in elderly caregivers will be measured using the TOFHLA in the pre-test and post-test stages.

Quality of life

The mean score of quality of life in elderly caregivers will be measured using the SF-36 in the pre-test and post-test stages.

Illness perception

The mean score of illness perception in elderly caregivers will be measured using the IPQ-R in the pre-test and post-test stages.

Ethical considerations

In order to comply with ethical issues, all those who constitute the research samples will be initially provided with the necessary explanations about the purpose of the research and the method of conducting the study, and their participation in the study will be voluntary. Ethical approval for this study has been obtained from the Ethics Committee of Islamic Azad University, Shahrekord Branch (reference number IR.IAU.SHK.REC.1403.402). In addition, sufficient considerations will be taken regarding the confidentiality and privacy of the samples' personal information, and the research samples will also be assured. This randomized controlled trial was registered in the Iranian Clinical Trials Registry with IRCT registration number (IRCT20181122041720N4||<https://irct.behdasht.gov.ir/trial/82557>) on 2025-03-27.

Discussion

This study aims to develop and evaluate the effectiveness of an intervention program based on the COPE model on resilience, health literacy, illness perception, and quality of life of family caregivers of elderly people with type 2 diabetes. The present article provides a supportive-educational program protocol that can be used in similar interventions.

This protocol outlines the development and evaluation of a structured supportive-educational program based on the COPE model for a notably underserved caregivers of elderly individuals with type 2 diabetes. The COPE model was selected as the theoretical framework for this intervention due to its strong alignment with the challenges of chronic disease management. Its core components—Creativity, Optimism, Planning, and Expert Information—directly target key areas of need, such as problem-solving in daily care, maintaining a positive outlook, organizing complex care regimens, and seeking reliable health information. We hypothesize that this tailored intervention will be feasible and acceptable to the caregivers. If proven effective in the subsequent trial, this protocol provides a replicable blueprint for implementing a low-cost, structured support system within similar healthcare contexts. The findings from the future trial have the potential to inform clinical

guidelines and public health policies aimed at supporting this critical caregiver population.

In line with the results, various studies have examined the effectiveness of the COPE model, for example in a study by Alaei et al., the experimental group received the COPE model-based intervention over 6 training sessions, and the control group received routine training. In the experimental group, resilience increased immediately and three months after the intervention, and in the control group, resilience decreased immediately and three months after the intervention (14). Also, Meyers et al., used the COPE model of care to examine the quality of life of elderly with advanced cancer and their caregivers. Elderly in the experimental group participated in an intervention with three joint educational sessions during the first month and learned the COPE problem-solving model. Elderly in the control group received usual care without the intervention. The COPE intervention allowed caregivers of these patients to achieve a much closer to stable quality of life during the 6-month follow-up (17). Also, in the study by Aghakhani et al., the results showed that virtual education via social networks such as WhatsApp Messenger can improve the resilience of family caregivers of people with cancer (28). As well as Sarcami et al.'s study entitled showed that the continuous care model can be considered as an effective intervention method in reducing the caregiving burden of caregivers with brain and spinal cord injuries (29).

Conclusion

This protocol paper details the methodology for a randomized controlled trial that will assess the feasibility and potential efficacy of a COPE model-based intervention for family caregivers of elderly people with type 2 diabetes. The development of this structured program addresses a significant gap in support for this underserved population. The findings from the forthcoming trial will provide crucial evidence on the intervention's impact, which could inform the integration of similar supportive-educational programs into standard healthcare practices to improve caregiver and patient outcomes.

Strengths of the study

1. Strong theoretical foundation: The use of the COPE model, which provides a structured framework for improving coping skills and stress management in caregivers.
2. Specific target population: Focus on family caregivers of elderly with type 2 diabetes—a highly stressed yet understudied group.
3. Multidimensional outcomes: Simultaneous assessment of resilience, health literacy, illness perception, and quality of life, offering a comprehensive evaluation of the intervention's impact.
4. Practical implications: Findings can inform the design of caregiver support programs in healthcare systems.
5. Rigorous methodology: Use of a randomized controlled trial (RCT) design to enhance internal validity.

Study limitations

1. Sampling limitations: Potential sample restriction to specific geographic areas or centers, limiting generalizability.
2. Self-reporting bias: Reliance on self-reported questionnaires, which subjective biases may influence.
3. Uncontrolled Confounders: Factors like socioeconomic status or duration of caregiving may affect outcomes.
4. Short follow-up period: Lack of long-term assessment of the intervention's effects.

Suggestions for future research

1. Longitudinal studies: Assess intervention effects over extended periods (e.g., 6–12 months post-intervention).
2. Model comparisons: Compare COPE with other interventions (e.g., PROMPT model or caregiver skill-training programs).
3. Qualitative integration: Conduct in-depth interviews to explore caregivers' subjective experiences.
4. Expanded sampling: Include caregivers from diverse regions to improve generalizability.
5. Mediating variables: Investigate the role of factors like social support or caregiver burden.
6. Technology-enhanced interventions: Develop online or app-based programs to improve accessibility.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

All authors were involved in study conception, design, drafting of the manuscript, ShM and ZK were involved in write and revise the manuscript. All authors have read and approved the final version of the manuscript.

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