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Development of health promotion model in patient with severe traumatic brain injuries: A mixed-method study protocol

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Abstract:

BACKGROUND: Patients with severe traumatic brain injury with some degree of long-term physical and cognitive disabilities are transferred from the hospital to home. So this study was conducted to the development a health promotion model in patient with severe traumatic brain injuries.

MATERIALS AND METHODS: This exploratory, mixed-methods, qualitative-quantitative study consists of 4 phases will be conducted in Isfahan University of Medical Sciences in 2023–2024. In The first phase, a literature review will be carried out to extract the patient need for care in postdischarge in many other countries. The second phase involves a directional content analysis of healthcare providers and caregivers of patients with severe-TBI to identify the needs of care of patients at home. In this phase, purposeful sampling will be used to collect data through semistructured interviews. In the third phase, the postdischarge care program will be designed based on the results of the first and second phases. In this phase, the classic Delphi method will be used to evaluate the final version of the program's initial draft and determine the program priorities and experts' consensus. In the last phase, the designed program will be implemented through a quasi-experimental study in two groups (before and after intervention), and the effectiveness of the intervention will be evaluated.

DISCUSSION: Using of care plan based on patient needs in postdischarge and improving the quality of life in patients with severe brain damage, taking into account the cultural, social, and religious context of Iran, will provide the possibility of effective home care for these patients.

Keywords:

Health promotion, mixed methods, severe traumatic brain injuries, study protocol

Background

Trauma stands out as the primary cause of mortality, disability, and inability among the economically active population in developing nations.^[1] Brain injury frequently results from trauma and significantly contributes to global mortality and disability rates.^[2] Statistics reveal that approximately 10 million individuals worldwide sustain traumatic brain injury annually.^[3] Those afflicted with severe-TBI, characterized by symptoms like unconsciousness lasting over

24 hours, memory loss exceeding seven days, and a Glasgow Coma Scale score ranging from 3 to 8, commonly^[4] experience enduring consequences, such as cognitive, psychological, and motor deficits.^[5]

Despite advancements in medical science and acute care enhancements, a majority of patients with moderate to severe brain injuries endure physical and cognitive impairments, affecting their functional, social, and neurological well-being.^[5] Neurological conditions such as seizures, sleep disorders, and psychiatric

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ailments, along with nonneurological issues like sexual dysfunction, urinary incontinence, gastrointestinal problems, breathing difficulties, motor impairments, and metabolic disorders, pose significant caregiving challenges for patients.^[6] Due to the chronic nature of this condition, patients are typically discharged from the hospital once their condition stabilizes;^[7] however, they often encounter various challenges thereafter.

In Iran's healthcare system, these patients receive continuous care at home postdischarge. Regrettably, many individuals experience heightened dependency and encounter a range of difficulties and complications, ultimately resulting in a deterioration of their quality of life.^[8,9] Studies by Odgaard *et al.* (2018) and Brito *et al.* (2019) have underscored prevalent postdischarge complications, including urinary tract infections, pneumonia, pressure ulcers, aspiration, and deep vein thrombosis, all of which may necessitate readmission.^[10,11] The obstacles faced by patients following discharge are substantial, with additional complications exacerbating their condition. These findings underscore the significance of establishing comprehensive postdischarge care protocols to tackle these challenges and enhance the overall well-being of those affected. The care of these patients is challenging due to their unique and continuous therapeutic needs, which demand thorough attention. Problems may arise when individuals without professional training take on the role of caregiver. This situation is further complicated by nonprofessional caregivers often shouldering the responsibility of providing care at home following early hospital discharge.^[12] In Iran, despite the increasing incidence of severe severe-TBI from accidents and work-related incidents,^[13] and the crucial role of caregivers in postdischarge care,^[14] there has been inadequate focus on addressing the care needs of these patients by non-professionals within the Iranian-Islamic cultural context. Therefore, this study aims to develop a postdischarge care program for severe-TBI patients based on a health promotion model, using a mixed-method approach.

Materials and Methods

This exploratory, mixed-methods, qualitative-quantitative study (in 2023) consists of four phases based on the Evans and Smith Health Promotion Model.^[15] The study is part of a doctoral thesis.

Phase 1: Literature Review

A literature review will be conducted to identify the needs for care of patients with severe severe-TBI after discharge in various contexts. To find relevant information, a search will be carried out in both Iranian and international databases, including, Scopus, Web of

Science, PubMed, CINAHL, ProQuest, Magiran, SID, Noormags, and ISC. The papers published between 2010 and 2023 in Persian and English will be included.

Phase 2: Qualitative Research (Identification of Needs and strategies)

At this stage, the qualitative study will be conducted to extract the care of needs and strategies of S-TBI patient, using semistructural interviews. The setting of this phase of the research will be two major governmental hospitals affiliated to Isfahan University of Medical Sciences. All of the interviews will be conducted in a private place selected based on the preference of the participants, after analyzing the qualitative data by the content analysis method.

Participants

The participants of the qualitative phase of this research consist of two groups. Family caregivers and healthcare professionals. The participants will be selected using a purposeful sampling method. We will consider the diversity of the age and work experience of healthcare professionals and the duration of the patient's TBI in family caregivers. We will interview the participants after we evaluate their inclusion criteria. Then, we will obtain their informed consent. The interviews will continue until the data is repeated and we reach data saturation.

Inclusion and exclusion criteria

In the qualitative study, family caregivers with experience in caring for a patient with severe-TBI at home and healthcare professionals (such as nurse, neurosurgery, speech therapy, physiotherapy, occupational therapy, and nutrition) with experience of caring for a patient with severe-TBI will be included.

Qualitative data collection method

In the qualitative phase of the research, the data will be collected using in-depth interviews. To observe ethical considerations, the participants will be explained about the aims of the study and their informed consent will be obtained for recoding their voice. The setting and the length of the interviews will be specified based on the preferences of the participants. Data analysis will be performed using the conventional content analysis. To assure the validity and reliability of the findings of the research, the four criteria of credibility, dependability, transferability, and confirmability will be considered.^[16] The following measures include selecting participants with maximum variation, allocating sufficient time to data gathering and using various data collection methods such as interviews and field notes, and check the accuracy of the researcher's perception through a review of a sample of the codes by an outsider observer and participants will be increased

credibility. Comprehensively describing all the phases of the research will be increased transferability. For confirmability, the study steps will be accurately recorded so that a thorough audit of the work is possible.

Phase III: Design and validation of the postdischarge care program

In this phase of the study, the program's priorities will be developed based on the results of the first and second phases. This program includes: identifying needs,^[2] determining general and specific goals,^[3] choosing the best strategies to achieve specific goals,^[4] identifying resources,^[5] designing evaluation methods,^[6] determining activities executive,^[7] program implementation and evaluation.

Holding a panel of experts

In this stage, the classic Delphi method will be used to evaluate the final version of the program's initial draft and determine the program priorities and experts' consensus. The members of the panel will consist of faculty members of nursing and medical and nursing supervisors. The program is expected to be finalized after four rounds. In the first round, an electronic version of the program (or hard copies just in case) together with open-ended questions will be sent to the panel members' email addresses. These questions intend to get the written comments of the experts about the components and details of the protocol. Likert items will be used for the responses, such as feasibility, cost-effectiveness, time efficiency, effectiveness, efficiency, acceptability, and compatibility, with the target group and implementation level. In the second round, after collecting the experts' written feedback, the content analysis method will be developed and the experts' opinions will be applied. Then, in the third round, the modified version along with an assessment checklist will be sent to the members via email. After the collection of their opinions, the final modified version will be given to the experts in the fourth round.

Phase IV: Implementation and evaluation of the postdischarge care program (quantitative research)

In this phase, quantitative research will be conducted with two groups in two stages before and after intervention carried out in the field. Implementation of the program included: assessing the care needs of patients, training the caregivers, preparation of guide books and educational materials for caregivers, and identification of supports for the implementation of the program (including creating a communication network between the treatment team and the caregiver). The control group will receive standard care interventions. After the implementation of the project, the evaluation will be performed. For this regard, a qualitative study

will be conducted with one group in two stages before and after intervention carried out in the field.

Study sample

The study is set in two major hospitals affiliated with Isfahan University of Medical Sciences. The target population consists of patients with *severe-TBI*. The samples will be selected randomly and the before-after design will be adopted. Considering a confidence interval of 95%, test power of 90%, and least mean differences of 0.8S between the groups, the number of samples in each group will be 32. The total sample size is 70.

Inclusion and exclusion criteria

The inclusion criteria are willingness to participate in this phase of the study, history of *severe-TBI* based on the diagnosis of the attending physician, level of consciousness less than 8, having a family caregiver to take care of the patient at home, discharge from the hospital within the last week at most. The exclusion criteria for this part of the study are unwillingness to continue cooperation by family caregivers and the death of the patient at any stage of the research.

Data collection method

The patient care assessment checklist

This checklist will be made by the researcher, which will be adjusted according to the care needs of patients with severe-TBI based on the results of the qualitative phase. The validity (content) and reliability of the questionnaire will be confirmed through Cronbach's alpha coefficient.

Zarit caregiver burden scale

The ZBI consists of 22 items rated on a five-point Likert scale that ranges from 0 (never) to 4 (nearly always) with the sum of scores ranging between 0 and 88.9. Higher scores indicate a greater burden. A score of 17 or more was considered a high burden. The validity and reliability of the questionnaire were verified by Navidian et al. (2004),^[17] ($r = 94\%$) in Iran.

Data analysis

To describe the state of the data, statistics such as the mean and standard deviation of the main research variables (The patient care assessment and caregiver burden) will be determined, and finally, by using SPSS version 22 the mean score of the main variables of the research before and after the intervention will be compared (if the data are normal) with paired t test and (if the data are not normal) with the non-parametric Wilcoxon test. Ninety-five percent confidence interval and P value <0.05 will be considered.

Ethical considerations

This study has been approved with the ethical code IR.MUI.NUREMA.REC.1401.160 by the Ethics Committee

of Isfahan University of Medical Sciences. Written informed consent will be obtained from all participants, ensuring the confidentiality of their information.

Integration of data

In this research, the integration of data that will be conducted by quantitative and qualitative results will be expressed together in the discussion section.

Discussion

The main goal of the comprehensive care program after discharge is to ensure the readiness of the patient and their family for the posthospital phase, establish ongoing posthospitalization care, and facilitate access to rehabilitation services.^[18,19] Caregivers need sufficient support to meet the care and treatment needs of those under their supervision. They cannot fulfill this crucial responsibility effectively without a well-defined care program.^[22]

Research by El-Tayar *et al.* (2021) showed that implementing a discharge program significantly improved parents' knowledge and caregiving skills for children.^[20] Additionally, a study by Lueckel *et al.* (2018) showed that introducing a postdischarge rehabilitation program in the home and community setting for patients with brain injuries led to a notable enhancement in the quality of care for these individuals.^[21] Overall, a postdischarge care program for individuals with *severe-TBI* can help reduce issues such as patient readmissions, urinary tract and airway infections, and pressure sores, and improve physical activity, thus enhancing their quality of life and overall health outcomes.^[22-24]

Other benefits of a care program include addressing challenges faced by family caregivers, such as reducing stress and anxiety levels, fostering a sense of responsibility among family members and healthcare professionals, increasing family members' self-assurance,^[21,22] building trust in healthcare institutions, ensuring smooth and healthy patient transitions to home or alternative care facilities, promoting improved coordination among care team members, and ultimately reducing caregiving burdens and enhancing the quality of life for family caregivers.

Continuity of care is a key aspect of patient-centered care, and by integrating this dimension into the program, holistic care provision can be achieved, aligning with the core objectives of nursing. Additionally, another benefit of the program would be to develop home-care strategies tailored to patients with S-TBI to improve the quality of care provided.^[22] This approach is particularly valuable when the treatment team sets and achieves short-term and long-term goals. The establishment of a

post-discharge care program based on Iran's cultural, social, and religious contexts, as explored in the present study, will lay the foundation for the effective delivery of care.

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Conflicts of interest

There are no conflicts of interest.

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