

SHIFA-PC

A Randomized Control Trial

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Structured Help for Families in Illness and Focused Assistance in Palliative Care: A Randomized Controlled Trial (SHIFA-PC-RCT)

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Background and Rationale

Families in the Middle East play a central role in patient care, particularly in palliative settings. However, limited evidence exists on the effectiveness of structured educational interventions tailored to regional and cultural contexts. This study aims to assess the impact of structured family education sessions on caregiver knowledge, satisfaction, and burden compared to standard verbal counseling.

Objectives

1. **Primary Objective:** Evaluate the effectiveness of structured family education sessions in improving family knowledge about palliative care.
2. **Secondary Objectives:** Assess caregiver satisfaction and measure the reduction in caregiver burden using the Zarit Burden Interview.

Methodology

Study Design

- Randomized Controlled Trial (Parallel Group Design)
- Conducted at Tawam Hospital's Palliative Care Unit
- Duration: 3 months

Population

Inclusion Criteria:

- Family members of patients receiving palliative care with life expectancy <6 months.
- Families willing to provide informed consent.

Exclusion Criteria:

- Families unable to attend structured sessions.

Sample Size

- Estimated 20 families.

Randomization

- Participants randomized using block randomization.
- Stratified by country to account for potential systemic differences.

Intervention and Control

Intervention Arm:

- Structured education sessions (3 sessions, 30 minutes each):
 - **Session 1:** Introduction to Palliative Care
 - **Session 2:** Symptom Management
 - **Session 3:** Emotional and Spiritual Support

- Delivered by trained healthcare professionals.

Control Arm:

- Standard verbal counseling during routine care.

Outcome Measures

Primary Outcome:

- Knowledge improvement scores (customized questionnaire).

Secondary Outcome:

- Caregiver satisfaction (survey-based).
- Reduction in caregiver burden (Zarit Burden Interview).

Study Workflow

Enrollment: Families recruited during consultations.

Baseline Assessment:

- Knowledge questionnaire.
- Zarit Burden Interview.

Intervention Assessment:

- Structured education sessions delivered to intervention group.

Follow Up:

Assess outcomes immediately after the 3rd session and 1 month after the 3rd session

Ethical Considerations

1. Approval from the Institutional Review Board (IRB) and Department of Health.
2. Informed consent obtained from all participants (Consent forms in Arabic and English).
3. Adherence to the Declaration of Helsinki.

Educational Session Outlines

Session 1: Introduction to Palliative Care

Objectives:

- Familiarize families with the principles of palliative care.
- Highlight the role of family in caregiving.

Content:

- Definition and goals of palliative care.
- Explanation of multidisciplinary care.
- Common myths and misconceptions.

Activities:

- Brief presentation.
- Open discussion for addressing questions or fears.

Session 2: Symptom Management

Objectives:

- Teach families how to recognize and manage common symptoms.
- Provide practical caregiving tips.

Content:

- Overview of pain management (e.g., opioid use, side effects).
- Handling nausea, breathlessness, and fatigue.
- Signs of disease progression.

Activities:

- Role-playing: Practicing symptom assessment.
- Visual aids (e.g., charts for symptom severity).

Session 3: Emotional and Spiritual Support

Objectives:

- Equip families with coping strategies.
- Enhance communication with the patient and healthcare team.

Content:

- Emotional support techniques (e.g., active listening, empathy).
- Managing caregiver stress and burnout.
- Spiritual care tailored to cultural/religious contexts.

Activities:

- Group sharing of experiences.
- Relaxation techniques (e.g., breathing exercises).