Cover page

Study Title: Evaluation of the Feasibility of a Mobile Phone-Based Intervention (Zalo Application) on Depression, Anxiety, and Stress Among Caregivers of Patients with Dementia

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Evaluation of the Feasibility of a Mobile Phone-Based Intervention (Zalo Application) on Depression, Anxiety, and Stress Among Caregivers of Patients with Dementia.

1- Objectives

The study aims to:

- Identify the information and skills that caregivers of dementia patients need to develop intervention content.
- Assess the feasibility of the intervention and the feasibility of conducting a randomized controlled trial of a mobile phone-based intervention for dementia caregivers, including recruitment rates, retention rates, completion of outcome measures, and acceptance of the intervention.

2- Literature Review

The total number of dementia cases is projected to reach 82 million by 2030 and 152 million by 2050 (1). The prevalence of dementia among older adults is estimated to be 5-8% (1). n Vietnam, community-based studies in the northern and southern regions indicate a dementia prevalence of 4.8-5%, while a study in Hue found a rate of 9.4% in 2014 (2,3). Most dementia patients live at home and are cared for by family members (4). As the number of dementia patients increases, the demand for caregivers rises. However, most caregivers lack adequate knowledge and support to fulfill their role. Dementia caregiving imposes significant psychological burdens, such as depression, anxiety, and stress, alongside physical and economic burdens. Studies indicate that caregivers of dementia patients experience significantly higher stress levels than caregivers of non-dementia patients and exhibit higher rates of depression and physical health problems. (5-7). Meta-analysis findings suggest that the prevalence of depression and anxiety among caregivers is 34% and 44%, respectively. These factors negatively impact caregivers' well-being, leading to poor quality of care and potential neglect of patients. Therefore, interventions targeting caregivers of dementia patients are essential to reducing psychological burdens and improving the quality of life for both caregivers and patients (8-11).

Information technology is considered a promising solution that can provide caregivers with benefits such as disease information, communication platforms, forums, and social support. Mobile phones are widely used in Vietnam. Research by Tremont has shown that using mobile phones reduces psychological burdens such as depression, anxiety, and stress among dementia caregivers while improving their ability to cope with patients' behavioral disorders. Other studies have demonstrated that video-based interventions providing exercise information and daily activity support reduce caregiver depression and anxiety while increasing caregiver satisfaction (12-16).

3- Inclusion and Exclusion Criteria

Inclusion Criteria:
Aged ≥ 18 years, the primary caregiver of a dementia patient for at least the past 6 months, and will continue caregiving for the next 6 months of intervention; Dementia patients are diagnosed according to DSM-5 criteria and are community-dwelling.
Able to read and understand Vietnamese and willing to participate in the study;
Owns a smartphone with the Zalo app installed or is willing to install Zalo (short training on using Zalo will be provided).

Exclusion Criteria: Caregivers with severe chronic illnesses preventing them from fulfilling study requirements, such as metastatic cancer, vision or hearing impairments, or cognitive impairment (Mini-Cog score <4).

Consent Procedures:
Eligible caregivers will be informed about the study. If interested, they will be provided with written consent forms.
A screening log will document non-eligible participants or those who decline participation.

4) Study Outcomes
Primary outcomes include recruitment rates, retention rates, completion of outcome measures, and acceptance of the intervention.
5) **Study Phases and Methodology**
Phase 1: In-depth interviews with 20 caregivers at the Geriatrics Department of Gia Dinh People's Hospital. Interviews will be audio-recorded, transcribed in Vietnamese, and analyzed thematically using NVivo software.

Phase 2: A parallel-group randomized controlled trial (RCT) with 60 participants randomly assigned to the intervention group or control group (1:1 ratio). Outcome measures will be assessed at baseline, immediately post-intervention, and three months post-intervention.

Randomization: Participants will be assigned using block randomization (block size = 4) by an independent statistician. Outcome assessors will be blinded.

Intervention Group: Participants will be added to a Zalo group managed by a researcher. Weekly, the researcher will post a topic determined from Phase 1 findings. Caregivers will be encouraged to discuss and share experiences.

Control Group: Participants will be directed to the Alzheimer's Association website for reliable information.

Psychological Distress Monitoring: Stress levels will be assessed biweekly using a stress thermometer. If a participant scores >4, they will be asked if they wish to continue.
6) Data and/or Sample Management and Security
Data Analysis
Phase 1: We will use Nvivo version 12 to manage data and code interview transcripts in Vietnamese. We will conduct content analysis, including data coding and category development.

The analysis will begin by identifying emerging concepts during the open coding process. The principal investigator will complete the coding with collaboration from two other researchers. The researchers will independently check and code the data, then discuss and refine it until consensus is reached. Final categories will be constructed, and all data will be reviewed and sorted into relevant categories. The data will be analyzed by the Vietnamese research team and later reviewed by two experienced qualitative researchers (one bilingual in Vietnamese and English) in Australia to establish higher-level categories and finalize the analysis. The most common issues caregivers need information and support for will be identified to develop interventions in Phase 2.

Phase 2: We will use Stata version 14 (StataCorp, College Station, TX, USA) for data analysis. Continuous variables will be presented as mean and standard deviation if normally distributed or as median and interquartile range if non-normally distributed. The recruitment rate, retention rate, and completion rate of outcome measures will be presented as percentages.

Data will be collected by trained researchers from the research team. Researchers involved in data analysis will have access to the data.

The information collected from this study will be kept confidential. All personally identifiable information of participants will be replaced with numerical codes. The de-identified study data will not be shared or provided to anyone except the study sponsor and the data safety monitoring committee. The data will be stored in a locked cabinet at the Department of Geriatrics - University of Medicine and Pharmacy, Ho Chi Minh City. Raw data will be collected using data collection forms and stored in a locked cabinet until analysis. Afterward, baseline and follow-up data will be entered into a secure, password-protected database by the research team.

7) Data and/or Sample storage
The data will not be stored for future use.

8) Data Monitoring Regulations to Ensure Participant Safety
Definition of Adverse Events, Severity, and Relevance
Adverse events are defined as any medical or health-related incident that is undesirable or harmful to the participant, occurring temporarily in connection with their participation in the study, regardless of whether it is considered related to the study participation.

Serious adverse events include any adverse event leading to death, life-threatening conditions, requiring or prolonging hospitalization, causing disability or significant long-term impairment, or any other condition that researchers consider to represent a significant risk.

Severity classification of adverse events:

Mild: Symptoms that do not require medical treatment or evaluation; transient signs and symptoms that do not affect normal activities.
Moderate: Events causing minor inconvenience or concern to participants and may interfere with daily activities but typically improve with simple treatment; moderate adverse events may cause some functional impairment.

Severe: Events that disrupt participants' normal daily activities, often requiring medical treatment and leading to functional incapacity.
Likelihood of adverse events:

Unexpected: The nature or severity of the event does not align with known information about the studied condition or intervention in the protocol, consent form, product documentation, or investigator materials.
Expected: The event is considered related to the intervention or the studied issue.
Relevance of adverse events to study participation:

Definitely related: The adverse event is linked to the research procedure—occurs in a reasonable sequence after the intervention, follows a known or expected reaction pattern, improves when the intervention is discontinued, and reoccurs with re-exposure. This adverse event cannot be reasonably explained by any other clinical characteristics of the participant.
Possibly related: The adverse event occurs in a reasonable time sequence following the intervention and follows a known or expected reaction pattern, but it may also be caused by other factors.
Unrelated: The adverse event is not related to the intervention—another cause is identified, and/or the timing of the event does not clinically align with the intervention, and/or the causal relationship is biologically implausible.
Reporting of Adverse Events
The method for reporting adverse and serious adverse events includes:

No serious adverse events are expected based on the nature of the intervention (i.e., behavioral, minimal risk), and no adverse events have been reported in caregiver intervention literature in Vietnam.
All serious adverse events (SAEs) and unexpected events (i.e., not previously reported for this intervention) will be reported to the IRB, NIA PO, and Safety Officer (SO) within 48 hours of becoming aware of the event. Additionally, all cases of death (expected or unexpected) will be reported within 24 hours to the IRB, NIA PO, and Safety Officer. A summary of all other SAEs will be reported to the NIA Program Officer and Safety Officer quarterly, unless otherwise required by the SO.
A standard form, either in paper or electronic format, will be used to document and record all reports of adverse and serious adverse events following the study protocol (from the start of the intervention to the completion of study participation).
Adverse events will be reported according to UC Davis IRB policies. They will also be reported to the NIA Program Officer and Safety Officer during regular meetings (at least semi-annually) and in annual progress reports.

9) Withdrawal from the Study

Participants may withdraw from the study at any time if they choose. We will ask them for their reason for withdrawing, should they wish to share, but no further data will be collected from them.

10) Risks to Participants

Potential risks to participants (caregivers of dementia patients) include psychological stress related to completing questionnaires and/or the intervention, as well as loss of confidentiality.

11) Potential Benefits to Participants

Potential benefits to participants include reduced psychological stress, decreased caregiver burden, improved knowledge, increased confidence in their abilities, and enhanced understanding of dementia.

12) Community Participation in the Study

This study involves hospital participation. The participants are caregivers of dementia patients treated at the Department of Geriatrics – Nhan dan Gia Dinh Hospital.

13) Sharing Results with Participants

The knowledge gained from this study will not be shared with participants before being widely disseminated to the public.

14) Ethics in Research

The study has been approved by the Ethics Committee - University of Medicine and Pharmacy, Ho Chi Minh City and is pending approval from NIA. The study will commence after receiving approval from NIA.

15) Measures to Protect Participants' Privacy

Participants will interact with one or two researchers from our study team. If they do not wish to post questions in the group chat, they may send private messages to the researcher.

To ensure participant comfort, we will explain the risks and benefits of the study. In Phase 1, participants will be interviewed by a trained researcher who will be empathetic and create a supportive environment during in-depth interviews.

In Phase 2, before intervention content is posted in the group chat, we will ask participants about their availability.

Within the research team, three researchers involved in in-depth interviews and data analysis will be allowed access to participant information. Any other team members wishing to access participant information must obtain approval from the principal investigator.

16) Compensation for Study-Related Injuries

The intervention aims to provide knowledge and skills for dementia patient care. Therefore, risks to participants in this study are minimal. However, participants in the intervention group may experience psychological stress from study participation. They may find weekly reminder phone calls intrusive. In cases of severe stress due to study participation, medical treatment will be available but provided at standard cost. The University of Medicine and Pharmacy, Ho Chi Minh City does not offer financial compensation or free medical treatment for stress related to study participation.

17) Financial Burden on Participants

Participants will not have to pay any fees for this study.

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