Title:

The Effectiveness of Augmented Dyadic Interventions to Boost Quality of Life Among Stroke Survivors and Preparedness of Care Partners in Pakistan.

ID: 2021-135 **Date: 1, October, 2021**

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Project Summary

Study Background

Stroke is a leading cause of mortality and disability worldwide, resulting in significant physical deficits and psychological problems for survivors and their families. The impact of stroke can be devastating, affecting not only the individual but also their loved ones.

Study Objective

1) The objective of the study is to evaluate the efficacy of skill building dyadic intervention in improving dyad (care partner based) quality of life after stroke by focusing on the quality of life and outcomes of the stroke survivors and their care partners living at home post stroke occurrence.

2) To assess and evaluate the effect of outcomes on quality of life of dyad members and reducing caregiver burden among stroke survivors and their care partners by using a dyadic intervention.

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Study Design

This study is classified as an interventional study, with the primary purpose of prevention. The study phase is not applicable (N/A). The interventional study model is a parallel assignment, where participants will be randomly assigned to either the experimental group or the control group. The study will employ single masking, where only the participant will be blinded to the group assignment.

The interventional study design is single-blind, randomized controlled trials with repeated measures. Each group will include 196 subjects (98 stroke survivor + 98 care partner). Total no. of individuals will be 392 which have 196 stroke survivor and 196 care partners. Out of 196 pairs the 98 pairs will be kept control. After baseline assessment, the responsible assessor will be telephoned with patients identification details obtained from hospital, rehabilitation centers of Pakistan. Permission from the patients or caregivers will be taken on consent form before the start of the assessment.

Randomization

Participants will be randomly assigned to either the experimental group or the control group. This randomization will ensure that the groups are comparable in terms of demographic characteristics, reducing the risk of bias and increasing the validity of the results.

Study Population

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This study will be conducted upon stroke survivors and their care partner after discharge from the hospital. A care partner is defined as the main person (Spouse, Mother, Father, Sister, Brother, Son and Daughter) helping with activities of daily living and advocating on behalf of the stroke survivors. A consent form will be obtained from targeted stroke survivors and care partners.

A total of 392 participants, comprising 196 stroke survivors and 196 care partners, will be recruited voluntarily from a tertiary care hospital. The participants will be selected based on specific inclusion and exclusion criteria.

Inclusion Criteria

To be eligible for participation, stroke survivors must meet specific criteria. They must be aged 18-75 years, have a confirmed diagnosis of stroke and be discharged from the hospital. Additionally, they must participate voluntarily, be able to speak Urdu, and have no significant physical or psychological disability. Furthermore, care partners must be identified as primary care partners.

Exclusion Criteria

Participants will be excluded from the study if they meet certain criteria. These include acute illness, preexisting diseases before stroke, life expectancy of 6 months or less, global aphasia, and dementia on the Mini-Mental State Examination (score <22). Additionally, participants with a

history of ongoing psychoactive substance abuse or terminal illnesses like renal failure or end-stage cancer will be excluded.

Intervention

Participants will be randomly assigned to either the experimental group or the control group. The experimental group will receive a five-session intervention, consisting of three face-to-face sessions and two telephonic sessions. In contrast, the control group will receive routine care. A five-session intervention will be delivered by trained nurses. The intervention aims to provide education, support, skills and guidance to stroke survivors and their care partners

Table 1: Nurse led Augmented dyadic interventions contents

Session	Key Content
Session 1 *(Two weeks later of discharge)*	**Introduction to stroke and different aspects of management:** The information on stroke, stroke consequences, prevention, and management aspects. Also to enhance the family dyad understanding regarding stroke and its effects. *Duration: 60 mins, Mode: Face to face, Format discussion*
Session 2 *(three weeks later of discharge)*	**Promotion of care and demonstration of self-care activities:** Instructions on the management of pressure areas and prevention of bedsores, dressing and how to keep personal hygiene, continence, physical activity, nutrition, positioning, facilitating transfers, daily living tasks and gait facilitation. It also include the hands-on training on lifting and handling techniques, facilitation of mobility and transfers, continence, assistance with personal activities of daily living and communication, tailored to the needs of individual patients.

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Duration: 60 mins, Mode: Face to face, Format: Demonstration and skill development

Data Collection:

Data will be collected at multiple time points. Pre-test data will be collected at baseline, followed by post-test data at 3, 6, and 12 months after the intervention. Structured interviews and self-report questionnaires will be used to collect data.

Outcome Measures:

The study will assess two primary outcomes. For stroke survivors, quality of life will be measured using a stroke-specific quality of life questionnaire. For caregivers, burden will be assessed using the Zarit Burden Interview.

Statistical Analysis Plan (SAP):

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The Statistical Analysis Plan (SAP) outlines the statistical methods and procedures that will be used to analyze the data collected in this study. SPSS 22 will be used for data analysis.

Descriptive statistics will be used to summarize the data, including frequency and percentage for categorical variables, and mean and standard deviation for continuous variables. This will provide an overview of the characteristics of the study sample and the distribution of the variables.

Inferential statistics will be used to examine the relationships between variables.. Specifically, independent t-tests will be used to compare means between two independent groups (e.g., experimental vs. control group), paired t-tests will be used to compare means between two related groups (e.g., pre-test vs. post-test scores), and Pearson correlations will be used to examine the relationship between two continuous variables.

Data will be collected at four time points: baseline (pre-test), 3 months after the intervention, 6 months after the intervention, and 12 months after the intervention. This will allow us to examine the changes in the outcome variables over time and assess the effectiveness of the intervention.
The data analysis procedure will involve several steps. First, the data will be cleaned and checked for missing values. Then, descriptive statistics will be used to summarize the data. Next, inferential statistics will be used to examine the relationships between variables and test hypotheses. Finally, the results will be interpreted and conclusions will be drawn. By following this SAP, we aim to

ensure that the data analysis is conducted in a systematic and rigorous manner and that the results are reliable and generalizable.

Informed Consent Form (ICF):

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ANNEXURE-I

CONSENT FORM
Zhengzhou University Henan China

I_____, son/daughter of_____,

Hereby, fully agree to contribute in the above-mentioned study. My ID No. is _____. I understand that the study is designed to add knowledge to nursing. I have been informed about the nature of the participation and possible risks/discomfort involved. I had the opportunity to ask any question about the study and I agree to give my response as requested by the researcher **(Nazia Shuaib).** I have no objection in case the data obtained from my investigation is published in a research publication while maintaining confidentiality.

_____ _____ _____
(The Supervisor) (The researcher) Signature of the Participant

Explanation letter for the participants:

ANNEXURE-II

Explanation letter for the participants
Zhengzhou University Henan China

Dear Participants,
Why is this research being done?

This research focuses on Augmented dyadic interventions to boost quality of life among stroke survivors and their care partners in Pakistan. This research is part of a requirement for a PhD in nursing at the Zhengzhou University Henan China and is being conducted by **NAZIA SHUAIB**, a PhD Scholar.

Why have you been asked?

You are invited to participate in this study because you are a Care partners of stroke survivors who is able to assess and successfully manage stroke survivors at home. Your experience and information are very important to give an exact picture of the dyad intervention to enhance quality of life of both dyad members.

Risk/Benefits Ratio:

A questionnaire will be given to you for data collection and assessment regarding SSQOL(stroke survivors quality of life) and Zarit burden scale for care partners as well as a brief demographic questionnaire.
There is no danger/risk factors linked with this study. Your participation in this study is entirely on your choice. There may or may not be direct benefits to you but it is hoped that your participation will enhance your awareness and knowledge regarding pain after review website of answers key.
Ethical Consideration/Consent:

Taking part in this study is entirely up to you. You have the right to refuse to participate in this study because it will be purely your voluntarily participation Your Confidentiality and privacy will be maintained sternly. The collected information will not be shared without your consent.

Participant's approval:

Participant's signature_____ **Date**_____

Thank you! Your contribution is greatly valued in improving QOL o stroke survivors and their care partners at home.

郑州大学护理与健康学院

School of Nursing and Health Zhengzhou University

ETHICAL CONSIDERATIONS

Zhengzhou University Henan China

TITLE: Augmented dyadic interventions to boost quality of life among stroke survivors and their care partners in Pakistan.

I undertake that:

I will abide by the declaration of World Medical Association (WMA) make at Helsinki (2008) regarding the ethical principles for medical research involving human subjects.

1. The Health of the subject will be the prior consideration.
2. All ethical considerations will be taken care according to the code and ethics review board of the university.
3. Confidentiality and privacy of the participants will be maintained sternly.
4. Proper written consent with all necessary information, will be taken from all the participants to take their voluntarily participation.
5. All Procedure shall be kept aseptic and painless.
6. The Confidentiality of the information shall be assured and maintained.

Researcher signature_____