

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

Effects of Virtual Reality on burden, quality of life and satisfaction in informal caregivers of stroke survivors.

Protocol summary

Registration timing: **retrospective**

Study aim

To determine the effects of virtual reality on burden, quality of life and satisfaction and to find out the association between caregiver burden and quality of life in informal caregivers of stroke survivors

Last update: **2021-11-25, 1400/09/04**

Update count: **0**

Registration date

2021-11-25, 1400/09/04

Design

Randomized, parallel groups

Settings and conduct

Rawal General Hospital

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Both Genders of 20 to 40 years Taking care of a stroke patient \geq 3 months. Exclusion Criteria: Caregivers taking care of more than one patient Caregivers who are suffering from a Neurological or Orthopedic disease. Included caregiver was no longer the primary caregiver.

Registrant information

Name

Mirza Obaid Baig

Name of organization / entity

Riphah International University

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Pakistan

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Intervention groups

Group A: Virtual reality therapy applied, every subject will be treated individually. Before the intervention, there will be a 5-minute warm-up time, and after the session there will also a 5-minute cool-down time. The virtual reality time will be 25 to 30 minutes periods, 3 days per week for 4 weeks. Group B: Undergo the psychotherapy using Cognitive Behavioral therapy. The therapy will be 25 to 30 minutes periods per day, 3 days per week, for 4 weeks. Group C: Provided with both cognitive behavioral therapy and virtual therapy training for 25 to 30minutes per day, 3 days per week for 4 consecutive weeks.

Recruitment status

Recruitment complete

Funding source

Main outcome variables

1. Caregiver Strain Index 2. 36-Item Short Form Health Survey 3. Adult Carer- Quality of Life

Expected recruitment start date

2020-08-01, 1399/05/11

Expected recruitment end date

2020-12-15, 1399/09/25

Actual recruitment start date

2020-08-13, 1399/05/23

Actual recruitment end date

2021-01-15, 1399/10/26

Trial completion date

2021-02-25, 1399/12/07

General information

Scientific title

Effects of Virtual Reality on burden, quality of life and satisfaction in informal caregivers of stroke survivors.

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211123053152N1**

Registration date: **2021-11-25, 1400/09/04**

Public title

VR and Informal Caregivers

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Taking care of a stroke patient \geq 3 months

Exclusion criteria:

Caregivers taking care of more than one patient
Caregivers who are suffering from a Neurological or Orthopedic disease. Included caregiver was no longer the primary caregiver

Age

From **20 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **66**

Actual sample size reached: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

Total sixty six envelopes (twenty two for each group) has designed and after taking consent from the individual to enter in the trial, the one envelope is being drawn to allocate a treatment group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethical Committee, Riphah International University

Street address

Westridge Campus, Potohar Tower, Near Nisar Hospital, Lane 5, Peshawar Road, Rawalpindi

City

Islamabad

Postal code

46000

Approval date

2020-08-13, 1399/05/23

Ethics committee reference number

RIPHAH/RCRS/REC/Letter-00753

Health conditions studied

1

Description of health condition studied

ICD-10 code

ICD-10 code description

2

Description of health condition studied

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The Caregiver Strain Index (CSI) made up of 13 items was developed by Robinson (1983) and assesses the subjective care load of the caregiver. The CSI can be used to quickly identify families with potential caregiving concerns. There is at least one item for each of the following major domains: Employment, Financial, Physical, Social and Time. Positive responses to 7 or more items on the index indicate a greater level of strain. This instrument can be used to assess individuals of any age who have assumed the role of carer for an older adult. It was developed with a sample of 132 carers providing assistance to recently hospitalized older adults. Validity of the index was found to be 0.41 and test-retest reliability 0.75

Timepoint

Before intervention and 4 weeks after intervention

Method of measurement

subjective method by CSI

2

Description

The 36-Item Short Form Health Survey (SF-36) is widely validated and popularly used in assessing the subjective quality of life (QOL) of patients and the general public. And it includes eight domains. The aim of the study is to assess the psychometric properties of the 36-Item Short Form Health Survey (SF-36) in medical students in mainland of China. SF-36 questionnaire reliability was >0.7 , Where as the validity of SF-36 is >0.5

Timepoint

Before intervention and 4 weeks after intervention

Method of measurement

subjectively by SF-36

Secondary outcomes

1

Description

Adult Carer-Quality of Life: A simple instrument for use with adult carers that measures quality of life in eight separate domains: support for caring; caring choice;

caring stress; money matters; personal growth; sense of value; ability to care; and carer satisfaction. The AC-QoL's internal consistency/reliability is 0.94, indicating that the AC-QoL is a useful tool to assess the QoL of adult caregivers whereas the validity is ranging from 0.78 to 0.89.

Timepoint

Before intervention and 4 weeks after intervention

Method of measurement

Subjectively through AC-QOL

Intervention groups

1

Description

Intervention group: Virtual reality, The procedures will be explained to the subjects, and a demonstration of games will be given by the therapist before starting the intervention. Before the intervention, there will be a 5-minute warm-up time, and after the session there will also a 5-minute cool-down time. The Kinect training time will be 25 to 30 minutes periods interspersed with 5-minute rest, 3 days per week for 4 consecutive weeks.

Category

Treatment - Other

2

Description

Intervention group: Cognitive behavioral therapy, will be 25 to 30 minutes periods per day, 3 days per week, for 4 consecutive weeks.

Category

Treatment - Other

3

Description

Intervention group: Virtual reality and cognitive behavioral therapy, for 25 to 30minutes per day, 3 days per week for 4 consecutive weeks.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Rawal General Hospital

Full name of responsible person

Marrium Batool

Street address

Lehtrar Road, Islamabd

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42200

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marriumbatool25@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Riphah International University

Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Riphah International University

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Riphah International University

Full name of responsible person

Research Ethical Committee, Riphah International University

Position

Assistant Professor

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

The data of participants who are undergone in the virtual reality group will be shared.

When the data will become available and for how long

The data will be available from March 2022 till December 2022.

To whom data/document is available

People working in academic, research institutes and clinical sites

Under which criteria data/document could be used

Advance analysis of the data, future prospects of research and clinical in this area of interest

From where data/document is obtainable

marriumbatool25@gmail.com

What processes are involved for a request to access data/document

Request through email and provided in response

Comments