Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

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

Protocol summary

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

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 ≥ 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.

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.

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

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211123053152N1**
Registration date: **2021-11-25, 1400/09/04**
Registration timing: **retrospective**

Last update: **2021-11-25, 1400/09/04**
Update count: **0**

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

Registrant information

Name
Mirza Obaid Baig

Name of organization / entity
Riphah International University

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Pakistan

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Recruitment status
Recruitment complete

Funding source

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

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

Public title
VR and Informal Caregivers

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Taking care of a stroke patient ≥ 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 envelops (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 İndex (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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Islamabad

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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
Mirza Obaid Baig

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obaid.baig@riphah.edu.pk

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

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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 realty 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