Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of telehealth-based acceptance and commitment therapy (online) on perceived social support, caregiving burnout, and emotional health of caregivers of Parkinson's patients: An intervention study with two-month follow-up

Protocol summary

Study aim
Investigating the effectiveness of online acceptance and commitment therapy on perceived social support, caregiver burnout, and emotional health of caregivers of Parkinson's patients

Design
A controlled clinical trial with parallel groups, single-blind (data analyst), randomized, on 40 patients. For randomization, SPSS software will generate a unique random number for each patient.

Settings and conduct
Sessions will be held online via WhatsApp, Skype, or Google Meet. The therapist's online sessions will be held in Mashhad and the patients' in their city of residence.

Participants/Inclusion and exclusion criteria
Inclusion criteria for the study: (1) age over 18 years, (2) caring for the patient for at least 6 months, (3) ability to participate in online sessions, and (4) informed consent to participate in the study. Exclusion criteria: (1) Severe mental disorders, (2) Unwillingness to complete the course.

Intervention groups
Intervention group: Participants in this group are caregivers of patients with Parkinson's disease who receive Acceptance and Commitment Therapy (ACT) via telehealth. The intervention consists of 8 weekly sessions, each lasting 45 minutes, based on Dr. Zettel's ACT treatment protocol, held via online video call. The content of the sessions focuses on increasing psychological resilience, improving caregiver burnout, promoting perceived social support, and increasing emotional well-being. The main techniques include mindfulness exercises, acceptance, cognitive distancing, value clarification, and commitment to action in line with these values.

Main outcome variables
Perceived social support, caregiving burnout, and emotional health

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250202064612N2**
Registration date: **2025-12-06, 1404/09/15**
Registration timing: **prospective**

Last update: **2025-12-06, 1404/09/15**
Update count: **0**

Registration date
2025-12-06, 1404/09/15

Registrant information

Name
Mohammad Farzaneh

Name of organization / entity
Hakim Toos Institute of Higher Education

Country
Iran (Islamic Republic of)

Phone
+98 51 3840 2726

Email address
h.farzane@hakimtoos.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-12-11, 1404/09/20

Expected recruitment end date
2026-01-20, 1404/10/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of telehealth-based acceptance and commitment therapy (online) on perceived social support, caregiving burnout, and emotional health of caregivers of Parkinson's patients: An intervention study with two-month follow-up

Public title
The effect of telehealth-based acceptance and commitment therapy (online) on perceived social support, caregiving burnout, and emotional health of caregivers of Parkinson's patients
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Patient care for at least 6 months Ability to participate in online meetings Informed consent to participate in research
Exclusion criteria:
Having severe mental disorders Lack of commitment to attend meetings
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, random allocation will be performed using a simple randomization method with individual participants as the unit of randomization (each participant as an independent unit). For this purpose, SPSS software will generate a unique random number for each patient. Based on these numbers, participants will be allocated in a balanced manner (1:1 ratio) exclusively according to the software's random output, without consideration of any individual or clinical characteristics, to either the intervention group (ACT therapy) or control group. The allocation sequence will be generated by the software prior to the commencement of the enrollment process.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, the data analyst will be blinded to group allocation. Following data collection, the final dataset containing clinical information and questionnaire responses will be provided to the analyst without labels identifying the intervention or control groups (ACT/Control). Instead, groups will be identified with neutral codes (e.g., Group A and Group B). The decryption key for these codes will be disclosed only after completion of the initial analysis by the research supervisor (who is not involved in the analysis). This method ensures results remain free from interpretive bias.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Mashhad University of Medical Sciences
Street address
Mashhad University of Medical Sciences, Health Knowledge City, Between Shahid Javan Square and Shahid Al Shahidi Square, End of Shahid Fakuri Boulevard, Mashhad
City
Mashhad
Province
Razavi Khorasan
Postal code
05138049
Approval date
2025-08-16, 1404/05/25
Ethics committee reference number
IR.MUMS.REC.1404.179

Health conditions studied

1

Description of health condition studied
Mental health in caregivers of Parkinson's patients
ICD-10 code
G20
ICD-10 code description
Parkinson's disease

Primary outcomes

1

Description
Increasing perceived social support
Timepoint
Pre-test and post-test and two-month follow-up
Method of measurement
Multidimensional Scale of Perceived Social Support

(MSPSS),

2

Description
Improving caregiver burnout
Timepoint
Pre-test and post-test and two-month follow-up
Method of measurement
Caregiver Burden Inventory (CBI)

3

Description
Increasing emotional health
Timepoint
Pre-test and post-test and two-month follow-up
Method of measurement
Emotional Style Questionnaire (ESQ)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Participants in this group are caregivers of patients with Parkinson's disease who receive Acceptance and Commitment Therapy (ACT) via telehealth. The intervention consists of 8 weekly sessions, each lasting 45 minutes, based on Dr. Zettel's ACT treatment protocol, held via online video call. The content of the sessions focuses on increasing psychological resilience, improving caregiver burnout, promoting perceived social support, and increasing emotional well-being. The main techniques include mindfulness exercises, acceptance, cognitive distancing, value clarification, and commitment to action in line with these values.
Category
Treatment - Other

2

Description
Control group: Participants in this group are caregivers of patients with Parkinson's disease who will continue their usual medical care and standard follow-up without receiving ACT treatment during the study period. After the study ends, ACT treatment sessions will be offered to this group on an optional and free basis.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Parkinson's House Iran
Full name of responsible person
Ms. Dr. Fatemeh Hosseini
Street address
Valil abad Blv
City
Mashhad
Province
Razavi Khorasan
Postal code
09056799303
Phone
+98 905 679 9303
Email
hesamfarzaneh98@gmail.com
Web page address
https://pdhome.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hakim Tous Institute of Higher Education
Full name of responsible person
Dr. Saeideh Behrouznia
Street address
Daneshgah St.
City
Mashhad
Province
Razavi Khorasan
Postal code
9361633384
Phone
+98 991 994 6489
Email
hesamfarzaneh98@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hakim Tous Institute of Higher Education
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

Hakim Tous Institute of Higher Education
Full name of responsible person
Mohammad Farzaneh
Position
Graduate student of clinical psychology
Latest degree
Bachelor
Other areas of specialty/work
Psychology
Street address
Daneshgah St.
City
Mashhad
Province
Razavi Khorasan
Postal code
9361633384
Phone
+98 991 994 6489
Email
h.farzane@hakimtoos.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Hakim Tous Institute of Higher Education
Full name of responsible person
mohammad farzaneh
Position
Graduate student of clinical psychology
Latest degree
Bachelor
Other areas of specialty/work
Psychology
Street address
Daneshgah St.
City
Mashhad
Province
Razavi Khorasan
Postal code
9361633384
Phone
+98 991 994 6489
Email
h.farzane@hakimtoos.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Hakim Tous Institute of Higher Education
Full name of responsible person
Mohammad Farzaneh
Position
Graduate student of clinical psychology
Latest degree
Bachelor
Other areas of specialty/work
Psychology
Street address
Daneshgah St.
City
Mashhad
Province
Razavi Khorasan
Postal code
9361633384
Phone
+98 991 994 6489
Email
h.farzane@hakimtoos.ac.ir

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
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
The data will be displayed in the form of graphs and tables and SPSS file.
When the data will become available and for how long
It will be presented after the thesis defense and publication of the paper.
To whom data/document is available
Students of psychology and neuroscience, as well as specialists in the fields of neurology and psychiatry and paramedical fields related to Parkinson's disease
Under which criteria data/document could be used
The data will only be sent for research studies and research analyses, and applicants are required to refer to my research and cite my article and thesis title in their own research.
From where data/document is obtainable
People can send SMS to my email address and also my academic email if available and my contact number. Email: hesamfarzaneh98@gmail.com Number: 09919946489 Academic email: h.farzane@hakimtoos.ac.ir
What processes are involved for a request to access data/document
After submitting the applicant's request, along with a summary of the research plan and proposal, and a letter from their university's research committee to validate that the researcher is a genuine individual, they will be notified within one to two weeks.
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