Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effectiveness of Self-Working Package on Quality of Life, Psychological Flexibility, and Psychological Well-Being among University Students

Protocol summary

Study aim
Determining the Effectiveness of the Self-Working Package Educational-Therapeutic Program on Quality of Life, Psychological Flexibility, and Psychological Well-Being of Students at Khatam Al-Nabia University of Technology, Behbahan

Design
This pilot phase randomized clinical trial with a control group employed a parallel-group design and was conducted without blinding (open-label) on 30 participants. Randomization was performed using the RV.UNIFORM function within the Compute Variable command of SPSS software, and participants were equally allocated into the intervention and control groups.

Settings and conduct
Following the initial sampling and a structured clinical interview conducted by a psychologist to ensure the absence of personality disorders, individuals who completed the informed consent form to participate in this phase of the study were randomly assigned to two groups and received treatment by a clinical psychologist. All participants were assessed both before and after the intervention.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Willingness to participate in the study, minimum age of 19 years. Exclusion Criteria: Diagnosis of personality disorders.

Intervention groups
In the present study, the Self-Working Package educational-therapeutic program will be implemented in a way that participants will attend two two-hour therapeutic sessions per week. Before the main therapy sessions, an introductory session will be held to explain the study, establish rapport, conduct the pre-test (administering assessments), collect information, and introduce the Self-Working educational-therapeutic model.

Main outcome variables
Quality of Life; Psychological Flexibility; Psychological Well-Being

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250228064878N1**
Registration date: **2025-08-04, 1404/05/13**
Registration timing: **prospective**

Last update: **2025-08-04, 1404/05/13**
Update count: **0**

Registration date
2025-08-04, 1404/05/13

Registrant information

Name
Saeed Ranginkaman

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-08-23, 1404/06/01

Expected recruitment end date
2025-09-22, 1404/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effectiveness of Self-Working Package on Quality of Life, Psychological Flexibility, and Psychological Well-Being among University Students

Public title

The Effectiveness of Self-Working Package on Quality of Life, Psychological Flexibility, and Psychological Well-Being

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Having tendency to participate in research

Exclusion criteria:

Having a personality disorder

Age

From **19 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

The statistical population of the present study consists of all students enrolled at Khatam Al-Anbia University of Technology in Behbahan. From this population, a total of 30 participants will be selected through a multi-stage cluster random sampling method. In the first stage, one faculty will be randomly selected, followed by the random selection of one class from that faculty. To ensure random assignment of participants into experimental and control groups, a list of all students in the selected class will be prepared and entered into SPSS software. Using the Compute Variable function and the formula RV.UNIFORM(0,1), a new variable will be generated for each participant, assigning a random value between 0 and 1. The data will then be sorted based on these random values, and participants will be assigned sequentially into two equal groups—15 in the experimental group and 15 in the control group. This procedure guarantees that each participant has an equal probability of being placed in either group, thereby ensuring unbiased group allocation.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Islamic Azad University - Ahvaz Branch

Street address

Islamic Azad University of Ahvaz, Farhangshahr, Golestan Blvd.

City

Ahvaz

Province

Khouzestan

Postal code

۶۱۳۴۹۳۷۳۳۳

Approval date

2025-07-21, 1404/04/30

Ethics committee reference number

IR.IAU.AHVAZ.REC.1404.202

Health conditions studied

1

Description of health condition studied

Quality of Life, Psychological Flexibility, and Psychological Well-Being

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Quality of life is defined as an individual’s perception of their position in life within the context of the culture and value systems in which they live, and in relation to their goals, expectations, standards, and concerns. This concept encompasses multiple dimensions, including physical health, psychological state, level of independence, social relationships, personal beliefs, and the individual’s relationship with salient features of their environment (World Health Organization, 1997).

Timepoint

At the beginning of the study (prior to the intervention) and after the completion of the intervention (14 weeks after its initiation).

Method of measurement

In this study, the scores obtained by the participants are derived from the short form of the World Health Organization Quality of Life questionnaire (WHOQOL-BREF, 1998).

2

Description
Psychological flexibility is defined as an individual's ability to modify or shift from ineffective thoughts to more effective ones. This construct comprises three components: the ability to consider multiple alternative perspectives on life events and human behaviors, a willingness to interpret difficult situations as manageable, and the ability to generate multiple alternative solutions to challenging situations (Dennis & Vander Wal, 2010).

Timepoint
At the beginning of the study (prior to the intervention) and after the completion of the intervention (14 weeks after its initiation).

Method of measurement
In this study, the scores are obtained by the participants from the Cognitive Flexibility Inventory (CFI).

3

Description
Psychological well-being is defined as a positive state of mental health, characterized by having a positive attitude toward oneself and others, a sense of purpose and meaning in life, satisfying and positive relationships, a sense of autonomy, environmental mastery, and personal growth. This concept was developed by Ryff (1989) as an indicator for assessing psychological health and individual functioning across various domains of life.

Timepoint
At the beginning of the study (prior to the intervention) and after the completion of the intervention (14 weeks after its initiation).

Method of measurement
In this study, the scores are obtained by the participants from the short form of the Ryff Psychological Well-Being Scale.

Secondary outcomes

empty

Intervention groups

1

Description
Control group: No intervention is provided. They only complete the pre-test and post-test simultaneously with the experimental group.

Category
Lifestyle

2

Description
Intervention group: They will receive the Self-Working Package therapeutic training program for 14 weeks, with two 2-hour sessions held each week. Additionally, before the main sessions, a single session will be conducted to establish rapport and explain the Self-Working therapeutic training model.

Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Khadem al-Anbia University of Technology

Full name of responsible person
Saeed Ranginkaman

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Beginning of Bandar Deylam Rd., Khadem al-Anbia University of Technology

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Islamic Azad University

Proportion provided by this source
100

Public or private sector
Public

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
Islamic Azad University

Full name of responsible person
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Position
Master's

Latest degree
Master

Other areas of specialty/work
Psychology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Ensuring the maximum confidentiality of the information of individuals involved in the research.

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
No - There is not a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
The data, in the form of participants' scores on pre- and post-treatment evaluations for both groups, will be presented in an Excel file where the individuals' identifiers are anonymized.

When the data will become available and for how long
The access period will begin 6 months after the publication of the results and will be available for one year.

To whom data/document is available
The information is available for specialists, researchers, and therapists in the fields of psychology, psychiatry, and cognitive sciences.

Under which criteria data/document could be used
Researchers in the field of mental health with the following conditions: A written request with an

explanation regarding the purpose of the research. Assurance of data confidentiality and non-disclosure. Data will not be used for writing scientific research articles or participating in scientific conferences.

From where data/document is obtainable

Saeed Rangin Kaman; Email address: saeed.ranginkaman@iau.ir

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

Requests received via email will be reviewed by the research team, and if the request is approved, data will be sent within 1 to 2 weeks.

Comments

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