Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

The Effectiveness of Online Acceptance and Commitment Therapy on Psychological Distress, Body Image, Sense of Personal Cohesion and Mindfulness in Pregnant Females

Protocol summary

Study aim
Determining the effectiveness of online acceptance and commitment therapy on psychological distress, body image, sense of personal coherence and mindfulness in pregnant females .

Design
Clinical trial with a pre-test, post-test and follow-up with a control group, selection of 50 eligible pregnant women by available sampling method among pregnant women referring to Urmia city health centers, randomized into two control and intervention groups.

Settings and conduct
Online individual psychotherapy sessions were held on the selected internet platforms of the participants as audio or video calls on a weekly basis.

Participants/Inclusion and exclusion criteria
entry: Being in the 24th to 32nd week of pregnancy, Not having mental disabilities, Not smoking and consuming alcohol and drugs, Monogamy. Non-entry: high-risk pregnancy, Occurrence of traumatic and critical events in the last 3 months, psychotherapy sessions at the same time as participating in this research, Participating in physiological childbirth classes, Physical diseases , psychiatric history and Taking psychiatric drugs.

Intervention groups
The intervention and control groups consisted of pregnant women with eligible conditions. first, by explaining the purposee and manner of holding meetings, the informed consent form was given to the participants. Kessler's standard psychological distress, Antonovsky's Sense of Individual Coherence, Body Image 8 questions extracted from the full version of Evans and Dolan, Brown and Bryan's Mindfulness questionnaires as a pre-test and only the intervention group received 8 online individual psychotherapy sessions based on acceptance and commitment protocol. At the end of the treatment, a post-test and one month follow-up were performed in both groups.

Main outcome variables
psychological distress, body image, sense of personal coherence, mindfulness

General information

Reason for update

Acronym
ACT

IRCT registration information
IRCT registration number: **IRCT20231023059816N1**
Registration date: **2023-11-08, 1402/08/17**
Registration timing: **retrospective**

Last update: **2023-11-08, 1402/08/17**
Update count: **0**

Registration date
2023-11-08, 1402/08/17

Registrant information

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Name of organization / entity
The University of Tabriz

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-05-16, 1402/02/26

Expected recruitment end date

2023-05-31, 1402/03/10

Actual recruitment start date

2023-05-18, 1402/02/28

Actual recruitment end date

2023-06-10, 1402/03/20

Trial completion date

2023-08-16, 1402/05/25

Scientific title

The Effectiveness of Online Acceptance and Commitment Therapy on Psychological Distress, Body Image, Sense of Personal Cohesion and Mindfulness in Pregnant Females

Public title

The Effectiveness of Online Acceptance and Commitment Therapy in Pregnant Females

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Informed consent to participate in the project, Primiparous pregnant woman, Being in the 24th to 32nd week of pregnancy, Not having mental disabilities, Not smoking, Not being addicted to drugs and alcohol, Monogamy.

Exclusion criteria:

Existence of high-risk pregnancy (risk of miscarriage, bleeding, pre-eclampsia), Occurrence of traumatic and critical events in the last 3 months, Receiving psychotherapy sessions at the same time as participating in the present research, Participating in physiological childbirth classes, Physical diseases and physical diseases specific to pregnancy such as diabetes , Blood pressure and Pregnancy Bleeding and Having a psychiatric history and Taking psychiatric drugs.

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Actual sample size reached: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization method: The study had two groups and it was agreed from the beginning that odd numbers would be given to the intervention group and even numbers would be given to the control group. Then, using the random number table, the corresponding numbers were extracted, each number was written on a card and placed in an envelope, and the envelopes were sealed and the patient's number was written on each envelope. The first patient who entered the study was assigned envelope number 1, patient number 2 envelope number 2 and so on.

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

دانشگاه تبریز

Street address

The Central Library and Document Center of Tabriz University, First floor, Secretariat of the Biomedical ethics committee of the university,Tabriz University, Tabriz, Iran

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Tabriz

Province

East Azarbaijan

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Approval date

2023-05-14, 1402/02/24

Ethics committee reference number

IR.TABRIZU.REC.1402.017

Health conditions studied

1

Description of health condition studied

Pregnant Women

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Psychological Distress

Timepoint

Body Image

Method of measurement

Individual Coherence

2

Description

Mindfulness

Timepoint

8 Weeks

Method of measurement

Kessler's Standard Psychological Distress, Body Image 8

questions extracted from the full version of Evans and Dolan, Antonovsky's Sense of Individual Coherence, Brown and Bryan's Mindfulness questionnaires.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Therapeutic protocol of ACT Pre session Each of the participants was contacted individually and while giving a brief explanation about the current research, the clients' preferred online platform (WhatsApp, Skype, IMO, etc.) was selected with their participation, and the time of 8 online individual psychotherapy sessions was set. Became The informed consent form and the link to the questionnaires as a pre-test (designed in the pors line) were sent to the participants as a WhatsApp message. The treatment steps are briefly explained, and its accurate implementation definitely requires supervision sessions and familiarity with the work steps, techniques and metaphors used, which are not fully explained in this article. First session Case Formulation: 1) Brief History a) The client's story of what the problem is b) The client's story of how the problem evolved c) What has the client tried, and how has it worked (short term & long term)? d) Why does the client see the presenting complaint as problematic? e) What would they start, stop, do more of or less of, if the problem was solved? f) What direction would they like to take their life in? g) When do they ever feel a sense of purpose or meaning? Doing what? 2) The Context This includes health, work, finances, relationships, family, culture, etc. Factors that reinforce the problem were investigated – e.g. getting attention, manipulating others, disability benefits, avoiding fears of rejection/ intimacy/failure, cultural beliefs, etc. 3) Psychological Inflexibility a) Loss of Contact With the Present Moment – how much time does the client spend dwelling on/ reliving the past or daydreaming/ worrying about the future? What is the client's ability to be "in-touch" with the present moment? b) Cognitive Fusion. What sort of unhelpful cognitive content is the client fused with – rigid rules, self limiting beliefs, unrealistic expectations, negative self-evaluations, reason-giving, being right etc.c) Experiential Avoidance – what private experiences is the client avoiding, and how? What are the costs of EA? How pervasive is E.A. in the client's life? d) Self-As-Content. What is the client's " conceptualised self"? (eg do they see themselves as broken/ damaged/ unlovable, defective etc..) How fused are they to this self-image? e) Remoteness From Values – how disconnected is the client from their own true values? To what degree are they able to connect with what they really want in life? f) Lack of Effective, Committed Action. In what ways are clients' actions self-defeating? Do they lack necessary skills for change? Do they fail to persist, when persistent action is required? Or do they inappropriately continue when such action is ineffective? 4) Motivational factors: Assess both positive (What would a valued, meaningful life look like to this client? What goals do they have?) and negative (barriers to change, as in the F.E.A.R. acronym, plus secondary gains maintaining the problem) 5) Psychological Flexibility: Assess areas of life in which the client exhibits psychological flexibility through defusion, acceptance, a sense of self-as-context, contacting the present moment, connection with values, and taking committed action. 6) 6) Goals & Treatment Plan (anticipating likely barriers) has been worked through the five stages in order (keeping in mind that they are all interconnected) Second session 1) A short mindfulness exercise, 2) What direction does the client want to take their life in? 3) What stands in their way? a) What are they fused with? b) What are they avoiding? c) What are their ineffective actions? Creating creative helplessness and using the "man in the well" metaphor and teaching how to do the daily experience note task. The Creative Hopelessness Technique: That is, the client will finally come to the insight that so far, any kind of effort to solve The problem is that it is useless .So instead of blaming yourself, use new ways to change the situation. The term "creative hopelessness" in the act refers to the process of abandoning experiential control strategies and instead creating a space to find an alternative approach. we learn by reference that avoidance or any other control method only reinforces the importance and role of what he is avoiding. For example, when medical services do not meet the client's expectations of treatment, he uses more experiential avoidance strategies and these strategies are a futile attempt to gain control. Such as avoiding friends and family and withdrawing from social activities, so clients will be taught that the use of experiential avoidance strategies makes people with physical problems more vulnerable to anxiety and depression. Diary practice: - In what location and time were you? - What thought came to your mind? - Rate your feeling from 0 to 10. - What were your reactions? Did you withdraw your thoughts and feelings? Or did you fight with your thoughts and feelings? Third session 1) Compassion meditation 2) Review of the previous session and review of the assignment 3) Explanation of the concepts of pain and suffering and their differences 4) Teaching and understanding that self-control is a problem and not a solution 5) Using the metaphor of "tug-of-war with a monster" 6) Explanation of the assignment Primary and secondary reaction to the sore situation: - Position: In what location and time were you? - What was your first reaction to the uncomfortable situation? - Grading the degree of suffering: rate your distress from 0 to 10. - What were your next reactions? Did you push back your thoughts and feelings or did you struggle with them? - Grading the amount of suffering (Distress): rate your distress from zero to 10. The fourth session 1) Review of the previous session 2) Receiving feedback on completing the task 3) Teaching the willingness to better substitute for controlling and explaining the concept of acceptance and its difference with the concepts of failure, despair, denial, resistance and then, the problems and challenges of acceptance 4)

Awareness of the consequences of avoidance using the metaphor of "uninvited guest" 5) Teaching exercises related to active acceptance The fifth session 1) A review of the experiences of the previous session 2) Receiving feedback from the task 3) Expressing the concept of cognitive defusion by using the metaphors of "bus and marching soldiers" 4) The task of observing thoughts in a room with two doors 5) Examining negative judgments Techniques: 1- Observation Thoughts are in a room with two doors, where thoughts enter through one door and exit through the other door. Which thought remained in the room the most, express that thought 2- Reducing negative judgments Explanation about the function of negative judgments, your mind is constantly It is comparison and judgment, because the mind has been trained in this way to be able to predict and plan, and this function of judgment causes the mind to judge constantly. - How many negative judgments have you had since morning until now? - How many of your judgments are about issues that you cannot change? Sixth session 1) Review the experiences of the previous session and receive feedback from the assignment 2) Training to focus on daily activities and being aware of your condition at every moment 3) Training techniques to focus on the body, breathing and attention. - In the technique of focusing on the body, we ask the client to express her emotion and then tell us in which part of her body she feels it, for example, where in the body does she feel the emotion of sadness. In the continuation, we explain to the client that sadness and failure are the necessities of life and you should experience it. Having absolutely no grief in life and removing it is an unrealistic and unattainable goal. - Breathing: training in deep breathing, which is accompanied by attention and concentration. - Attention exercise: Exercise one: conscious attention while eating raisins. (Attention to taste, smell, texture, etc.) Exercise two: When was the last time you carefully paid attention to the important people in your life? Set aside time in the day for this. Exercise Three: Conscious attention to daily activities and pleasurable activities. Seventh session 1) Review the experiences of the previous session and receive feedback from the assignment 2) Explain the concept of values and express the difference between values, goals and needs 3) Exercises to identify the values of the clients 4) Explanation of the values worksheet form. Clarifying Your Values: Domains of Parenting ,Personal Growth, Leisure Spirituality, Health, Work ,Community & Environment, Family Relationships, Intimate Relationships, Social Relationships. Write a few key words about what is important or meaningful to you in these domains of life: What sort of person do you want to be? What do you want to do? What sort of qualities do you want to develop? What you want to stand for? (If a domain seems irrelevant to you, that’s okay: just leave it blank. If you get stuck on a domain, then skip it, and come back to it later. And it’s okay if the same words appear in several or all domains.) Then mark on a scale of 0-10 how important these values are to you, at this point in your life. (0= no importance, 10= extremely important) (It’s okay if several domains all have the same score.) Now have a good look at what you’ve written. What does this tell you about: a) What is important in your life? b) What you are currently neglecting? Eighth session 1) Review of the previous session and receive feedback from the assignment 2) Self-as-context Task 3) Teaching commitment to action 4) Identifying behavioral plans in accordance with values and creating a commitment to act on them 5) Practicing identifying obstacles Internal and external 6) At the end of the treatment, the post-test link (designed in the pors line) was sent to the participants as a WhatsApp message. After completing the treatment, the questionnaires were again sent to them as a follow-up. Self-as-context Exercises a) Who’s doing the noticing? 1. Notice your feet on the floor. 2. Be aware you’re noticing 3. Notice what you can smell 4. Be aware you’re noticing 5. Notice the sounds in this room. 6. Be aware you’re noticing 7. Notice what you’re thinking right now. 8. Be aware you’re noticing 9. Notice what you’re feeling right now. 10. Be aware you’re noticing 11. So there’s a ‘you’ in there that’s aware of everything you can see, hear, touch, taste, smell, think and feel. 12. This ‘you’ that notices these things – is it ‘good’ or ‘bad’ – or is it just there? b) Letting go of the Conceptualized Selves 1. Bring an image to mind that represents your Professional Self. 2. Notice that image. 3. Be aware that you’re observing it. 4. If you can observe it, you can’t be it. 5. Silently say to yourself, ‘I let it go’ – then see that image ‘walk away’ 6. Bring an image to mind that represents your Ideal Self. 7. Notice that image. 8. Be aware that you’re observing it. 9. If you can observe it, you can’t be it. 10. Silently say to yourself, ‘I let it go’– then see that image ‘walk away’ 11. Bring an image to mind that represents your Suffering Self. 12. Notice that image. 13. Be aware that you’re observing it. 14. If you can observe it, you can’t be it. 15. Silently say to yourself, ‘I let it go’ – then see that image ‘walk away’ 16. Of course, these selves won’t go away for long; but you can more and more see them for what they are; and you can hold that self lightly, like a butterfly in the hand.

Category

Treatment - Other

2

Description

Control group: 50 eligible Primiparous pregnant women were selected by the available method and after their informed consent to participate in the project in two groups of 25 people for the experiment (25 people) and control (25 people) were randomized. At first, the control group completed the standard questionnaires of Kessler's Psychological Distress, Antonovsky's Sense of Personal Coherence, 8-question Body Image extracted from the full version of Evans and Dolan, Brown and Bryan's Mindfulness as a pre-test and did not receive treatment. At the end, the post-test was conducted and one month after that, the questionnaires were again sent to the control group as a follow-up.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

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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
The University of Tabriz

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
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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
Due to the possibility of publication of the article, no decision has yet been made to publish the data.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available