

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Investigating the effectiveness of Processing of Positive Memories Technique (PPMT) on Positive Emotion Dysregulation and rumination in women with post-traumatic stress disorder caused by breast cancer

Protocol summary

Study aim

Investigation of positive memory processing techniques on positive emotion dysregulation and rumination

Design

In a clinical trial with the control group, with parallel groups, single-blinded randomized on 60 patients, the lottery method was used for randomization.

Settings and conduct

The intervention will be carried out at Shahid Motahari Clinic in Shiraz city, and both groups will complete pre-test questionnaires before participating in treatment sessions, and post-test questionnaires after completing life skills training sessions and positive memory processing techniques. Also, meetings will be held weekly.

Participants/Inclusion and exclusion criteria

Female patients diagnosed with post-traumatic stress disorder caused by breast cancer inclusion criteria included PTSD diagnosis exclusion criteria included major depression preceding post-traumatic stress disorder.

Intervention groups

The intervention group includes women with post-traumatic stress disorder caused by breast cancer, who first receive the intervention of positive memory processing techniques and then participate in 5 training sessions of three life skills, and the comparison group includes women with post-traumatic stress disorder. The accident is caused by breast cancer, they are first taught three life skills, and then they receive the intervention of processing positive memories techniques.

Main outcome variables

Positive emotion dysregulation, rumination

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230701058638N1**

Registration date: **2023-07-22, 1402/04/31**

Registration timing: **prospective**

Last update: **2023-07-22, 1402/04/31**

Update count: **0**

Registration date

2023-07-22, 1402/04/31

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-23, 1402/05/01

Expected recruitment end date

2023-11-22, 1402/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effectiveness of Processing of Positive

Memories Technique (PPMT) on Positive Emotion
Dysregulation and rumination in women with post-
traumatic stress disorder caused by breast cancer

Public title

Processing positive memories

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Getting a PTSD diagnosis Age range from 18 to 60 years

Exclusion criteria:

Diagnosing psychotic disorders major depression
preceding post-traumatic stress disorder

Age

From **18 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, 60 observations will be allocated to two intervention and control groups (30 observations each). Since the sample size in this study is relatively small, the permutation block randomization method will be used to provide equal groups, and since building blocks with a size of 2 may lead to the identification of the second type of intervention in each block, blocks with a size larger than 2 will be used. In this study, 5 blocks with a volume of 6 observations will be used. In this way, in the beginning, all the possible permutations will consist of different types of blocks, which will consist of 20 possible states, which are mentioned below in two states: B A B A B A B B B A A A Then by chance and using random number selection software or random number table at the time of patients' visit, the block mode will be selected and the referring patients will be assigned to each of the groups at the time of visit.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz University

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Faculty of Educational Sciences and Psychology

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Shiraz

Province

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Postal code

7194684759

Approval date

2023-07-12, 1402/04/21

Ethics committee reference number

IR.US.PSYEDU.REC.1402.023

Health conditions studied

1

Description of health condition studied

Post-traumatic stress disorder

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

positive emotion dysregulation

Timepoint

Measurement of variables at the beginning of the study
(before the implementation of the treatment protocol)
and after the implementation of the protocol

Method of measurement

positive emotion dysregulation self-report scale DERS-P,

2

Description

rumination

Timepoint

Measurement of variables at the beginning of the study
(before the implementation of the treatment protocol)
and after the implementation of the protocol

Method of measurement

rumination responses scale

Secondary outcomes

1

Description

Individual's score in post-traumatic stress symptoms

Timepoint

Measurement of variables at the beginning of the study
(before the implementation of the treatment protocol)
and after the implementation of the protocol

Method of measurement

PTSD Inventory PCL-5

Intervention groups

1

Description

Session 1 (120 minutes): Goals of Session 1 include establishing rapport, reviewing confidentiality, assessing psychiatric history, and providing psychoeducation about PTSD and positive memories. Session 1 content includes providing an overview of the protocol, obtaining a psychiatric history, providing psychoeducation about PTSD from a cognitive behavioral perspective, and presenting the rationale for PPMT. Specifically, the therapist states that by eliciting positive memories, clients may (1) increase access to values, emotions, strengths, and positive thoughts to connect with a positive identity, (2) engage in subsequent positive behaviors, (3) improve their mood and access to positive thoughts, and (4) use this information to confront/confront (vs. avoid) trauma memories and related components in subsequent trauma-focused interventions. Session 1 assignments include a review of an informational handout ("Psychoeducation about PTSD and Positive Memories") and a report showing values, influences, strengths, and different thoughts that will be used in subsequent sessions. Session 2 (60 minutes): Objectives of Session 2 include imaginal experience training, elicitation and processing of a positive memory narrative (audio-recorded), and identification of response modulation (behavioral) and task review between sessions. The content of session 2 includes an assessment of PTSD severity, survey questions/thoughts, and obtaining ratings of the degree of experience of positive emotions on a scale of 0-100 (subjective units of positivity;) during the session and imaginal experience training. The recall stage, the imaginative experience stage (narrating), and the processing stage are described below. In the imaginal experience training phase, clients are asked to imagine being in pleasant places (eg, the beach) and answer the therapist's questions (eg, "What do you hear and see") to relive the experience. In the recall phase, the therapist presents a positive memory to the client as one that refers to significant positive events, is personally meaningful, and evokes positive emotions. Next, the therapist emphasizes that the client must recall a memory of a positive event that occurred within 24 hours. Finally, the therapist provides instructions for eliciting a detailed description of a specific salient positive autobiographical memory and asks the client to provide ratings based on valence (0-4 scale). In the imaginative experience (narrating) phase, the therapist provides the client with instructions such as closing the eyes to enhance concentration (if comfortable), using the present tense and "I" perspective, and answering questions to revive the identified positive memory (eg, "What do you hear/see?" "Who was present with you?"). In the processing stage, the therapist elicits the elements related to the identified positive memory by inquiring about the most important thoughts, feelings, values, and strengths of the person that the positive memory brought to mind, that is, the meaning of the positive

experience for the client, as well as the client's role in that experience. Notably, if customers narrate negative elements, they are directed toward the desired task. Session 2 assignments include listening to an audio recording of a daily positive memory narrative to reinforce the positive memory. Completing a report identifying an activating event for a positive memory recalled during the week and identifying and engaging in a response-modulation activity (eg, sharing a positive experience with one's partner resulting from the positive emotion [love, joy] of the positive memory, engaging in volunteer activities due to the identified altruistic value). Sessions 3-4 (each session focuses on a specific positive memory; each session is 60 minutes): The goals of sessions 3 and 4 include eliciting and processing a second or third different positive memory narrative and identifying response (behavioral) modulation between tasks. The content of sessions 3 and 4 is similar to the content of session 2. Finally, the assignments for sessions 3 and 4, similar to the assignments for session 2, were set based on the content of the second and third positive memories elicited. Session 5 (60 minutes): Objectives of Session 5 include assessment of progress and transition of care/termination. Session 5 content includes assessment of PTSD severity, review of intersession thoughts/questions and tasks from the last session, and termination/transition of care.

Category

Treatment - Other

2

Description

The first step in the process of problem-solving skills: is a precise definition of the problem: often when we face a problem, we focus on the methods and techniques that exist to solve the problem, but before that, we need to first define our task by defining the problem. The second step in the process of problem-solving skills: Brainstorming: Brainstorming means that a person leaves his mind open so that the mind freely expresses any solution it sees, whether good or bad, compatible or incompatible, without censorship. The third step in the process of problem-solving skills: evaluating solutions and choosing the best solution: in this step, each of the obtained solutions is evaluated and the person evaluates their usefulness or not to reach the appropriate solution and judges its consequences with himself and others. The fourth step in the process of problem-solving skills: is the implementation of the solution and review: in this step, the implementation of the solution that has priority and fits the individual's value system is discussed. After implementing the solution, attention is paid to the consequences of that solution, if the result is satisfactory, the problem is solved and the problem-solving process ends. If the solution is not effective, the person should use other solutions at his disposal. The steps of decision-making skills include Step 1: Identify the problem or problem. If you want to make correct and informed decisions, you must first identify the problem well. As long as the issue is not well clarified, making a decision will be hasty and therefore will not bring a perfect result. Therefore, the first step is to see what the

problem is. Write this issue down on paper and give it to other members of the group, family, or managers so that they can also think and research on this issue. If you want to hold a brainstorming session or a brainstorming session about that issue, the issue must be identified and communicated to the other members of the group.

Step 2: Gather Comprehensive Information Now that you've identified the problem and shared it with the rest of the group, it's time to find comprehensive information about the problem. Ask the other members of the group to do it properly. Be careful to take time for this step and gather information well. To gather information, you can conduct an internal assessment of your family or business and see what actions your organization has taken on the identified issue. Also, try to get information from external sources. For example, if you have a family issue, you can talk to trusted and knowledgeable people or a family counselor. If the issue is related to your business, you can go to specialists and experts in your field of work and ask them for advice, or you can have a meeting with the managers of your organization and get complete information about the problem from them.

Step 3: Identify Possible Solutions Now that you have identified the problem and obtained the necessary information about it, it is time to identify the solutions and solutions available. See how to solve this problem. To identify possible solutions, you can have a meeting with the managers and specialists of your organization or use the help of consultants. Because of their vast experience, consultants usually provide excellent solutions. Of course, you can use various methods for generating ideas and presenting solutions, including brainstorming.

Step 4: Work on the implications and evidence. Now think about the implications of possible solutions. See what advantages and disadvantages each of these decisions can have. You can think about the actions of your competitor companies and see how competing businesses have solved this problem and how well this solution has worked in their organization. You can also talk to experts and consultants and see what they think about your solutions.

Step 5: Choose the best option or decision. Now it's time for the most important step in the decision-making process. At this stage, you have to choose the best option among possible solutions. In fact, at this stage you have to make your decision. Fortunately, this stage is not so difficult; Because everything has been checked and evaluated in the previous stages, and now it's just time to choose the option that has the most advantages and the least disadvantages.

Step 6: Take action. In this step, you must enter the implementation phase. In this phase, it is better to formulate a suitable plan so that you can proceed according to this plan and implement your decision in the best possible way. Of course, the responsibility of each person in the group or the responsibility of each unit in the organization must be specified so that the organization can implement the plan very carefully and not encounter any obstacles or problems.

Step 7: Review and revise your decision some organizations think that once they have made the decision and implemented it, the work is over, but you should know that after the implementation of the

decision, you should evaluate its results and consequences. You should see what consequences this decision had for the organization. Has the issue or problem been solved by implementing the decision or is the organization still struggling with it? If you feel that this decision is not appropriate, you should change the way you implement it or skip this decision altogether and take another approach.

Critical thinking steps include

- 1- Identify the problem. Before you can apply critical thinking skills, you must first identify the problem you are trying to solve. This step involves looking at the problem from several different perspectives and asking questions such as: What is happening? Why does this happen? What are my assumptions? At first glance, I think how can we solve this problem? A big part of developing your critical thinking skills is learning how to come to unbiased conclusions. To do this, you must first accept the biases you currently have. Does anyone on your team think they know the answer? Are you making assumptions that aren't necessarily true? Identifying these details will help you in the next steps.
- 2- Research At this stage, you probably have a general idea of the problem, but you need to dig deeper to find the best solution. During the research process, gather information about the problem, including data, statistics, information from past projects, team input, and more. Make sure you gather information from a variety of sources, especially if those sources conflict with your own ideas about what the problem is or how to solve it. Gathering diverse information is essential to your ability to apply the critical thinking process. If you don't get enough information, your ability to make a final decision will be skewed. Remember that critical thinking helps you identify the best conclusion. You are not working for your heart, you are researching to find the best option.
- 3- Determine the relationship between the data. Just as it is important to collect a variety of information, it is also important to determine how relevant the different sources of information are. After all, just because data exists doesn't mean it's relevant. Once you have gathered all the information, sift through the noise and identify what information is relevant and what information is not. Combining all this information and determining its importance will help you weigh different data sources and arrive at the best results later in the critical thinking process. To determine the relevance of data, ask yourself: How reliable is this information? How significant is this information? Is this information out of date? Is it in a specific field of expertise?
- 4- Ask questions One of the most useful parts of the critical thinking process is making decisions without prejudice. To do this, you need to take a step back and challenge your assumptions. We all have biases, and that's not necessarily a bad thing. Unconscious biases (also known as cognitive biases) often act as mental shortcuts to simplify problem-solving and aid decision-making. But even when biases aren't inherently bad, you need to be aware of your biases so you can set them aside if necessary. Before you arrive at a solution, ask yourself: Do I have any assumptions about this information? Are there additional variables I haven't considered? Have I evaluated the information from any perspective? Are

there any views that have been missed? 5- Identify the best solution finally, you're ready to go. Make connections between cause and effect to identify the best solution. Use the facts you have gathered to evaluate the most objective outcome. Note that there may be more than one solution. Often, the problems you face are complex. The process of critical thinking does not necessarily lead to a definitive solution, instead, it helps you understand the various variables so that you can make an informed decision. 6 - Present your solution Communication is a key skill for critical thinkers. It's not enough to think on your own, you also need to share your results with other project stakeholders. If there are multiple solutions, provide them all. There may be cases where you implement one solution, then test whether it works before implementing another solution. 7- Analyze your decision The seven-step critical thinking process yields results, and then you need to put that solution in place. After you have implemented your decision, evaluate whether it was effective. Solved the initial problem? What lessons—both positive and negative—can you learn from this experience to improve your critical thinking for next time? Depending on how your team shares information, document lessons learned in a database. That way, team members who make similar or related decisions in the future can understand why you made that decision and what the outcome was.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Motahari specialized and super specialized clinic in Shiraz

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

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?

No

Title of funding source

Shiraz University

Proportion provided by this source

90

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

shiraz University

Full name of responsible person

Tayebeh Mahmoodi

Position

P.h.D Student

Latest degree

Master

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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

There is no need to publish patient information

Study Protocol

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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