

Consent to take part in research



Azad Hamedan University

Consent to Participate in Research

Invitation to be Part of a Research Study

You are invited to be part of a research study. This consent form will help you choose whether or not to participate in the study. Feel free to ask if anything is not clear in this consent form.

TITLE OF STUDY

[Efficacy of the Unified Protocol on Difficulties Emotion Regulation in People with Multiple Sclerosis]

You are being asked to take part in a research study. Before you decide to participate in this study, it is important that you understand why the research is being done and what it will involve. Please read the following information carefully. Please ask the researcher if there is anything that is not clear or if you need more information.

You can allow to consult to anybody about the participation.

This research is in related with Ph.D. thesis of Dr. Nabi NAZARI in psychology.

You may decline to answer any or all questions and you may terminate your involvement at any time if you choose.

You receive 12 to 14 sessions of the skills and the standard programs in related with the unified protocol. You receive the results and psychological interpretation in according to the standard questionnaires and interviews.

Confidentiality:

You will be assigned a code number which will protect your identity. All data will be kept in secured files, in accord with the standards of the **INTERNATIONAL RULES**.

We do not register any identifiers across in WHO identifiers.

Each of the participants receive an 8-digit code.

Consent to take part in research

The list of the codes is concealed by an Ethic evaluator.

All Information Keeps in Secure Place.

All identifying information will be removed from questionnaires as soon as your participation is complete.

We never recorded any information by any devices. (e.g., Voice, video, picture, and camera or ...).

No participants allow use of the recording information in during all sessions.

No one will be able to know which your questionnaire responses are. Finally, remember that it is no individual person's responses that interest us; we are studying the usefulness of the tests in question for people in general.

Opportunities to Question:

Any technical questions about this research may be directed to:

Principal Investigator: Nabi Nazari **Phone:** 09197119027

Any questions regarding your rights as a research participant or research-related injuries may be directed to AZAD UNIVERSITY.

Opportunities to withdraw at will:

If you decide now or at any point to withdraw this consent or stop participating, you are free to do so at no penalty to yourself. You are free to skip specific questions and continue participating at no penalty.

- The purpose of the study is to investigation about effectiveness of the unified protocol on the psychological consequences of MS.
- In order to participate, you must be meet the eligibility criteria.
- The risks involved in this study are not greater than everyday life
- The possible benefits of this study include The better cope to your conditions
- Taking part in this research study is voluntary. You do not have to participate, and you can stop at any time.

You are always free to stop participating in the study if you would like. Your decision to stop participating will not affect your standard medical care or any other benefit you would receive if you were not in a research study.

Description of the group

- Experimental: Unified Protocol

The Unified Protocol for the Transdiagnostic Treatment of Emotional Disorders will be individually administered in accordance with a treatment protocol.

Intervention: Behavioral: Unified Protocol (UP)

- No Intervention group

Waitlist participants will not receive treatment during a 16-week waitlist period, but will receive the treatment of their choice immediately following the 16 week waiting period.

Why you are being invited to join

Multiple sclerosis (MS) is a potentially disabling disease of the brain and spinal cord (central nervous system). In MS, the immune system attacks the protective sheath (myelin) that covers nerve fibers and causes communication problems between your brain and the rest of your body.

Eventually, the disease can cause permanent damage or deterioration of the nerves. Signs and symptoms of MS vary widely and depend on the amount of nerve damage and which nerves are affected. Some people with severe MS may lose the ability to walk independently or at all, while others may experience long periods of remission without any new symptoms.

In addition to physical impairment, a broad range of mental and emotional problems are typical in this condition. Unfortunately, some patients focus only on physical symptoms, and they do not pay attention to psychological consequences. We call it MS focus. Emotional problems are more widespread in people with MS.

The UP is a new psychological Transdiagnostic intervention that helps people learn how to face inappropriate emotions and respond to their emotions in a more adaptive way. This method tries to reduce the intensity and occurrence of emotional habits by adjusting the emotional ordering habits, increasing the amount of damage, and increasing the functionality.

Consent to take part in research

Description the risk

- The risks involved in this study are not greater than everyday life

We anticipate two nurses who are professional in MS. They monitor your situation during all sessions.

Detailed procedure

At the first session, the researcher explain the process to participants and attracted their satisfaction. Having obtained informed written consent from all participants fill up the researcher-made demographic questionnaire. All patients are asked not to change their lifestyle during the study and continue their daily routines, exercise, diet, and medications.

Participants are randomly assigned to two groups of Transdiagnostic Therapy experiment and tau group using random digits table. Random assignment is done for the blinding researchers in assigning the groups. However, the researcher involved in the interventions was informed of the assignments, while the data collection assistance is blinded in terms of assigned groups and interventions. Pre-test and post-test measurements were done.

The participants in experimental group receive the UP based on 8 module.

1	Module1	Setting Goals and Maintaining Motivation (1 session)	
2	Module2	Understanding Emotions (1– 2 sessions)	
3	Module3	Mindful Emotion Awareness (1– 2 sessions)	Core module
4	Module4	Cognitive Flexibility (1– 2 sessions)	Core module
5	Module5	Countering Emotional Behaviors (1– 2 sessions)	Core module
6	Module6	Understanding and Confronting Physical Sensations (session)	Core module
7	Module7	Emotion Exposures (4– 6 sessions)	Core module
8	Module8	Recognizing Accomplishments and Looking to the Future	

Content each module in the following tables.

Consent to take part in research

Session number	Summary of content Table depicted the structure and techniques presented per session.
Session1	Unified model of psychopathology; motivation enhancement strategies; Treatment goal setting, decisional balance exercise, changing versus staying
Session2	Psychoeducation on the adaptive function of emotions; three- component The model of emotional experiences describe the sequence of events around emotions. anchoring in the present
Session3, 4	Review <i>primary emotions</i> , Natural course of emotions and role of avoidance; present-focused, nonjudgmental emotion awareness, recognize the interaction between their thoughts, feelings, and behaviors during an emotional experience
Session5,6	flexible thinking, automatic appraisals, thinking traps, Distress tolerance skills, familiarizing with various emotional avoidance strategies, their impact on emotional experience, and knowledge of the contradictory effects of avoiding emotions
Session7	Examining EDBs, knowledge, and identification of their effects on emotional experiences, identifying maladaptive EDBs, and creating alternatives for acting through behaviors
Session 8	increase patients' awareness and tolerance of somatic sensations, Knowledge, and tolerance of physical senses, increase awareness of the role of emotional feelings in emotional experiences, practice exercises or visceral confrontation in order to be aware of physical sensations and increase tolerance of these symptoms
Session9-13	emphasizes the practice of treatment concepts through in- session and out- of- session exposures to emotion experiences, focus on provoking the emotion, replace interpretations about the dangerousness of situations with more adaptive appraisals, extinguish anxious reactions to intense emotional experiences, modify EDBs, visceral confrontation, providing the opportunity for skills rehearsal and consolidation in the context of a strong emotion
Session 14	Overview of significant treatment concepts and the patient's progress is reviewed. Specific strategies for preserving and extending treatment gains are discussed. Prevention of recurrence, an overview of treatment concepts and discussion about patient's healing and progress and plans for future practices

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Please read carefully.

- I..... voluntarily agree to participate in this research study.
- I understand that even if I agree to participate now, I can withdraw at any time or refuse to answer any question without any consequences of any kind.
- I understand that I can withdraw permission to use data from my interview within two weeks after the interview, in which case the material will be deleted.
- I have had the purpose and nature of the study explained to me in writing and I have had the opportunity to ask questions about the study.
- I understand that I will pay no payment for participation
- I understand that I will receive the psychological benefits directly from participating in this research.
- I understand that all information I provide for this study will be treated confidentially.
- I understand that the participation has no risk for me
- I understand that in any report on the results of this research my identity will remain anonymous. This will be done by changing my name and disguising any details of my interview which may reveal my identity or the identity of people I speak about.
- I understand that if I inform the researcher that I or someone else is at risk of harm they may have to report this to the Azad university Hamedan branch. They will discuss this with me first and they report with my permission.
- I understand that a transcript of my interview in which all identifying information has been removed.

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I understand that under freedom of information legalisation I am entitled to access the information I have provided at any time while it is in storage as specified above.

I understand that I am free to contact any of the people involved in the research to seek further clarification and information.

This consent is provided in two version, and I receive a signed version.

Signature of research participant and date

Signature of researcher and date

Nabi Nazari

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The irb id is: wirb IR 20192297 LO