Informed Consent Form

You are invited to voluntarily participate in a medical experiment. A medical experiment is an innovative procedure that is not yet approved as a routine treatment in Israel. Therefore, there is some uncertainty regarding its safety or effectiveness. This form provides information about the experiment you are being invited to join. Please read it carefully and feel free to discuss it with anyone you wish: friends, family, or healthcare professionals not directly involved in the study. Additional information and answers to any questions can be obtained from the principal investigator or their staff.

Before deciding whether to participate, it is very important to understand the potential risks and benefits so you can make an informed decision. This process is called “informed consent.”

Your participation is voluntary. You may choose not to participate and not to sign the form. You can withdraw at any time without having to provide a reason. Your decision will not affect your current or future medical care. All available treatment options will be explained to you.

If you agree to participate, you will be asked to sign this form. You will receive a signed copy, and the original will be kept at the medical institution.

Full Name: _____

ID number: _____

Address: _____

1) Information about the study

Study Number: 0062-24-RMB
Title: *Dialectical thinking as a mediator of the effectiveness of acceptance training for pain in patients with psychological distress and somatic symptoms*

Principal Investigator: Dr. Shulamit Grinapol
The study was approved by the Institutional Helsinki Committee and the Director of Rambam Health Care Campus, according to the Public Health Regulations (Medical Experiments in Humans), 1980.

1.2) Objectives:

1. To assess the effectiveness of pain acceptance training in alleviating pain in patients with psychological distress and somatic symptoms.
2. To examine the role of dialectical thinking in enhancing the effectiveness of emotional pain acceptance training.

1.3) Procedure:

After signing the consent form, you will undergo a screening process via a Zoom interview and a short questionnaire evaluating psychological symptoms and pain.

If you will be found eligible for participation, you will complete an initial assessment either at Rambam Hospital or at the Emotion-Cognition Interaction Lab at the University of Haifa. It includes:

- Psychological questionnaires (pain, depression, anxiety, thinking styles).
- A computerized task with emotional and pain-related images.
- Cold water pain threshold and tolerance test using an ice bath (10–12°C; 20–30 seconds hand immersion).

At the end of the assessment, you will be randomly assigned to one of the two study groups: the intervention group or the control group.

• **Intervention Group:** In this group, you will receive instruction on the emotional acceptance strategy for pain.
The training will include an introduction, an explanation of the associations between pain and emotions, and a description of the treatment method (pain acceptance training). After the instruction, you will be asked to actively practice the treatment method with the guidance of the research team. The practice will involve exercises to develop skills in observing sensations and emotions, as well as learning to use the acceptance strategy when experiencing physical pain induced by placing your hand in a container filled with cold water.

Following the instruction, the research team will provide guidance on how to continue practicing at home. This practice period will begin on the day of the session and continue for two weeks. During these two weeks, you will be asked to use the treatment strategy each time you feel pain. You will be requested to report every time you use the strategy by clicking a link sent to your mobile phone and pressing a button labeled "I used the strategy." In addition, during this two-week period, you will be asked to complete a short questionnaire each evening (including Fridays and Saturdays, unless you observe Shabbat and have informed the research team in advance) via a link sent daily to your mobile phone. The questionnaire will assess your pain severity, functional difficulty that day, and use of the pain acceptance strategy. Completing the questionnaire should take about 2 minutes. Furthermore, at the end of the first week, a short video call lasting 15 minutes will be held to review your progress and discuss any difficulties you may have encountered while using the pain acceptance strategy.

At the end of the intervention period (two weeks), you will be asked to complete a post-intervention assessment that includes:

(a) Several questionnaires assessing pain severity and pain symptoms, psychological symptoms such as anxiety and depression, and cognitive styles;

(b) A short computerized task featuring various images, some of which depict emotionally and pain-related stimuli;

(c) An assessment of pain threshold and tolerance using a container filled with cold water, into which you will be asked to immerse your hand.

Two weeks after the post-intervention assessment, you will be asked to complete additional online questionnaires assessing pain severity and symptoms, psychological symptoms such as anxiety and depression, and cognitive styles.

• **Control Group:** If you are assigned to the control group, you will be asked to continue your regular treatment as usual. Additionally, for the next two weeks, you will be asked to complete a short questionnaire every evening (including Fridays and Saturdays, unless you observe Shabbat and have notified the research team) via a daily link sent to your mobile phone. The questionnaire will assess your pain severity, your functional difficulties that day, and your use of the pain acceptance strategy. Completion time is approximately 2 minutes.

At the end of the first week, a short 15-minute video call will take place, during which general questions will be asked about your experiences during the week and your completion of the daily reports.

At the end of the two-week monitoring period, you will be asked to complete a post-monitoring assessment that includes:

(a) Several questionnaires assessing pain severity and pain symptoms, psychological symptoms such as anxiety and depression, and cognitive styles;

(b) A short computerized task featuring various images, some of which depict emotionally and pain-related stimuli;

(c) An assessment of pain threshold and tolerance using a container filled with cold water, into which you will be asked to immerse your hand.

You will also be offered the opportunity to receive training in the emotional acceptance strategy for pain. The training will include an introduction, an explanation of the relationship between pain and emotions, and an overview of the treatment method (pain acceptance training). If you

are interested, you will be able to actively practice the treatment strategy with the research team through guided imagery, and learn to apply the strategy while experiencing physical pain induced by placing your hand in a container of cold water. This practice will include exercises in observing sensations and emotions.

Two weeks after the post-intervention assessment, unrelated to the assigned group, you will be asked to complete additional online questionnaires assessing pain severity and symptoms, psychological symptoms such as anxiety and depression, and cognitive styles.

All daily questionnaire data will be collected via the "Qualtrics" platform, which is secure and requires a username and password. The questionnaires will be sent to your mobile number via a unique link that identifies you using a participant ID number only, so that your identity and responses will remain anonymous.

For the purposes of the current study, information will also be collected from medical records. This information will include medical diagnoses, drug treatments, and recommendations for emotional therapy (individual or group). The data will be collected without your personal or identifying details and will be used to assess the effectiveness of the treatment.

1.4) Number of participants: 100 in total, equally divided between the groups.

1.5) Duration: About one month of participation for each participant.
Full study duration: one year.

1.6) Methods: Clinical interview, questionnaires, tasks as detailed above.

1.7) Participant responsibilities: You may not participate in any other studies involving experimental products aimed at altering pain during the entire duration of this study.

You will be asked to answer questions as part of the clinical evaluation. In addition, as detailed in Section 1.4, you will be asked to undergo a clinical assessment and complete a battery of questionnaires measuring pain intensity and pain symptoms, psychological symptoms such as anxiety and depression, and cognitive styles. You will also be asked to complete a short

computerized task involving various images, some of which depict emotionally and pain-related stimuli, and to undergo an assessment of pain threshold and tolerance using a container filled with cold water.

In addition, you will be asked to complete short daily questionnaires over a two-week period (a total of 14 daily questionnaires). At the end of the two weeks, a post-intervention assessment will be conducted. Two weeks after that, you will be asked to complete follow-up questionnaires online. If you fail to complete more than two questionnaires, the research team will contact you to understand why and to assist if any difficulties have arisen.

1.8) Risks and discomforts: No risks are expected as a result of participating in the study. However, during the two study sessions (at the beginning and at the end of the experiment), you may experience a certain level of pain while immersing your hand in a container filled with cold water. It is important to emphasize that the pain will stop immediately once you remove your hand from the container, and therefore, the process is under your control—you may decide to remove your hand at any time. Additionally, you may experience discomfort while completing questionnaires that include emotionally sensitive topics, or during exposure to images related to emotional or pain-related content.

In any case of discomfort or psychological distress, you are encouraged to contact Dr. Shulamit Greenapple, the principal investigator, at: 050-8118500 or 04-7771718.

Furthermore, there may be risks that are currently unknown or cannot be anticipated in advance.

1.9) Benefits: No guaranteed direct benefit. However, you will have the opportunity to learn and practice an emotional pain acceptance strategy, which has been shown in previous studies to help in coping with pain. This method is relatively simple to understand and use in daily life, is non-invasive, and does not involve medication. Its goal is to support coping and functioning in the presence of pain and to reduce the suffering it causes. Additionally, during the training, you will learn about the connection between pain and emotional state, and how you can influence your emotional state in order to affect your experience of pain. Throughout the study, you will remain in regular contact with the research team and may receive support at any stage regarding difficulties that arise while using the emotional coping strategy.

1.10) Alternative treatments: This study supplements your existing treatments. It is not a replacement.

1.11) Grounds for withdrawal by the researcher:

- Missing more than 3 daily questionnaires.
- Not practicing the strategy as instructed.
- Not attending assessments.

1.13) Compensation:

Participation is free. You will be reimbursed for travel and time, as follows:

- 100 NIS – Initial assessment.
- 100 NIS – Daily questionnaires (if not disqualified).
- 20 NIS – Video check-in.
- 130 NIS – Final assessment.
- 50 NIS – Follow-up questionnaires.

2) Privacy and Confidentiality:

2.1) In the study you are invited to participate in, medical and personal information will be collected as part of the research. This information will be stored in your medical record, and it is the responsibility of your healthcare team to maintain medical confidentiality. You have the right to access your medical record in accordance with the Patient's Rights Law. If you are aware that any of the information in your record is incorrect or incomplete, you must inform the medical team.

2.2) The medical record will contain information such as: results of medical tests, administration of medications, use of medical devices or implants, and performance of treatments or experimental procedures, etc.

2.3) Your consent to participate in the study also includes your agreement that medical and personal information collected during the study may be transferred to an external party for the purpose of data processing. This information will only be transferred in coded form. It will not

include your first or last name, ID number, residential address, or any other identifying number assigned to you by state authorities.

In general, coded information is still considered potentially identifiable. The link between your code and identifying details will be securely stored by the principal investigator in Israel. In certain cases, the code may be decrypted by the investigator.

2.4) The coded data and information will be retained by the sponsor for a period defined by law (at least 15 years from the end of the study).

2.5) Viewing rights for the purpose of verifying the study methods and data will be granted only to authorized personnel (e.g., qualified representatives of the sponsor, the Helsinki Committee, institutional audit bodies, and inspectors from health authorities). Access to your medical information will be made via the principal investigator and in accordance with laws and confidentiality regulations.

2.6) Your identifying details will not appear in any scientific or other publication.

3) Withdrawal from Study:

You may withdraw at any time without explanation. Data collected until withdrawal may still be used, but no further data will be gathered. You may decline future updates about health-related findings.

4) Consent Documentation:

Participant: I confirm I have read and understood the information and agree to participate.

Name: _____ Signature: _____ Date: _____

Explaining Researcher: I confirm I explained the study orally, believe the participant understood, and had enough time to decide.

Name: _____ Signature: _____ Date: _____

Independent Witness *(if needed)*: I confirm I was present during the oral explanation and that the participant gave verbal consent.

Name: _____ Signature: _____ Date: _____

Required only if participant is illiterate, blind, or under urgent medical circumstances.