Clinical Protocol

REPAT- Role of Emotional Processing in Art Therapy for Breast Cancer Palliative Care Patients: A Mechanistic Study

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Study Title

REPAT- Role of Emotional Processing in Art Therapy for Breast Cancer Palliative Care Patients: A Mechanistic Study

Objectives

The purpose of this study is to examine two mechanistic changes: emotion processing (awareness, expression and acceptance) and cholinergic anti-inflammatory processes (HRV and cytokine expression) through which an Art Therapy (AT) intervention reduces depression, pain and fatigue.

Design and Outcomes

For this means, we have designed a randomized controlled study with careful controls. Our study population is comprised of 240 BC patients in palliative and curative care (comprised of 50% Jewish and 50% Arab). This population will be randomized (using a permuted block design to account for ethnicity and level of traditionalism) to receive a standard art therapy intervention or a comparison group. The intervention is designed to increase emotion processing via art making in a supportive environment. The sham Art Therapy comparison group will engage in the coloring of prefabricated shapes (mandalas) and will receive Psychoeducation on topics related to coping with BC, identical to the topics of the AT group. This design will allow the study to test the mechanism of AT that is beyond the effects of time with a group, focus on a task and engagement with art materials.

Interventions and Duration

The AT intervention is an 8-week group intervention comprised of 8 1.5-hour weekly sessions conducted by an experienced Art Therapist who received special training in conducting the treatment protocol as designed. The intervention and comparison group were piloted on BC patients at Beilinson hospital and the protocol was modified based on feedback from the participants. Each intervention module is described below.

The comparison group will be an 8-week group intervention comprised of 8 1-hour weekly mandala coloring sessions with a self-care educational component, conducted by someone with experience conducting groups who will be trained in providing a well-planned comparison group, with fidelity checks that includes coloring pre-fabricated mandalas.

There will be an additional follow up time point 8 weeks after the intervention is over to assess

the lasting effects of the intervention.

Sample Size and Population

240 BC survivors will be randomized to the intervention and comparison groups. We are targeting 300 women and expect an attrition rate of 15%. We also will be targeting the recruit of 50% of our sample to be of Arab origin and 50% Jewish.

1. STUDY OBJECTIVES

To examine two mechanisms: 1) emotional processing (awareness, acceptance and expression) and 2) cholinergic anti-inflammatory processes (resting HRV and inflammatory cytokines), through which AT reduces depression, pain and fatigue in Arab and Jewish BC survivors.
To examine ethno-cultural differences in the effect of Art Therapy in women from a traditional collectivist ethno-cultural background, in comparison to women from a more individualist western ethno-cultural background.

2. BACKGROUND AND RATIONALE

2.1 Background on Condition, Disease, or Other Primary Study Focus

Over 200,000 women are diagnosed with breast cancer (BC) in the United States annually[1]. As of January 1, 2016 there were 3,560,570 breast cancer survivors in the United States [2]. Cancer survivorship is defined as living with the challenges that occur as the result of a cancer diagnosis and treatment [3]. Thus, in this document patient and survivor are used interchangeably.

Many breast cancer patients cope with depression. Stress and negative emotion are normative responses to cancer diagnosis and treatment, but approximately one-third of individuals coping with cancer experience the debilitating consequence of depressive disorders[4] which have been linked with functional limitation in survivorship[5]. Depressive symptoms are persistently elevated in the year following cancer diagnosis; 38% of BC survivors experience depressive symptoms in the clinical range[6,7]. These individuals suffer more physical symptoms, problems with treatment adherence, functional limitation in survivorship[6] and increased mortality[8].

There are several physical symptoms that occur commonly in BC survivors. Pain and fatigue are some of the most prominent symptoms that affect quality of life (QoL) and well-being of cancer survivors. A reported 25% to 60% of women develop chronic pain after BC treatment and chronic fatigue is reported in between 30-60% of survivors[3,8,9]. **Physical symptoms co-occur with distress and are very difficult to treat**. Cancer survivors with high symptom burden suffer from diminished QoL, which compromises physical, psychological and social functioning[6].

2.2 Emotion processing has been associated with improved physical and psychological health in BC survivors. Emotion processing is comprised of 1) emotional awareness, 2) expression, and 3) acceptance. Increased **emotional awareness** occurs when knowledge is transferred from sensorimotor or bodily information to patterns of explicit thought that include conscious processing through language or other symbolic formations, such as visual art[10-12]. Low levels of emotion awareness were found in individuals with somatoform disorders[13]. **Emotional**

expression refers to the extent to which feelings are intentionally[14] (mainly verbally) and non-intentionally[15] (body language, facial expressions) conveyed to others. Increased emotion expression and reduced avoidance have long been associated with improved wellbeing[16-19]. Increased emotional expression is associated with improved psychological and physical adjustment to BC[20-23]. **Acceptance of emotion** is an emotion regulation strategy in which individuals embrace an attitude of being accepting, friendly, and nurturing toward their feelings[19,24]. Acceptance of emotion has been associated with experiencing less fear, catastrophic thoughts, avoidance behavior and better recovery from negative affect as compared to suppression[25]. Women coping with BC who were less accepting of their emotions also reported greater distress[26] and sickness symptoms[27].

2.3 There are ethno-cultural differences in response to cancer diagnosis. Women from traditional backgrounds, in which there is an emphasis on collectivism as opposed to individualism and a reliance on religion as a major coping strategy, may respond differently to cancer diagnosis and treatment than do more modern/secular women. Women from traditional backgrounds may see cancer diagnosis as fate and fear stigma related to exposing their diagnosis[28]. Furthermore, out of fear of their loss of role in the traditional family, women may not express their distress openly, which leaves them at risk for loneliness and not receiving help for their symptoms[28-30]. BC survivors from ethnic minorities report poorer social, emotional, spiritual and physical quality of life[31]. Since expression of emotion and venting is distressing for some ethnic minorities[32,33], art making and the use of metaphors as a form of emotion processing may be less distressing and more helpful in reducing symptoms and increasing quality of life[34,35]. Israel is a multi-cultural country with differences between the Jewish and Arab population. Israeli Arabs of different subgroups in comparison to Israeli Jews were found to be more conservative and hierarchical, and less autonomous[36-38].

2.4 Art Therapy interventions encourage emotion processing. Art therapy is a form of psychotherapy that involves the use of visual art-making (drawing, painting, sculpting, collage, etc.) for expression and communication within a safe and supportive relationship, in a therapeutic setting[39]. The Art Therapy session includes (i) an introductory period in which the therapist engages with participants to establish rapport and begins to understand participants' current state of mind, (ii) an art making period which entails much of the time, and (iii) a processing period in which the art made is looked at and discussed. Art Therapy has been well documented in cancer settings to alleviating psychological symptoms and reducing physical complaints[40-44]. In a qualitative study, women with breast cancer reported that art making was helpful through increased access to emotional content and its expression[45].

We hypothesize that increased Emotion Processing is a primary mechanism through which Art Therapy effects psychological and physical symptom reduction in breast cancer patients.

2.5 Heart rate variability and inflammation are related to emotion processing and depression, anxiety, fatigue and pain.

The **cholinergic anti-inflammatory pathway** is comprised of vagus nerve signals leading to acetylcholine-dependent interaction with the alpha 7 nicotinic acetylcholine receptor subunit (a7nAChR) on monocytes and macrophages, resulting in reduced cytokine production[46]. Vagal modulation is related to physiological adaptability and emotional regulation[53]. Decreased vagus nerve activity and the associated loss of the tonic inhibitory influence of the cholinergic anti-inflammatory pathway on innate immune responses and cytokine release, are hypothesized to pathologically enhance cytokine responses to stimuli, such as psychological stress[47]. **Heart rate variability** (HRV) is a measure of beat-to-beat temporal changes in heart rate and these changes reflect the output of the central autonomic network. The vagus nerve is a core component of the parasympathetic nervous system (PNS) within the central autonomic network and it regulates metabolic output in response to environmental stimuli and enables social engagement[48]. HRV can encompass both Sympathetic nervous system and PNS influences, but our primary interest is on the PNS influences, and at rest, a majority of HRV is related to PNS influence. In reviewing the literature, which reports a wide variety of metrics, we will use the more general term HRV, whereas our specific hypotheses will involve the subset of HRV that is specifically linked to PNS influence: high frequency (HF) HRV that reflects respiratory sinus arrhythmia (RSA) [49].

The **neuro visceral-integration model** views psychopathology such as anxiety being 'stuck' in a behavioral pattern that is not responsive to the demands placed upon it by the environment[54 50] and asserts that lower HRV is associated with poor health because it reflects excess allostatic load as indexed by excess **pro-inflammatory cytokines[47]**. High levels of **pro-inflammatory cytokines and low HRV are related to depressed mood, fatigue and pain** in cancer patients[51-54]

Low HRV has been linked to difficulties in emotion regulation[55-57] in the prediction of anxiety in BC patients[62], and reports of sadness and crying in depressed individuals[58,59]. Disrupted nocturnal sleep was related to lower HRV the following day along with a flattened diurnal cortisol rhythm in women with metastatic BC[60,61].

3. STUDY DESIGN

We will accomplish the aims by a randomized controlled trial of 240 Jewish and Arab women (>18 years) who have been diagnosed with BC and have completed chemotherapy, recruited in Israel and randomized to undergo an 8-week (1.5 hours per week) program of group Art Therapy compared to women who will be designated to an 8-week sham Art Therapy group. We chose this design to be able to isolate and examine emotional processing and the effect of enhancing emotional processing on HRV and inflammatory cytokines and examine how these may mediate the effect of art therapy on depressive symptoms, pain and fatigue.

The primary outcomes are emotion processing, comprised of emotion awareness, expression and acceptance and the cholinergic anti-inflammatory pathway, comprised of resting HRV and inflammatory (pro and regulatory) cytokines. The secondary outcome measures are depression, pain and fatigue.

The study will take place at the cancer centers of 3 study sites: Rabin Medical Center, Rambam Medical Center and Ziv Medical Center, the enrollment period will vary until each cohort is collected and is expected to be approximately a month or a month and a half.

The interventions will be administered by an experienced Art Therapist who will be trained in this specific protocol by the PI Czamanski-Cohen who is an Art Therapy Professor. The intervention is designed to follow the Bodymind model of AT[62]. Each session will start with a ten-minute rapport building and touching base and continue with 50 minutes of art making in a calm and supportive environment. Art materials are on the table and after the art therapist provides a brief explanation of the use of the materials; participants are encouraged to explore and experience as they wish. The art therapist is present to guide and assist. Participants are encouraged to minimize conversation; instrumental music is played to encourage introspective experiences. The session ends with 30 minutes of processing and discussion in which each participant shares and briefly presents their work and group participants can respond and or provide support.

The comparison group will meet for a half an hour. The interventionist will encourage the participants to color prefabricated shapes for 30 minutes. The same art materials as in the intervention group will be on the table as will the same instrumental music. We will not be controlling for the whole 90 minutes of the intervention group as are concerned that comparison group participants will become bored and this will defeat the purpose of the comparison group. The detailed role of the interventionist is described in section 5.2, and it is tailored to ensure optimal opportunities for participants to engage in emotional processing in a supportive environment.

The interventionists of both groups will keep scores that will be rated by the PI against the treatment manual to ensure fidelity (see Table 2).

4. SELECTION AND ENROLLMENT OF PARTICIPANTS

We will accomplish the aims by recruiting 240 Jewish and Arab Women (>18 years) who have been diagnosed with breast cancer and have completed chemotherapy and are still undergoing some form of treatment, to include adjuvant treatment or within 5 years of completing chemotherapy, surgery and/ or radiation therapy. There is evidence that elevated depression, anxiety, fatigue and pain continue over 5 years of survivorship. We plan to recruit 50% Jewish women and 50% Arab women (30% more than represented both in general society and in the cancer population), for comparison. We plan to identify and approach women as they come in for their simulation visit to Radiation Oncology as this usually occurs about a week before radiation therapy starts and will be a good time to obtain baseline measures, however each site nurse will have the freedom to recruit patients who fit the enrollment criteria at other stages of treatment, after chemotherapy. The site nurse will be in charge of identifying and recruiting appropriate candidates for the trial and will use a screening log in order to document reasons for ineligibility or non-participation for eligible candidates.

4.1 Inclusion Criteria

1) adult (>18) females with initial or recurrent BC; 2) study entry within one year of diagnosis and 3 months after adjuvant cancer care (chemotherapy and radiotherapy (RT)) or reconstructive surgery; any additional or replacement standard medical treatment for cancer is allowed (i.e., surgery, chemotherapy, radiotherapy, neo-adjuvant chemotherapy, endocrine therapy); 4) additional medication is allowed, excluding what is described in exclusion criteria, and will be assessed for potential inclusion as a covariate; 5) can complete assessments in Arabic or Hebrew; 6) provides informed consent.

4.2 Exclusion Criteria

1) male (While we are aware of the NIH preference for studying men with BC, there presence would likely reduce the feeling of safety within the groups due to the sensitive subject matter); 2) lifetime history of bipolar disorder, schizophrenia, schizoaffective disorder or with a pre-cancer diagnosis of fibromyalgia or chronic fatigue syndrome 3) active suicidal plan (will ensure immediate intervention); 4) dementia/other disorder that would preclude informed consent or comprehension of assessments; 5) Individuals taking anticholinergic medications, and post myocardial infarction (6 months before recruitment) or with a pacemaker, which would render the

metric of HRV invalid. 6) Flare-up in systemic autoimmune disease (such as arthritis, lupus or multiple sclerosis), thyroid dysfunction that requires increases in medication

We will inquire about and document any illness in the previous week with infection or acute viral disease as well as having dental work[63] to account for these in our analyses. Additionally, should we encounter 6 or more men with BC we will conduct an Art Therapy intervention group for qualitative data gathering.

After assessing eligibility and providing verbal consent to be contacted the site nurse will document their contact information in the Screening Log. The research coordinator will contact the potential participant by phone and will schedule a face to face meeting with the eligible participant. During the face to face meeting the research coordinator will use the following script to inform the eligible participant about the study:

"We are conducting a study about how art therapy is beneficial for Breast Cancer patients and survivors. Should you agree to participate in this study, you will be requested to provide your written consent to participate in the study. You will then be randomized to one of 2 types of Art interventions. The intervention period will be 8 weeks and the sessions will be between an hour to 1.5 hours each week, depending on which group you are randomized to. You will be requested to answer questionnaires for about half an hour twice before the 1st session, once in after the intervention and one more time 8 weeks after the intervention is over. In addition, before and after the intervention you will be requested to measure your heart rate and respiration for an hour using a bio-patch that is attached below your sternum with 2 Gel electrodes. For half of the time you will be answering a questionnaire and for the second half hour you will be resting and listening to music. You will also be requested to provide us with 10ccs of blood for the analysis of health-related variables, such as cytokines. Our goal is to investigate the effects of the intervention on different indicators of Quality of Life of Breast Cancer patients and survivors. You will be compensated for your time and transportation. Should you attend all study sessions you will receive the equivalent of $200US in NIS and you will receive a fraction of that sum calculated for the sessions you attended, if you do not attend them all. For each session you attend, you will receive compensation for public transportation costs to the site from your home and back. You can withdraw from the study at any point in time by contacting the research coordinator of the PI, Dr. Czamanski-Cohen".

5. STUDY INTERVENTIONS

5.1 Interventions, Administration, and Duration

Both interventions will be administered in a group format by a trained individual. Each session will be 1.5 hours (intervention) and an hour (comparison) once a week for 8 weeks. There is a risk of participants feeling distress due to the exposure to emotional content either discussed in the group or that arises in the art therapy intervention group. The psychosocial team at each study site will be prepared to meet with any participant who requests so. Interventionists will be trained to identify and refer distressed participants to the psychosocial team.

5.2 Handling of Study Interventions

Participants will be blinded to whether they are receiving the intervention or comparison group. The treatment protocol derives its theoretical framework from the Bodymind model of AT[62] and from the application of Focusing to Art Therapy[64,65] for the purpose of body awareness and developing a focusing ("being friendly, accepting, non-judgmental and welcoming to one's inner felt sense")[66]. All sessions start with a ten-minute rapport building and touching base and continue with 50 minutes of art making in a calm and supportive environment. Art materials are on the table and after the art therapist provides a brief explanation of the use of the materials; participants are encouraged to explore and experience as they wish. Group leader is present to guide and assist. The role of the art therapist is to encourage a non-judgmental and exploratory approach to artmaking in which the process is emphasized over product. The art therapist obtains these goals by creating an atmosphere that is calm and by remaining tuned in to the verbalizations and body language of participants. If needed she can provide individual attention that is geared toward neutralizing concerns regarding performance during the art making. This approach is defined as providing a "Third-hand" [67]: assisting in problem solving and dilemmas related to the

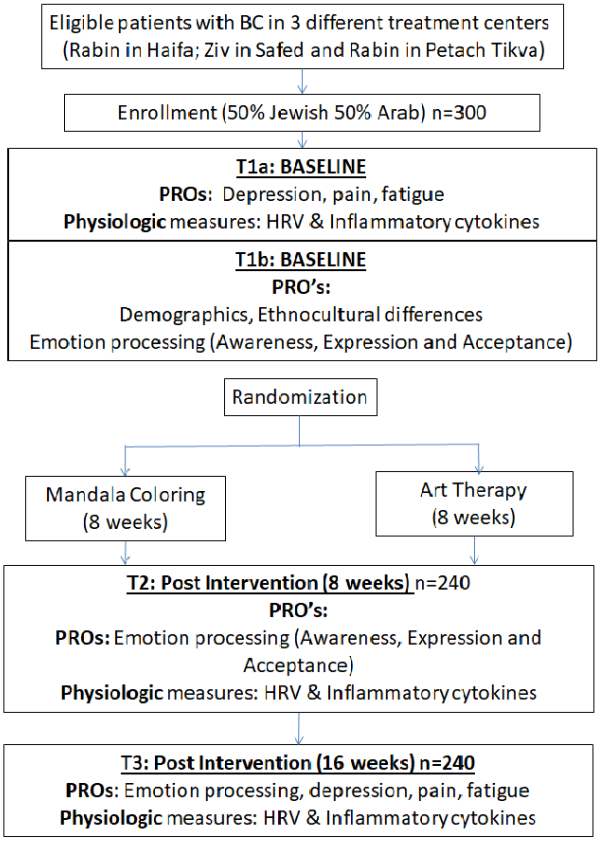

Figure 1: Flow chart of time-points

art making process. The art therapist encourages participants to refrain from conversation and instrumental music is played to encourage introspective experiences. The session ends with 30 minutes of processing and discussion in which the art therapist requests each participant to share and briefly presents their work and group participants can respond and or provide support. The art therapist will remind group members to be respectful and non-judgmental toward other participants and themselves.

Session 1: getting familiar and safe: An introduction to the group, the group leader will speak about motivation for exploration via art and remaining open to new experiences. The leader will introduce the art materials and art making from a non-judgmental stance and the importance of process of product. The concept of safe place will be introduced to the group and members will be asked to create a safe place via art. The goals of this session: Rapport Building, Contract Building and getting familiar and comfortable with the art materials.

Session 2: Art making will be exploratory in the framework of open studio in which a specific topic is not provided and participants are encouraged to explore the art materials. The goal of this session is to provide an experiential encounter with the art making process. There will be a 10-minute Psychoeducation presentation on the nature of emotions at the beginning of the session.

Session 3: Group members will introduce themselves to the group by making a drawing about an emotion. The goal of this session is to continue learning on the nature of emotions and increase awareness of emotion responding patterns.

Session 4: The art therapist requests the participants to create an image of somethings that is distressful to them and sit with it for a while. Then, they are requested to create an additional drawing that changes one element of the distress drawing, a feature, a color, a shape, or just a change in composition. The images are discussed among group members and implications for real life situations are discussed. The goal of this session is twofold- to identify the location of distress in the body, increase distress tolerance, cognitive flexibility and reframing.

Session 5: This session is open studio in which participants are encouraged to engage freely with the art materials. The goal of this session is to help participants identify how they react and respond to their emotions and bring an awareness of emotional experiences and learn the skill of “Clearing the Space”-using artmaking to identify feelings and experiences without the need to identify with them.

Session 6: Clients are requested to draw two sides of a current conflict in their life. It can be something small, like deciding where to go for lunch, or something large, like which treatment to

engage in. All conflicts are welcome, but it should have significance to its creator and be something that they are struggling with and would like to learn more about. After the drawing period, clients are requested to look at both options and examine their sensations, feelings and thoughts about each. Their art, thoughts and feelings are shared with the group. The goal of this session is to increase cognitive flexibility and reframe. This means that through creating 2 pictures participants will be able to view a situation from 2 points of view and identify more than one option for coping with the conflict they presented.

Session 7: Body image: In this module participants will create art using body outline templates as a framework for art making. The goal of this session is to increase introceptive awareness and assist in processing emotional content from implicit experience to explicit expression. Distress tolerance.

Session 8: Summary: This session will be a summary of all that has been experienced and clients will be provided with a letter that summarizes their progress. Each client will receive a package of oil pastels and blank journal for the encouragement of their continued process at home. The goal of this session is to review achievements and encourage incorporating what was learned in day to day life after the intervention is over.

The comparison group is designed to control for the impact of the aspect of the group experience that are not explicitly focused on emotional processing, ie, the time with art materials and focused attention aspects that occur during an Artmaking session. These sessions will not have a rapport building component and will include 40 minutes of coloring pre-fabricated shapes (Mandalas- see figure 3) in a calm environment and 20 minutes of self-care instruction. Coloring Mandala's has been demonstrated to reduce anxiety[68-70]. Participants are encouraged to minimize conversation; instrumental music is played to encourage introspective experiences. Due to our concerns that participants will become bored after more than 40 minutes of coloring we will not be equally comparing the amount of time that participants are together in the group format.

Figure 3: Mandala example

5.3 Concomitant Interventions

5.3.1 Allowed Interventions

Any standard medical treatment for cancer is allowed (i.e., surgery, chemotherapy, radiotherapy,

neo-adjuvant chemotherapy, endocrine therapy). However, participants should not be on chemotherapeutic agents during the study period.

5.3.2 Prohibited Interventions

Participants should not be engaged in another form of Psychotherapy or support group at the time of the intervention. Anticholinergic medications and beta-blockers are prohibited as they render the HRV and cytokine measures invalid.

5.4 Fidelity Assessment

Adherence to the study regimen will be defined as attending 80% of the group sessions, which will be monitored and recorded by the interventionist. The moderation of the effect of attending less than 80% will be assessed and dealt with during data analysis. Furthermore, fidelity of the intervention itself will be ensured by scoring the sessions against the treatment manual and observational fidelity checks by the gold standard rater (PI Czamanski-Cohen initially and then trained PhD student 20% of sessions). Fidelity below an average of 4 will indicate the need for further training of the interventionist.

Table 2 Fidelity assessment

	1 not at all	2 a little bit	3 neither yes or no	4 quite a bit	5 very much so	Not applic-able
1. Was there a sense of calm in the room?	1	2	3	4	5	N/A
2. Did you feel like you were able to support the participants?	1	2	3	4	5	N/A
3. Were the participants deeply engaged in art making?	1	2	3	4	5	N/A
4. Was the session divided in to 10-minute intro, 60 minutes art making and 20 minutes discussion?	1	2	3	4	5	N/A
5. Was the art making done with minimal conversations?	1	2	3	4	5	N/A
6. Was the group discussion respectful and safe?	1	2	3	4	5	N/A

6. STUDY PROCEDURES

6.1 Schedule of Evaluations

Assessment	Screening Visit-1 (Day-14 to Day -1)	Baseline Visit 1 (Day 0)	Tx Visit 2 (W1)	Tx Visit 3 (W2)	Tx Visit 4 (W3)	Tx Visit 5 (W4)	Tx Visit 6 (W5)	Tx Visit 7 (W6)	Tx Visit 8 (W7)	Tx Visit 9 (W8)	Tx Visit 10 (W9)	Follow-up Final Visit (W16)
Verbal consent	X											
Informed Consent Form		X										
Demographics	X											X
Medical Chart Review	X											
Current Medications	X	X										
Inclusion/Exclusion Criteria	X											
Enrollment/ Randomization		X										
Adverse Events		X	X	X	X	X	X	X	X	X	X	X
Questionnaires		X									X	X
Heart rate measurement		X									X	X
Blood draw		X								X		

6.2 Description of Evaluations

6.2.1 Screening Evaluation

During clinic hours, research staff at the oncology practices will introduce potentially eligible patients to the study using a verbal script. Interested patients (having received a letter, flyer or referral) will call our office and receive an initial phone screening to assess age, stage, and Hebrew or Arabic language use. If initial criteria are met, an in-person visit will be scheduled either in our University office or at one of the 3 hospital recruitment sites where private rooms are arranged, depending on convenience to prospective participants to complete evaluation of eligibility, including major clinical depression, detailed medical history and current medications.

Consenting Procedure

The research nurse will obtain verbal consent from the patient agreeing to participate in the screening session. During the screening session, there will be a single informed consent form that describes both the screening and study procedures. Once eligibility is established, Subject's Consent Form and Health Information Privacy Protection Act (HIPAA) information will be reviewed and, if consenting, participants will sign. Each site will have a designated MD or nurse to review documents related to medical and symptom-based eligibility criteria. Informed consent will be documented on a University of Haifa Ethics committee-approved form. A copy of the signed form will be given to the subject. Signed consent forms will be kept in Dr. Czamanski-Cohen's office,

which is an administrative office separate from research data and available for audit even when the PI is not. Additional information contained in a case book will be relevant demographic and medical/psychiatric information about the subject obtained during the interview with the site representative. Because this case book will contain personal identifiers and PHI, it will be kept separate from any data gathered as part of the study, and will be kept in a locked office. After consent is obtained, potential subjects will be screened by study personnel to determine that the subject meets all inclusion and exclusion criteria for study participation.

6.2.2 Enrollment, Baseline, and/or Randomization

Enrollment

Enrollment date is considered immediately following the signing of the consent form after which the enrollment date is recorded in the case book. The participant will be scheduled for a baseline visit in which she will be requested to fill out the baseline questionnaires and provide half an hour of baseline HR and Respiration measurements and 10 ccs of blood. Following this session, the participant will be randomized to the intervention or comparison group.

Baseline Assessments Visit 1 day 0- can be split in to 2 visits to reduce patient burden (see study schema- figure 1)

T1A

DEMOGRAPHICS AND TRADITIONALISM

A. We will be collecting baseline demographic data (age, marital status, children (if yes, and how many), religion, religiosity, education, employment, residence (city, village, etc).

B. We will measure ethnocultural differences using the Portrait Values Questionnaire (PVQ-RR), which is a 57-item scale consisting of items designed to measure 19 cultural values43. The scale has been validated in 15 samples across 10 countries (n=6059) including Israel. The mean Cronbach α for the tradition values (which we will use as a covariate to enrich the ethno-cultural differences between Jews and Arabs, was 0.8343.

C. CHOLINERGIC ANTI-INFLAMMATORY PATHWAY

A. HRV: 20 minutes of resting ECG data will be recorded. The participants will be given instructions not to drink coffee or smoke for several hours before the lab visit as well as to sit quietly without talking or moving during the ECG recording.

B. Inflammation: We will collect 10 cc's of blood in order to measure immune dysregulation (pro-inflammatory cytokines IL-6, IL-8, IL-1β, TNF-α), anti-inflammatory (IL-4, IL-10) and regulatory cytokine (TGF-β).

D. PATIENT REPORTED OUTCOMES (PRO):

A. Depression: The **Center for Epidemiologic Studies-Depression** (**CES-DR)** scale[71- 10] ITEM SCALE.

B. Fatigue will be assessed using the Fatigue Symptom Inventory (**FSI**)[72].

C. Pain: The **Breast Cancer Prevention Trial (BCPT) Symptom Scales**[73]. The **PROMIS** Pain Impact Scale[74] measures how much pain interfered with different aspects of life in the past 4 weeks.

T1B

A. The **Levels of Emotional Awareness Scale** is a written performance index of variation in the differentiation and complexity of emotional words used to answer the question "how would you feel and how would the other person feel" when presented with 10 evocative scenarios[75].

B. **Emotional Approach Coping** scales (e.g., **emotional processing, emotional expression**[76]) and COPE **avoidance-oriented coping** subscales (e.g., denial, mental disengagement[77]), all completed with reference to women's experience of breast cancer.

C. The **Acceptance of Emotions Scale** assesses the extent to which subjects are accepting and nurturing toward their feelings[26].

B. Fatigue will be assessed using the Fatigue Symptom Inventory (**FSI**) [72].

Randomization

Randomization will occur immediately following the baseline visit which will occur within 14 days of the screening visit and one week before the intervention begins. The University statistician will generate numbered envelopes to be opened consecutively as subjects enroll and the envelopes will designate individuals to the intervention through use of a random numbers table.

6.2.3 Blinding

Participants will be blinded to their randomization as will the research nurses and research coordinators.

6.2.4 T 2 – POST intervention

EMOTION PROCESSING

A. The **Levels of Emotional Awareness Scale** is a written performance index of variation in the differentiation and complexity of emotional words used to answer the question "how would you feel and how would the other person feel" when presented with 10 evocative scenarios [75,78].

B. **Emotional Approach Coping** scales (e.g., **emotional processing, emotional expression** [79,80]) and COPE **avoidance-oriented coping** subscales[79] (e.g., denial, mental disengagement), all completed with reference to women's experience of breast cancer.

C. The **Acceptance of Emotions Scale** assesses the extent to which subjects are accepting and nurturing toward their feelings[24].

D. PATIENT REPORTED OUTCOMES (PRO):

A. Depression: The **Center for Epidemiologic Studies-Depression** (**CES-DR)** scale[71- 10] ITEM SCALE.

B. Fatigue will be assessed using the Fatigue Symptom Inventory (**FSI**)[72].

C. Pain: The Breast Cancer Prevention Trial (BCPT) Symptom Scales73. The PROMIS Pain Impact Scale74 measures how much pain interfered with different aspects of life in the past 4 weeks.

CHOLINERGIC ANTI-INFLAMMATORY PATHWAY

A. HRV: 20 minutes of resting ECG data will be recorded. The participants will be given instructions not to drink coffee or smoke for 3 hours before the lab visit as well as to sit quietly without talking or moving during the ECG recording.

B. Inflammation: We will collect 10 ccs of blood in order to measure immune dysregulation (pro-inflammatory cytokines IL-6, IL-8, IL-1β, TNF-α), anti-inflammatory (IL-4, IL-10) and regulatory cytokine (TGF-β).

T3-8 WEEKS AFTER END OF INTERVENTION Completion/Final Evaluation

CHOLINERGIC ANTI-INFLAMMATORY PATHWAY

A. HRV: 20 minutes of resting ECG data will be recorded. The participants will be given instructions not to drink coffee or smoke for 3 hours before the lab visit as well as to sit quietly without talking or moving during the ECG recording.

B. Inflammation: We will collect 10 ccs of blood in order to measure immune dysregulation (pro-inflammatory cytokines IL-6, IL-8, IL-1β, TNF-α), anti-inflammatory (IL-4, IL-10) and regulatory cytokine (TGF-β).

D. PATIENT REPORTED OUTCOMES (PRO):

A. Depression: The **Center for Epidemiologic Studies-Depression** (**CES-DR)** scale[71- 10] ITEM SCALE.

B. Fatigue will be assessed using the Fatigue Symptom Inventory (**FSI**)[72].

C. Pain: 4 pain specific items to assess pain from the **Breast Cancer Prevention Trial (BCPT) Symptom Scales**[73]. In addition, we will use the 6 items for pain from the **PROMIS** Pain Impact Scale[74] measuring how much pain interfered with different aspects of life in the past 4 weeks.

EMOTION PROCESSING

A. The **Levels of Emotional Awareness Scale** is a written performance index of ability to express emotion in a differentiated and complex way.

B. **Emotional Approach Coping** scales (i.e., **emotional processing, emotional expression**[80] and COPE **avoidance-oriented coping** subscales[79] (e.g., denial, mental disengagement, all completed with reference to women's experience of breast cancer.

C. The **Acceptance of Emotions Scale** assesses the extent to which subjects are accepting and nurturing toward their feelings[24].

7. SAFETY ASSESSMENTS

7.1 Specification of Safety Parameters

N/A

7.2 Methods and Timing for Assessing, Recording, and Analyzing Safety Parameters

N/A

7.3 Adverse Events and Serious Adverse Events

An **adverse event (AE)** is generally defined as any unfavorable and unintended diagnosis,

symptom, sign (including an abnormal laboratory finding), syndrome or disease which either occurs during the study, having been absent at baseline, or if present at baseline, appears to worsen. Adverse events are to be recording regardless of their relationship to the study intervention.

A **serious adverse event (SAE)** is generally defined as any untoward medical occurrence that results in death, is life threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly.

Adverse events are not expected because of the intervention or comparison groups.

7.4 Reporting Procedures

PI's Czamanski-Cohen and Weihs will create a **Data and Safety Monitoring Board (DSMB)**, which will meet at approximately six-month intervals. DSMB members will represent expertise in psycho-oncology and in research monitoring. Members of the committee will agree to keep all information confidential. The board members will review summaries of study progress to ensure that consent documentation is properly obtained and stored. They will review progress in subject recruitment and anticipated race/ethnicity participant representation. They will determine whether study coordinators and investigators are collecting and organizing data properly.

7.5 Safety Monitoring

PI Czamanski-Cohen will closely monitor and supervise the research team at their respective sites, as well as conduct coordinated oversight of psychological status of all participating women taking part in the research. She will consult with PI Weihs with any concern or consideration. PI Czamanski-Cohen will also meet regularly with the research teams at the clinical sites and the University every other week to ensure appropriate conduct.

INTERVENTION DISCONTINUATION

Should the PI or site PI discover based on research nurse, patient reports or assessments of outcomes in the initial cohort that the intervention is causing harm rather than benefit (statistically significant mean increases in depression) the intervention will be discontinued.

8. STATISTICAL CONSIDERATIONS

8.1 General Design Issues

A randomized trial with careful controls was chosen to control for the active mechanism of emotion processing that we expect to increase following the art therapy intervention. Our comparison

group is designed to entails aspects of art therapy, such as engaging with art materials and being in a group setting that we believe are not related to the mechanism at hand.

8.2 Sample Size and Randomization

A power analysis was conducted via Monte Carlo simulation in Mplus showed that a sample size of 240 (120 per condition), provides: (1) >90% power to detect a moderate effect size (Cohen's d = 0.50) of treatment on mechanisms, (2) >90% power to detect a moderate association (r = 0.30) between mechanisms and symptoms, and (3) >90% power to detect an indirect effect from treatment to symptoms via mechanisms. The sample size will also provide >80% power to detect a moderate effect size for the Condition by Ethno-Cultural group interaction.

Consented participants will be randomized into the Art Therapy or Sham condition using block randomization stratified by site, ethnicity and traditionalism to ensure equal sample sizes between groups over time in each site and in each ethnicity. Permutations of group assignment will be generated in random blocks of 4, 6, and 8 so that staff cannot guess the condition of the final participant as the block size varies. Condition assignment will be stored in sealed, numbered envelopes to be opened consecutively as subjects enroll and the envelopes will designate individuals to the intervention through use of a random numbers table. PI Czamanski-Cohen will provide the PhD students with the randomized lists (60 each cohort), who will schedule sessions and make weekly calls to encourage attendance, therefore both will be un-blinded to study assignment. The Research Nurse will collect and enter data, collect bio specimens and manage the database, and thus will be un-blinded after randomization. The research assistant (RA) will remain blinded throughout the study, and will receive lists of participants to call, without knowing which group they are assigned to. Participants will be told they are participating in an "art making" study where they will be assigned to an art making group. Participants will not be told which is expected to be superior.

8.3 Treatment Assignment Procedures

Consented participants for each cohort will be randomized (PI- Czamanski-Cohen) The University statistician will generate numbered envelopes to be opened consecutively as subjects enroll and the envelopes will designate individuals to the intervention through use of a random numbers table. PI Czamanski-Cohen will provide the PhD students with the randomized lists (60 each cohort), who will schedule sessions and make weekly calls to encourage attendance and conduct the intervention and thus will be unblinded. The Research Nurse will collect and enter data, collect bio specimens and manage the database, but will remain blinded after randomization. The research assistant will remain blinded throughout the study, and will receive lists of participants

to call, without knowing which group they are assigned to. Participants will be told they are participating in an “art making” study where they will be assigned to either the intervention group or the sham intervention (Mandala) group. Participants will not be told which is expected to be superior.

Table 4: Roles in the study

Title	Blinded to group assignment	Roles	Rambam	Ziv	Beilin-son
Research nurse (employee of each hospital).	Yes	Recruit and obtain verbal consent, collect blood.	1	1	1
Research coordinator (employee of each hospital).	Yes	Assist MD in recruiting patients, collect data (questionnaires and HRV), transfer blood to the lab for processing (separation to serum, divide in 4 aliquots and cryopreservation -80)	1	1	1
Art Therapist	No	Conduct intervention groups (8.5 weeks)- Art Therapy and SHAM in Hebrew or Arabic	2	2	2
PhD student	No	Conduct groups, supervise interventionists, assist in fidelity assurance, assist in data analysis.	3		
Laboratory worker	Yes	Conduct inflammatory cytokines analysis.	1		
Research coordinator	Yes	Coordinate between study site, transport frozen serum to lab, input data	1		

9. DATA COLLECTION AND QUALITY ASSURANCE

9.1 Data Collection Forms

PI Czamanski-Cohen will provide the research coordinators with the randomized lists (60 each cohort), who will schedule sessions and make weekly calls to encourage attendance, therefore both will be un-blinded to study assignment. The Research Nurse will collect and enter data, collect bio specimens and manage the database, and thus will be un-blinded after randomization. The research assistant will remain blinded throughout the study, and will receive lists of participants to call, without knowing which group they are assigned to. Signed

consent forms and all study questionnaires will be kept in an administrative office separate from research data and available for audit even when the PI is not. Additional information contained in this case book will be relevant demographic and medical/psychiatric information about the subject obtained during the interview with the site representative. Because this case book will contain personal identifiers and PHI, it will be kept separate from any data gathered as part of the study and will be kept in a locked office.

9.2 Data Management

At the point of first contact by potential participant contacting us, a brief overview of the study will be provided by the study coordinator. At screening, the consent form will be reviewed, and potential subjects will have an opportunity to address any concerns they might have. During this conversation, the detailed nature, purpose, procedures, benefits, risks of, and alternatives to this study will be explained to each subject and written informed consent will be obtained by the site PI. Informed consent will be documented on a Hospital IRB-approved form. A copy of the signed form will be given to the subject. Signed consent forms will be kept in a locked office in the hospital, which is an administrative office separate from research data and available for audit even when the PI is not. Additional information contained in this case book will be relevant demographic and medical/psychiatric information about the subject obtained during the interview with the site representative. Because this case book will contain personal identifiers and PHI, it will be kept separate from any data gathered as part of the study and will be kept in a locked office. After consent is obtained, potential subjects will be screened by study personnel to determine that the subject meets all inclusion and exclusion criteria for study participation. The contact MD at each site will be contacted immediately in the event of a subject meeting criteria for major depression or any other acute untreated psychiatric condition or for suicidal ideation. All such subjects will be evaluated for the need for acute hospitalization for safety and will be given appropriate treatment referrals.

9.3 Quality Assurance

9.3.1 Training

Interventionists will be experienced MA level art therapists who will be trained by PI Czamanski-Cohen and the PhD students. Weekly and bi-weekly training session will be conducted prior to commence of the proposed research, and PI Czamanski-Cohen will be available for additional support and guidance as needed.

To ensure the quality and consistency of the intervention the interventionists of both the intervention and comparison groups will be scored each session (see Table 2) and against the treatment manual reviewed by the blinded RA. Discrepancies will be flagged and then reviewed by PI Czamanski-Cohen, who will subsequently address this with the intervention team for correction. Adherence to the study regimen will be defined as attending 80% of the group sessions, which will be monitored and recorded by the interventionist.

Each of the three hospitals that have approved their participation in this study have an independent Institutional Review Board (IRB), which approve the conduct of clinical trials. The boards strictly adhere to the Helsinki Treaty on Human Medical Experimentation. Hospitals consent to the Public Health Regulations (Medical Experiments in Human Subject) – 1980 of Israel Ministry of Health, including additions and amendments, and operate in accordance with the regulations for conducting Medical Trials on Humans – 1999 of the Pharmacological Unit of the Israel Ministry of Health provisions of the current Harmonized International Guidelines for Good Clinical Practice namely: ICH-GCP.

9.3.2 **Safety Monitoring Committee (SMC)**

PI's Czamanski-Cohen and Weihs will create a **Safety Monitoring Committee (SMC)**, which will meet at approximately six-month intervals via Skype or Zoom, as the committee is comprised of individuals in different locations. SMC members will represent expertise in psycho-oncology, in research monitoring and statistics. Members of the committee will agree to keep all information confidential. The committee members will review summaries of study progress to ensure that consent documentation is properly obtained and stored. They will review progress in subject recruitment and anticipated race/ethnicity participant representation. They will determine whether study coordinators and investigators are collecting and organizing data properly.

Data and Safety Monitoring

a. The SMC will monitor the study. The SMC is comprised of the following individuals:

   Dr. Tzipi Hornik-Lurie who has a background in epidemiology, statistics and public health and mental health research, she will monitor data collection and documentation as well as examine the data checks.

   Prof. Hadas Goldblatt who specializes in nursing research, and Psycho oncology and will oversee examining the fidelity checks and proper implementation of the intervention, subject recruitment and anticipated race/ethnicity participant representation.

   Both PI's will be on the SMC

Co-I Dr. Joshua Wiley, who oversees the statistical analyses will also be part of the SMC. **PI Dr. Czamanski-Cohen** will be responsible for submitting necessary reports to NINR.

b. **Monitoring schedule for study safety:** The PI will review all events and unanticipated problems on a weekly basis. The SMC will monitor study safety bi-annually. Confidentiality: Study staff will notify the PI immediately of any breaches in participant confidentiality. The PI will notify SMC, IRB and NINR of breaches in confidentiality within 24 hours or notification by study staff.

Compliance of regulatory documents and study data accuracy and completeness will be maintained through an internal study team quality assurance process. Quality control will include semi-annual data verification and protocol compliance checks by the PI, Co-Is, and the Safety Monitoring Committee (SMC). Protocol adherence will be monitored by the PI and the SMC by auditing 5 cases semi-annually for compliance with IRB requirements, compliance with informed consent requirements, verification of source documents and compliance with the study protocol.

c. **Identification of AEs/unanticipated problems:**

Adverse event. For this study, since our subjects are breast cancer patients, they are likely to have many changes in their health status that are related to the time during treatment that they are participating in the study. Thus, since this is not a medical intervention study we will record only AEs that are possibly or definitely related to study participation. The following standard AE definitions are used:

Serious adverse event. An AE that results in any of the following:

• Death
• Life-threatening condition
• Inpatient hospitalization or prolongation of existing hospitalization
• Persistent or significant disability/incapacity

Not related. An AE for which a cause outside the study procedures is most plausible and/or a clinically plausible temporal sequence is inconsistent with the onset of the event.

Possibly related. An AE that follows a reasonable temporal sequence from the initiation of study procedures, but that could readily have been produced by a number of other factors.

Related. An AE that is clearly linked to the study procedures.

Review of AEs: The PI will compile quarterly report to the SMC detailing the study progress and participant status, any related or possibly related adverse events (AEs), and any protocol deviations. Unrelated or possibly related AEs will be reported to NINR in the yearly RPPR unless the event or unanticipated problem will affect the study risk level or progress, In this case, the PI will notify NINR staff within one week of completing the report.

Reporting of AEs: Serious Adverse Events will be reported immediately to the PI by study staff. The PI will report to SMC, IRB, NINR within 24 hours of notification by study staff. The PIs will follow OHRP Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events.

d. **Multisite reporting:** PI Czamanski-Cohen will report "unanticipated problems" involving risks to participants to the IRB, as well as NINR unrelated to the bi-annual reports of the monitoring committee that will submitted by the PIs. PI Czamanski-Cohen will distribute the bi-annual and special (if unanticipated problems arise) reports to all site PIs for submission to their local IRBs. The SMC will also ensure compliance with the monitoring plan and reporting requirements across study sites. PI Czamanski-Cohen will meet on a regular basis (every 3 months, at minimum) with all study staff to ensure compliance with the monitoring plan and reporting requirements across study sites. Furthermore, she will make sure the SMC is monitoring study progress as delineated above and submit reports as stated

e. The PI's will conduct an ongoing assessment of external factors or relevant information (e.g., developments in the literature, results of related studies) that may have an impact on the safety of participants or on the ethics for the research study.

f. The interim analysis will take place at the end of the first year of the study (after 6 months of data collection) and at the end of the second year (after 18 months of data collection). Since this is a mechanistic study, we are not concerned about not finding statistically significant differences between the groups, however, our pilot study findings do indicate that we should. In the case of unexpected findings, we will further explore the fidelity assessments to ensure the interventions are being conducted as designed (above and beyond the ongoing fidelity checks in place. PI Czamanski-Cohen will closely monitor and supervise the research team at their respective sites, as well as conduct coordinated oversight of psychological status of all participating women taking part in the research. She will consult with PI Weihs with any concern or consideration. PI Czamanski-Cohen will also meet regularly with the research teams at the clinical sites and the University every other week to ensure appropriate conduct.

9.3.3 Monitoring

PI Czamanski-Cohen will closely monitor and supervise the research team at their respective sites, as well as conduct coordinated oversight of psychological status of all participating women taking part in the research. She will consult with PI Weihs with any concern or consideration. PI Czamanski-Cohen will also meet regularly with the research teams at the clinical sites and the University every other week to ensure appropriate conduct.

All local legal requirements regarding protection of personal data must be adhered to.

To ensure the quality and consistency of the intervention administration both the intervention and comparison groups in both Hebrew and Arabic will be scored against the treatment manual, using a check list which will be assessed daily by the research assistant who is blind to group allocation. Adherence to the study regimen will be defined as attending 80% of the group sessions, which will be monitored and recorded by the interventionist. Participant confidentiality will be well protected, as any data, specimens, forms, reports, and other records that leave the site will be identified only by a participant identification number (PID). All records will be kept in a locked file cabinet. All computer entry and networking programs will be done using Patient ID numbers only. Information will not be released without written permission of the participant, except as necessary for monitoring by IRB.

The Board will issue a report every six months to the PI and annually to the IRB.

9.3.4 Protocol Derivations

Should the PI identify discrepancies between the treatment manual and the fidelity scores PI Czamanski-Cohen will immediately engage with the interventionist to discuss and provide guidance for getting back on track of the treatment protocol.

10. PARTICIPANT RIGHTS AND CONFIDENTIALITY

10.1 Institutional Review Board (IRB) Review

This protocol and the informed consent document and any subsequent modifications will be reviewed and approved by the IRB or ethics committee responsible for oversight

of the study. The consent form should be separate from the protocol document.

10.2 Informed Consent Forms

A signed consent form will be obtained from each participant. The consent form will describe the purpose of the study, the procedures to be followed, and the risks and benefits of participation. A copy will be given to each participant or legal guardian and this fact will be documented in the participant's record.

10.3 Participant Confidentiality

Any data, specimens, forms, reports, video recordings, and other records that leave the site will be identified only by a participant identification number (Participant ID, PID) to maintain confidentiality. All records will be kept in a locked file cabinet. All computer entry and networking programs will be done using PIDs only. Information will not be released without written permission of the participant, except as necessary for monitoring by IRB, the FDA, the NIH, and the OHRP.

10.4 Study Discontinuation

The study may be discontinued at any time by the IRB, the NIH, the OHRP, the FDA, or other government agencies as part of their duties to ensure that research participants are protected.

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11. SUPPLEMENTS/APPENDICES

I. Procedures Schedule Oct. 2018- Sept. 2021.

Table 3: Study Timeline						
Months	**1-6**	**7-12**	**13-18**	**19-24**	**25-30**	**31-36**
Prep/Training	X					
Team mtgs	X4	X4	X2	X1	X2	X6
Intervention		Cohort1	Cohort 2	Cohort 3	Cohort 4	
Data chk**		X		X		
Analysis				X (prelim)		X
Writing/discussion			X			X
Presentation at Conferences						X
Travel	Dr. Weihs to Israel- Nov. 2018 Dr. Wiley to Israel Jan 2019					Drs. Czamanski-Cohen, Wiley and Prof. Cohen to Tucson, AZ- spring/ summer 2021
Final cohort begins mo. 25, allows final data mo. 31. **Data check/quality. Balance across arms on factors used in minimization technique will be monitored and adjusted.						

II. Informed Consent Form Template

Informed Consent form

הפקולטה למדעי הרווחה והבריאות
Faculty of Social Welfare & Health Sciences | الكلية لعلوم الرفاه والصحة

Name of Principal Investigators: Dr. Johanna Czamanski-Cohen and Dr. Karen Weihs

You will be given a copy of the full Informed Consent Form

Purpose of the research

Breast cancer is the most common cancer that women suffer from. Many breast cancer survivors suffer from symptoms of depression, anxiety, pain and fatigue that negatively affect their quality of life. Art Therapy provides an alternative to verbal Psychotherapy and has been shown to help alleviate Psychological and Physical symptoms. The purpose of our research is to understand more about the ways in which art therapy helps BC survivors.

Type of Research Intervention

This research will involve your participation in one of two intervention groups that entail art making. Each group will take place for 8 weeks for either 1 ½ hours or 30 minutes. In addition, you will be requested to answer questionnaires for about an hour, once before the start of the intervention, once during the week after the intervention is over and once 8 weeks later. We will also request that you provide us with 10 ccs of blood at 3 time points, once before, once in the middle and once after the intervention. The blood will be drawn by a qualified nurse. Furthermore, you will be requested to sit for 20 minutes, 3 times while you are connected to a biopatch that collects data about your heart rate and breathing. The biopatch is a small round device that will be adhered to your skin for 20 minutes, at each collection point via 2 gel electrodes slightly below your sternum.

Participant selection

We are inviting all breast cancer survivors at this hospital who have completed chemotherapy to participate in this study.

Voluntary Participation

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this clinic will continue and nothing will change. If you choose not to participate in this research project, you will be offered

the treatment that is routinely offered in this hospital for Breast Cancer, and we will tell you more about it later. You may change your mind later and stop participating even if you agreed earlier. The biological samples obtained during this research procedure will be used only for this research, and will be destroyed after 5 years, when the research is completed.

B. Description of the Process

Duration

The research takes place over 16 weeks in total. During that time, it will be necessary for you to come to hospital 11 times, for 1-2hours each day. In total, you will be asked to come up to 11 times to the clinic in 2.5 months. At the end of 3 months, the research will be finished.

Time table of data collection and interventions				
Week 0	**Week 1-3**	**Weeks 4-16**	**Week 16**	**Week 24**
Enrollment in Study	Filling out questionnaires	Intervention group at the hospital 1 time a week for 1-1.5-hours	Filling out questionnaires	Filling out questionnaires
Signing informed consent	10 cc of blood		10 cc of blood	10 cc of blood
Randomization to intervention group	20 minutes of EKG monitoring via the bio patch		20 minutes of EKG monitoring via the bio patch	20 minutes of EKG monitoring via the bio patch

Risks

We do not expect any risks from participating in this study, however, you may feel a temporary increase in emotional distress. Should you feel significant distress, we have professionals available to provide you with additional support. You will be asked to provide 20 cc of blood at 3 time points and there may be some local discomfort associated with the needle prick. You will be asked to connect a biopatch to your chest using 2 electrodes, at 3 time points for 20 minutes each. You may have some minor and temporary skin irritation at the site of adherence. If you feel any emotional or physical distress related to the intervention or physiological data collection, please contact the research nurse for assistance.

Benefits

We believe that you may benefit from participating in this study by experiencing an alleviation of existing symptoms or prevention of depressive, anxiety, pain or fatigue that often accompany Breast cancer patients.

Reimbursements

We will give you $67 USD to pay for your travel to the hospital for all the sessions and we will give you $200 USD for your time, should you complete all the sessions. You will not be given any other money or gifts to take part in this research.

Confidentiality

With this research, something out of the ordinary is being done in your community. It is possible that if others in the community are aware that you are participating, they may ask you questions. We will not be sharing the identity of those participating in the research.

The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no-one, but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is, and we will lock that information up with a lock and key. It will not be shared with or given to anyone except the PI's of the study, the research nurse and the interventionists. The artwork created in the groups may be used in publications and presentations, however, these works will not be personally identified, and any personal information (ie, your name) will be edited out of the image before publication.

Right to Refuse or Withdraw

You do not have to take part in this research if you do not wish to do so. You may also stop participating in the research at any time you choose. It is your choice and all your rights will still be respected.

Alternatives to Participating

If you do not wish to take part in the research, you will be provided with the established standard treatment available at the hospital.

Who to Contact

If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following: Johanna Czamanski-Cohen joczamanski@gmail.com, the research nurse _____.

This proposal has been reviewed and approved by the hospital Helsinki committee which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the IRB, contact _____.

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Print Name of Participant_____
Signature of Participant _____
Date _____
Day/month/year

Print Name of Researcher taking the consent_____

Signature of Researcher taking the consent_____
Date _____
Day/month/year

DEMOGRAPHICS HEBREW-T0

דמוגרפי

אנא עני על השאלות הבאות. בשאלות שיש לצדן תשובה, אנא הקיפי את התשובה המיטיבה לתאר את מצבך. בשאלות שאין לצדן אפשרות תשובה, אנא השלימי בעצמך:

גיל	25-18	35-26	45-36	70-46	מעל 70
ארץ לידה	ישראל	אחר_____			
מצב משפחתי	רווקה	נשואה	גרושה	אלמנה	אחר:
האם יש לך ילדים?	לא	כן	כמה ילדים יש לך?		
השכלה	תיכונית	לימודי תעודה	אקדמאית – תואר ראשון	אקדמאית - תארים מתקדמים	אחר_____
האם את עובדת?	לא	כן	מקצוע / עיסוק מרכזי:		
דת	יהודיה	מוסלמית	נוצריה	אחר_____	
כיצד היית מגדירה את מידת הדתיות שלך?	חילונית	דתיה	מסורתית	אחר_____	
האם את עוסקת באמנות?	לא	כן, באופן חובבני	כן, באופן מקצועי		

DEMOGRAPHICS ARABIC T0

فيما يلي عدة أسئلة, يرجى احاطة رقم الإجابة ألصحيح وإكمال المعلومات الناقصة:

كم عمرك؟	25-18	35-26	45-36	70-46	من فوق 70	
1. ارض الولادة:	اسرائيل	الاتحاد السوفييت ي سابقا	اثيوبيا	اخر		
2. الوضع العائلي:	متجوزة	ارمل/ة	مطلق/ة	مفصول/ة	عازب/ة	اخر
1. هل لديك اولاد؟	لا	نعم				
هل تسكن في:	مدينة	قرية	مستوطنة	اخر_____		
1. ما هي درجتك التعليمية ?	ثانوية	اكاديمية- طالب/ة او لقب اول	اكاديمية- لقب ثاني	اكاديمية – لقب ثالث		اخر
هل تعمل/ين؟ الوضع الاقتصادي	نعم اقل من الوسط	لا متوسط	اعلى من الوسط			
الديانة	يهودي/ة	مسلم/ة	مسيحي/ة	درزي/ة		اخر
كيف تعرف نفسك؟	علماني/ة	متدين/ة	ارثودوكسي/ة	تقليدي/ة		اخر
هل انخرطت في الفن؟	لا	نعم, بطرية هواة	نعم, مهنيا			

PVQ-RR F Hebrew T0

המשפטים הבאים מתארים בקצרה אנשים שונים. קראי בבקשה כל תיאור וחשבי עד כמה האדם הזה דומה, או לא דומה לך. סמני X בריבוע משמאל המתאר עד כמה האדם המתואר דומה לך.

		עד כמה אדם זה דומה לך?					
		בכלל לא דומה לי	**לא דומה לי**	**קצת דומה לי**	**די דומה לי**	**דומה לי**	**מאד דומה לי**
1.	חשוב לה לעצב את השקפותיה באופן עצמאי.	☐	☐	☐	☐	☐	☐
2.	חשוב לה שהמדינה שלה תהיה בטוחה ויציבה.	☐	☐	☐	☐	☐	☐
3.	חשוב לה לבלות בנעימים.	☐	☐	☐	☐	☐	☐
4.	חשוב לה להימנע מלהרגיז אנשים אחרים.	☐	☐	☐	☐	☐	☐
5.	חשוב לה שהחלשים והפגיעים בחברה יהיו מוגנים.	☐	☐	☐	☐	☐	☐
6.	חשוב לה שאנשים יעשו מה שהיא אומרת שעליהם לעשות.	☐	☐	☐	☐	☐	☐
7.	חשוב לה **לא** לראות את עצמה ראויה ליותר מאחרים.	☐	☐	☐	☐	☐	☐
8.	חשוב לה לשמור על הטבע.	☐	☐	☐	☐	☐	☐
9.	חשוב לה שאף אחד אף פעם לא יבייש אותה.	☐	☐	☐	☐	☐	☐
10.	חשוב לה לחפש כל הזמן דברים שונים לעשות.	☐	☐	☐	☐	☐	☐
11.	חשוב לה לדאוג לאנשים הקרובים אליה.	☐	☐	☐	☐	☐	☐
12.	חשוב לה שיהיה לה הכוח שכסף יכול להביא איתו.	☐	☐	☐	☐	☐	☐
13.	חשוב לה מאוד להימנע ממחלות ולשמור על בריאותה.	☐	☐	☐	☐	☐	☐
14.	חשוב לה להיות סובלני כלפי כל סוגי האנשים והקבוצות.	☐	☐	☐	☐	☐	☐
15.	חשוב לה לעולם לא להפר חוקים או תקנות.	☐	☐	☐	☐	☐	☐
16.	חשוב לה לקבל בעצמה את החלטות שלה לגביי חייו.	☐	☐	☐	☐	☐	☐
17.	חשוב לה שיהיו לה שאיפות בחיים.	☐	☐	☐	☐	☐	☐
18.	חשוב לה לשמר ערכים ודרכי חשיבה מסורתיים.	☐	☐	☐	☐	☐	☐
19.	חשוב לה שאנשים שהיא מכירה יתנו בה אמון מלא.	☐	☐	☐	☐	☐	☐
20.	חשוב לה להיות עשיר.	☐	☐	☐	☐	☐	☐
21.	חשוב לה להשתתף בפעולות להגנה על הטבע.	☐	☐	☐	☐	☐	☐
22.	חשוב לה לא לעצבן אף אחד אף פעם.	☐	☐	☐	☐	☐	☐
23.	חשוב לה לפתח דעות משלה.	☐	☐	☐	☐	☐	☐

עד כמה אדם זה דומה לך?

	בכלל לא דומה לי	לא דומה לי	קצת דומה לי	די דומה לי	דומה לי	מאד דומה לי
24. חשוב לה להגן על התדמית שלה בעיני אחרים.	☐	☐	☐	☐	☐	☐
25. מאד חשוב לה לעזור לאנשים היקרים לה.	☐	☐	☐	☐	☐	☐
26. חשוב לה להיות בטוחה ומוגנת באופן אישי.	☐	☐	☐	☐	☐	☐
27. חשוב לה להיות חברה אמינה שניתן לבטוח בו.	☐	☐	☐	☐	☐	☐
28. חשוב לה לקחת סיכונים שהופכים את החיים למרגשים.	☐	☐	☐	☐	☐	☐
29. חשוב לה שיהיה לה הכוח לגרום לאנשים לעשות מה שהיא רוצה.	☐	☐	☐	☐	☐	☐
30. חשוב לה לתכנן את הפעילויות שלה באופן עצמאי.	☐	☐	☐	☐	☐	☐
31. חשוב לה לנהוג לפי החוקים גם כשאף אחד לא מסתכל.	☐	☐	☐	☐	☐	☐
32. חשוב לה להצליח מאוד בחיים.	☐	☐	☐	☐	☐	☐
33. חשוב לה לדבוק במנהגים משפחתיים או במנהגים דתיים.	☐	☐	☐	☐	☐	☐
34. חשוב לה להקשיב לאנשים השונים ממנה ולהבין אותם.	☐	☐	☐	☐	☐	☐
35. חשוב לה שמדינתה תהיה חזקה ומסוגלת להגן על אזרחיה.	☐	☐	☐	☐	☐	☐
36. חשוב לה ליהנות מתענוגות החיים.	☐	☐	☐	☐	☐	☐
37. חשוב לה שלכל אדם בעולם יהיו הזדמנויות שוות בחיים.	☐	☐	☐	☐	☐	☐
38. חשוב לה להיות ענוה.	☐	☐	☐	☐	☐	☐
39. חשוב לה לפענח ולהבין דברים בעצמה.	☐	☐	☐	☐	☐	☐
40. חשוב לה לכבד את המנהגים המסורתיים של התרבות שלה.	☐	☐	☐	☐	☐	☐
41. חשוב לה להיות זאת שאומרת לאחרים מה לעשות.	☐	☐	☐	☐	☐	☐
42. חשוב לה לציית לכל החוקים.	☐	☐	☐	☐	☐	☐
43. חשוב לה שיהיו לה כל מיני חוויות חדשות.	☐	☐	☐	☐	☐	☐
44. חשוב לה שיהיו לה דברים יקרים המעידים על עושרה.	☐	☐	☐	☐	☐	☐
45. חשוב לה להגן על הטבע מהרס ומזיהום.	☐	☐	☐	☐	☐	☐
46. חשוב לה לנצל כל הזדמנות ליהנות.	☐	☐	☐	☐	☐	☐
47. חשוב לה לדאוג לכל צורך של יקיריה.	☐	☐	☐	☐	☐	☐
48. חשוב לה שאנשים יכירו בהישגים שלה.	☐	☐	☐	☐	☐	☐
49. חשוב לה לעולם לא להיות מושפלת.	☐	☐	☐	☐	☐	☐

עד כמה אדם זה דומה לך?

		בכלל לא דומה לי	לא דומה לי	קצת דומה לי	די דומה לי	דומה לי	מאד דומה לי
.50	חשוב לה שמדינתה תגן על עצמה מפני כל איום.	☐	☐	☐	☐	☐	☐
.51	חשוב לה אף פעם לא להכעיס אנשים אחרים.	☐	☐	☐	☐	☐	☐
.52	חשוב לה שכולם יקבלו יחס צודק, גם אנשים שאינה מכירה.	☐	☐	☐	☐	☐	☐
.53	חשוב לה להימנע מכל דבר מסוכן.	☐	☐	☐	☐	☐	☐
.54	חשוב לה להסתפק במה שיש לה ולא לבקש יותר.	☐	☐	☐	☐	☐	☐
.55	חשוב לה שכל חבריה ובני משפחתה יוכלו לסמוך עליה לחלוטין.	☐	☐	☐	☐	☐	☐
.56	חשוב לה להיות חופשיה להחליט בעצמה מה היא עושה.	☐	☐	☐	☐	☐	☐
.57	חשוב לה לקבל אנשים אחרים גם כשאינה מסכימה איתם.	☐	☐	☐	☐	☐	☐

PVQ-RR F ARABIC T0

גרסא 1

استبيان القِيَم الوصفية - النسخة العربية (PVQ-RR)، إناث(2013/10)

فيما يلي نقدّم وصفاً مختصراً لأشخاص مختلفين. الرجاء قراءة كل وصف والتفكير في مدى التشابه او الاختلاف بينك وبين الشخص الموصوف.ثم نرجو وضع اشارة X في المربع الذي يشير إلى مدى التشابه بينك وبين الشخص الموصوف.

الى أي مدى تشبهك هذه الشخصية؟

	لا تشبهني أبدا	لا تشبهني	تشبهني قليلا	تشبهني الى حد ما	تشبهني	تشبهني كثيرا
1. من المهم لهاتكوين آرائها بشكل مستقل.	☐	☐	☐	☐	☐	☐
2. من المهم لها أن يكون وطنها آمناً ومستقرّاً.	☐	☐	☐	☐	☐	☐
3. من المهم لها قضاء أوقات ممتعة.	☐	☐	☐	☐	☐	☐
4. من المهم لها أن تتجنّب مضايقة الآخرين.	☐	☐	☐	☐	☐	☐
5. من المهم لها أن تتم حمايةالضعفاء والمساكين والمهمشين في المجتمع.	☐	☐	☐	☐	☐	☐
6. من المهم لهاأن يفعل الأخرون ما تأمرهم بفعله.	☐	☐	☐	☐	☐	☐
7. من المهم لها أن لا تعتقد أبداً أنهاتستحق أكثر من الآخرين.	☐	☐	☐	☐	☐	☐
8. من المهم لهاالمساهمة في حمايةالطبيعة.	☐	☐	☐	☐	☐	☐
9. من المهم لهاألّا تتعرض أبداً لتشويه السُمعة من قبل أي شخص.	☐	☐	☐	☐	☐	☐
10. من المهم لها البحث دائماً عنأشياءمختلفةللقيامبها.	☐	☐	☐	☐	☐	☐
11. من المهم لها الاهتمامبالأشخاص المقرّبين إليها.	☐	☐	☐	☐	☐	☐
12. من المهم لها امتلاك القوة التي يمكن للمال أن يوفّرها.	☐	☐	☐	☐	☐	☐
13. من المهم جدّاً لهاأن تتجنّب الأمراض وأن تحافظ على صحّتها.	☐	☐	☐	☐	☐	☐
14. من المهم لها تقبّلكافّة نوعيات الناس والمجموعات السكانية.	☐	☐	☐	☐	☐	☐
15. من المهم لها أن لا تُخالفأبداً القوانين والنُظُم.	☐	☐	☐	☐	☐	☐
16. من المهم لها أن تتخذ قراراتها بنفسها بخصوص حياتها.	☐	☐	☐	☐	☐	☐
17. من المهم لهاأن تكون طَمُوحة في حياتها.	☐	☐	☐	☐	☐	☐
18. من المهم لها الحفاظ على طرق التفكير والقيم المجتمعية التقليدية/المُحافِظة.	☐	☐	☐	☐	☐	☐
19. من المهم لها أن يثق بها الأشخاص الذين تعرفهم بصورة كاملة.	☐	☐	☐	☐	☐	☐

	لا تشبهني أبدا	لا تشبهني	تشبهني قليلا	تشبهني الى حد ما	تشبهني	تشبهني كثيرا
20. من المهم لها أن تكون غنيّةً.	☐	☐	☐	☐	☐	☐
21. من المهم لها المشاركة بالفعاليات التي تهدف لحماية الطبيعة.	☐	☐	☐	☐	☐	☐
22. من المهم لها الّا تُزعجأحدا.	☐	☐	☐	☐	☐	☐
23. من المهم لها تطوير آرائها الشخصية.	☐	☐	☐	☐	☐	☐
24. من المهم لها الدفاععن سمعتهاأمام الناس.	☐	☐	☐	☐	☐	☐
25. من المهم جدّاً لها أن تساعد الاشخاص الأعزاء بالنسبة لها.	☐	☐	☐	☐	☐	☐
26. من المهم لهاأن تعيش بأمن وأمان.	☐	☐	☐	☐	☐	☐
27. من المهم لها أن تكون صديقةً وفيةً ويمكن الاعتمادعليها.	☐	☐	☐	☐	☐	☐
28. من المهم لها القيام بالمخاطراتالتي تجعل الحياة مشوّقة.	☐	☐	☐	☐	☐	☐
29. من المهم لها امتلاك القوة التي تمكّنها من إملاء إرادتها على الآخرين.	☐	☐	☐	☐	☐	☐
30. من المهم لها التخطيط لنشاطاتها باستقلالية.	☐	☐	☐	☐	☐	☐
31. من المهم لها الانصياع للقوانين حتى إن لم يكن أحد يراقبها.	☐	☐	☐	☐	☐	☐
32. من المهم لهاانتكوننناجحةً جداً.	☐	☐	☐	☐	☐	☐
33. من المهم لها أن تتبع عادات عائلتها أو تقاليد دينها.	☐	☐	☐	☐	☐	☐
34. من المهم لها الاستماع إلى الاشخاص المختلفين عنها وفهمهم.	☐	☐	☐	☐	☐	☐
35. من المهم لهاأن تكون الدولة قوية وقادرة على الدفاع عن مواطنيها.	☐	☐	☐	☐	☐	☐
36. من المهم لها التمتّع بملذات الحياة.	☐	☐	☐	☐	☐	☐
37. من المهم لها أن تتوفر فرص متساويةلكل شخص في العالم.	☐	☐	☐	☐	☐	☐
38. من المهم لها أن تكون متواضعةً وزاهدةً.	☐	☐	☐	☐	☐	☐
39. من المهم لها أن تُدركالاشياء بنفسها.	☐	☐	☐	☐	☐	☐
40. من المهم لها احترام العادات والتقاليد الخاصة بمجتمعها.	☐	☐	☐	☐	☐	☐
41. من المهم لها أن تكون هي الشخص الذيُخبر الآخرين بما عليه فعله.	☐	☐	☐	☐	☐	☐
42. من المهم لهاأن تطيع كافة القوانين.	☐	☐	☐	☐	☐	☐
43. من المهم لهاأن تعيش تجارب جديدة بكافة اشكالها.	☐	☐	☐	☐	☐	☐
44. من المهم لهاأن تمتلك أشياء ثمينة تُظهر مدى ثرائها.	☐	☐	☐	☐	☐	☐

	لا تشبهني أبدا	لا تشبهني	تشبهني قليلا	تشبهني الى حد ما	تشبهني	تشبهني كثيرا
45. من المهم لهاأن تتم حماية البيئة الطبيعية من التدمير أو التلوث.	☐	☐	☐	☐	☐	☐
46. من المهم لهاأن تستغل كل فرصة لتُمضي وقتاً في الاستمتاع.	☐	☐	☐	☐	☐	☐
47. من المهم لهاأن تعتني بكافة احتياجات الأشخاص الأعزاء على قلبها.	☐	☐	☐	☐	☐	☐
48. من المهم لهاأن يُلاحظالآخرون إنجازاتها.	☐	☐	☐	☐	☐	☐
49. من المهم لهاأن لا تتعرض للإهانة أبداً.	☐	☐	☐	☐	☐	☐
50. من المهم لهاأن تحمي دولتهانفسها من كافة التهديدات.	☐	☐	☐	☐	☐	☐
51. من المهم لها أن لا تُغضِبالآخرين أبداً.	☐	☐	☐	☐	☐	☐
52. من المهم لهاأن يحظى كل إنسان– حتى الذين لا تعرفهم– بمعاملة عادلة.	☐	☐	☐	☐	☐	☐
53. من المهم لهاأن تتجنّبأي شيء قد يعرضها للخطر.	☐	☐	☐	☐	☐	☐
54. من المهم لهاأن تكون قنوعةبما تملك وأن لا تطلب المزيد.	☐	☐	☐	☐	☐	☐
55. من المهم لهاأن يَقدِر جميع اصدقائها وأفراد أسرتهاعلى الاعتماد عليها بشكل تام.	☐	☐	☐	☐	☐	☐
56. من المهم لها أن تكون حُرّةً في اختيار ما ترغب في فعله.	☐	☐	☐	☐	☐	☐
57. من المهم لها أن تتقبّل الآخرين حتى وإن خالفتهم في الرأي.	☐	☐	☐	☐	☐	☐

HEB CESD-R-10 שאלון דיכאון T0, T1, T2

למטה רשומים מספר דרכים שאולי הרגשת או התנהגת. אנא ספרי לנו באיזו תדירות הרגשת כך בשבוע האחרון.

	0= לעיתים רחוקות או בכלל לא (פחות מיום אחד)	1= חלק מהזמן (1-2 ימים)	2= לעיתים או בצורה בינונית (3-4 ימים)	3= חלק ניכר או רוב הזמן (5-7 ימים)
1. הפריעו לי דברים שבדרך כלל לא מפריעים לי	0	1	2	3
2. היה לי קשה להתרכז במה שאני עושה	0	1	2	3
3. הרגשתי מדוכאת	0	1	2	3
4. הרגשתי שכל מה שאני עושה הוא מאמץ	0	1	2	3
5. הרגשתי תקווה לגבי העתיד	0	1	2	3
6. הרגשתי פחד	0	1	2	3
7. השינה שלי היתה טרופה	0	1	2	3
8. הרגשתי שמחה	0	1	2	3
9. הרגשתי בודדה	0	1	2	3
10. הרגשתי שאני לא מצליחה "להתניע"	0	1	2	3

ARB T0, T1, T2 CESD-R-10

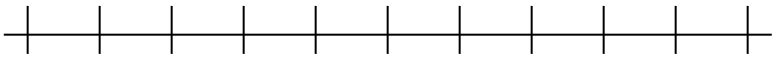
التعليمات:
ضع دائرة على رقم محدد لكل عبارة تصف معدل شعورك أو سلوكك بهذه الطريقة خلال الأسبوع الماضى.

خلال الأسبوع الماضى:	نادراً أو أبداً (أقل من يوم واحد)	بعض الوقت أو قليلاً (يوم إلى يومين)	أحياناً أو قدر معتدل من الوقت (3-4 أيام)	معظم أو كل الوقت (5-7 أيام)
1-كنت أشعر بالضيق من أمور عادةً لا تضايقنى	0	1	2	3
2- شعرت بصعوبة فى التركيز على ما أفعله	0	1	2	3
3- شعرت بالاكتئاب	0	1	2	3
4- شعرت أن كل ما فعلته مجهداً	0	1	2	3
5- شعرت بالأمل فى المستقبل	0	1	2	3
6- شعرت بالخوف	0	1	2	3
7- كان نومى مؤرق	0	1	2	3
8- كنت سعيداً	0	1	2	3
9- شعرت بالوحدة	0	1	2	3
10- لا استطع أن "أواصل"	0	1	2	3

FSI HEB T0, T1, T2

בכל אחד מהמשפטים הבאים, הקיפי בעיגול את הספרה המתארת באופן המדויק ביותר את הרגשתך.

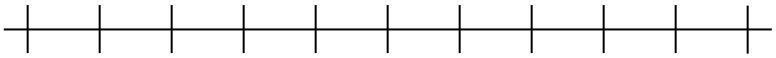
1. מידת העיפות שלך ביום בו הרגשת הכי עייפה במהלך השבוע החולף.



0 1 2 3 4 5 6 7 8 9 10

לא עייפה כלל — הכי עייפה שאפשר

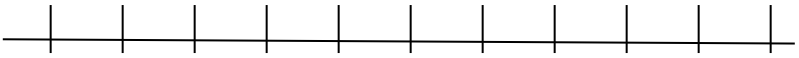
2. מידת העיפות שלך ביום בו הרגשת הכי פחות עייפה במהלך השבוע.



0 1 2 3 4 5 6 7 8 9 10

לא עייפה כלל — הכי עייפה שאפשר

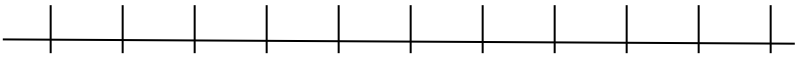
3. מידת העיפות בממוצע לאורך השבוע האחרון.



0 1 2 3 4 5 6 7 8 9 10

לא עייפה כלל — הכי עייפה שאפשר

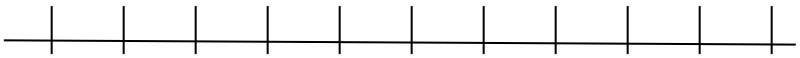
4. מידת העיפות שלך כרגע.



0 1 2 3 4 5 6 7 8 9 10

לא עייפה כלל — הכי עייפה שאפשר

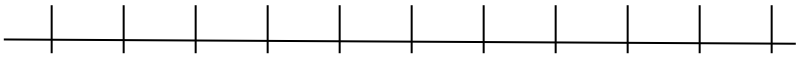
5. המידה בה העיפות הפריעה לפעילות הכללית שלך בשבוע האחרון.



0 1 2 3 4 5 6 7 8 9 10

לא הפריע כלל הפרעה חזקה ביותר.

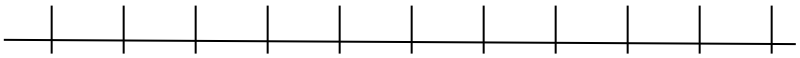
6. המידה בה העיפות הפריעה ליכולתך להתקלח ולהתלבש בשבוע האחרון.



0 1 2 3 4 5 6 7 8 9 10

לא הפריע כלל הפרעה חזקה ביותר.

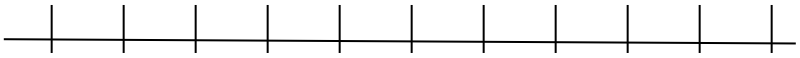
7. עד כמה, במהלך השבוע האחרון העיפות הפריעה לפעילות העבודה הרגילה שלך (כולל עבודות מחוץ לבית וגם עבודות בית).



0 1 2 3 4 5 6 7 8 9 10

לא הפריע כלל הפרעה חזקה ביותר.

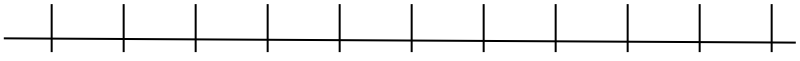
8. עד כמה, במהלך השבוע האחרון העיפות הפריעה ליכולת שלך להיות מרוכזת.



0 1 2 3 4 5 6 7 8 9 10

לא הפריע כלל הפרעה חזקה ביותר.

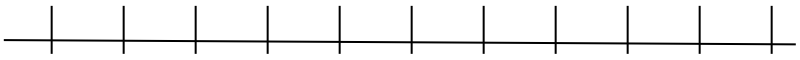
9. דרגי עד כמה, במהלך השבוע האחרון העיפות השפיעה על יחסיך עם אנשים אחרים.



0 1 2 3 4 5 6 7 8 9 10

לא הפריע כלל הפרעה חזקה ביותר.

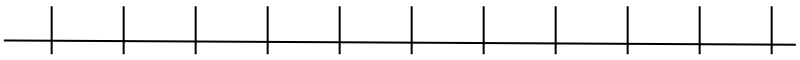
10. עד כמה, במהלך השבוע האחרון העיפות הפריעה להנאה מחייך.



0 1 2 3 4 5 6 7 8 9 10

לא הפריע כלל הפרעה חזקה ביותר.

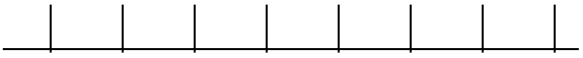
11. עד כמה, במהלך השבוע האחרון העיפות הפריעה לרמת הפעילות הכללית שלך.



0 1 2 3 4 5 6 7 8 9 10

לא הפריע כלל הפרעה חזקה ביותר.

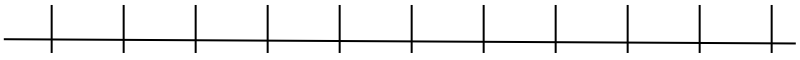
12. כמה ימים, במהלך השבוע האחרון חשת עייפות בחלק כלשהו של היום.



0 1 2 3 4 5 6 7

ימים ימים

13. ציין **איזה חלק מהיום** בממוצע, חשת עייפות במהלך השבוע האחרון.



0 1 2 3 4 5 6 7 8 9 10

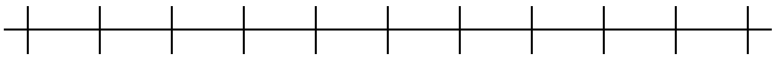
כלל כל היום כולו.

לא

FSI ARB T0, T1, T2

بكل جملة من الجمل الاتية, أحيطي بدائرة حول الرقم الذي يصف شعورك بدقة.

1. مستوى التعب الذي شعرتِ به في اليوم الاكثر مُتعب خلال الاسبوع الماضي(الاخير).



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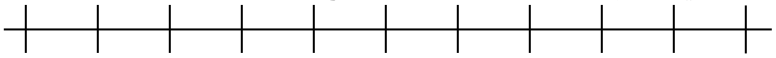
غير تعبة بالمرة متعبة جداً

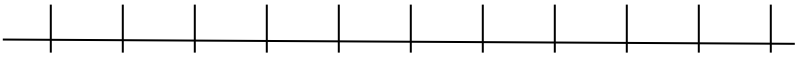
2. مستوى تعبك في اليوم الاقل تعباً خلال الاسبوع الاخير



10 9 8 7 6 5 4 3 2 1 0

غير تعبة بالمرة تعبة جداً

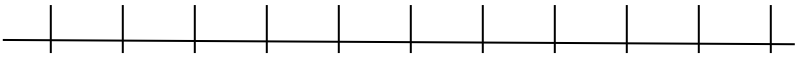
3. معدل مستوى التعب خلال الاسبوع الاخير



10 9 8 7 6 5 4 3 2 1 0

غير تعبة بالمرة تعبة جداً

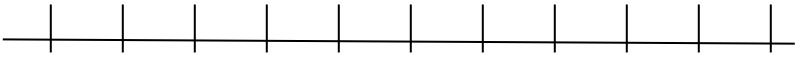
4. مستوى تعبك الان



10 9 8 7 6 5 4 3 2 1 0

غير تعبة بالمرة تعبة جداً

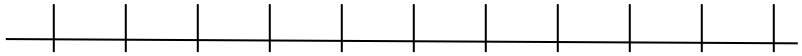
5. درجة تأثير التعب بشكل سلبي على نشاطك اليومي في الاسبوع الاخير



10 9 8 7 6 5 4 3 2 1 0

لم يؤثر بالمرة تأثير قوي جداً

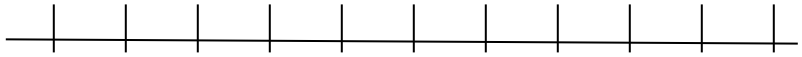
6. درجة تأثير التعب بشكل سلبي على قدرتك بالاستحمام او اللبس بالأسبوع الاخير



10 9 8 7 6 5 4 3 2 1 0

لم يؤثر بالمرة تأثير قوي جداً

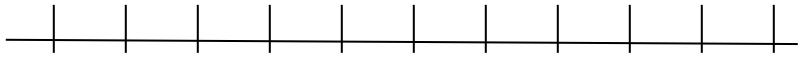
7. حتى اي (لأي) درجة أثر التعب بشكل سلبي على نشاط عملك المُعتاد خلال الاسبوع الاخير(يشمل العمل خارج البيت وداخل البيت ايضاً).



10 9 8 7 6 5 4 3 2 1 0

لم يؤثر بالمرة تأثير قوي جداً

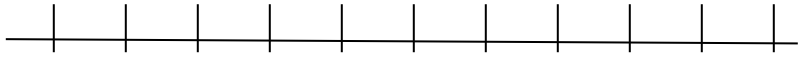
8. حتى اي (لأي) درجة أثر التعب بشكل سلبي على قدرتك في التركيز خلال الاسبوع الاخير



10 9 8 7 6 5 4 3 2 1 0

لم يؤثر بالمرة تأثير قوي جداً

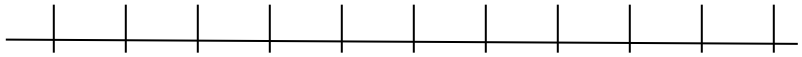
9. حددي ,حتى اي درجة أثر التعب على علاقاتك مع الاخرين خلال الاسبوع الاخير



10 9 8 7 6 5 4 3 2 1 0

لم يؤثر بالمرة تأثير قوي جداً

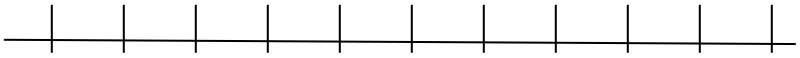
10. حتى اي درجة, أثر التعب بشكل سلبي على متعتك بالحياة في الاسبوع الاخير



10 9 8 7 6 5 4 3 2 1 0

لم يؤثر بالمرة تأثير قوي جداً

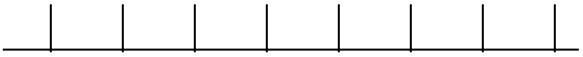
11.حتى اي درجة, أثر التعب بشكل سلبي على مستوى نشاطك العام في الاسبوع الاخير



10 9 8 7 6 5 4 3 2 1 0

لم يؤثر بالمرة تأثير قوي جداً

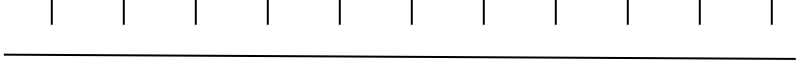
12.كم يوم من ايام الاسبوع الاخير شعرتِ مُتعبة بجزء معين من اليوم



7 6 5 4 3 2 1 0

ايام ايام

13.حددي **اية جزء من اليوم** بالمعدل, شعرتِ تعبة خلال الاسبوع الاخير



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اليوم كله بالمرة لا

BCPT- HEB T0, T1, T2

אנחנו מעוניינים לדעת עד כמה סבלת ב-**4 השבועות האחרונים** מהבעיות המתוארות בטבלה. אנא סמני מספר אחד בכל שורה. אם אין לך את הבעיה בכלל, אז צייני "בכלל לא".
במשך ארבעת השבועות האחרונים עד כמה הפריעו לך:

	בכלל לא	מעט	באופן בינוני	די הרבה	באופן קיצוני
1. גלי חום	0	1	2	3	4
2. בחילה	0	1	2	3	4
3. הקאות	0	1	2	3	4
4. בריחת שתן בזמן צחוק או בכי	0	1	2	3	4
5. בריחת שתן בזמן אחר	0	1	2	3	4
6. יובש נרתיקי	0	1	2	3	4
7. כאב בזמן יחסי מין	0	1	2	3	4
8. כאבים כלליים בגוף	0	1	2	3	4
9. כאבים בפרקים	0	1	2	3	4
10. נוקשות בשרירים	0	1	2	3	4
11. עלייה במשקל	0	1	2	3	4
12. חוסר שביעות רצון ממראה גופי	0	1	2	3	4
13. שכחנות	0	1	2	3	4
14. הזעות לילה	0	1	2	3	4
15. קושי להתרכז	0	1	2	3	4
16. דעתי מוסחת בקלות	0	1	2	3	4
17. נפיחות בזרוע (לימפדמה)	0	1	2	3	4
18. מוגבלות בתווך התנועה של היד בצד של הניתוח	0	1	2	3	4
19. הפרשה מהנרתיק	0	1	2	3	4
20. דימום מהנרתיק	0	1	2	3	4
21. גירוד או גירוי באיברי המין (גניטלי)	0	1	2	3	4
22. חוסר אנרגיה	0	1	2	3	4
23. עייפות	0	1	2	3	4
24. חוסר עניין ביחסי מין	0	1	2	3	4
25. הנאה מועטה מיחסי מין	0	1	2	3	4

BCPT ARB T0, T1, T2

نريد أن نعرف مدى المعاناة التي تعرضت لها خلال **الأسابيع الأربعة الماضية** من المشكلات الموضحة في الجدول. يرجى وضع علامة على رقم واحد في كل سطر. إذا لم تكن لديك المشكلة على الإطلاق، فيمكنك الإشارة إلى "لا على الإطلاق."
خلال الأسابيع الأربعة الماضية، ما مدى ازعاج كل من:

	لا على الاطلاق	قليل	باعتدال	كثير جدا	بأقصى حد
1. موجات الحرارة	0	1	2	3	4
2. غثيا	0	1	2	3	4
3. قيء	0	1	2	3	4
4. سلس البول أثناء الضحك أو البكاء	0	1	2	3	4
5. سلس البول في وقت آخر	0	1	2	3	4
6. جفاف المهبل	0	1	2	3	4
7. ألم أثناء الجماع	0	1	2	3	4
8. ألم عام في الجسم	0	1	2	3	4
9. ألم في المفاصل	0	1	2	3	4
10. تصلب العضلات	0	1	2	3	4
11. زيادة بالوزن	0	1	2	3	4
12. عدم الرضا عن مظهر جسدي	0	1	2	3	4
13. نسيان	0	1	2	3	4
14. التعرق الليلي	0	1	2	3	4
15. صعوبة في التركيز	0	1	2	3	4
16. ذهني يتشوش بسهولة	0	1	2	3	4
17. تورم في الذراع (سرطان الغدد الليمفاوية)	0	1	2	3	4
18. صعوبة في حركة اليد من جهة الجراحة- العملية.	0	1	2	3	4
19. إفرازات مهبلية	0	1	2	3	4
20. نزيف مهبلي	0	1	2	3	4
21. الحكة التناسلية أو تهيج	0	1	2	3	4
22. نقص القوى- الطاقة	0	1	2	3	4
23. تعب-ارهاق	0	1	2	3	4
24. عدم الاهتمام بالعلاقات الجنسية	0	1	2	3	4
25. متعة قليلة من العلاقة الجنسية	0	1	2	3	4

T0, T1, T2 PROMIS HEB ARB

HEB T0, T1, T2 LEAS

הנחיות למשתתפ/ת

כעת נתאר בפנייך מספר מצבים. אנא תאר/י כיצד להערכתך היית מרגיש/ה בכל אחד מהמצבים. את/ה יכול/ה לענות בתשובה קצרה או ארוכה, לפי מה שנחוץ לך על מנת לבטא כיצד היית מרגיש/ה. **הדרישה היחידה היא שתשתמש/י בתשובתך במילה "מרגיש/ה"**. בכל אחד מהמצבים מוזכר אדם נוסף. תאר/י בבקשה גם מה את/ה חושב/ת שהאדם האחר ירגיש.

1. שכן/ה מבקש/ת ממך לתקן פריט ריהוט. בזמן השכן/ה מתבונן/ת, את מתחילה לדפוק מסמר אבל מפספסת ופוגעת באצבעך.
   כיצד את מרגישה?

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כיצד השכן מרגיש?

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2. את הולכת במדבר עם מדריך/ה. אזלו לכם המים לפני שעות. לפי המפה של המדריך/ה, מקור המים הקרוב הוא בעוד שני ק"מ.
   כיצד את מרגישה?

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כיצד המדריך/ה מרגיש/ה?

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3. מישהו\מישהי אהוב\ה עושה לך עיסוי גב לאחר שחזרת מיום עבודה קשה.
כיצד את מרגישה?

כיצד האחר מרגיש?

4. את משתתפת בתחרות ריצה יחד עם חבר/ה לאחר שהתאמנתם/ן יחד תקופה ארוכה. כאשר את קרובה לקו הסיום, את מעקמת את הקרסול, נופלת על האדמה, ואת לא מסוגלת להמשיך.

איך את מרגישה?

איך החבר/ה שלך מרגיש/ה?

5. את מטיילת בארץ זרה. מכר/ה מעיר/ה הערה משפילה בנוגע לארץ המוצא שלך.

כיצד את/ה מרגיש/ה?

כיצד המכר/ה שלך מרגיש/ה?

6. בעת שאת נוסעת על גשר חבלים, את רואה אדם עומד מעבר למעקה, מביט מטה אל המים. כיצד את מרגישה?

כיצד האדם האחר מרגיש?

7. אהובך/תך שב/ה הביתה לאחר מספר שבועות. כשהוא/היא פותח/ת את הדלת... כיצד את מרגישה?

כיצד אהובך/תך מרגיש/ה?

8. המנהל/ת אומר/ת לך שהעבודה שלך לא מספיק טובה ושעלייך להשתפר. כיצד את מרגישה?

כיצד המנהל/ת מרגיש/ה?

9. את עומדת בתור בבנק. האדם לפניך ניגש לדלפק ומתחיל בעסקה מורכבת שצפויה להמשך זמן רב. כיצד את מרגישה?

כיצד האדם לפניך מרגיש?

10. את ובן/בת הזוג שלך נוסעים הביתה מערב בילוי עם חברים. כשאתם פונים לרחוב מגוריכם את רואה רכבי כיבוי אש ליד ביתכם. כיצד את מרגישה?

כיצד בן/בת הזוג מרגיש/ה?

11. עבדת קשה על פרויקט במשך מספר חודשים. מספר ימים לאחר הגשתו, המנהל/ת עובר/ת ואומר/ת לך שעשית עבודה מצוינת.

כיצד את מרגישה?

כיצד המנהל/ת שלך מרגיש/ה?

12. את מקבלת שיחת טלפון לא צפויה מרופא/ה המודיע/ה לך שאמך נפטרה.

כיצד את מרגישה?

כיצד הרופא/ה מרגיש/ה?

13. את אומרת לחבר/ה שחש/ה בודד/ה שהוא/היא יכול/ה להתקשר אליך בכל זמן שהוא/היא חש/ה צורך לדבר. הוא/היא מתקשר/ת אליך בארבע לפנות בוקר.

כיצד את מרגישה?

כיצד החבר/ה שלך מרגיש/ה?

14. רופא/ת השיניים אומר/ת לך שיש לך מספר חורים וקובע לך תור נוסף.

כיצד את מרגישה?

כיצד רופא/ת השיניים מרגיש/ה?

15. אדם שהיה ביקורתי כלפיך בעבר נותן לך מחמאה.

כיצד את מרגישה?

כיצד האדם האחר מרגיש?

16. הרופא אמר כי עליך להימנע מאוכל שמן. חבר/ה חדש/ה בעבודה מתקשר/ת להגיד שהוא/היא יוצא/ת לאכול פיצה ומזמין/ה אותך להצטרף.

כיצד את מרגישה?

כיצד החבר/ה מרגיש/ה?

17. את וחבר/ה מחליטים להשקיע יחד כסף על מנת להתחיל עסק חדש. מספר ימים לאחר מכן, את מתקשרת לחבר/ה ומגלה שהוא/היא שינה/תה את דעתו/ה.

כיצד את מרגישה?

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כיצד החבר/ה מרגיש/ה?

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18. את מוכרת פריט אהוב עליך על מנת לקנות מתנה יקרת ערך לבן/בת הזוג שלך. כשאת מעניקה לו/לה את המתנה הוא/היא שואל/ת האם מכרת את הפריט יקר הערך.

כיצד את מרגישה?

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כיצד בן/בת הזוג מרגיש/ה?

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19. את מתאהבת במישהו/י גם מושכ/ת וגם חכמ/ה. לא אכפת לך שמצבו/ה הפיננסי לא טוב, הכנסתך מספקת. כשאתם מתחילים לדבר על חתונה, את/ה מגלה שהוא/היא בעצם מגיע/ה ממשפחה מאוד עשירה. הוא/היא לא רצה/תה שהדבר יתגלה מתוך חשש שיתעניינו בו/ה רק בגלל הכסף.

כיצד את מרגישה?

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כיצד הוא/היא מרגיש/ה?

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20. את וחברך/תך הטוב/ה ביותר עוסקים באותו תחום עבודה. יש פרס שנתי שניתן עבור הביצועים הטובים ביותר. שניכם/שתיכן עבדתם/ן קשה עבור הפרס. ערב אחד מכריזים על הזוכה: ...החבר/ה שלך.

כיצד את מרגישה?

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כיצד החבר/ה שלך מרגיש/ה?

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LEAS ARB T0, T1, T2

ألتعليمات:
من فضلك اوصف/ي ماذا سيكون شعورك في هذه الحالات. الشرط الوحيد هو أن تستعمل/ي كلمة "أشعر" في اجاباتك.
بإمكانك أن تختصر/ي او تطيل/ي بالإجابة طالما كان ذلك ضروريا للتعبير عن كيفية شعورك.
في كل حالة, هناك شخص آخر مذكور. يرجى أن توضح/ي ماذا تعتقد/ين انه سوف يشعر ايضا.

1. يطلب\تطلب منك أحد الجيران\ت أن تصلح/ي له قطعة من الأثاث. وعندما كان\ت هو \هي ينظر\تنظر إليك بدأت/ي بدق المسمار ولكنك اضعته وضربت/ي اصبعك. كيف سيكون شعورك؟ وكيف سيشعر\ستشعر الجار\الجارة؟

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2. بعد عودتك من يوم شاق في العمل شخص مقرب محب يأتي ليدلك لك ظهرك. كيف سيكون شعورك؟ وكيف سيشعر هذا الشخص؟

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3 . وأنت تقود\ي السيارة على جسر معلق, هناك شخص يقف بالجانب الاخر من الدرابزين وينظر الى الماء في الأسفل, كيف سيكون شعورك؟ وكيف سيكون شعور الشخص؟

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4. رئيسك/رئيستك في العمل يخبرك بأن عملك كان غير مقبول ويحتاج الى تحسين. كيف سيكون شعورك؟ وكيف سيكون شعوره\ا؟

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5. وأنت تقف لتنتظر\ي دورك في البنك. الشخص الذي أمامك يتقدم الى الشباك ويبدأ بمعاملة معقدة جدا. كيف سيكون شعورك؟ كيف سيكون شعور الشخص الذي أمامك؟

6. كنت قد عملت بجد على مشروع لعدة اشهر. بعد عدة أيام من تقديمه, رئيسك\رئيستك في العمل يقف\تقف ليخبرك\لتخبرك بأن عملك كان ممتازا. كيف سيكون شعورك؟ كيف سيكون شعور رئيسك\رئيستك؟

7. يخبرك\تخبرك طبيب\ة الأسنان بأن لديك عدة تجاويف ويعين\تعين لك موعد لزيارة قادمة. كيف سيكون شعورك؟ كيف سيكون شعور طبيب\ة الأسنان؟

8. أخبرك\أخبرتك طبيبك\طبيبتك بتجنب الأطعمة الدهنية. زميلك/زميلتك الجديد/ة في العمل يدعوك/تدعوك لتناول البيتزا. كيف سيكون شعورك؟ كيف سيكون شعور زميلك/زميلتك؟

9. أنت وصديق/ة تتفقان لاستثمار المال معا للبدأ بمشروع تجاري جديد. بعد عدة أيام تتصل به/ا لتعلم بأنه/ا غير/ت رأيه/ا. كيف سيكون شعورك؟ كيف سيشعر صديقك؟

10. وقعت\ي بالحب مع احداهن\احدهم بشخصية جذابة وذكية. على الرغم من ان هذا الشخص حالته/ا المادية ليست جيدة, هذا ليس مهم بالنسبة لك—فدخلك كاف. عندما تبدءوا بالحديث عن الزواج تعلم بأنه/ا من عائلة غنية للغاية. وهو\هي لم يخبرك/تخبرك بسبب مخاوفه/ا بأن الناس سوف يهتمون به/ا لأجل ماله/ا. كيف سيكون شعورك؟ كيف سيشعر\ستشعر هو\هي؟

11. انت تمشي في الصحراء مع مرشد. نفذت معكم المياه من قبل ساعة. حسب خارطة المرشد اقرب بئر يبعد عنكم 3 كيلومتر. كيف سيكون شعورك؟ كيف سيكون شعور المرشد؟

12. انت تركض\ين في سباق مع صديق/ة تدربت معه/ا لبعض الوقت. وانت تقترب\ين من خط النهاية, يلتوي كاحلك, وتسقط على الأرض, ولا تقدر على الاستمرار. كيف سيكون شعورك؟ كيف سيكون شعور صديقك/صديقتك؟

13. انت مسافر\ة في بلد اجنبي. شخص من احد معارفك يقول\تقول تصريحات مهينة لبلدك الأصلي. كيف سيكون شعورك؟ كيف سيشعر الشخص؟

14. حبيبك/حبيبتك ذهب/ت لعدة أسابيع واخيرا اتى/اتت الى المنزل. وهو/وهي يفتح/تفتح الباب...كيف سيكون شعورك؟ كيف سيكون شعوره/ا؟

15. انت وزوجك/زوجتك رجعتم في السيارة الى المنزل بعد سهرة مع الأصدقاء, وعند اقترابكم من حيكم ترون سيارات اطفاء مصطفه بالقرب من منزلكم. كيف سيكون شعورك؟ كيف سيكون شعور زوجك/زوجتك؟

16. تتلقى\تتلقي مكالمة هاتفية غير متوقعة بعيدة المدى من طبيب\ة يخبرك\تخبرك بأن امك قد توفت. كيف ستشعر؟ كيف سيشعر الطبيب\ة؟

17. تخبر صديقك/صديقتك الذي/التي يشعر/تشعر بالوحدة انه/ا بإمكانه/ا الاتصال بك بأي وقت هو/هي يحتاج/تحتاج الى التحدث. في احدى الليالي يتصل/تتصل بك الساعة الرابعة قبل الفجر. كيف ستشعر؟ كيف سيشعر/ستشعر صديقك/صديقتك؟

18. احدهم\احدهن كان/ت ينتقدك/تنتقدك في الماضي, يقدم/تقدم لك اطراء. كيف ستشعر؟ كيف سيشعر الشخص؟

19. تبيع\ين شيء غالي عليك من ممتلكاتك لكي تشتري هدية ثمينة لزوجتك/زوجك. عندما تعطيها/تعطيه اياها تسألك/يسألك ان كنت قد بعت غرض لك. كيف ستشعر؟ كيف ستشعر/سيشعر زوجتك/زوجك؟

20. انت وصديقك/صديقتك المفضل/ة في نفس خط العمل. هناك جائزة سنوية تقدم لأفضل اداء للسنة. كلاكما عملتما جاهدا للفوز بالجائزة. في احد الليالي اعلنوا عن الفائز: صديقك/صديقتك. كيف ستشعر؟ كيف سيشعر/ستشعر صديقك/صديقتك؟

COPE EAC HEB T0, T1, T2					
אנא קראי כל משפט, והעריכי באיזו מידה הנך משתמש/ת בכל דרך התמודדות עם חווית סרטן השד בארבעת השבועות האחרונים:					
	אני לא עושה זאת	אני עושה זאת מעט	אני עושה שזאת במידה בינונית	אני עושה זאת לעיתים קרובות	מסרבת לענות
1. אני לומדת משהו מההתנסות עם המצב	1	2	3	4	8
2. אני לוקחת זמן להבין איך אני באמת מרגישה	1	2	3	4	8
3. אני מרכזת את כוחותיי כדי לעשות משהו	1	2	3	4	8
4. אני מודה בפני עצמי שאיני יכול/ה לטפל במצב ומפסיק/ה לנסות	1	2	3	4	8
5. אני משלימה עם העובדה שזה קרה ושזה לא ניתן לשינוי	1	2	3	4	8
6. אני מנסה להתייעץ עם מישהו לגבי מה כדאי לעשות	1	2	3	4	8
7. אני קובעת תכנית פעולה	1	2	3	4	8
8. אני מעמיקה ברגשותיי כדי להבין אותן בצורה יסודית	1	2	3	4	8
9. אני פועלת כדי לשפר את המצב	1	2	3	4	8
10. אני מתנהגת כאילו זה כלל לא קרה	1	2	3	4	8
11. אני מנסה לקבל עזרה ויעוץ מאחרים	1	2	3	4	8
12. אני אומרת לעצמי ש " זה לא באמת "	1	2	3	4	8
13. אני לוקחת זמן כדי לבטא את רגשותיי	1	2	3	4	8
14. אני מעמידה פנים כאילו זה לא קרה	1	2	3	4	8
15. אני לומדת לחיות עם זה	1	2	3	4	8
16. אני חושבת הרבה על הצעדים שעלי לנקוט	1	2	3	4	8
17. אני מרשה לעצמי להביע את רגשותיי	1	2	3	4	8
18. אני מנסה לראות את הדברים באור חיובי יותר	1	2	3	4	8
19. אני מקבלת נחמה והבנה ממישהו	1	2	3	4	8
20. אני מחפש/ת משהו טוב בדברים שקרו	1	2	3	4	8
21. אני מרגישה חופשיה להביע את רגשותיי	1	2	3	4	8
22. אני מקבלת תמיכה רגשית מאחרים	1	2	3	4	8
23. אני מסרב/ת להאמין שזה קרה	1	2	3	4	8
24. אני מתרגלת לרעיון שזה קרה	1	2	3	4	8
25. אני מרגישה שהרגשות שלי תקפים וחשובים	1	2	3	4	8
26. אני חולמת בהקיץ על דברים אחרים	1	2	3	4	8
27. אני מוותרת על הניסיון להתמודד עם זה	1	2	3	4	8
28. אני פונה לפעילויות חלופיות כדי להסיח את דעתי מהמצב	1	2	3	4	8
29. אני מדבר/ת על רגשותיי בחופשיות	1	2	3	4	8
30. אני מוותרת על הניסיון להתמודד	1	2	3	4	8
31. אני ישנה יותר מבדרך כלל כדי לחשוב על זה פחות	1	2	3	4	8
32. אני מכירה ברגשותיי	1	2	3	4	8
33. אני מנסה לצמוח כאדם כתוצאה מהחוויה	1	2	3	4	8
34. אני מפחיתה את כמות המאמצים שאני משקיעה בהתמודדות	1	2	3	4	8
35. אני פונה לעבודה או פעילויות אחרות כדי להסיח את דעתי	1	2	3	4	8
36. אני מקבלת את זה שזה מה שקרה וזה לא ניתן לשינוי	1	2	3	4	8

COPE ARB T0, T1, T2					
خلال الأسابيع الأربعة الماضية: لطفاً، اقرئي كل جملة وحاولي تقييم درجة استعمالك لكل طريقة تأقلم مع تجربة سرطان الثدي.					
	لا أفعل هذا	أفعل هذا بشكل قليل	أفعل هذا بشكل معتدل	أفعل هذا بشكل كبير	أرفض الإجابة
1. أنا اتعلم من تجربتي مع الوضع.	1	2	3	4	8
2. اَخذ بعض الوقت لكي افهم ماذا اشعر بالفعل.	1	2	3	4	8
3. ارّكز كل طاقاتي لكي انفذ امر معين.	1	2	3	4	8
4. أنا اعترف لنفسي بأنني لا أستطيع ان اتعامل مع الموقف وأتوقف عن المحاولة.	1	2	3	4	8
5. أنا اقبل حقيقة أن الأمر حدث ولا يمكن تغييره.	1	2	3	4	8
6. أحاول استشارة شخص ما حول ما يجب علي فعله.	1	2	3	4	8
7. أنا اضع خطة عمل.	1	2	3	4	8
8. أنا اتعمق بمشاعري لكي افهمها جيداً.	1	2	3	4	8
9. انا اعمل لكي أحسن الوضع.	1	2	3	4	8
10. أنا اتصرف كأن الامر لم يحدث ابداً.	1	2	3	4	8
11. أحاول ان اتلقى مساعدة وإستشارة من الآخرين.	1	2	3	4	8
12. أقول لنفسي أن " هذا غير صحيح".	1	2	3	4	8
13. اَخذ بعض الوقت لكي اعبر عن مشاعري.	1	2	3	4	8
14. اتظاهر كأن الأمر لم يحصل.	1	2	3	4	8
15. اتعلم ان اتعايش مع الأمر.	1	2	3	4	8
16. افكر كثيرا حول الخطوات التي يتوجب علي اتخاذها.	1	2	3	4	8
17. اسمح لنفسي ان اعبر عن مشاعري.	1	2	3	4	8
18. أحاول ان أرى الأمور بصورة إيجابية أكثر.	1	2	3	4	8
19. احصل على الراحة- التفهم والاحتواء من شخص ما.	1	2	3	4	8
20. ابحث عن امر جيد بالأمور التي حصلت.	1	2	3	4	8
21. اشعر بحرية التعبير عن مشاعري.	1	2	3	4	8
22. احصل علي دعم عاطفي من الاخرين.	1	2	3	4	8
23. ارفض التصديق بان هذا حصل.	1	2	3	4	8
24. اعتدت على فكرة ان الامر قد حصل.	1	2	3	4	8
25. انا اشعر بان مشاعري صحيحة-ملائمة ومهمة.	1	2	3	4	8
26. احلم بان استيقظ على امور اخرى.	1	2	3	4	8
27. اتخلى عن محاولة التعامل- الاعتياد مع هذا الامر.	1	2	3	4	8
28. اتوجه لفعاليات وانشطة بديلة لصرف نفسي –الهي نفسي عن الوضع.	1	2	3	4	8
29. انا اتحدث عن مشاعري بحرية.	1	2	3	4	8
30. اتخلى عن محاولة التأقلم.	1	2	3	4	8
31. انام لوقت اطول من المعتاد لكي افكر بالامر اقل.	1	2	3	4	8
32. أنا أعي-اعرف مشاعري.	1	2	3	4	8
33. احاول ان أنضج وانمو من هذه التجربة.	1	2	3	4	8
34. أقوم بتقليل المجهود الذي ابذله واستثمره في التأقلم.	1	2	3	4	8
35. اتوجه للعمل او فعالية اخرى لكي اشغل واصرف تفكيري بأمور اخرى.	1	2	3	4	8
36. اتقبل الامر بأن هذا ما حدث ولا يمكن تغييره.	1	2	3	4	8

שאלון קבלה רגשית T0 T1 T2

אנא צייני (על ידי הקפה בעיגול) עד כמה כל הצהרה מתארת את יחסך לרגשותייך בצורה מיטבית. 0= בכלל לא כמוני ; 100= בדיוק כמוני.

1. אני מנסה להבין בדיוק מה קורה עם הרגשות שלי, מכיוון שאני רוצה לעזור לעצמי

0 10 20 30 40 50 60 70 80 90 100

2. נוח לי עם רגשותיי כפי שהם, למרות שאני יודעת שאינם "מושלמים"

0 10 20 30 40 50 60 70 80 90 100

3. אני נותנת לעצמי להרגיש שמחה ושבעת רצון עם רגשותיי, בדיוק כפי שהם

0 10 20 30 40 50 60 70 80 90 100

4. אני עובדת ומתאמנת על פיתוח רגשות בעלי ערך

0 10 20 30 40 50 60 70 80 90 100

5. אני מוקירה את רגשותיי בצורה רכה ואוהבת

0 10 20 30 40 50 60 70 80 90 100

6. אני מתייחסת לרגשותיי בקלות ובאופן טבעי

0 10 20 30 40 50 60 70 80 90 100

7. אני מאוד נהנית מהרגשות שלי

0 10 20 30 40 50 60 70 80 90 100

8. אני מעריכה את רגשותיי, בצורה עדינה וחמה, בדיוק כפי שהם

0 10 20 30 40 50 60 70 80 90 100

9. אני משחררת בנוחות את רגשותיי מכיוון שהם משקפים את העצמי הפנימי והעמוק

0 10 20 30 40 50 60 70 80 90 100

10. אני מטפלת ושמה לב לרגשותיי בנוחות

0 10 20 30 40 50 60 70 80 90 100

11. אני משקיעה הרבה כוחות בלהבין את רגשותיי ולבחור איך להתמודד איתן

0 10 20 30 40 50 60 70 80 90 100

12. אני מבינה ומחבבת את רגשותיי בדיוק כפי שהן

0 10 20 30 40 50 60 70 80 90 100

13. אני מרשה לעצמי להיות מחוברת לרגשותיי מכיוון שזה טוב עבורי

0 10 20 30 40 50 60 70 80 90 100

שאלון קבלה רגשית ערבית TO,T1,T2

لطفاً، أحيطِ بدائرة الى أي مدى تصف كل عبارة علاقتك بمشاعرك بأفضل شكل . 0= لا يمثلني على الاطلاق؛ 100= يمثلني تماما.

1. أحاول أن أفهم بالضبط ماذا يحدث مع مشاعري، بحيث أريد أن أساعد نفسي.
0 10 20 30 40 50 60 70 80 90 100

2. انا مرتاحة مع مشاعري كما هي، على الرغم من انني اعي بانها غير "مثالية"
0 10 20 30 40 50 60 70 80 90 100

3. اعطي نفسي ان اشعر بالسعادة والرضا مع مشاعري، بالضبط كما هي.
0 10 20 30 40 50 60 70 80 90 100

4. انا اعمل واتمرن على تطوير مشاعر ذات قيمة.
0 10 20 30 40 50 60 70 80 90 100

5. اعتز بمشاعري بشكل لطيف ومحب.
0 10 20 30 40 50 60 70 80 90 100

6. اتعامل مع مشاعري ببساطة وبشكل طبيعي.
0 10 20 30 40 50 60 70 80 90 100

7. انا استمتع كثيراً من مشاعري.
0 10 20 30 40 50 60 70 80 90 100

8. انا اقدّر مشاعري، بشكل لطيف ودافئ، تماما كما هي.
0 10 20 30 40 50 60 70 80 90 100

9. انا أطلق مشاعري بكل راحة من منطلق بانها تعكس حقيقتي ونفسيتي بشكل عميق.
0 10 20 30 40 50 60 70 80 90 100

10. انا اعتني وانتبه لمشاعري بشكل مريح.
0 10 20 30 40 50 60 70 80 90 100

11. ابذل طاقات كبيرة لكي افهم مشاعري واختار كيف اتعامل معها.
0 10 20 30 40 50 60 70 80 90 100

12. انا افهم واحب مشاعري واجدها مناسبة تماما كما هي.
0 10 20 30 40 50 60 70 80 90 100

13. اسمح لنفسي بالتواصل مع مشاعري لأنه جيد بالنسبة لي.
0 10 20 30 40 50 60 70 80 90 100