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# A pilot study of a mindfulness intervention among women in recovery from breast cancer

**Submission date**
30/01/2021

**Recruitment status**
No longer recruiting

**Registration date**
16/02/2021

**Overall study status**
Completed

**Last Edited**
05/03/2024

**Condition category**
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[X] Individual participant data

**Plain English summary of protocol**
Background and study aims
Practicing mindfulness has mental health benefits among people with cancer. The aim of this pilot study is to assess whether attending an 8-week Mindfulness-Based Stress Reduction (MBSR) program is associated with a reduction of psychological symptoms, such as depression, anxiety, stress and sleep disturbances, and an increase in psychological well-being among women in remission from breast cancer. In addition, the aim is to assess the levels of stress-related biomarkers across the MBSR program among participants; and the quantity of independent mindfulness practice and its relationship to psychological symptoms and biomarkers. Lastly, the aim is to understand participants' experiences of mindfulness practice and the MBSR program.

Who can participate?
Women (aged 25-65) who were treated for breast cancer 1 year earlier and have depressive symptoms

What does the study involve?
MBSR is a structured 8-week program developed for systematic training of mindfulness skills. The program consists of eight weekly group sessions, one day long silent retreat, and mindfulness home practice (recommendation 45 min daily). The MBSR program is led by a general practitioner and certified MBSR-instructor (Dr Outi Hilgert).
Participants fill in questionnaires measuring depression symptoms, anxiety, stress, insomnia, quality of life, resilience, self-compassion and mindfulness skills. Biomarkers measuring stress levels and chronic inflammation are obtained from blood/serum and urine samples. Questionnaires and biomarkers are measured at three time points: before the start of the MBSR program, mid-program (4 weeks), and at the program completion (8 weeks). Experiences of mindfulness practice and the MBSR program are gathered in a written format by eight open-ended questions at the program completion (8 weeks).

What are the possible benefits and risks of participating?
Possible benefits of participating in the study include experienced peer support from the fellow participants, support from the MBSR group instructor, and care for depression and other symptoms beyond treatment as usual. Potential risks include unexpected or difficult

experiences related to mindfulness practice that could lead to worsening of the psychological symptoms. The burden of completing the questionnaires (30 minutes at each three assessment point) and open-ended questions (60 minutes at the last assessment point) and providing the blood and urine samples (each three assessment point) is considered moderate.

Where is the study run from?
Helsinki University Central Hospital Comprehensive Cancer Centre (Finland)

When is the study starting and how long is it expected to run for?
June 2016 to December 2017

Who is funding the study?
The study was funded by Gyllenberg Foundation and a special government grant for health science research at the Comprehensive Cancer Centre, Helsinki University Hospital (Finland)

Who is the main contact?
Dr Anu Raevuori
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# Contact information

**Type(s)**
Scientific

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# Additional identifiers

**EudraCT/CTIS number**
Nil known

**IRAS number**

**ClinicalTrials.gov number**

Nil known

### Secondary identifying numbers
60/13/03/03/2016

# Study information

### Scientific Title
Mindfulness in rehabilitation of breast cancer: is mindfulness associated with alleviation of psychological symptoms among women in remission?

### Study objectives
The first hypothesis was that compared to the baseline, depression symptoms, anxiety, perceived stress, and sleep disturbances would be reduced at mid-program, and continue decreasing towards the end of the Mindfulness-Based Stress Reduction (MBSR)-program.
The second hypothesis was that compared to the baseline, quality of life, resilience, self-compassion and mindfulness skills would be increased at mid-program, and continue increasing towards the end of the MBSR-program.
The third hypothesis was that biomarkers indicating stress response and low-grade inflammation (cortisol, adrenocorticotropine, hs-CRP, 24-hour urine cortisol) would change across the 8-week MBSR-program. The researchers assumed that their levels at mid-program (4 weeks) and at the program completion would be lower compared to the baseline levels.
The fourth hypothesis was that that greater engagement (practice time) to the independent mindfulness practice would be associated with greater changes in the self-reported questionnaire scores and in biomarker values at mid-program and at the program completion.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Approved 06/06/2016, ethical committee of gynecology, paediatrics and psychiatry, Helsinki University Hospital (HUS; Piia Paavilainen, Biomedicum Helsinki 2 C-talo, 7.krs, Tukholmankatu 8 C, PL 705, 00029 HUS; +358 (0)50 427 9493; piia.paavilainen@hus.fi), ref: 60/13/03/03/2016

### Study design
Non-randomized interventional single-arm pilot study with systematic sampling

### Primary study design
Interventional

### Secondary study design
Non randomised study

### Study setting(s)
Hospital

### Study type(s)
Treatment

### Participant information sheet

Not available in web format, please use the contact details to request a participant information sheet

## Health condition(s) or problem(s) studied
Psychological symptoms and stress biomarkers among women in remission from breast cancer

## Interventions
MBSR is a structured 8-week program developed for systematic training for mindfulness skills. The program consists of eight weekly group sessions, one day long silent retreat, and mindfulness home practice (recommendation 45 min daily).

Participants fill in questionnaires measuring depression symptoms (BDI-II), anxiety (Beck Anxiety Inventory, BAI), stress (Perceived Stress scale, PSS-10), insomnia (Insomnia Severity Index, ISI), quality of life (World Health Organization Quality of Life–questionnaire, WHOQOL-BREF), resilience (Resilience Scale), self-compassion (Self-compassion Scale, SCS-SF) and mindfulness skills (Five Facet Mindfulness Questionnaire, FFMQ). Biomarkers measuring stress levels and chronic inflammation (cortisol, adrenocorticotropine, hs-CRP, 24-hour-urin cortisol) are obtained from the blood/serum samples and from a urine sample. Questionnaires and biomarkers are addressed at three time points: at baseline before the start of the MBSR program, mid-program (4 weeks after baseline), and at the program completion (8 weeks after baseline). Experiences of mindfulness practice and the MBSR program are gathered in a written format by eight open-ended questions (potential unexpected or difficult experiences related to mindfulness practice, and their effect on daily life; learnings from the MBSR course; experienced support from the MBSR group; bodily sensations related to mindfulness practice; verbal description of the experience of mindfulness practice; personal conception of the mindfulness practice) at the program completion (8 weeks after baseline). Background characteristics such as health status, medication, employment and social support are collected at baseline.

Repeated measures analysis of variance (ANOVA) is used to analyze changes in the self-reported questionnaire scores and in the biomarker values between baseline, 4-week and 8-week follow-ups; and the follow-up scores are compared to baseline scores using Dunnett's adjustment in pairwise comparisons. The association between the quantity of mindfulness practice and the change in the self-reported questionnaire scores is examined using Pearson correlation coefficients. Exploratory, content-driven thematic analysis is used to analyze participants' written answers to the open-ended questions.

## Intervention Type
Behavioural

## Primary outcome measure
Measured at baseline before the start of the MBSR program, mid-program (4 weeks after baseline), and at the program completion (8 weeks after baseline):
1. Psychological symptoms and mental wellbeing assessed by the following self-reported questionnaires:
1.1. Depression symptoms measured using the Beck Depression Inventory-II (BDI-II)
1.2. Anxiety measured using the Beck Anxiety Inventory (BAI)
1.3. Insomnia measured using the Insomnia Severity Index (ISI)
1.4. Stress measured using the Perceived Stress Scale (PSS-10)
1.5. Quality of life measured using the World Health Organization Quality of Life–questionnaire (WHOQOL-BREF)
1.6. Resilience measured using the Resilience Scale

1.7. Self-compassion measured using the Self-compassion Scale, short form (SCS-SF)
1.8. Mindfulness skills measured using the Five Facet Mindfulness Questionnaire (FFMQ)
2. Stress and low-grade inflammation assessed using the following biomarkers: cortisol (sera), adrenocorticotropine (sera), hs-CRP (sera), 24-hour- cortisol (urine)

### Secondary outcome measures
1. Quantity of independent mindfulness practice (time in minutes) collected with a written diary filled in by the participants every day during the 8-week program (8 x 7), i.e. 56 timepoints
2. Experiences of mindfulness practice and the MBSR program gathered in a written format by eight open-ended questions at the program completion (8 weeks after baseline):
1. Did you have difficult experiences related to mindfulness practice?
2. If you had difficult experience/s related to mindfulness practice, how did it/they affect your life?
3. The most important learnings from the MBSR course to you?
4. Do you apply learnings from the MBSR course to your everyday life?
5. Do you feel that you received support from the members of the MBSR group?
6. Did you have bodily sensations related to mindfulness practice?
7. Are you able to verbalize your mindfulness experience?
8. Do understand mindfulness practice similarly or differently compared to your understanding prior to attending the MBSR program?

### Overall study start date
06/06/2016

### Completion date
01/12/2017

## Eligibility

### Key inclusion criteria
1. Women (aged 25-65 years) with curatively treated, operated invasive breast cancer (T1-4 N0-3 M0) 1 year earlier
2. Self-reported depressive symptoms (BDI-II score >13 points)
3. Motivation to attend

### Participant type(s)
Patient

### Age group
Adult

### Sex
Female

### Target number of participants
25

### Total final enrolment
23

### Key exclusion criteria
1. Metastatic disease
2. Lack of motivation to attend
3. Substance abuse
4. Suicidality
5. Psychotic symptoms
6. Untreated posttraumatic stress disorder
7. Severe social phobia

### Date of first enrolment
08/01/2017

### Date of final enrolment
01/05/2017

## Locations

### Countries of recruitment
Finland

### Study participating centre
**Helsinki University Central Hospital Comprehensive Cancer Centre**
Paciuksenkatu 3
Helsinki
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HUS 00029

## Sponsor information

### Organisation
Helsinki University Central Hospital

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Comprehensive Cancer Centre
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### Sponsor type
Hospital/treatment centre

### Website

https://www.hus.fi/en/patient/hospitals-and-other-units/comprehensive-cancer-center

**ROR**
https://ror.org/02e8hzf44

# Funder(s)

**Funder type**
Charity

**Funder Name**
Signe ja Ane Gyllenbergin Säätiö

**Alternative Name(s)**
Signe and Ane Gyllenberg Foundation, Signe och Ane Gyllenbergs Stiftelse

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
Trusts, charities, foundations (both public and private)

**Location**
Finland

**Funder Name**
Special government grant for health science research at the Comprehensive Cancer Centre, Helsinki University Hospital

# Results and Publications

**Publication and dissemination plan**
1. One original article reporting the quantitative data in a peer-reviewed journal
2. Another original article reporting the qualitative data in a peer-reviewed journal
3. No additional documents are available

**Intention to publish date**
01/12/2022

**Individual participant data (IPD) sharing plan**

Potential requests for the data should be addressed to Principal Investigator Dr Anu Raevuori by email: anu.raevuori@helsinki.fi. The dataset is in Excel format and contains the quantitative data. It is available by request by the end of 31/12/2025. The qualitative data (for thematic analysis) is in Finnish and is not available.

## IPD sharing plan summary

Available on request

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 12/12/2022 | 13/12/2022 | Yes | No |
| Dataset | Excel file | | 05/03/2024 | No | No |