

# Islamic caring mindfulness-based program on spiritual well-being and fatigue in Indonesian women with advanced breast cancer

<b>Submission date</b>	<b>Recruitment status</b>	<input type="checkbox"/> Prospectively registered
24/08/2019	No longer recruiting	<input type="checkbox"/> Protocol
<b>Registration date</b>	<b>Overall study status</b>	<input type="checkbox"/> Statistical analysis plan
11/09/2019	Completed	<input checked="" type="checkbox"/> Results
<b>Last Edited</b>	<b>Condition category</b>	<input type="checkbox"/> Individual participant data
07/09/2021	Cancer	

## Plain English summary of protocol

### Background and study aims

There has been limited research on Islamic caring mindfulness-based program for enhancing spiritual well-being and fatigue for women with advanced breast cancer in Indonesia. Since spiritual practice including mindfulness practice through prayer and dhikr meditation are part of Muslims' daily life practice, therefore, it is feasible and worth promoting this program. The aim of this study was to evaluate the effects of the Islamic caring mindfulness-based program on spiritual well-being and fatigue on Indonesian women with advanced breast cancer undergoing chemotherapy.

### Who can participate?

All Muslim patients with advanced breast cancer either new or recurrent cases that came for chemotherapy treatment were the target for this study.

### What does the study involve?

A program based on Islamic philosophy (the True Faith and the Five Pillars) for enhancing spiritual well-being and alleviating the fatigue of Indonesian women with advanced breast cancer undergoing chemotherapy. The program follows the standard care during chemotherapy with the adjunct of specific ICMB activities attached, namely, Islamic prayer, breath dzikr meditation, and Islamic caring. The duration of the program was six weeks.

### What are the possible benefits and risks of participating?

By becoming a participant, the participants will get knowledge about breast cancer, the side effects of chemotherapy and its management, as well as get information about how to do prayer and dhikr meditation properly, so that it is beneficial for health. In addition, the program did not have a negative side effect.

### Where is the study run from?

The chemotherapy unit at the Teaching Hospital, Bandung West Java Province, Indonesia

When is the study starting and how long is it expected to run for?

January 2018 to July 2018

Who is funding the study?

Graduate School, Prince of Songkla University, Thailand

Who is the main contact?

Maria Komariah

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## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

Nil known

## Study information

### Scientific Title

Islamic caring mindfulness-based program on spiritual well-being and fatigue in Indonesian women with advanced breast cancer

### Acronym

## **Study objectives**

1. The mean scores of the intervention group on days 2-3 (Time-2), on days 23-24 (Time-3), and days 44-45 (Time-4) will be higher than those of the control group.
2. The mean scores of fatigue of the intervention group after receiving the program on days 2-3 (Time-2), on days 23-24 (Time-3), and day 44-45 (Time-4) will be higher than those of the control group.
3. The mean scores of spiritual well-being of the intervention group after receiving the program on days 2-3 (Time-2), on days 23-24 (Time-3), and days 44-45 (Time-4) will be higher than at baseline.
4. The mean scores of fatigue of the intervention group after receiving the program on days 2-3 (Time-2), on days 23-24 (Time-3), and days 44-45 (Time-4) will be higher than at baseline.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Approved 15/01/2018, The Institutional Review Board of the Faculty of Nursing (Center for Social and Behavioral Sciences, Institutional Review Board, Faculty of Nursing, Prince of Songkla University, 15 Karnjanavanich Road, Hat Yai, Songkla 90110, Thailand; +66 74 286 422; sasitorn.ph@psu.ac.id), ref:2017 NSt-Qn 054

## **Study design**

Randomized controlled trial

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Advanced breast cancer undergoing chemotherapy

## **Interventions**

This nursing intervention program refers to a program based on Islamic philosophy (the True Faith and the Five Pillars) for enhancing spiritual well-being and alleviating fatigue of Indonesian women with advanced breast cancer undergoing chemotherapy. The program follows the standard care during chemotherapy with the adjunct of specific ICMB activities attached, namely, Islamic prayer, breath dzikr meditation, and Islamic caring. The duration of the program was six weeks.

The researcher assigned randomly the eligible participants by using the software i.e. the minimized randomization software (version 2.01) into two intervention arms.

First Group (experimental group) was given ICMB program

Second Group (control group) was given usual care

## **Contents of ICMB program session:**

Provision of knowledge about the disease and complications (i.e., what is the breast cancer, stages of breast cancer, causes and risk factors, treatment and its side effect, symptoms

management).

Training, coaching & practicing prayer and breath dzikr meditation (i.e., what Quran says about prayer and dzikr meditation, benefits of prayer and dzikr meditation, how to perform prayer and dzikr meditation, how prayer and dzikr meditation is useful for advanced breast cancer)

Reflection

Preparation (15 min):

-Forming a caring relationship by greeting, touching, respecting and blessing in Islamic way.

-Praying together for healing and asking help from Allah.

-Encouraging the patient and the families to be patient with the illness

Individual practice(the participants):

-Prayer (10 min)

-Breath dzikr meditation (30 min)

-Reflection (5 min)

## **Intervention Type**

Behavioural

## **Primary outcome(s)**

1. Spiritual well-being measured using the Functional Assessment of Chronic Illness Therapy (Spiritual) (FACIT-Sp) at baseline (Time-1), on day 3-4 (Time-2), on day 23-24 (Time-3), and day 44-45 (Time-4)
2. Fatigue measured using the Functional Assessment of Chronic Illness Therapy - Fatigue (FACIT- Fatigue) at baseline (Time-1), on day 3-4 (Time-2), on day 23-24 (Time-3), and day 44-45 (Time-4)

## **Key secondary outcome(s)**

level of Islamic mindfulness (khushu prayer) measured using the Khushu Prayer Questionnaire, at baseline

## **Completion date**

03/07/2018

## **Eligibility**

### **Key inclusion criteria**

1. Muslim
2. Aged over 18 years
3. Diagnosis of stage III breast cancer
4. Can perform basic daily activities with the Eastern Cooperative Oncology Group (ECOG) with a Performance Score of 0 – 2, 0 refers to fully active, no performance restrictions, 2 refers to able to carry out all self-care but incapable to perform any work activities, up and about >50% of waking hours, it was important for screening the patient's ability to perform prayer perfectly
5. Cognitively intact and without a documented diagnosis of mental illness
6. Speak and understand Bahasa Indonesian
7. Access to a telephone
- 8) Received chemotherapy treatments every 21 days at any cycle ≤ 4 cycles including the current cycle

## **Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

Female

**Total final enrolment**

120

**Key exclusion criteria**

1. Regularly used complementary alternative medicine (e.g., reflexology, foot massage, pedicure with massage)
2. Could not completely follow the program

**Date of first enrolment**

17/01/2018

**Date of final enrolment**

03/05/2018

## Locations

**Countries of recruitment**

Indonesia

**Study participating centre**

Bandung Teaching Hospital

Jl. Pasteur No. 38

Bandung

Indonesia

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## Sponsor information

**Organisation**

Universitas Padjadjaran

**ROR**

<https://ror.org/00xqf8t64>

# Funder(s)

## Funder type

University/education

## Funder Name

Graduate School, Prince of Songkla University, Thailand

# Results and Publications

## Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date

## IPD sharing plan summary

Data sharing statement to be made available at a later date

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		16/07/2020	07/09/2021	Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes