

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

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

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?
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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
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

ICMB

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

No participant information sheet available

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 measure

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)

Secondary outcome measures

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

Overall study start date

17/01/2018

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 \leq 4 cycles including the current cycle

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

120

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

Sponsor details

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Sponsor type

University/education

ROR

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

Funder(s)

Funder type

University/education

Funder Name

Graduate School, Prince of Songkla University, Thailand

Results and Publications

Publication and dissemination plan

Current publication and dissemination plan as of 19/03/2020:

Opcion

Previous publication and dissemination plan:

Nursing & Health Sciences journal

Intention to publish date

05/09/2020

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?
Results article		16/07/2020	07/09/2021	Yes	No