ISRCTN12570738 https://doi.org/10.1186/ISRCTN12570738

A self-help psycho-education programme to reduce diagnosis delay in women with breast cancer symptoms in Indonesia

Submission date
04/11/2016

Recruitment status
No longer recruiting

Registration date
19/11/2016

Overall study status
Completed

Last Edited
20/12/2023

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
In Indonesia breast cancer is the most common cancer and the leading cause of cancer deaths among women. Delay in breast cancer diagnosis leads to a worse prognosis (outcome). Many Indonesian women with breast cancer are already at an advanced stage when they start treatment. Therefore, the delay in diagnosis has become a serious problem that needs to be addressed. The aim of this study is to find out whether a newly developed self-help psycho-educational programme, PERANTARA, reduces the delay of breast cancer diagnosis.

Who can participate?
Women aged 18 years or older with breast cancer symptoms

What does the study involve?
In the first period the four participating hospitals are randomly allocated to deliver PERANTARA or treatment as usual. In the second period the hospitals cross over (swap) to deliver the other treatment. PERANTARA consists of both printed and audiovisual material that provides a brief explanation of breast cancer, treatment and its side effects, and a guide to a healthy lifestyle. In addition to regular medical procedures, treatment-as-usual is very limited and consists of incidental supportive talks with the nurses. Data is collected at the start of the study, 7 days after, and at 3 months follow-up. Diagnostic delay, breast cancer knowledge, anxiety, depression and quality of life are assessed.

What are the possible benefits and risks of participating?
Participants may benefit from expressing their thoughts, feelings and experiences about their health condition. Their participation will be useful to develop programs and tools to improve the quality of Indonesian women's health, especially those with breast cancer symptoms. Participants who receive PERANTARA may benefits from better understanding and adherence to the cancer treatment. There is no risk for participants' physical health because it only requires answering some questions and reading the PERANTARA materials if they are allocated to

PERANTARA. However, some of the information presented or questions asked by the research assistants may be distressing or uncomfortable, in which case additional support may be arranged. Information will be kept confidential and each participant will be anonymous.

Where is the study run from?
1. Rumah Sakit Al Ihsan Baleendah (Indonesia)
2. RSAU Salamun (Indonesia)
3. RSUD Cibabat (Indonesia)
4. RS Al Islam Bandung (Indonesia)

When is the study starting and how long is it expected to run for?
December 2013 to August 2018

Who is funding the study?
KWF, The Dutch Cancer Society (Netherlands)

Who is the main contact?
Mr Hari Setyowibowo
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
KWF2012

Study information

Scientific Title
A cluster-randomized controlled trial of a self-help psycho-education programme to reduce diagnosis delay in women with breast cancer symptoms in Indonesia

Acronym
PERANTARA

Study objectives
The aims of this study are to evaluate the effectiveness of PERANTARA in reducing the delay of breast cancer diagnosis in women who visit the hospital with the symptoms prior to formal diagnosis based on pathological examination.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Review Committee of Hasan Sadikin Hospital, 23/12/2013, ref: LB.04.01/A05/EC/127/XII /2013

Study design
Cluster-randomized controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Early stage breast cancer

Interventions
The study will be a multi-center, cluster randomized trial (cRCT), with hospitals as the unit of randomization (clusters). Four hospitals have agreed to participate in this study. Because of the limited number of hospitals, a cross-over design will be used in which each hospital will be given PERANTARA or treatment as usual (TAU) control at successive periods. This study uses two predefined periods. We will randomize the two hospitals on a 1:1 basis into either PERANTARA+TAU or TAU only. The two hospitals that are randomized into PERANTARA+TAU for the first period, will be assigned to TAU only for the second period and vice versa.

PERANTARA + treatment as usual
PERANTARA is a psycho-education material package that consists of both printed and audiovisual material. This package provides information and persuades the patients to follow doctors' recommendations to prevent patient delay and facilitates them to improve the quality of the relationship with healthcare providers and her caregivers. The following information is provided in the material:
1. A brief explanation of breast cancer in order for the patients to have an accurate understanding and stimulation to seek information from reliable sources (oncologist)

2. Information on various kinds of breast cancer treatment and its side effects to inform the patients that the treatment may cause some side effects but they are all treatable so they don't have to worry. It is also suggested that the patients to follow doctors' recommendations regarding which treatment is best
3. Spirituality, to help the patients to employ a reframing coping strategy so they may see their conditions from a different point of view
4. Recommendation to seek social support to make them feel cared for
5. Guide to a healthy lifestyle to ensure the patients to stay healthy after receiving the diagnosis.

Treatment as usual only
In addition to regular medical procedures, treatment-as usual is very limited and consists of incidental supportive talks with the nurses.

Data will be collected at baseline (pre-assessment), 7 days after the intervention (post-assessment), and at 3 months (follow-up assessments). Total duration of treatment is 7 days and the follow-up time is three months.

Intervention Type
Behavioural

Primary outcome(s)
Diagnostic delay, defined as the number of days between the date of the first consultation at the hospital and the date of final breast cancer diagnosis based on pathological examination

Key secondary outcome(s))
1. Breast cancer knowledge measured using the Breast Cancer Knowledge Test (BCKT) at baseline, 7 days and 3 months after finishing PERANTARA
2. Anxiety and depression measured using the Hospital Anxiety and Depression Scale (HADS) at baseline, 7 days and 3 months after finishing PERANTARA
3. Quality of life measured using the WHO Quality Of Life-BREF (WHOQOL-BREF) and the European Quality of Life 5D-5L at baseline, 7 days and 3 months after finishing PERANTARA

Completion date
31/08/2018

Eligibility

Key inclusion criteria
1. Female outpatients who visit to the hospital with breast symptoms, suspected of having breast cancer
2. Age 18 years or older

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Total final enrolment
132

Key exclusion criteria
1. Presence of major psychiatric disorders (presence of consultation history/record with the psychiatric department)
2. Inadequate command of the Indonesian language.

Date of first enrolment
01/12/2016

Date of final enrolment
31/08/2017

Locations

Countries of recruitment
Indonesia

Study participating centre
Rumah Sakit Al Ihsan Baleendah
Jl. Kiastramanggala
Baleendah
Bandung
Indonesia
40381

Study participating centre
RSAU Salamun
Jl. Ciumbuleuit No.203
Ciumbuleuit
Cidadap
Bandung
Indonesia
40142

Study participating centre
RSUD Cibabat
Jl. Jend. H. Amir Machmud No.140

Cigugur Tengah
Cimahi Tengah
Cimahi
Indonesia
40522

Study participating centre
RS Al Islam Bandung
Jl. Soekarno-Hatta No. 644
RT. 001 RW. 001
Kel. Manjahlega
Kec. Rancasari
Bandung
Indonesia
40286

Sponsor information

Organisation
KWF, The Dutch Cancer Society

ROR
https://ror.org/0368jnd28

Funder(s)

Funder type
Charity

Funder Name
KWF Kankerbestrijding

Alternative Name(s)
Dutch Cancer Society, Dutch Cancer Society (KWF Kankerbestrijding), KWF, DCS

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location

Netherlands

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	06/01/2020	12/02/2020	Yes	No
Protocol article	protocol	20/04/2017		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Statistical Analysis Plan		06/01/2020	20/12/2023	No	No