Early detection of symptoms using digital patient-reported symptom monitoring and a Fitbit to optimize care in metastatic breast cancer (SYMPHA, BOOG 2024-01).

Published: 27-12-2024
Last updated: 18-01-2025

This study aims to determine the effect of real-time symptom monitoring on HRQoL in patients with mBC who start first-line chemo(immune)therapy. Further objectives include analyzing the effect of PRS monitoring on physical functioning, the severity…

Ethical review	Approved WMO
Status	Pending
Health condition type	Breast neoplasms malignant and unspecified (incl nipple)
Study type	Interventional

Summary

ID

NL-OMON57204

Source
ToetsingOnline

Brief title
SYMPHA

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
metastatic breast cancer

Research involving
Human

Sponsors and support

Primary sponsor: Integraal Kankercentrum Nederland (IKNL)
Source(s) of monetary or material Support: KWF

Intervention

Keyword: early detection, Fitbit, metastatic breast cancer, patient reported symptoms

Outcome measures

Primary outcome

The main endpoint is the difference of HRQoL between the control and intervention arms on the mean difference between T0 (start of the first line systemic chemo(immune)therapy for mBC) and the mean HRQoL during the first line of therapy until first switch of therapy or, in case of no switch, 6 months.

Secondary outcome

Secondary endpoints include differences between the control and intervention arms in the severity of symptoms, treatment patterns, therapy adherence, healthcare resource use, cost-effectiveness, long-term HRQoL, overall survival and patient empowerment. In addition, we strive for a first step towards a trained and (internally) validated model for early detection and prediction of symptoms through Fitbit data.

Study description

Background summary

New pharmaco-therapeutic options for metastatic breast cancer (mBC) improve prognosis only slightly but can cause severe toxicities and symptoms affecting health-related quality of life (HRQoL). Early identification of Patient-Reported Symptoms (PRS), resulting from treatment toxicities or disease progression may preserve HRQoL, improve adherence of the anti-tumor therapy or

might lead to an earlier switch to second-line chemo(immune)therapy with less toxicity which may improve cost-effectiveness.

Study objective

This study aims to determine the effect of real-time symptom monitoring on HRQoL in patients with mBC who start first-line chemo(immune)therapy. Further objectives include analyzing the effect of PRS monitoring on physical functioning, the severity of symptoms, treatment patterns, therapy adherence, healthcare resource use, cost-effectiveness, long-term HRQoL, overall survival and patient empowerment. The main secondary objective is to explore the role of a Fitbit in objectifying, early detection and prediction of symptoms. Additionally, the usage, experiences, facilitators and barriers for the implementation of PRS-apps and a Fitbit will be evaluated.

Study design

We will perform 3 separate randomized clinical trials (RCTs) within the 3 different mBC subtypes (TNBC, HR+Her2- or Her2+) preceded by a run-in phase.

Intervention

Patients allocated to the intervention arm will use a PRS-app to report their symptoms. Patients receive an alert to contact the healthcare professional (HCP) when the severity of symptoms exceeds a clinically relevant threshold. The control arm will notify symptoms as usual in standard care, i.e. without using a PRS-app. All patients will fill in HRQoL questionnaires and will be asked to wear a Fitbit.

Study burden and risks

There are no medical risks associated with the use of the PRS-app and the Fitbit. All patients will receive systemic therapy, which is standard care. The intervention arm will use the PRS-app in addition to standard of care monitoring. The PRS-app gives patients the opportunity to enhance their own disease management. Early recognition of symptoms may lead to more timely clinical intervention.

Contacts

Public
Integraal Kankercentrum Nederland (IKNL)

Rijnkade 5

Utrecht 3511 LC
NL
Scientific
Integraal Kankercentrum Nederland (IKNL)

Rijnkade 5
Utrecht 3511 LC
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Women diagnosed with mBC (either synchronous or metachronous) starting with first line systematic chemo(immune)therapy for mBC. This can be preceded by endocrine treatments in the mBC setting;
Age >=18 years at diagnosis;
Ability to read and understand the Dutch, Turkish or Arabic language;
WHO PS <=1;
Access to internet via a mobile phone, tablet, laptop or computer.

Exclusion criteria

Participation in a trial with an investigational product (because more frequent and structured symptom reporting is performed in these studies);
Already participating in a treatment study that includes structured symptom reporting.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2024
Enrollment:	454
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	27-12-2024
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL87687.100.24