Towards OPtimal TIming and Method for promoting sUstained adherence to lifestyle and body weight recommendations in postmenopausal breast cancer survivors: the OPTIMUM-study.

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The OPTIMUM-study aims to gain insight into the optimal timing and method for promoting sustained adherence to lifestyle and body weight recommendations in PMBC survivors.The aim of the extra measurement during the second COVID-19 lockdown is to...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Breast neoplasms malignant and unspecified (incl nipple)
Study type	Observational invasive

Summary

ID

NL-OMON54802

Source
ToetsingOnline

Brief title
The OPTIMUM-study.

Condition

- Breast neoplasms malignant and unspecified (incl nipple)
- Breast disorders

Synonym
breast cancer; breast carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit van Tilburg
Source(s) of monetary or material Support: aanvullende subsidie biomarkers PROFIEL 2.0,KWF kankerbestrijding

Intervention

Keyword: behaviour change, breast cancer survivors, health promotion, lifestyle recommendations

Outcome measures

Primary outcome

Adherence to the recommendation not to smoke, and adherence to the WCRF lifestyle recommendations (bodyweight; physical activity; limit red and processed meat; limit sugar sweetened drinks; eat wholegrains, vegetables, fruits, and grains; limit fastfood; limit alcohol consumption), and adherence to the recommendation to sleep at least 7 hours per night. Adherence to these recommendations will be assessed by use of questionnaires, such as the *Dutch Healthy Eating Index*, and the *PASE*. The questionnaires also include items on self-reported length and body weight, and include a measuring tape to measure hip- and waist-circumference. The questionnaire also includes detailed instructions to perform a simple functional muscle strength test at home (i.e., Five Times Sit To Stand (5TSTS)).

Biological markers include markers related to inflammation (i.e., pro- and anti-inflammatory cytokines (TNFα, IL-6, IL-10, IL-1Ra, CRP), metabolism (i.e., leptin, insulin, insulin growth factor-1, glucose,HbA1C, total cholesterol,

triglycerides, HDL cholesterol, LDL cholesterol, Vitamin D), to breast cancer recurrence risk (i.e., estradiol (total estradiol, free estradiol, estrone, estrone sulfate, dehydroepiandrosterone sulfate (DHEAS), testosterone), cellular aging (leukocyte telomere length), and the kynurenine pathway (including tryptophan, kynurenine, and kynurenic acid).

By use of the accelerometer (and the Fitbit in the Fitbit validation), energy usage, metabolic equivalent (MET), physical activity intensity, sedentary and activity bouts, steps taken, total sleep time, sleep latency, wake after sleep onset, and sleep efficiency, will be assessed.

Outcome measures of the extra measurement during the second COVID-19 lockdown are physical activity level (self-reported by use of the PASE questionnaire) and sleep pattern (determined by the PSQI). In addition we will directly measure physical activity duration and intensity, total sleep time, number of wakes after sleep onset, and sleep efficiency by use of the accelerometer (ActiGraph Wgt3x).

Outcome measures of the measurement among the norm population are: adherence to the recommendation not to smoke, and adherence to the WCRF lifestyle recommendations (bodyweight; and limit alcohol consumption), and adherence to the recommendation to sleep at least 7 hours per night. Adherence to these recommendations will be assessed by use of questionnaires, such as the *Pittsburgh Sleep Quality Index*. The questionnaires also include items on

self-reported length and body weight, and include a measuring tape to measure hip- and waist-circumference. Additionally, biological markers will be determined, related to inflammation (i.e., pro- and anti-inflammatory cytokines (TNFα, IL-6, IL-10, IL-1Ra, CRP), metabolism (i.e., leptin, insulin, insulin growth factor-1, glucose,HbA1C, total cholesterol, triglycerides, HDL cholesterol, LDL cholesterol, Vitamin D), cellular aging (leukocyte telomere length), and the kynurenine pathway (including tryptophan, kynurenine, and kynurenic acid).

Secondary outcome

PMBC patients:

The questionnaire assesses *Readiness for lifestyle change* and *Need for support* using 1 item per recommendation. Additionally, also non-changeable determinants (as ethnicity, cancer stage at diagnose) and changeable determinants (as self-efficacy and post-traumatic growth) of adherence to recommendations will be assessed.

The norm population:

The questionnaire also assesses anxiety and depressive symptoms, health-related quality of life, and physical and mental fatigue. These aspects are also measured among PMBC patients (changeable determinants).

Study description

Background summary

The risk of developing postmenopausal breast cancer (PMBC) is related to physical inactivity, consumption of alcoholic drinks, weight gain, and greater body fatness (i.e., an 8-13% increased risk of PMBC per 5kg/m2 increase in body fatness). Therefore, lifestyle and body weight are suboptimal in the majority of PMBC survivors, i.e., *people who are living with a diagnosis of PMBC, including those who have recovered from the disease*. In addition, PMBC survivors have an increased risk for second primary cancers (e.g., a 2 to 5 fold increased risk for second primary breast cancer), type II diabetes mellitus, cardiovascular disease, and mortality. To decrease these risks and to increase health related quality of life, lifestyle and body weight recommendations have been issued, e.g., by the World Cancer Research Fund. However, preliminary research suggests that promotion of adherence to these recommendations is currently not well-embedded in Dutch health care for PMBC survivors.

Extra measurement during the COVID-19 lockdown.
The COVID-19 lockdown may impact physical activity level and sleep pattern of PMBC survivors. We expect that the effect of the second COVID-19 lockdown may be larger than the first lockdown with respect to the physical activity level and sleep pattern of PMBC survivors. PMBC survivors are a vulnerable group (often high age, recent surgery, recent treatment or ongoing treatment) and therefore they lived in social and physical distance since the COVID-19 outbreak. In other situations in which lifestyle habits are abruptly affected (such as change of neighborhood), like the first and second COVID-19 lockdown, individuals change their habits to an alternative physical activity routine thereby maintaining their physical activity level. However, due to the long time COVID-19 is already affecting the life of PMBC survivors, and they may start to feel depleted, it is possible that their physical activity level and sleep quality and duration decreases (e.g., due to decreased mental flexibility, fatigue, fear of being infected by COVID-19, fear of effect of COVID-19 on treatment plan).

Measurement among the norm population.
Within the OPTIMUM study, we examine whether adherence to the lifestyle and bodyweight recommendations (e.g., smoking, alcohol consumption, sleep, and healthy weight) is associated with positive patient-reported outcomes such as health-related quality of life, anxiety and depressive symptoms, and fatigue. In addition, we also examine the association between adherence to the lifestyle and bodyweight recommendations with biological markers. Furthermore, we examine the association between biological markers and patient-reported outcomes. By including a norm sample - individuals without cancer - we will be able to get more insight into these associations. It is unclear whether potential associations are specifically related to the (breast)cancer(treatment) or whether they are also present among a norm population. Cancer(treatment) could have a negative effect on certain biological mechanisms that lead to worse psychosocial and physical symptoms. By including a norm sample, we can thus examine the specific effect of cancer and its treatment on the associations

that we examine in the OPTIMUM study.

Fitbit validation.
De Fitbit activitytracker is being using by many patients and offers opportunities in future research and daily clinical practice. Specifically, while Actigraphs are expensive, Fitbits are promising for ease of use in practice, lower price and in the new generation of Fitbits the inclusion of a heart rate sensor. Moreover, Fitbits - and not Actigraphs - can be used for self-monitoring and may thus lead to behavioral changes. Assessing its validity is therefore highly relevant both for physical activity as well as for sleep.

Study objective

The OPTIMUM-study aims to gain insight into the optimal timing and method for promoting sustained adherence to lifestyle and body weight recommendations in PMBC survivors.

The aim of the extra measurement during the second COVID-19 lockdown is to gain insight into possible differences and similarities in physical activity level and sleep pattern (via self-reported and directly measured methods) in comparison to the time before initial lockdown, the time during the initial lockdown, and the time in-between both lockdowns.

Objective of the measurement among the norm population: Inclusion of this norm sample will allow us to examine the relation between adherence to lifestyle and bodyweight recommendations, psychological wellbeing, and biological markers in the context of cancer(treatment).

To validate the wrist-worn Fitbit Inspire HR against the wrist-worn research-grade Actigraph wGT3Xin a population of breast cancer survivors to measure physical activity and sleep.

Study design

We plan to perform a longitudinal observational mixed-methods study in which we include PMBC patients 4/6 months after diagnosis identified by the research nurses or case managers (dependent upon hospital). Patients will be asked to fill out questionnaires on adherence to lifestyle recommendations diet, exercise, body weight and alcohol use (as stated by the World Cancer Research Fund; www.wcrf.com), smoking behavior, and sleep. Questionnaires additionally contain items regarding, fatigue, health related quality of life, symptoms of depression and anxiety, posttraumatic growth, self-compassion, and emotion regulation. Repeated measures will take place at 4/6 months after diagnosis (wave 1), 1 year after diagnosis of breast cancer (wave 2) and at 2 years after diagnosis (wave 3). The baseline measurement, directly before diagnosis and before treatment will take place retrospectively at wave 1, at 4/6 months after

diagnosis. Furthermore, we hypothesize that adherence to lifestyle recommendations will result in biological changes, such as reduced inflammation, optimized metabolism, and reduced cellular ageing. Therefore, patients will be asked to donate blood. Patients will be asked to donate a blood sample twice, at wave 2 and wave 3 (2x 10ml, 10min). The blood draws will take place at the treating hospital. Furthermore, in half (selected by lot) of the hospitals , patients are asked wear an accelerometer for 7 days and in the other half of the hospitals patients are asked to fill out a digital food diary for 3 days. The accelerometer will provide objective information concerning the exercise- and sleeping pattern. The food diary will provide detailed information regarding nutritional intake. Based on individual answers on the questionnaires at wave 2 and wave 3, participants will be asked to take part in an in-depth interview (approximately 40 patients) or focus group (approximately 30 patients). We will invite patients with a large variety in characteristics to obtain a complete and representative view of experiences, thoughts and opinions of patients regarding optimal lifestyle care. Additionally, interviews will be held with oncology health professionals and other relevant stakeholders to determine facilitators and barriers for incorporating lifestyle care in clinical care.

97 participants of the OPTIMUM-study will be invited to participate in the extra measurement during the second COVID-19 lockdown. Specifically, 30 participants who wore the accelerometer before the COVID-19 crisis, 32 participants who wore the accelerometer during the initial COVID-19 lockdown, and 35 participants who wore the accelerometer in-between both lockdowns. They will all receive a telephone call with an explanation of the extra measurement. If they agree to participate in this extra measurement they will receive an information package via mail containing an information letter, an informed consent form, a short questionnaire (self-reported physical activity (PASE) and sleep (PSQI)), the accelerometer, and a pre-stamped return envelope.

Additionally, a norm population - that is those not diagnosed with cancer - will be included to function as a normative sample. The norm population will fill out a set of questionnaires to assess adherence to four of the lifestyle and bodyweight recommendations (i.e. Body Mass Index, sleep, alcohol consumption, and smoking), and psychological wellbeing (i.e. health-related quality of life, symptoms of anxiety and depression, and fatigue) at one point in time. Moreover, they will be asked to donate a blood sample (2x 10 ml) at a hospital near their home. Inclusion of this norm sample will allow us to examine the relation between adherence to lifestyle and bodyweight recommendations, psychological wellbeing, and biological markers in the context of cancer(treatment).

A random selection of 80 OPTIMUM study patients will be asked to wear the Fitbit Inspire HR and the Actigraph during one week, and to complete a short questionnaire including the PASE to assess physical activity and the PSQI to

assess sleep. We expect 50 patients to participate.

Study burden and risks

We expect no risk for patients due participating in this study. At three time-points patients will be asked to fill out questionnaires, determine their hip- waist-circumference, perform a simple functional muscle strength test, and at two time points patients will be asked to draw blood. The blood draw will take place in the treating hospital in the morning in fasted state. At wave 2 and wave 3, participants will take part in an in-depth interview (approximately 40 participants), a focus group (approximately 30 participants), half of them will wear an accelerometer for 7 days, and half of them will complete a digital food diary for 3 days.

The risk and burden of the extra measurement during the second COVID-19 lockdown is low. Participants fill in a short questionnaire (maximum of 10 minutes) and will wear the accelerometer for 7 days. The accelerometer is worn like a watch and does not affect daily activities (experience by previous participants).

We expect no risk for the norm population due to participating in this study. They will be asked to fill out a questionnaire, determine their hip-waist-circumference, and to draw blood at one time point.

The risk and burden of the validation is low. Participants fill in a short questionnaire (maximum of 10 minutes) and will wear the accelerometer+Fitbit for 7 days. The accelerometer and Fitbit are worn like a watch and do not affect daily activities (experience by previous participants).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

For PMBC patients:
- Diagnosed with breast cancer
- Postmenopausal (not having menstruated for at least 1 year)

For the norm population:
- Aged 18 years or older
- Living near one of the OPTIMUM-hospitals for blood draw

Exclusion criteria

For PMBC patients:
- Patients with cognitive impairment will not be included because of expected difficulties in completing these questionnaires without assistance.
- Patients who are not able to read or write Dutch will be exlcuded, as they are not able to complete the Dutch questionnaire.

For the norm population:
- Having cognitive impairments which would interfere with completing the questionnaire without assistance (already not included in the LISS panel)
- Not being able to read or write Dutch (already not included in the LISS panel)
- Ever being diagnosed with a carcinoma, except for basal cell carcinoma of the skin
- Another household member is already invited to this study

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-03-2019
Enrollment:	1437
Type:	Actual

Ethics review

Approved WMO Date:	29-11-2018
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	14-01-2019
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	16-09-2019
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	21-12-2020
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	02-08-2021

Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	14-06-2022
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	13-07-2022
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	21-04-2023
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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	NL66913.028.18