Optimizing accelerometer data analysis to assess physical activity and sedentary behavior among breast cancer survivors: a laboratory study

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1. To validate accelerometer cut-points to asses physical activity and sedentary behavior of breast cancer survivors. 2. To investigate the validity of accelerometers, inclinometers, heart rate and oxygen consumption to assess time spent in...

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

Summary

ID

NL-OMON43591

Source
ToetsingOnline

Brief title
METRIC 2.0 validation study

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
Breast cancer, mammacarcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: Zuidas Run;Dutch Cancer Society

Intervention

Keyword: Accelerometers, Cancer, Physical activity, Sedentary behavior

Outcome measures

Primary outcome

Oxygen consumption during different activities

Secondary outcome

ActiTrainer accelerometer data

ActivPAL inclinometer data

Heart rate

Study description

Background summary

Survival after cancer has substantially improved due to advances in early detection and treatment. In the Netherlands, 14.631 patients were diagnosed with breast cancer in 2014 and the current 5-year survival rate of patients diagnosed with breast cancer is 87%.

Currently, (neo-) adjuvant systemic therapy is one of the standard cancer treatments. (Neo-) adjuvant systemic therapy includes chemotherapy, hormonal therapy or a combined treatment of both types of therapy, and aims to delay or even prevent relapses and death. Although great improvements in disease free and overall survival rates are achieved after (neo-) adjuvant systemic therapy, cancer survivors (defined as patients following first diagnosis, until the end of life) often experience negative side effects of cancer and cancer treatment, with fatigue and a decrease in Quality of Life (QoL) as the most common and distressing symptoms.

Physical activity during and after cancer treatment has beneficial effects on a number of physical and psychosocial outcomes. Several reviews and meta-analyses demonstrate beneficial effects of physical activity (PA) and exercise (i.e. form of PA that is planned, structured and repetitive and aims to improve fitness, performance or health) in cancer survivors during and after treatment

on physical and psychosocial outcomes, including increased aerobic fitness, reduced fatigue and depression, and improved health-related quality of life (HRQoL). Observational studies showed higher levels of moderate-to-vigorous PA to be associated with lower mortality risk in survivors of breast, colon, and prostate cancer.

Physical activity guidelines for cancer survivors suggest that physical activity should be an integral and continuous part of care for all cancer survivors. In 2010, the American College of Sports Medicine (ACSM) organized a roundtable and formulated exercise guidelines for cancer survivors. The ACSM recommends avoiding inactivity and being as physically active as abilities and conditions allow. If possible, adult cancer survivors are recommended to engage in at least 150 minutes per week of moderate intensity or 75 min per week of vigorous intensity aerobic physical activity or an equivalent combination of moderate and vigorous intensity aerobic physical activity, for at least 10 min per session. In addition, muscle-strengthening activities involving all major muscle groups are recommended at least 2 days per week. The ACSM acknowledges that some activity is better than nothing and exceeding the guideline is likely to provide additional health benefits. At present, the guidelines are rather generic and resemble the age-appropriate physical activity guidelines for the general population.

Physical activity levels of cancer survivors are lower than in the general population, and they tend to decline during cancer treatment and remain lower for years after cancer treatment. In addition, breast cancer survivors are more sedentary and participate in less low intensity physical activity than matched non-cancer controls. Sedentary behavior is characterized by a low energy expenditure (i.e. * 1.5 metabolic equivalent multiple of rest (METs)). Similar to findings in the general population, excessive sedentary behavior, as distinct from insufficient physical activity, may be linked to negative health effects. Recent experimental studies have indicated the importance of breaking up prolonged sedentary time for improving health. Thus far, studies on the pattern in which both sedentary behavior and physical activity is accumulated and the effects of such patterns on health outcomes (e.g. fatigue and HRQoL) are lacking in cancer survivors. Objective measurement of both physical activity and sedentary behavior are obtained using accelerometers. Following data reduction procedures (e.g. non-wear time, valid day definition), time spent in sedentary, light, moderate or vigorous physical activity behavior are subsequently assessed by applying cut-points. As these cut-points are validated in the general population, which generally have a higher fitness level, they may not be appropriate for cancer survivors. Therefore, alternative cut-points or innovative predictions of accelerometer-based physical activity and sedentary behavior may be required to capture the pattern of both physical activity and sedentary behaviour in cancer patients. This information can be used to better tailor exercise prescriptions to patients which may lead to faster physical recovery and an increase in quality of life.

Study objective

1. To validate accelerometer cut-points to asses physical activity and sedentary behavior of breast cancer survivors.
2. To investigate the validity of accelerometers, inclinometers, heart rate and oxygen consumption to assess time spent in sedentary behavior and light, moderate-to vigorous intensity physical activity of breast cancer survivors.

Study design

Cardiorespiratory fitness will be measured during a maximal exercise test at a cycle ergometer. The patient will be asked to cycle on a cycle ergometer according to a ramp protocol which is tailored to the individual. The protocol aims at achieving peak oxygen consumption (PeakVO2) within 8-12 minutes. In addition, the following activities will be performed in random order for 6 minutes each, with resting intervals of 2 minutes in between:

1. Lying supine.
2. Sitting naturally in a lounge chair while watching TV.
3. Sitting in a chair behind a desk using a computer.
4. Standing upright while reading a newspaper.
5. Cycling on a cycle ergometer (i.e. 8.9 km/hr).
6. Cycling on a cycle ergometer (i.e. 15.1 km/hr.
7. Walking on a treadmill (i.e. 3.2 km/hr).
8. Walking on a treadmill (i.e. 4.8 km/hr).
9. Walking on a treadmill (i.e. 6.4 km/hr).
10. Stair climbing at a comfortable speed.

A heart rate monitor (Polar; RS800XC) will be used to monitor a participant*s heart rate during the activities. Participant*s heart rate will be used to estimate energy expenditure during the activities. Furthermore, oxygen consumption will be measured continuously (breath-by-breath) using an (mobile) oxycon. Metabolic equivalents (METs) will be calculated for every activity by dividing the average oxygen consumption during the different activities by the resting metabolic rate (determined when the patient is lying supine). In addition, participants will wear ActiTrainer accelerometers (tri-axial, 51 gram; 86x33x15mm) at their right hip and wrist. ActiTrainer accelerometers collect data on the amount and frequency of sedentary behaviour and ambulatory activities. This device provides information on activity counts, vector magnitude, steps taken and subject position and has a sample rate up to 100Hz. An ActivPAL inclinometer (15 gram; 53x35x7mm) is worn on their right thigh. ActivPAL is a single-site instrument to quantify free-living sedentary and ambulatory activities. Using this device, the pattern of sedentary and ambulatory activities and the intensity of the participants activities can be captured and analysed. This device gives an accurate measurement of dynamic

acceleration and inclination.

Study burden and risks

Minimal risks are associated with the maximal exercise test. In the general population, serious adverse events requiring hospitalization have been reported in <1 to 5 times per 10000 tests.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

Female patients with histological confirmed primary breast cancer (with or without positive lymph nodes) stage I/II/III. aged > 18- 70 years, 2-4 months after completion of (neo-

)adjuvant chemotherapy.
Patients who receive (neo-) adjuvant chemotherapy for breast cancer are patients who are diagnosed with positive lymph nodes, or patients without positive lymph nodes but 1. aged <35 years (unless tumor <1 cm), 2. aged > 35 years (tumor 1.1 > cm) or 3. a Her2 positive tumor.

Exclusion criteria

Male patients will be excluded from this study. Furthermore, patients who are not able to perform basic activities such as walking or biking, who show cognitive disorders or severe emotional instability, who are suffering from other disabling co-morbidity that might hamper physical exercise (e.g. heart failure, chronic obstructive pulmonary disease (COPD), orthopaedic conditions and neurological disorders), and patients who are unable to understand and read the Dutch language will be excluded from the study

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-12-2016
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	04-08-2016
Application type:	First submission

Review commission: METC Amsterdam UMC

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	NL55544.029.16