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Testing Curves as a physical activity program for breast cancer survivors

Submission date
25/09/2017

Recruitment status
No longer recruiting

Registration date
18/10/2017

Overall study status
Completed

Last Edited
25/11/2020

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Breast cancer is the most common cancer diagnosis among Canadian women. With 5-year survival rates approaching 90%, there are many women who are living with the long-term effects of breast cancer diagnosis and treatment. Identifying practical ways of reducing the acute and longer-term health burden of breast cancer is a public health priority. Increasing physical activity may be a cost-effective, feasible, safe, and effective way of helping women to manage the aftermath of breast cancer. The aim of this study was to compare Curves™ and a lifestyle physical activity (PA) intervention on improving PA levels among breast cancer survivors (BCS) over 12 weeks. The lifestyle PA strategy was evidence-based using simple strategies such as providing PA information, guidelines and a pedometer (step counter) for increasing PA behavior. Compared to structured exercise programs, lifestyle interventions have led to similar fitness gains and adherence and have previously demonstrated positive health benefits among BCS. This evidence suggests that it may be feasible and efficient to target lifestyle strategies among BCS.

Who can participate?
Women over the age of 18 who are breast cancer survivors, understand English or French, and have been patients at the McGill University Health Centre Cedars Breast Clinic

What does the study involve?
Participants are asked join one of two groups that a researcher chooses. They either attend Curves gyms as much as possible or are given educational materials and tools about physical activity. Participants wear a pedometer for the study (12 weeks total) during the day. Questionnaires are completed at weeks 1, 6 and 12.

What are the possible benefits and risks of participating?
Participants may or may not directly benefit from taking part in this study. With exercise, some benefits may include increases in strength, increases in skills, and improvements in fitness and endurance. Also, information from this study may benefit other women who have been treated for breast cancer by increasing knowledge and helping to understand what type of physical activity program is helpful to improve health and wellbeing after a breast cancer diagnosis. As with any study, there are risks that are not known. The risks of experiencing any problems during

exercise are minimal. The amount of exercise is well within the recommendation from the American Heart Association for 5 to 6 hours a week of moderate-intensity activity. Participants might feel some discomfort while exercising and if this persists after stopping the exercise they are asked to call the research team and are provided you with advice or are seen at the hospital. Sweating and a faster heart beat are likely to occur during exercise. There is also a possibility that participants may experience some emotional problems while completing the questionnaires. If this occurs, they should inform the study doctor and appropriate measures are taken to ensure that they receive appropriate care. Participants are also under no obligation to answer every question in the questionnaire.

Where is the study run from?
The study is run from the McGill University Health Centre Cedars Breast Clinic (Canada) and takes place in the surrounding community, wherever there are Curves locations.

When is the study starting and how long is it expected to run for?
August 2010 to July 2013

Who is funding the study?
The Cedar's Breast Center Fundraising initiative and the Fonds de Recherche du Québec - Santé (Canada)

Who is the main contact?
Dr Catherine Sabiston

Contact information

Type(s)
Scientific

Contact name
Dr Catherine Sabiston

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

288817

Study information

Scientific Title
A mixed-methods evaluation of a community physical activity program for breast cancer survivors

Study objectives
It was hypothesized that breast cancer survivors enrolled in the Curves program would report increased physical activity levels (both self-report and objectively measured) post-intervention compared to breast cancer survivors enrolled the lifestyle-education program.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. The Health Sciences Research Ethics Board at the University of Toronto, 13/09/2010, ref: REB# 29262
2. McGill University Health Centre Ethics Board, ref: REB# GEN-10-022

Study design
Single-center mixed-methods quasi-experimental (partial random allocation to intervention and control arms) qualitative interviews and cross-sectional post-intervention survey

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Breast cancer survivors

Interventions
At the time of baseline data collection, five women had not yet started Curves and the remaining nine had begun training at Curves. These participants composed the intervention group and were not randomized.

For identification of the lifestyle group (attention control group), this study used a randomized-controlled trial design, where a blinded researcher used a random number generator to allocate eligible participants to either a free Curves membership (not included in the trial) or lifestyle education group.

Women were asked to attend Curves™ as much as the program guidelines recommend (e.g., 3 to 5 days per week) to ensure ecological validity. At the time of this study, Curves™ memberships were estimated at a cost of $420 per year, per person, but were offered at a reduced rate given a collaboration with the hospital fundraising team responsible for providing the funding for the provision of the memberships. Guidelines and materials were free, and pedometers cost the research team $12 per person.

Participants in the LET group were given all lifestyle intervention materials without Curves™ membership (i.e., guidelines, information, and a pedometer). Women in the LET group were asked to follow the recommendations outlined in the educational and guideline materials, which included striving towards 150 minutes of moderate-to-vigorous PA per week.

All participants completed self-report measures at baseline, were given these materials (Curves™ memberships had already been distributed), and then completed measures at 6 weeks and 12 weeks post-baseline (i.e., intervention completion).

Intervention Type
Behavioural

Primary outcome measure
Women self-reported physical activity, measured using Short Questionnaire to Assess Health-Enhancing Physical Activity (SQUASH). Women were also given a pedometer (StepsCount, Ontario, Canada) to wear each day from time awakening until bedtime except for during water activities and showering/bathing. A logbook was also provided to keep track of daily steps. Average number of steps per week was computed. Data were collected for both measures (total SQUASH scores and average steps per week) at week 1 (baseline), week 6 and week 12

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/08/2010

Completion date
25/07/2013

Eligibility

Key inclusion criteria
1. Patients at the MUHC Cedars Breast Clinic
2. Over 18 years of age
3. Could provide written informed consent
4. Had completed all surgical, systemic and radiation treatments with the exception of hormone blockade treatment
5. Able to understand English or French
6. Not already participating in a PA research study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
30

Total final enrolment
30

Key exclusion criteria
1. Not patients at the McGill University Health Centre Cedars Breast Clinic
2. Not adults
3. Could not offer consent
4. Had not completed treatments (excludes hormonal treatments)
5. Not able to understand English or French
6. Already participating in another physical activity research study

Date of first enrolment
01/09/2010

Date of final enrolment
29/06/2012

Locations

Countries of recruitment
Canada

Study participating centre
McGill University Health Centre Cedars Breast Clinic
Montreal
Canada
H3A 0G4

Sponsor information

Organisation
McGill University Health Center

Sponsor details
1001 Decarie Boulevard
Montreal
Canada
H4A3J1

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04cpxjv19

Funder(s)

Funder type
Government

Funder Name
Fonds de recherche du Québec – Santé

Results and Publications

Publication and dissemination plan
Results will be presented at a conference and published in BMC Cancer or similar journal. The additional files/documents can be made available by contacting the corresponding author (Dr Catherine Sabiston).

Intention to publish date
01/12/2017

Individual participant data (IPD) sharing plan
Please contact Dr Catherine Sabiston for access to the dataset. Individual participant data have been de-identified and will be made available immediately following publication of the article for five years. Researchers who request the data and who provide a methodologically sound proposal will be given permission to use the data for analyses that achieve the aims in the approved proposal. Participants in this study have offered consent to participating in the study with the aims specified in this protocol. For research that aligns with the aims of the protocol, proposals should be directed to Dr Catherine Sabiston. To gain access, data requestors will need to sign a data access agreement.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	19/06/2019	25/11/2020	Yes	No