ISRCTN11333136 https://doi.org/10.1186/ISRCTN11333136

Efficacy of neurocognitive training as an intervention for helping breast cancer survivors improve and sustain their work ability

Submission date
10/01/2019

Recruitment status
No longer recruiting

Registration date
14/01/2019

Overall study status
Completed

Last Edited
06/01/2022

Condition category
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English Summary

Background and study aims
Breast cancer is the most common cancer amongst women in the UK with over 55,000 new cases each year. Recent figures have revealed that diagnoses are increasingly being given to younger women who are of a working age (< 55 years old). Whilst ongoing improvements in cancer treatments have led to increased long-term survival rates there are also emotional issues such as anxiety and depression as well as changes in thinking skills such as difficulties with memory, attention/concentration, and planning skills. Research has shown that for some women these changes in thinking skills can persist for many years after the completion of treatment and impact their everyday life, including their ability to work. The aim of this study is to explore whether online training can help breast cancer survivors stay in work over time by improving their work ability.

Who can participate?
Breast cancer survivors between the age of 18 and 65 years old diagnosed with primary breast cancer, 6-months to 60-months after receiving active treatment, for example, chemotherapy and /or radiotherapy, attending some form of paid work at the time of recruitment, and experiencing a decline in their cognitive function ('thinking skills') which is directly reducing their work ability.
(Updated 20/05/2019, previously: Breast cancer survivors between the age of 18 and 50 years old diagnosed with primary breast cancer, 12 to 36 months after receiving active treatment, for example, chemotherapy and/or radiotherapy, attending some form of paid work at the time of recruitment, and experiencing a decline in their cognitive function ('thinking skills') which is directly reducing their work ability.)

What does this study involve?
Participants are randomly allocated to 12 sessions of either computerised neurocognitive training (intervention group) or control training. Each session lasts about 30 minutes and participants are asked to complete the sessions consecutively over a two-week period. The intervention group receive adaptive training in which the level of difficulty changes across the blocks of trials depending on their performance. Whilst the control group receive non-adaptive

training with a fixed level of difficulty across all trials. At the start of the study (pre-intervention), after the intervention, 6-month follow-up, and 1-year follow-up all participants complete a series of questionnaires regarding their perceived cognitive function, emotional well-being, quality of life and work-related ability. At baseline and post-intervention participants are also asked to attend the MERLiN laboratory to complete two computerised working memory tasks and undergo electroencephalogram (EEG) testing. A smaller sub-group of 20 participants from each group is consecutively approached to participate in a telephone interview at the start of the study (pre-intervention), and 1 month, 6 months and 1 year after the training. During the telephone interview all participants are asked questions regarding various aspects of their diagnosis and treatment, thinking skills ('cognitive function'), emotional well-being, quality of life, work ability and coping and management methods. In addition, the neurocognitive training group are also asked at the start of the study about their expectations of the intervention and at the follow-up sessions about the effectiveness of the intervention. The aim of the interview is to develop a greater understanding of the cognitive difficulties experienced by breast cancer survivors and the impact that these difficulties have on their emotional well-being, quality of life and work ability. Equally, the interview aims to explore the effectiveness of the neurocognitive training as an intervention for helping breast cancer survivors improve and sustain work ability.

What are the possible benefits and risks of participating?
Women participating in this study will be given the opportunity to receive a neurocognitive intervention (computerised active adaptive training) that is not currently available through healthcare or occupational services. In addition, participants will receive a single payment of £120 on completion of the final session or at the point of withdrawal. There are no known risks associated with the present study.

Where is this study run from?
Birkbeck College, University of London (UK)

When is the study starting and how long is it expected to run for?
October 2018 to July 2021

Who is funding the study?
Economic and Social Research Council (ESRC) (UK)

Who is the main contact?
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Contact information

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Public

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
A randomised control trial to examine the efficacy of neurocognitive training as an intervention for helping breast cancer survivors improve and sustain their work ability by targeting impaired cognitive function

Acronym
BRiC@Work

Study hypothesis
1. Women who receive the neurocognitive intervention will experience greater levels of improvement in their cognitive function, emotional wellbeing and quality of life compared with the control group immediately, 6 months and 1-year after the intervention.
2. Women who receive the neurocognitive intervention will report a greater improvement in

their work ability at the 6-month and 1-year follow-up compared with the control group.
3. Women in the neurocognitive intervention group will show better cognitive functioning at behavioural as well as neural measures compared to the control group at the immediate post-training interval, 6-month follow-up and 1-year follow-up.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Department of Psychological Science Research Ethics Committee at Birkbeck College, University of London, Malet Street, Bloomsbury, London, WC1E 7HX, Email: ethics@psychology.bbk.ac.uk, 12/12/2018, ref: 181935

Study design
Single-centre one-year interventional randomised control trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

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

Condition
Breast cancer

Interventions
Breast cancer survivors (N = 80) will be recruited through voluntary sampling using online advertisements placed on social media platforms including, Facebook and Twitter. In particular, advertisements will be presented on the Building Resilience in Breast Cancer (BRiC), MacMillan, Breast Cancer Care, and Breast Cancer Now public and private support group pages.

After registering an interest in the research participants will be screened to assess their eligibility and suitability to the study. In order to be suitable, the participant must report experiencing a decline in their cognitive function ('thinking skills') which is directly reducing their work ability.

Using sealed envelope simple randomisation software, breast cancer survivors (N= 80) will be assigned in a 1:1 ratio to participate in one of two conditions:
1. Neurocognitive training (intervention) (n =40)
2. Control training (n =40)

Women in both groups will be asked to consecutively complete the 12 sessions of computerised online training over a two-week period. Each session will last approximately 30 minutes and consist of 20 blocks of trials. For the intervention group, the difficulty of each block of trials will adapt depending on their performance, whilst the control training group will have a fixed level of difficulty across all 20 blocks.

Specifically, the women in both training groups will be asked to remember the position of a green square (presented in 3 x 3 grid) and a spoken consonant (i.e. t). They will then have to match this pair of stimuli to the stimuli shown 'n' number of trials before. For example, if n = 2 the participant would respond correct or incorrect if the current stimuli matched what was presented two trials before.

At baseline (pre-intervention), post intervention, 6-month follow-up, and 1-year follow-up all participants will be asked to complete a series of questionnaires regarding their (1) perceived cognitive function, (2) emotional well-being, (3) quality of life and (4) work-related ability. At each time-point participants will also be asked to attend the MERLiN laboratory to complete two computerised working memory tasks (OSPAN and Change Detection Task (CDT)) and undergo electroencephalogram (EEG) testing whilst completing the standard letter flanker task (Eriksen & Eriksen, 1974).

A smaller sub-group of 20 participants from each the intervention group and control group will be consecutively approached to participate in a telephone interview at baseline (pre-intervention), 1-month, 6-month, and 1-year post-training. During the telephone interview all participants will be asked questions regarding various aspects of their (1) diagnosis and treatment, (2) thinking skills ('cognitive function'), (3) emotional well-being, (4) quality of life, (5) work ability and (6) coping and management methods. In addition, the neurocognitive training group will also be asked at baseline about their expectations of the intervention and at the follow-up sessions about the effectiveness of the intervention. The Framework method will be used to develop a series of themes across the verbatim transcripts. The aim of the interview is to develop a greater understanding of the cognitive difficulties experienced by breast cancer survivors and the impact that these difficulties have on their emotional well-being, quality of life and work ability. Equally, the interview aims to explore the effectiveness of the neurocognitive training as an intervention for helping breast cancer survivors improve and sustain work ability.

Updated 10/11/2021:
At registration it was stated that participants would be asked to attend the MERLiN laboratory to complete two computerised working memory tasks (OSPAN and Change Detection Task (CDT)) and undergo electroencephalogram (EEG) testing whilst completing the standard letter flanker task at four points including baseline, post-intervention, 6 months and 1 year, however, due to the outbreak of COVID-19 and the closure of the laboratory the researchers were only able to collect this data at baseline and post-intervention for most participants. They collected questionnaire and interview data at all four points (baseline, post-intervention, 6 months, and 1 year).

Intervention Type
Behavioural

Primary outcome measure
Objective and subjective cognitive function, assessed at four timepoints using:
1. Computerised working memory tasks (OSPAN and CDT) at baseline (pre-training), immediately post-training, 6-month follow-up and 1-year follow-up

2. Cognitive questionnaires at baseline (pre-training), immediately post-training, 6-month follow-up and 1-year follow-up:
2.1. Functional Assessment of Cancer Therapy-Cognitive Scale (FACT-Cog, version 3)
2.2. Rumination Response Scale (RRS)

Secondary outcome measures
1. Perceived emotional well-being and quality of life, assessed at four timepoints (baseline [pre-training], immediately post-training, 6-months follow-up and 1-year follow-up):
1.1. Quality of life measured by the European Organization for Research and Treatment Quality of Life (EORTC-QLQ-C30)
1.2. Anxiety symptomology measured by Hospital Anxiety and Depression Scale (HADS)
1.3. Depression symptomology measured by the center for Epidemiologic Studies Depression Scale (CES-D)
2. Perceived work ability assessed using the Work Limitations Questionnaire (WLQ) at four timepoints (baseline [pre-training], immediately post-training, 6-month follow-up and 1-year follow-up)
3. Event-related potential (ERP) markers of attentional control measured by EEG at four timepoints: baseline (pre-training), immediately post-training, 6-month follow-up and 1-year follow-up

Overall study start date
01/10/2018

Overall study end date
25/07/2021

Eligibility

Participant inclusion criteria
Current inclusion criteria as of 06/02/2019:
1. 'Must be between 6 months to 60 months since the end of their active cancer treatment (i.e. no longer receiving chemotherapy and/or radiotherapy)
2. Receiving hormone replacement therapies or target therapies (i.e. Herceptin injections)
3. Clinical diagnosis of primary breast cancer
4. Aged between 18 years old and 65 years old
5. Attending paid work at the time of recruitment (note, there is no limit to the number of hours but the work must be considered regular)
6. Experiencing a decline in their work ability as a direct result of cognitive difficulties

Previous inclusion criteria as of 05/02/2019:
1. 'Must be between 12 months to 60 months since the end of their active cancer treatment (i.e. no longer receiving chemotherapy and/or radiotherapy)
2. Receiving hormone replacement therapies or target therapies (i.e. Herceptin injections)
3. Clinical diagnosis of primary breast cancer
4. Aged between 18 years old and 65 years old
5. Attending paid work at the time of recruitment (note, there is no limit to the number of hours but the work must be considered regular)
6. Experiencing a decline in their work ability as a direct result of cognitive difficulties

Previous inclusion criteria:
Breast cancer survivors:

1. Must be between 12 months to 36 months since the end of their active cancer treatment (i.e. no longer receiving chemotherapy and/or radiotherapy)
2. Receiving hormone replacement therapies or target therapies (i.e. Herceptin injections)
3. Clinical diagnosis of primary breast cancer
4. Aged between 18 years old and 50 years old
5. Attending paid work at the time of recruitment (note, there is no limit to the number of hours but the work must be considered regular)
6. Experiencing a decline in their work ability as a direct result of cognitive difficulties

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
N = 80 (Intervention n =40; Control n =40)

Total final enrolment
80

Participant exclusion criteria
Current exclusion criteria as of 20/05/2019:
Breast Cancer survivors:
1. Receiving active cancer treatments including, chemotherapy and/or radiotherapy
2. Under 6-months since the completion of active treatment for both chemotherapy and/or radiotherapy
3. Clinical diagnosis of secondary or metastatic breast cancer
4. Over the age of 65 years old at the time of recruitment
5. Not attending paid work at the time of recruitment
6. Not experiencing any changes or difficulties in their work ability associated with cognitive impairment(s)
7. Unable to read or understand English

Previous exclusion criteria:
Breast cancer survivors:
1. Receiving active cancer treatments including, chemotherapy and/or radiotherapy
2. Under 12 months since the completion of active treatment for both chemotherapy and/or radiotherapy
3. Clinical diagnosis of secondary or metastatic breast cancer
4. Over the age of 50 years old at the time of recruitment
5. Not attending paid work at the time of recruitment
6. Not experiencing any changes or difficulties in their work ability associated with cognitive impairment(s)
7. Unable to read or understand English

Recruitment start date
01/02/2019

Recruitment end date
29/02/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Birkbeck College, University of London
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Sponsor information

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Birkbeck College, University of London

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Sponsor type
University/education

Website
http://www.bbk.ac.uk/departments/psychology/

ROR
https://ror.org/02mb95055

Funder(s)

Funder type
Research council

Funder Name
Economic and Social Research Council

Alternative Name(s)
ESRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high impact peer-reviewed journal with an intended publication of the trial by September 2022. No additional documents will be made available.

Intention to publish date
01/09/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to an ethics agreement.

IPD sharing plan summary
Not expected to be made available