ISRCTN96294982 https://doi.org/10.1186/ISRCTN96294982

Testing of the eHealth Pain Education after CANcer (PECAN) program for breast cancer survivors with persistent pain

Submission date
24/09/2021

Recruitment status
No longer recruiting

Registration date
01/10/2021

Overall study status
Completed

Last Edited
09/11/2023

Condition category
Signs and Symptoms

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

Plain English summary of protocol

Background and study aims
Both in research and in clinical practice, interest in pain science educational interventions for the treatment of persistent pain after breast cancer treatment has increased significantly over the past decades. Modern Pain Science Education (PSE) explains the mechanisms of (chronic) pain, the nervous system's ability to modulate and perpetuate the pain experience, and highlights the influence of other factors (such as sleep, thoughts, feelings, and culture) on pain. Despite emerging evidence, some important issues should be addressed about current methods of delivery of PSE. First, the provision of individual face-to-face sessions requires considerable resources and may be prohibitive to participation if breast cancer survivors have limited means, mobility, motivation/courage, or access to such services. Second, given the complex nature of persistent pain after breast cancer treatment, a personalized approach is warranted. Therefore, more blended educational approaches and eHealth modalities with individualized information might be more suitable for this specific population.
Using a digital approach for delivering PSE is a new, innovative, and meanwhile challenging cancer rehabilitation. With the Pain Education after Cancer (PECAN) eHealth program, a personalized PSE intervention was developed and barriers for pain self-management are removed. Also, the PECAN eHealth will provide the necessary information specified to the needs of the cancer survivors by using an algorithm, instead of leaving survivors prone to Dr. Google where they drown in non-individualized information, often providing a very biomedical and threatening message. Before testing the PECAN eHealth program on its effectiveness in a large clinical trial, two research questions need to be answered:
1) What is the acceptability, comprehensibility, and satisfaction with the PECAN eHealth program?; and 2) What is the efficacy of the PECAN eHealth program in a small group of breast cancer survivors with persistent pain after finishing primary cancer treatments?

To answer the first research question, acceptability, comprehensibility, and satisfaction were measured quantitatively with a self-constructed questionnaire and described quantitatively using focus groups. Research question two was investigated quantitatively by a set of self-reported outcome measures.

Who can participate?
Female patients aged over 18 years with a history of surgery for breast cancer followed by persistent pain.

What does the study involve?
After a baseline assessment, participants will go through the PECAN eHealth program in the next 6 weeks at their own pace. After 6 weeks and 3 months two follow-up assessments are scheduled.

What are the possible benefits and risks of participating?
As this intervention is under investigation, no benefits can be guaranteed. There is no risk associated with the intervention.

Where is the study run from?
University of Antwerp (Belgium)

When is the study starting and how long is it expected to run for?
September 2020 to December 2021

Who is funding the study?
University of Antwerp (Belgium)

Who is the main contact?
Prof. An de Groef, an.degroef@uantwerpen.be

Contact information

Type(s)
Scientific

Contact name
Prof An De Groef

ORCID ID
https://orcid.org/0000-0001-6771-2836

Contact details
Campus Drie Eiken, Universiteit Antwerpen
Universiteitsplein 1
Wilrijk
Belgium
2610
+32 (0)16376668
an.degroef@uantwerpen.be

Additional identifiers

Protocol serial number
PS ID: 41776

Study information

Scientific Title
Feasibility and pilot testing of the eHealth Pain Education after CANcer (PECAN) program for breast cancer survivors with persistent pain: a mixed-method study

Acronym
PECAN pilot study

Study objectives
1. What is the acceptability, comprehensibility, and satisfaction with the PECAN eHealth program?
2. What is the efficacy of the PECAN eHealth program in a small group of breast cancer survivors with persistent pain after finishing primary cancer treatments?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/12/2020, University Hospital of Antwerp and the University of Antwerp (Universiteitsplein 1, 2610 Wilrijk, Belgium; +32 3 821 30 00; EthischComite@uza.be), ref: 001432

Primary study design
Interventional

Study design
Mixed-method pilot cohort study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Breast cancer survivors with persistent pain

Interventions
After signing informed consent, a baseline assessment (T0) was performed. All outcome measures were self-reported and questioned online. After completing the baseline assessment, participants received to access the PECAN eHealth program. The eHealth program consists of 22 sessions of 3-5 minutes. Based on targeted questions (by means of an underlying decision-tree-based algorithm), automated and personalised information is given about the pain mechanisms and pain self-management tips. The goal is to go through all information (+3 hours) over a period of max. 6 weeks at their own pace. At 6 weeks post-baseline (T1), an automated invite was sent to complete 1) the same questionnaires on the self-reported outcome measures and 2) the self-constructed questionnaire to evaluate the acceptability, comprehensibility, and satisfaction of the PECAN eHealth program. At T1, participants were invited to participate within one of the two focus groups. Three months post-baseline (T2) an automated email was sent again to complete the questionnaire one more time.

Intervention Type
Behavioural

Primary outcome(s)
1. Acceptability, comprehensibility, and satisfaction were measured quantitatively with a self-constructed questionnaire and described qualitatively using focus groups at 6 weeks (T1)
2. Pain Disability Index for pain-related disability at baseline (T0), after 6 weeks (T1) and 3 months (T2)

Key secondary outcome(s)
1. Pain symptoms and characteristics measured using the Numeric Rating Scale for pain intensity, the Brief pain inventory (pain severity and pain interference) , the Self-administered Leeds Assessment of Neuropathic Symptoms and Signs and the Central Sensitisation Inventory
2. Physical function measured using the PROMIS physical function short form
3. Emotional functioning measure using the Pain Catastrophizing Scale, the Depression Anxiety Stress scales 21, the Bodily Threat Monitoring Scale and the McGill Quality of Life Questionnaire
4. Self-efficacy measures using the Pain self-efficacy questionnaire
All self-reported outcome measures were collected at baseline (T0), after 6 weeks (T1) and 3 months (T2) to estimate the change form baseline.

Completion date
01/12/2021

Eligibility

Key inclusion criteria
1. History of unilateral axillary lymph node dissection or sentinel node biopsy; mastectomy (with or without autologous reconstruction) or wide excision of the tumour for primary unilateral breast cancer
2. Chemotherapy and radiotherapy finished; hormone and/or immunotherapy finished or ongoing
3. Age >18 years
4. Native Dutch speaking
5. Pain NRS a minimum of 3/10 during the past week

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Female

Total final enrolment
29

Key exclusion criteria
1. Adolescents
2. Breast cancer patients were surgery/chemotherpy/radiotherapy are still ungoing
3. NRS below 3/10 during the past week
4. No native Dutch speaker

Date of first enrolment
14/01/2021

Date of final enrolment
10/06/2021

Locations

Countries of recruitment
Belgium

Study participating centre
University Hospital of Antwerp
Drie Eikenstraat 655
Edegem
Belgium
2650

Sponsor information

Organisation
University of Antwerp

ROR
https://ror.org/008x57b05

Funder(s)

Funder type
University/education

Funder Name
Universiteit Antwerpen

Alternative Name(s)
University of Antwerp, UAntwerp, Universiteit van Antwerpen, Uantwerpen

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Belgium

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. an.degroef@uantwerpen.be

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		16/01/2023	09/11/2023	Yes	No