QLIPP-CIPN: Effectiveness of online Acceptance and Commitment Therapy for pain interference in cancer survivors with chronic painful chemotherapy-induced neuropathy (CIPN)

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Ethical review	Approved WMO
Status	Completed
Health condition type	Peripheral neuropathies
Study type	Interventional

Summary

ID

NL-OMON54077

Source
ToetsingOnline

Brief title
Effectiveness of online ACT for cancer survivors with chronic painful CIPN

Condition

- Peripheral neuropathies

Synonym
chemotherapy-induced peripheral neuropathy, neuropathy

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit van Tilburg
Source(s) of monetary or material Support: KWF

Intervention

Keyword: Acceptance and Commitment Therapy, chemotherapy-induced peripheral neuropathy, online intervention, pain interference

Outcome measures

Primary outcome

Pain interference in daily life: Multidimensional Pain Inventory (MPI) -

subscale Interference.

Secondary outcome

Pain intensity: 11-point Numeric Rating Scale (NRS), Psychological distress:

Hospital Anxiety and Depression Scale (HADS), Quality of life: EORTC QLQ-C30,

CIPN symptom severity: EORTC QLQ - CIPN20 , Psychological flexibility:

Psychological Inflexibility in Pain Scale (PIPS), Freiburg Mindfulness

Inventory (FMI-NL), Values-based Living: Engaged Living Scale (ELS), Pain

Catastrophizing: Pain Catastrophizing Scale (PCS).

Study description

Background summary

An average of 30% of adult cancer survivors suffers from chemotherapy-induced peripheral neuropathy (CIPN) >= 6 months after completion of chemotherapy, and their quality of life (QoL) is strongly affected due to these symptoms.
Treatment options are limited.

Study objective

The goal of this study is to examine the effectiveness of an online

psychological intervention based on Acceptance and Commitment Therapy (ACT) in a Randomized Controlled Trial (RCT) and compared to a treatment-as-usual control condition (TAU). We aim to improve pain interference in cancer survivors with persistent chronic painful CIPN (present for at least 3 months) in the curative disease phase who were treated with chemotherapy treatment at least 6 months ago (irrespective of disease site).

Study design

It concerns a test of effectiveness of the ACT intervention in an RCT on quality of life. In total, 146 participants will be randomly allocated to one of two groups: the online ACT intervention with therapist email guidance or a control condition that receives treatment-as-usual. Patients in the control condition can follow the online ACT intervention directly after the 3 month-follow up measurement. Self-reported questionnaires will be conducted at baseline, after the intervention, and at 3- and 6-month follow-up. Additionally, interviews will be executed afterwards to explore intervention effects more in-depth. Participants will be sampled via various patient organizations, oncologists, and advertisements distributed via the PROFILES-registry that contains ongoing research projects on CIPN. Data will be collected online via the PROFILES-registry.

Intervention

An online ACT intervention was developed in the first phase of the QLIPP-CIPN study. In this study phase insights into daily limitations and quality of life of the patient population were gained, which served as the basis of the patient-centered development of the online ACT intervention following the CeHRes roadmap for participatory eHealth design. The intervention includes an 8-week self-management course containing 6 modules regarding psycho-education and ACT- processes . By means of text and exercises people learn to carry out value-oriented goals in daily life with pain. To do this, they learn new ways of coping with pain, including reducing pain avoidance and increasing pain acceptance. Additionally, participants will receive email guidance.

Study burden and risks

Participation is not expected to have any risks. Participants can quit the study at any moment and will not be excluded based on medication use or other current treatment for CIPN. If participants regress during the intervention and need new chemotherapy treatment, they can choose if they will continue or not. Participants do need to invest time to follow the intervention, which takes around 2 hours per week. Furthermore, it might be confronting to work on pain acceptance for participants. Benefits of participation are foremost a possible improvement in pain interference and reductions in pain and CIPN symptoms.

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

- 18 years or older
- Cancer patient or survivor
- Chemotherapy ended at least 6 months ago
- Identified by a clinician/self as having painful sensations bilaterally in the feet/legs and/or hands for at least 3 months. Neuropathic pain may present as aching, burning, **pins-and-needles,** and/or shock-like, and also covers painful tingling, numbness and/or cramps.
- Scoring a 4 or higher on an 11-point Numeric Rating Scale (NRS).
- Pain was not present prior to receiving chemotherapy but related temporally to the initiation of chemotherapy.

Exclusion criteria

- New chemotherapy scheduled during study involvement
- Very low scores on psychological inflexibility (PIPS; more than 1 SD below mean of population of chronic pain patients in pain rehabilitation centers. These participants already scored highly beneficial on the expected working mechanism of treatment which will lead to ceiling effects)
- No access to the Internet at home/no email address
- Not enough time to follow the intervention (2hours per week)
- Problems with Dutch language
- Enrollment in cancer, pain, or psychiatric related treatment upon entry

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	06-01-2022
Enrollment:	146
Type:	Actual

Ethics review

Approved WMO

Date:	18-10-2021
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

Approved WMO Date:	08-08-2022
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	01-02-2023
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	06-03-2023
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	07-04-2023
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	NL78436.028.21