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REACT-CIPN: a study to assess the feasibility of a behavioural intervention for chemotherapy-induced peripheral neuropathy

Submission date
20/06/2023

Recruitment status
No longer recruiting

Registration date
26/06/2023

Overall study status
Completed

Last Edited
11/02/2025

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
The REACT-CIPN study is focused on determining the feasibility of a randomized controlled trial (RCT) that investigates an intervention to alleviate the symptoms of chemotherapy-induced peripheral neuropathy (CIPN). In this study, participants are randomly assigned to either an experimental group that receives the intervention being tested or a comparison/control group that receives a placebo or conventional treatment. The primary goal is to assess whether the intervention can effectively reduce and mitigate the impact of CIPN symptoms. The study aims to evaluate the feasibility and acceptability of conducting such a trial. The REACT-CIPN behavioural intervention has been co-designed and developed by patients and staff at Guy's and St. Thomas' NHS Foundation Trust (GSTFT) with the intention of providing patients with strategies for managing symptoms. The intervention is compromised of two components: a printed booklet that is given to the participant before chemotherapy starts and a short film that is delivered during or after cycle 2 of treatment.

Who can participate?
Adult patients aged over 18 years old who have been diagnosed with breast or colorectal cancer

What does the study involve?
This is a single-centre study that will be conducted at GSTFT. The REACT-CIPN intervention will be compared with standard care (the control condition) and patients will be randomised to either standard care and intervention or standard care alone in a 1:1 ratio. In addition, clinician participants will be recruited to explore their views about delivering the intervention or delivering CIPN information as standard care.

Clinicians involved in the delivery of REACT-CIPN intervention will receive appropriate training. Patients will be enrolled in the study for up to 12-24 weeks i.e. from the start of chemotherapy treatment until the end of treatment.

What are the possible benefits and risks of participating?
There are no guaranteed benefits from taking part in this study. The findings are expected to

improve the experiences of patients when receiving information about their chemotherapy treatment. Although this may not benefit individuals personally, the information they give may help influence and shape practice and services in the future. The researchers do not anticipate any serious adverse events (SAEs) occurring because of study participation.

Where is the study run from?
King's College London (UK)

When is the study starting and how long is it expected to run for?
January 2023 to December 2023

Who is funding the study?
King’s College London (UK)

Who is the main contact?
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Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
297838

Protocol serial number
IRAS 297838, CPMS 53097

Study information

Scientific Title
REACT-CIPN Study: a feasibility randomised controlled trial with process evaluation of a co-designed intervention for chemotherapy-induced peripheral neuropathy

Acronym
REACT-CIPN FRCT

Study objectives
To evaluate study processes to determine if the design is feasible and acceptable to carry out in the chemotherapy treatment pathway.

To evaluate patient and clinician experiences and opinions of receiving and delivering the intervention to inform refinement for a definitive trial.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 14/04/2023, London-Surrey Research Ethics Committee (Nottingham Centre, The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, United Kingdom; +44 (0)207 1048 088; surrey.rec@hra.nhs.uk), ref: 23/LO/0192

Study design
Single-centre feasibility randomized controlled trial with nested process evaluation

Primary study design
Interventional

Study type(s)
Safety, Efficacy

Health condition(s) or problem(s) studied
Cancer (breast and colorectal)

Interventions
The REACT-CIPN intervention comprises two components: (a) a printed booklet given to the participant before chemotherapy starts and (b) a short film which is provided during or after cycle 2 of treatment. Participants randomised to the intervention arm will also receive standard care.

Participants will be randomised in a 1:1 ratio to receive either REACT-CIPN + standard care (intervention group) or standard care (control group). Using the King's Clinical Trials Unit (KCTU), blocked randomisation (1:1) will be used to allocate participants between two arms: the intervention group (n = 15) and the control group (n = 15).

The clinicians will go through the booklet with the patient participant by telephone or in the clinic before they start chemotherapy. There is a section in the booklet that allows patients to write their questions and record their symptoms. The booklet is broadly divided into the following sections:
1. CIPN, symptoms and impact on physical functions
2. Self-assessment and communication of symptoms with the clinical team
3. Self-management strategies
4. Available services and support from clinicians
5. Living with CIPN

The ten-minute film, which reinforces key messages from the booklet, will be provided on or after the second cycle of chemotherapy. The film will be shown during cycle 2 if the patient wants to view it during chemotherapy treatment. As well as watching it during their infusion, the link will be sent to them by the lead researcher or another member of the research team to access at home. The film and an electronic copy of the booklet will be hosted on a virtual platform which the participants are able to access –as many times as they wish– until the end of their study participation.

Clinicians who give information about CIPN (chemotherapy unit nurses, clinical nurse specialists or pharmacists), who will be involved in delivering the REACT-CIPN intervention, will receive training that covers the theoretical basis and overview of the intervention.

Intervention Type
Behavioural

Primary outcome(s)
Feasibility outcomes will be measured using a mixed methods approach. Quantitative data regarding recruitment, adherence and attrition will be collected using a study case report form and qualitative data regarding the acceptability of the study processes and intervention will be collected via telephone interviews. These will be collated at the end of the study to assess the following components of the feasibility study:
1. Willingness of participants to be randomised
2. Number of eligible patients
3. Recruitment and retention rate
4. Reasons for refusal/withdrawal
5. Estimate effect size and sample size for a future study
6. Time needed to collect and analyse data

7. Defining the main outcome measure of the full RCT
8. Descriptive analysis of patient-reported outcome measures (PROMs) data to assess the appropriateness of PROMs i.e. item and questionnaire level of missing data, floor and ceiling effects, internal consistency etc

Key secondary outcome(s))
To assess the potential efficacy in adult patients who are at risk of developing chemotherapy-induced peripheral neuropathy (CIPN). CIPN outcomes are measured using the following:
1. The EORTC quality of life (EORTC QLC CIPN20) scale at baseline, week 8 and week 12
2. The Numerical Rating Scale (NRS) at baseline, week 8 and week 12
3. The EuroQol quality of Life (EQ-5D-5L) health questionnaire
4. EQ Visual Analogue Square (EQ-VAS) at baseline, week 8 and week 12

To explore potential therapeutic mechanisms of change in relation to CIPN outcomes using the following
1. Illness perception using the Brief Illness Perception Questionnaire at baseline, week 8 and week 12
2. General self-efficacy using the General Self-Efficacy Scale at baseline, week 8 and week 12

Completion date
31/12/2023

Eligibility

Key inclusion criteria
Adult patients who are:
1. Able to give informed consent
2. Diagnosed with either colorectal or breast cancer
3. Due to receive their first neurotoxic chemotherapy treatment, and
4. At the risk of developing neuropathy (CIPN) due to chemotherapy such as Oxaliplatin, Docetaxel or Paclitaxel.
5. Can understand and communicate in English

Clinicians in the chemotherapy unit or outpatient clinics who provide information about CIPN will be recruited.

Participant type(s)
Patient, Health professional

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
99 years

Sex
All

Key exclusion criteria
Patients will be excluded if they:
1. Are unable to provide informed consent
2. Have received prior neurotoxic chemotherapy
3. Have pre-existing self-reported peripheral neuropathy due to other conditions e.g. diabetes or complication of previous surgery

Date of first enrolment
20/06/2023

Date of final enrolment
20/10/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Guy's Cancer Centre, Guy's and St. Thomas' NHS Foundation Trust (GSTFT)
Great Maze Pond
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Sponsor information

Organisation
King's College London

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
University/education

Funder Name
King's College London

Alternative Name(s)
King's College, King's College London UK, KCL, King's

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Data Storage
All participants' personal data and non-personal research data provided will be secured for a further seven years after the end of the study and then destroyed securely, in keeping with standard research practice. Paper copies and password-protected storage devices will be securely archived for seven years through the King's College London account with Iron Mountain and can only be accessed by the chief investigator and lead co-researcher. Data will be stored as per Data Protection Act (2018) and King's College London Data Management Policy and Guidelines which may be found on: https://www.kcl.ac.uk/governancezone/Research/Research-Data-Management-Policy.aspx; https://www.kcl.ac.uk/library/researchsupport/research-data-management/index.aspx

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			20/09/2023	No	No