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SURECAN: Survivors rehabilitation evaluation after cancer

Submission date	Recruitment status	[X] Prospectively registered
18/11/2019	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[X] Statistical analysis plan
09/12/2019	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
15/04/2025	Mental and Behavioural Disorders	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Some two million people in the UK are living with or beyond cancer -"cancer survivors". About a third of these patients report poor quality of life (QoL), or well-being, due to problems such as fatigue, fear of cancer recurrence, and concerns about returning to work.

From talking to patients we have found that important aspects of QoL include physical abilities and psychological wellbeing. We surveyed cancer services to see what aftercare is provided and found it did not address important issues highlighted by patients. We therefore are in need of better aftercare for "cancer survivors".

Since the best approaches are only moderately effective, we decided to adopt Acceptance and Commitment Therapy (ACT). ACT puts patients' views about what they value most in their lives at the heart of the therapy, in order to improve their quality of life. ACT helps patients to accept what they cannot change (e.g. the cancer might recur) and commit themselves to goals they are able and want to achieve, based on their own values (e.g. becoming closer to loved ones). We know that exercise is helpful and return to work/vocational activity is important to many patients, therefore will integrate ACT with options for physical activity and work support, if these are deemed important by the patient (thus: ACT+).

This study will consist of a pilot RCT, which if meets set criteria will seamlessly progress into a definitive trial comparing ACT+ and usual aftercare, with usual aftercare only, answering if ACT+ with usual aftercare is more effective and cost-effective in improving the QoL of participants living with and beyond cancer than usual aftercare only.

Who can participate?
Patients aged 18 years or above who have completed cancer treatment in the past 24 months.

What does the study involve?
Patients will be randomly allocated to receive ACT+ and usual aftercare, or usual aftercare only for a 14 – 20 week period.

What are the possible benefits and risks of participating?
The benefit to participants is that the intervention may lead to improvements in their quality of life compared to the usual aftercare currently available, which is the aim of the SURECAN study. The trial is considered to have a very low risk, but there is a risk of psychological distress. The therapy is designed to minimise this and the therapists delivering the therapy are fully trained and experienced to deal with such circumstances.

Where is the study run from?
1. Queen Mary University of London, UK (lead centre)
2. The Royal London Hospital, UK
3. Northern General Hospital, UK
4. University College London Hospitals NHS Foundation Trust, UK
5. North East London NHS Foundation Trust, UK
6. East London NHS Foundation Trust, UK
7. NHS City and Hackney CCG, UK
8. St. Pancras Hospital, UK
9. Cavendish Cancer Care, UK

When is the study starting and how long is it expected to run for?
February 2020 to January 2025

Who is funding the study?
National Institute for Health Research (NIHR), UK

Who is the main contact?
Imran Khan
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Study website
https://surecanstudy.qmul.ac.uk/

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 43122

Study information

Scientific Title
A multi-centre, pragmatic, randomised controlled trial of comparing enhanced Acceptance and Commitment Therapy (plus) added to usual aftercare, versus usual aftercare only

Acronym
SURECAN

Study objectives
ACT+ with usual aftercare is more effective and cost-effective in improving the QoL of participants living with and beyond cancer than usual aftercare only

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 20/01/2020, South West – Cornwall and Plymouth (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8079; cornwallandplymouth.rec@hra.nhs.uk), ref: 19/SW/0214

Study design
Multi-centre pragmatic randomized controlled 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

Health condition(s) or problem(s) studied
Mental health, quality of life in cancer survivors

Interventions
Patients will be randomised with an allocation ratio 1:1 to enhanced Acceptance and Commitment Therapy (plus) added to usual aftercare (intervention), versus usual aftercare only (control).

Acceptance and Commitment Therapy (ACT) puts patients' views about what they value most in their lives at the heart of the therapy, to improve their quality of life. ACT helps patients to accept what they cannot change and commit themselves to goals they are able and want to achieve, based on their own values. If physical activity and work support are deemed important by the patient the relevant support will be integrated into the therapy (ACT+).

Number of sessions
The intervention will take the form of up to eight sessions at weekly or fortnightly intervals using different modalities of delivery to suit individual needs: face-to-face sessions, over the phone or skype. The first session will be conducted face-to-face with the therapist. The intervention will be introduced and participants will be provided with the ACT+ participant handbook. Therapy will be delivered by therapists trained in the approach i.e. ACT. They could be situated in Improving Access to Psychological Therapies (IAPT), specialist services, cancer psychological services, or cancer charities.

Duration of sessions
Each session will take around one hour to complete and will include further exercises to be completed at home in time for the next session.

Scheduling of sessions
All sessions should be scheduled and take place within a 14 - 20 week period starting from when a participant is allocated to the therapist (i.e. from randomisation).

Control (usual aftercare)
All participants in the study will receive usual aftercare provided by the NHS or support services. Participants randomised to the usual aftercare arm will receive a Macmillan Cancer Support leaflet about aftercare to all participants, to ensure that appropriate guidance is provided.

Randomisation
Allocation will be by stratified randomisation, overseen by the Pragmatic Clinical Trials Unit at Queen Mary, remote to researchers, to preserve strict allocation concealment. Participants will be randomised in a 1:1 ratio with 172 participants in each arm.

Intervention Type
Behavioural

Primary outcome measure
1. Functional Assessment of Cancer Therapy: General scale (FACT-G) at 12 months
2. Primary health economics outcome: Quality-adjusted life-years based on EQ5D5L and net monetary benefit at 12 months

Secondary outcome measures
Self-reported by patient response to questionnaires:
1. Quality of life measured using Functional Assessment of Cancer Therapy: General scale (FACT-G) at screening, baseline, 7 weeks, 16 weeks, 52 weeks, 2 years
2. Health economics measured using the Client Service Receipt Inventory (CSRI) at baseline, 16 weeks, 52 weeks, 2 years
3. Fear of cancer recurrence measured using the Fear of Cancer Recurrence (FCR4) at baseline, 7 weeks, 16 weeks, 52 weeks, 2 years
4. Depression and anxiety measured using the Hospital Anxiety and Depression Scale (HADS) at baseline, 7 weeks, 16 weeks, 52 weeks, 2 years
5. Fatigue measured using the Chalder Fatigue Scale (CFS) at baseline, 7 weeks, 16 weeks, 52 weeks, 2 years
6. Impact of cancer on QoL measured using the Impact Of Cancer scale (IOC) at baseline, 7 weeks, 16 weeks, 52 weeks, 2 years
7. Psychological flexibility measured using the Acceptance and Action Questionnaire (AAQ-II) at baseline, 7 weeks, 16 weeks, 52 weeks, 2 years
8. Values measured using the Valuing Questionnaire (VQ) at baseline, 7 weeks, 16 weeks, 52 weeks, 2 years
9. Goal-directed behaviour measured using the Committed Action Questionnaire (CAQ) at baseline, 7 weeks, 16 weeks, 52 weeks, 2 years
10. Beliefs about emotions measured using Beliefs about Emotions Scale (BES) at baseline, 7 weeks, 16 weeks, 52 weeks, 2 years

Overall study start date
09/04/2018

Completion date
29/01/2025

Eligibility

Key inclusion criteria
Current inclusion criteria as of 28/11/2023:

1. Within 24 months of having completed cancer treatment, (or about to complete) with curative intent for breast cancer, lower gastro-intestinal cancer, urological cancer, a haematological cancer, head and neck cancer, and any other common cancer with good survival
2. Aged 18 years or over
3. Participant's GP practice falls within a participating IAPT service catchment, or if other psychological service provider, participant resides within their catchment area
4. Ability to give informed consent
5. Sufficient fluency in spoken English to be able to participate in a talking-based therapy delivered in English
6. With a score of 78 or less on the Functional Assessment of Cancer Therapy – General (FACT-G)

Previous inclusion criteria:

1. Within 24 months of having completed cancer treatment, (or about to complete) with curative intent for breast cancer, colorectal cancer, prostate cancer, a haematological cancer, head and

neck cancer, and any other common cancer with good survival
2. Aged 18 years or over
3. Participant's GP practice falls within a participating IAPT service catchment, or if other psychological service provider, participant resides within their catchment area
4. Ability to give informed consent
5. Sufficient fluency in spoken English to be able to participate in a talking-based therapy delivered in English
6. With a score of 78 or less on the Functional Assessment of Cancer Therapy – General (FACT-G)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
344 in total: 45 recruited for internal pilot and 299 recruited for main trial

Key exclusion criteria
Current exclusion criteria as of 28/11/2023:

1. Will not have not completed their cancer treatment by the commencement of the trial (excepting those receiving long-term, ongoing maintenance treatment e.g. androgen suppression therapy in urological cancer)
2. Receiving palliative or terminal care
3. Currently receiving another psychological intervention (NB participants taking antidepressants or anxiolytic drugs remain eligible)
4. Other serious co-morbid condition which would make it difficult for the participant to receive a talking-based one-to one intervention
5. Require urgent psychiatric or clinical psychology assessment

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Previous exclusion criteria:

1. Will not have not completed their cancer treatment by the commencement of the trial (excepting those receiving long-term, ongoing maintenance treatment e.g. androgen suppression therapy in prostate cancer)
2. Receiving palliative or terminal care
3. Currently receiving another psychological intervention (NB participants taking antidepressants or anxiolytic drugs remain eligible)
4. Other serious co-morbid condition which would make it difficult for the participant to receive a talking-based one-to one intervention
5. Require urgent psychiatric or clinical psychology assessment

Date of first enrolment
01/03/2021

Date of final enrolment
30/11/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The Royal London Hospital
Barts Health NHS Trust
Whitechapel Rd
London
United Kingdom
E1 1BB

Study participating centre
Northern General Hospital
Sheffield Teaching Hospitals NHS Foundation Trust
Herries Road
Sheffield
United Kingdom
S5 7AU

Study participating centre
University College London Hospitals NHS Foundation Trust
250 Euston Road
London
United Kingdom
NW1 2BU

Study participating centre
Queen Mary University London
58 Turner Street
Whitechapel
London
United Kingdom
E1 2AB

Study participating centre
North East London NHS Foundation Trust
West Wing, C E M E Centre
Marsh Way
Rainham
Ilford
United Kingdom
IG3 8XJ

Study participating centre
East London NHS Foundation Trust
9 Alie Street
Aldgate
London
United Kingdom
E1 8DE

Study participating centre
NHS City and Hackney CCG
Second Floor
The Lawson Practice
85 Nuttall Street
London
United Kingdom
N1 5HZ

Study participating centre
St. Pancras Hospital
Camden and Islington NHS Foundation Trust
4 St. Pancras Way
London
United Kingdom
NW1 0PE

Study participating centre
Cavendish Cancer Care
34 Wilkinson Street
Sheffield
United Kingdom
S10 2GB

Sponsor information

Organisation
Queen Mary University of London

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Sponsor type
University/education

Website
http://www.surecanstudy.qmul.ac.uk

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: RP-PG-0616-20002

Results and Publications

Publication and dissemination plan
Results are planned to be published in peer reviewed scientific journals, conference presentations, publication on study website and submission to regulatory authorities.

Intention to publish date
30/06/2024

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.
Approaches to share data will be handled by the QMUL PCTU's Data Sharing Committee which includes a Senior Statistician and a Senior Data Manager. All requests for data sharing will follow the PCTU data sharing procedures, regarding assessing access requests with guarantees of confidentiality and pre-specified analysis plans.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 5.0	02/10/2023	28/11/2023	No	No
Protocol article		02/04/2024	03/04/2024	Yes	No
Statistical Analysis Plan		30/01/2025	30/01/2025	Yes	No