

# SURECAN: Survivors rehabilitation evaluation after cancer

<b>Submission date</b> 18/11/2019	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 09/12/2019	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 15/04/2025	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> 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

[surecan.study@qmul.ac.uk](mailto:surecan.study@qmul.ac.uk)

## Contact information

### Type(s)

Public

### Contact name

Mr Imran Khan

### ORCID ID

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### Contact details

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## Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

**ClinicalTrials.gov (NCT)**

Nil known

**Protocol serial number**

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

**Study type(s)**

Quality of life

**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(s)**

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

### **Key secondary outcome(s)**

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

**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)

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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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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**

United Kingdom

England

**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

**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

### 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?
<a href="#">Protocol article</a>		02/04/2024	03/04/2024	Yes	No
<a href="#">Protocol file</a>	version 5.0	02/10/2023	28/11/2023	No	No
<a href="#">Statistical Analysis Plan</a>		30/01/2025	30/01/2025	Yes	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes