STUDY PROTOCOL

REVISED Qualitative study of experience of acceptance and commitment therapy (ACT+) amongst Survivors' Rehabilitation Evaluation after Cancer (SURECAN) trial participants and therapists: A protocol. [version 2; peer review: 2 approved with reservations, 1 not approved]

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Abstract

Background

This interview study forms part of a mixed methods process evaluation of the Survivors' Rehabilitation Evaluation after Cancer (SURECAN) trial to understand the experiences of participants (who are living with and beyond cancer) in receiving a form of acceptance and commitment therapy, and therapists providing the intervention. SURECAN is a multi-centre, pragmatic, individual participant randomised controlled trial of an intervention based on acceptance and commitment therapy supplemented by support for return to meaningful work and/or physical activity (ACT+). This qualitative study addresses the ways in which participants believe they benefit from ACT+ (or not), and how the ACT+ intervention might best be implemented into routine National Health Service (NHS) care.

Methods

The study investigates experiences of ACT+ by different participants to

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understand how we can optimise the ACT+ intervention and its delivery (assuming the intervention is successful). We will conduct individual interviews with participants who have taken part in the active arm of the SURECAN trial to understand their experiences of engaging with and receiving ACT+, their perceptions of the impact of the therapy, and relevant contextual factors influencing these experiences. In particular, we will focus on comparing our interview findings between those trial participants who improved and those who failed to improve (or worsened), in terms of quality of life following ACT+. Additionally, we will conduct individual interviews with therapists who have delivered ACT+ as part of the SURECAN trial, to understand their experiences of delivering ACT+.

Conclusions

Consistent with other qualitative protocols, this protocol is not registered. Instead, it is shared as a means of documenting ahead of time, how we are endeavouring to understand the ways in which a newly trialled talking therapy is received by patients and therapists, and how (if successful) it might be incorporated into the NHS.

Keywords
Cancer, Quality of Life, Qualitative, Protocol, Acceptance and Commitment Therapy

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Any reports and responses or comments on the article can be found at the end of the article.

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REVISED **Amendments from Version 1**

This updated version (following the three reviewer comments) includes a range of revisions and improvements to the protocol including: an explanation as to why the five cancer groups in the protocol initially appeared inconsistent to the SURECAN trial study website; a justification about why we do not focus on a particular type of cancer in our evaluation; an outline as to why we believe our qualitative study is important and useful; a clarification as to why we refer to participants in the SURECAN trial as "living with and beyond cancer"; more information on the ACT+ intervention itself; a note about why we are not attempting to standardise behaviour patterns when it comes to patients with varying cancers, genders and conditions; a justification for the minimum four ACT+ sessions for trial participant inclusion; specifying how improvement vs. non-improvement groups of participants will be defined for the analysis (and we have noted that it will not be possible to ensure equal numbers in each group); inclusion of new research question for the therapists sample; the inclusion of a justification for both the trial participant and therapist sample sizes; an explanation of how patient and public involvement was included in the study, as well as how the interview guide was iteratively developed; a statement about how we will include relevant additional topics in the interview; an explanation as to why we have not pre-registered the qualitative protocol, as well as why we use qualitative reporting guidelines as advisory only; and finally an update of the old improving access to psychological therapies (IAPT) name to the current "NHS Talking Therapies" title.

Any further responses from the reviewers can be found at the end of the article

Introduction

This interview study will form part of the mixed methods process evaluation of the Survivors' Rehabilitation Evaluation after Cancer (SURECAN) trial, which will be conducted following Medical Research Council guidance[1]. The SURECAN trial is directed to people who have completed cancer treatment with curative intent. For example, some people with prostate cancer continue with long-term, ongoing maintenance treatment in the form of androgen suppression therapy. People receiving this type of maintenance treatment are eligible for recruitment into the SURECAN trial. In addition, people with certain haematological cancers are treated with the intention of long-term remission, which means they are never technically disease-free. This is why we have included within our eligibility definition "treated with curative intent/long-term remission". For these reasons, we prefer to use the term 'living with and beyond' cancer. SURECAN is a multi-centre, pragmatic, individual participant randomised controlled trial of an intervention based on acceptance and commitment therapy (a talking therapy) supplemented by support for return to meaningful work and/or physical activity, according to the preferences of the individual study participant, known as 'ACT+'.

ACT+ is personalised to participants and includes a range of theoretically informed interventions which target people's experience of symptoms, distress and quality of life. As part of the intervention, behavioural goals are not standardized. Instead, we are interested in understanding the full range of experiences and behaviours of participants in relation to their health. We do not standardise behaviour patterns. While quantitative research aims to standardise and limit variables under investigation, qualitative research (separate from the therapy under investigation) as undertaken in this study does not pre-specify what should be attended to, as it is designed to explore complex phenomena[2].

Trial participants receive up to eight one-hour sessions of ACT+ weekly or fortnightly delivered by telephone or online. Therapists attend an ACT+ training workshop delivered over two to three days, and receive regular supervision during the trial from an experienced cognitive behavioural therapist with extensive training in ACT. We have reported in more depth on the development and evaluation of the training programme[3]. Additional information about the intervention will be available in the protocol for the main quantitative trial looking at the effectiveness and cost-effectiveness of the ACT+ intervention (to be published in the public domain in due course). The ACT+ intervention in addition to usual aftercare is compared to usual aftercare only, for patients living with and beyond cancer (SURECAN Trial IRAS: 260823 Protocol v3.0 06/02/2022). Trial participants comprise individuals who have completed treatment with curative intent for one of five cancer groups (breast, lower gastrointestinal, haematological, head and neck, urological) and are experiencing low quality of life as assessed by the Functional Assessment of Cancer Therapy: General scale (FACT-G)[4].

Importantly, instead of evaluating cancer types, we are evaluating the impact of acceptance and commitment therapy (ACT), which is an empirically supported trans-diagnostic psychological therapy for wide-ranging health conditions, including varying types of cancer[5]. While psychological contexts vary broadly for different cancers and patient characteristics, the focus of acceptance and commitment therapy (ACT) is to help patients better adapt to the significant challenges they face, by promoting psychological flexibility, and helping them choose what they focus on, rather than invest energy in trying to suppress or ignore difficulties. Research suggests that ACT is helpful across a range of cancer types[6], although more research is needed to identify the features of the interventions and patient characteristics that could be used to improve results. Hence, the qualitative research proposed with diverse patients and types of cancers – where we will compare those who improve and do not improve - is crucial. Trial participants are recruited through participating hospital cancer clinics, and the ACT+ intervention is delivered by trained therapists working in either participating NHS Talking Therapies services in primary care mental health services or the charity sector.

Purpose

This interview study addresses the ways in which participants believe they benefit from ACT+ (or not), and how the ACT+ intervention might best be implemented into routine National Health Service (NHS) care. The purpose of the study is to investigate the experience of ACT+ by different participants to understand how we can optimise the ACT+ intervention and its delivery (assuming the intervention

is successful). In particular, we will focus on comparing our interview findings from those trial participants who improved and from those who failed to improve (or worsened), in terms of quality of life following ACT+. Improvement will be identified as an increase of more than 6 points on the FACT-G scale. This will only be determined for individual participants at the end of the study after data lock. Participants are sampled and interviewed by researchers who are blind to their change in FACT-G score. We anticipate our sample is large enough to meaningfully compare participants who appear to have improved and not improved on these criteria. The change or not in FACT-G will then be used to interpret the analysis. We will also capture the experience of therapists who delivered the ACT+ intervention.

We will investigate experiences of ACT+, and ACT+ delivery, in two parts:

In Part A we will conduct individual interviews with participants who have taken part in the active arm of the SURECAN trial to understand their experiences of engaging with and receiving ACT+, their perceptions of the impact of the therapy, and relevant contextual factors influencing these experiences.

In Part B we will conduct individual interviews with therapists who have delivered ACT+ as part of the SURECAN trial, to understand their experiences of delivering ACT+ to people who are living with and beyond cancer.

Importance and theoretical framework

We will draw on Normalisation Process Theory[7], a theory that focuses on how innovations are incorporated into systems like the NHS. This approach essentially means that in our lines of questioning both participants and therapists, we will ensure to cover specific contexts of the trial; coherence (i.e. how people make sense) of the approaches used; cognitive participation (how people think about the delivery of the innovation); collective action (what people do to deliver an innovation); and reflective monitoring (how people evaluate their contributions and/or the consequences of the trial). This will ensure we ask pertinent questions of both trial participants and therapists; that we elicit narratives in order to explore how trial participants subjectively appraise their experiences related to ACT+; and explore how to best integrate ACT+ into the NHS should the therapy prove useful[8,9]. This current qualitative study is particularly important because if the SURECAN trial is successful, and ACT+ is integrated into the NHS, it is critical to know more about why some patients benefit and others do not. This is so that ACT+ can be optimised to help the greatest number of patients possible in the NHS. When we used a similar study approach in a previous trial of Graded Exercise Therapy, we discovered factors linked to participant improvement (e.g. patient motivation, being able to tolerate an initial phase of no improvement)[10]. Thus, this information allows practitioners to subsequently refine their treatment approach to address factors that will improve the likelihood of success.

Preregistration

Currently, templates for preregistering qualitative protocols are generally not yet well developed for qualitative research (e.g. quantitative assumptions, templates not fitting qualitative research paradigms), especially given qualitative research involves ongoing iterative changes to study designs to respond to emerging insights in the field[11]. There is still some work needed to ensure templates are suitable for qualitative preregistration[12], and for this reason we have not preregistered our protocol.

Research questions

Our research questions for part A are:

1) What are the differences in treatment perceptions and experiences between those trial participants who improved and those who did not following ACT+?
2) Why might different kinds of participants do better than others with ACT+?
3) How do participants explain the influence of life contexts on their outcomes?
4) How can we optimise the ACT+ intervention and its delivery, with regard to future implementation?

Our research question for part B is:

1) How can we optimise the ACT+ intervention and its delivery, with regard to future implementation?
2) Why do therapists think different kinds of participants might do better than others with ACT+?

Sample and recruitment for part A

Eligibility criteria

The inclusion criteria are:

1. participant in intervention arm of trial
2. received at least four sessions of ACT+ (Note: Four sessions of ACT+ were considered the minimum 'optimal dose', where improvements generally take at least 4 sessions for those with common mental health problems who are likely to respond to short-term psychological treatments[13].)
3. no longer receiving ACT+

The exclusion criteria are:

1. did not give consent to be approached for an interview
2. more than 14 months since final ACT+ session

Sampling

Size of sample. We aim to recruit up to 30 participants randomised to the intervention arm of the trial. Our previous research has shown that we need to recruit at least 9 participants in each of the improvement and non-improvement groups to make useful comparisons between participants[10]. As we will not know which group the participants fall into until after the trial is unblinded, we believe that a sample of up to 30 will

ensure we have sufficient numbers in each group to be able to compare patients with improved and not improved 'quality of life' scores.

Sampling strategy. We will conduct purposive sampling to obtain variation in participant characteristics. Dimensions of interest are cancer group, age, gender, and ethnic group (White, Black or Black British, Asian or Asian British, Mixed, Other), although other dimensions of interest may emerge iteratively.

Recruitment

Sample identification. A list of participants eligible for this study, and their demographic characteristics, will be extracted from the SURECAN trial database. Data extraction will take place while the trial is live.

From this list of eligible participants a sample of participants will be selected to approach for interview. This sample will be selected to provide variation in participant characteristics like cancer group, age, gender, and ethnicity. Where multiple participants share the same characteristics the selections from that group will be made randomly. Once participants have been approached for interview they will be removed from any future eligible participant lists.

The process of sample selection will be iterative, with the first sample chosen to provide overall diversity but assigning more weight to selecting a variety of different 'cancer groups' as far as possible, the aim being to identify a group of potential participants who have been treated for different cancers. We will not aim to identify equal numbers for each cancer group as it is likely that not everyone invited into this interview study will agree to participate. The trial statistician (CR) will work closely with the qualitative researcher (SD) to determine how many trial participants need to be identified in each sampling cycle.

When interviews have been conducted with individuals recruited from the first sample selected, information regarding their cancer group, age, gender, and ethnicity (available from the extracted data and confirmed with participants at the time of interview) will be collated by the qualitative researcher to produce an overview of the variation in the sample to date. This information on the make-up of the sample will be reviewed by the research team to determine which of the categories (our dimensions of interest) should receive more weight in the second sample selection in order to increase the variation in the sample. The need for any subsequent sample selection will be determined in a similar way. The need for any subsequent data extraction/s will depend on the number of participants recruited for interview from the samples selected (as described above) in relation to our target sample size of up to 30 interviewees.

The qualitative researcher will liaise with the interview study lead (DR), the trial manager (IK), the trial statistician (CR), and the research team at regular intervals to review how the process of forming the sample is progressing and to agree the timing and objectives of any subsequent data extraction/s. See Figure 1 (Study flow diagram) for an illustration of how participants for Part A will be identified.

Consent. Consent to be approached about post-therapy interviews was sought at the time that consent to participate in the trial was obtained.

Initial contact will be made by post or email. The qualitative researcher will send potential participants, by post or electronically, an invitation pack containing an invitation letter, study information sheet, consent (or e-consent) form, and prepaid envelope (where appropriate) to return the consent form. The invitation letter will explain that the researcher can be contacted for further information and to address any queries. Between seven and 10 days after posting the invitation pack (and if the consent form has not been returned), the qualitative researcher will follow up with a telephone call to discuss the individual's potential participation and answer any questions they have about the study. Subsequent to the invitation letter, a total of up to three phone attempts, and one email attempt (if appropriate) will be made to speak/communicate with the potential participant over a 30-day period. No further attempt will be made to make contact.

The researcher will explain to potential participants that although invited to participate in an interview, their involvement is entirely voluntary, and they can stop the interview at any time, no questions asked.

Patient and Public Involvement. Two Patient and Public Involvement (PPI) representatives were grant co-applicants for the SURECAN research programme. Along with other PPI representatives, they have been actively involved in SURECAN through regular programme management meetings as well as specific PPI meetings, and through participation in reviewing and commenting on patient-facing materials used in the ACT+ therapy sessions. Five SURECAN PPI representatives reviewed the invitation letter/email, the study information sheet and the interview schedule for trial participants in this qualitative study. Interim findings from this qualitative study will be presented to the SURECAN PPI representatives for debate.

Sample and recruitment for part B

Eligibility criteria

The inclusion criteria are:

1. therapist trained to deliver ACT+ in the SURECAN trial
2. delivered ACT+ sessions to at least two trial participants

The exclusion criterion is:

1. did not give consent to be approached for an interview

Sampling

Size of sample and strategy. We aim to recruit 10 therapists participating in the SURECAN trial, out of around 25–30 therapists who are participating in the SURECAN trial. This

sample size allows us to purposefully sample[14], to improve rigour by including a range of views according to differences in host organisations, core professions, levels of experience and genders.

Recruitment

Sample identification. A list of therapists eligible for this study, and details of their host organisation, core profession, and gender, will be extracted from the SURECAN therapist database. From this list, a purposive sample selected to provide variation in the dimensions of interest will be approached for interview. See Figure 1 (Study flow diagram) for an illustration of how participants for Part B will be identified.

Consent. Consent to be approached about post-intervention delivery interviews was sought at the time that consent to participate in the trial was obtained.

Initial contact will be made by email. The qualitative researcher will send an invitation pack (containing an invitation letter, study information sheet, and e-consent form) to potential participants electronically. The invitation letter will explain that the researcher can be contacted for further information and to address any queries. Between seven and 10 days after sending the invitation pack, (and if the consent form has not been returned), the qualitative researcher will follow up with an email, to remind the therapist about

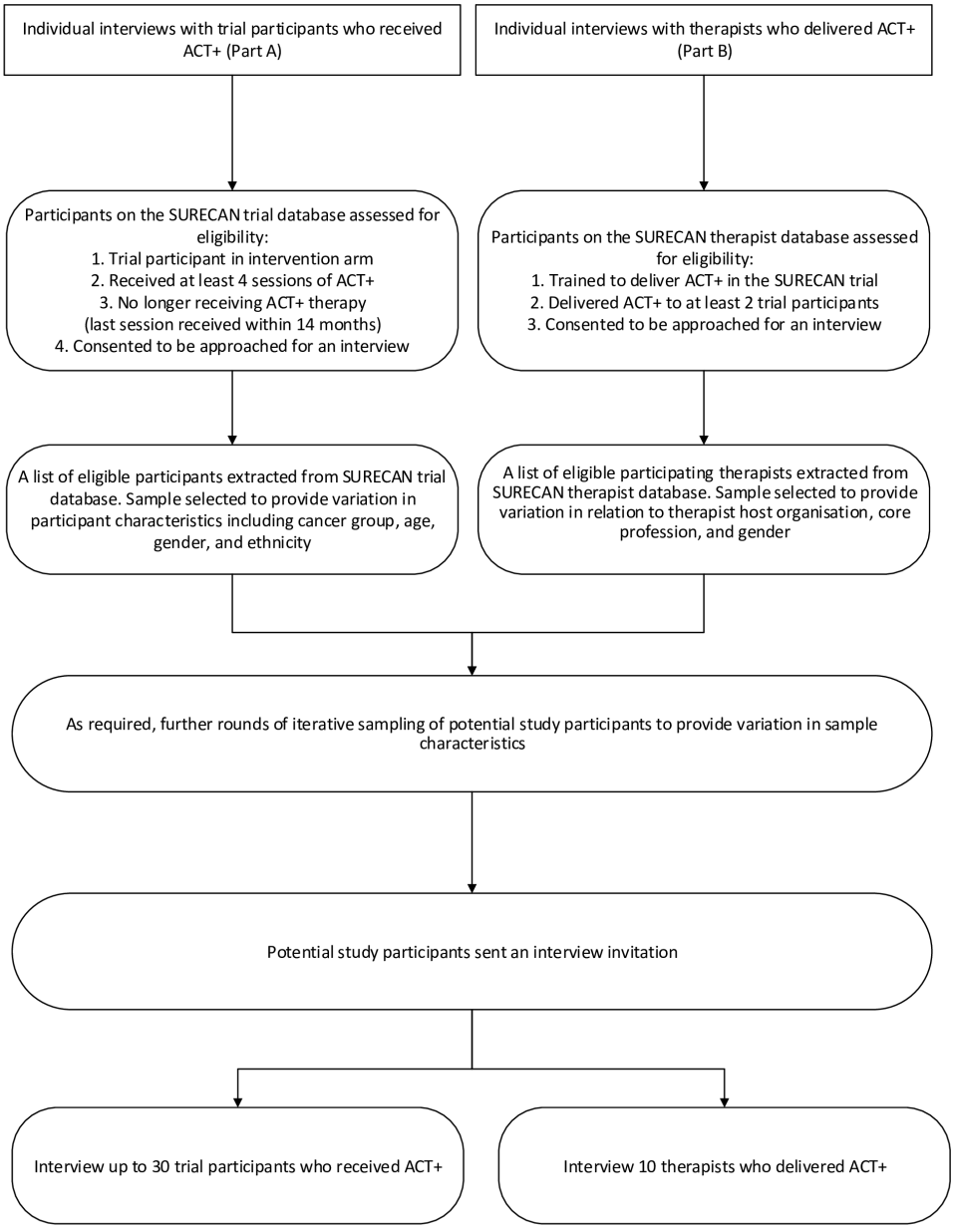

Figure 1. Study flow diagram.

the invitation pack, ask if they have any questions about the study, and offer to speak on the phone at a convenient time to discuss their possible participation. Subsequent to the invitation letter, up to five reminders via email and/or phone will be made during a period of 30 days. No further attempt will be made to make contact.

The researcher will explain to potential participants that although invited to participate in an interview, their involvement is entirely voluntary, and they can stop the interview at any time, no questions asked.

Participant involvement

Participants in this interview study (Parts A and B) will take part in a one-off, individual semi-structured interview, conducted either by telephone or via a data protection-compliant online platform (Skype or Microsoft Teams), whichever is their preference. Interviews will last for 40 to 60 minutes.

Data collection

The use of a semi-structured interview approach will i) allow us to address the same topics in each set of interviews and in so doing, generate comparable data about participants' experience of receiving or delivering the ACT+ intervention, and ii) provide sufficient flexibility within the interviews to enable participants to highlight their concerns and elaborate on particular aspects in their accounts[15].

While the interview guides were not pilot tested, they were developed collaboratively by the study team, drawing on: members' wide expertise, and interview guides we had developed for the SURECAN pre-pilot study (a small test-run of ACT+, followed by individual interviews with participating patients and ACT+-trained therapists). We also drew from interview guides used in a similar study comparing trial participants' experiences of improvement and non-improvement for an intervention[10]. Additionally, the interview guide for trial participants was reviewed by five of the SURECAN study PPI representatives. Finally, in qualitative research, it should be noted that interview guides are seen as 'a work in progress'[16]. It is recommended that guides be further refined periodically as the researcher conducts interviews in the field, as emerging insights suggest how topics should be refined or added. Topics for interviews with trial participants (Part A) will include the decision to take part in the SURECAN trial, expectations of the therapy, concerns about the therapy, understanding of ACT+, barriers and facilitators to ACT+, engagement in the ACT+ sessions, use of the ACT+ Participant Handbook, perceived impact of the therapy, why ACT+ worked/did not work, anything important going on at the time of ACT+, challenges emerging after completing the course of therapy. The interviewer will specifically enquire about issues highlighted by participants as relating to ACT+ and/or its effectiveness, including but not limited to, the anatomical site of cancer, comorbidities, functional implications, gender and patient age.

Topics for interviews with therapists (Part B) will include working with the client group (people living with and beyond cancer), delivering the therapy in a trial context, delivery of ACT+ sessions, use of the ACT+ Therapist Manual, ending the therapy, perceived value of ACT+ for the client (their allocated trial participant).

Data analysis and data management

Data analysis

Interviews will be audio-recorded and transcribed *verbatim* by a professional transcribing service with which the university has an agreement, including to treat audio recordings and the resultant transcripts as strictly confidential. The qualitative researcher will review transcripts against the audio recordings to correct any errors and remove any identifying information.

Data will be managed in the qualitative data analysis software environment NVivo. All transcripts, once checked for accuracy and anonymised, will be uploaded to NVivo and coded. A close thematic analysis of the data will be conducted to identify 'repeated patterns of meaning'[17]. The analysis will incorporatea 'constant comparison' approach, to ensure that relevant data are compared with similar data systematically[18].

Blinding. Initially, analysis of the trial participant interview data set will be conducted using baseline data only. When the SURECAN trial has been completed and we are unblinded to the study outcomes, we will conduct further analysis, comparing interview findings from participants who improved and those who did not improve following ACT+. It will not be possible to ensure equal numbers of trial participants who improved versus those who did not. Nor will it be possible to purposively sample trial participants who improved versus those who did not, as the researchers will be blinded to treatment outcome during the sampling phase.

The data extraction to identify eligible participants will be conducted by a statistician independent to the SURECAN trial to ensure the SURECAN trial statisticians remain blind to treatment group allocation of participants.

Data management

Information related to participants will be kept confidential and managed in accordance with the General Data Protection Regulation (GDPR), NHS Caldicott Principles, The Research Governance Framework for Health and Social Care, and the conditions of Research Ethics Committee Approval.

The study information sheet will set out arrangements relating to confidentiality, security, storage and accessibility of data only to the study team.

The signed consent forms will kept in a locked cabinet at Queen Mary, University of London, accessible by authorised study staff only. All data collected will be fully anonymised by a unique participant ID. For telephone interviews, the qualitative researcher will use an encrypted digital audio-recorder to record the interview. The recording will be downloaded onto a secure and encrypted USB storage device immediately following the interview. For interviews conducted using a secure online calling platform, the recording function of the secure platform will be used to record the interview. The recording will be downloaded onto a secure and encrypted USB storage device immediately

following the interview. Encrypted USBs are kept in a locked cabinet in a locked room.

A copy of the recordings will be downloaded onto an encrypted USB storage device and sent securely to a professional transcriber for transcription. The transcriber will upload the transcribed documents onto the USB storage device and return it securely to the study team.

All recording file data will be uploaded onto a dedicated folder on the secure virtualised environment at the Barts Cancer Centre (BCC) at Queen Mary, University of London, and deleted from the digital recorder and, after analysis, the encrypted storage devices. The folders where the data are stored will be accessible only to the appropriate members of the SURECAN study team.

Ethical and regulatory considerations

Research ethics approval

A favourable opinion from a Health Research Authority Research Ethics Service for the study protocol, consent forms, invitation letters and participant information sheets has been obtained (**IRAS Number** 314406, **REC Number** 22/SW/0157).

Ethical considerations

The Co-Chief Investigators will ensure that the study is carried out in accordance with the ethical principles in the Research Governance Framework for Health and Social Care, Second Edition, 2005, and its subsequent amendments as applicable together with applicable legal and regulatory requirements.

The informed consent process has been described in the consent section above. Consent materials comprise a study information sheet, an invite letter, and a consent form. We have made a particular effort to use clear, accessible language in these documents and have received advice on them from our study patient advisors. The information sheet covers the purpose of the study, why potential participants have been approached to take part and what would it mean for them if they chose to participate, the benefits and risks of participation, assurance that participation is voluntary and that withdrawal from the study can be at any time, the type of data collection, data storage, confidentiality and security, who the study is funded and sponsored by, who reviewed the study, and whom to contact for further information. Participants will be given a copy of their signed consent form at the time of their recruitment into the study.

There is potential for patient participants to become upset about their situation or their condition. If an interviewee becomes distressed, the interviewer will stop the interview and will stay with the participant while they recover, and check in with such participants by telephone in the days subsequent to the interview. Information as to how they can seek further help will be offered to participants.

Sponsorship and indemnity

Queen Mary University of London will be the study sponsor. The sponsorship will be given on the basis of meeting the 'Conditions of sponsorship' which means that the research should be conducted and managed as per the Research Governance Framework for Health and Social Care 2005 and/or the Medicines for Human Use (Clinical Trials) Regulations 2004.

Queen Mary University of London has a no-fault indemnity insurance policy for research participants. These compensation arrangements apply where harm is caused to a participant that would not have occurred if they had not taken part in the study. These arrangements do not affect participants' rights to pursue a claim through legal action.

Data availability

No data are associated with this article.

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It is a well-written protocol; however, this reviewer observed some methodologic design details related to clinical and oncologic issues:

1. The protocol is qualitative about of experience of acceptance and commitment therapy (ACT+) amongst Survivors' Rehabilitation Evaluation after Cancer (SURECAN). However, the protocol does not specify which type of cancer will be evaluated by the intervention.

2. The psychological context varies broadly in different cancers and different patients' characteristics (women with mastectomy, men with prostate cancer and erectile dysfunction, patients with head and neck cancer and mutilating face surgeries, among others)

3. How will the researchers standardize the behavior patterns in patients with various cancers, genders, and conditions?

4. Despite the qualitative nature of the protocol is essential to the capacity to distinguish the differential response patterns in the patients according to the anatomical site of cancer, the functional implications, the gender, and the role function affected or not by the tumor or patient age, and the influence of the aging or comorbidities.

5. Even the therapeutic team will develop a differential behavior in front of different types of cancer, so it is imperative to delimitate the specific cancer and even the clinical stage or the

treatment for the cancer.

6. Authors must decide on anatomic site, histologic characteristics, clinical stage, and treatment modality and evaluate according to specific selection criteria, considering clinical and disease-specific characteristics.

Is the rationale for, and objectives of, the study clearly described?
Partly

Is the study design appropriate for the research question?
Partly

Are sufficient details of the methods provided to allow replication by others?
Partly

Are the datasets clearly presented in a useable and accessible format?
Partly

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Surgical Oncology and its impact in Health Related Quality of Life, functionality and Nutritional State

I confirm that I have read this submission and believe that I have an appropriate level of expertise to state that I do not consider it to be of an acceptable scientific standard, for reasons outlined above.

Author Response 14 Dec 2023

Damien Ridge

Dear Professor Sat-Muñoz

Many thanks for noting our protocol is "well-written". We have carefully considered and responded to your points in turn below:

1. **protocol is qualitative about of experience of acceptance and commitment therapy (ACT+) amongst Survivors' Rehabilitation Evaluation after Cancer (SURECAN). However, the protocol does not specify which type of cancer will be evaluated by the intervention.**

We are not evaluating cancer types *per se*. However, we do list the details of the five cancer types included in the study in the 'Introduction' section of the protocol, specifically, we include breast, lower gastrointestinal, haematological, head and neck, and urological. Instead of evaluating cancer types, we are evaluating the impact of acceptance and commitment therapy (ACT), which is an empirically supported *trans-diagnostic* psychological therapy for wide-ranging health conditions, including varying types of cancer (Dindo et al., 2017). We have added this information:

"Importantly, instead of evaluating cancer types, we are evaluating the impact of acceptance and commitment therapy (ACT), which is an empirically supported trans-diagnostic psychological therapy for wide-ranging health conditions, including varying types of cancer (Dindo et al., 2017) ."

1. **The psychological context varies broadly in different cancers and different patients' characteristics (women with mastectomy, men with prostate cancer and erectile dysfunction, patients with head and neck cancer and mutilating face surgeries, among others)**

This is an important point made by the reviewer. The focus of acceptance and commitment therapy (ACT) is to help patients adapt more productively to these very significant challenges as outlined by the reviewer, by increasing psychological flexibility and assisting patients to choose what to focus on, rather than investing energy in trying to suppress or ignore difficulties. Research suggests that ACT is helpful across a range of cancer types, although more is needed to understand the features of the interventions and patient characteristics that could improve results (González-Fernández & Fernández-Rodríguez, 2019). Hence, the qualitative research proposed with diverse patients and types of cancers – where we will compare those who improve and do not improve - is needed. We have added the following note:

"While psychological contexts vary broadly for different cancers and patient characteristics, the focus of acceptance and commitment therapy (ACT) is to help patients better adapt to the significant challenges they face, by increasing psychological flexibility, and helping them choose what they focus on, rather than invest energy in trying to suppress or ignore difficulties. Research suggests that ACT is helpful across a range of cancer types (González-Fernández & Fernández-Rodríguez, 2019), although more research is needed to identify the features of the interventions and patient characteristics that could be used to improve results. Hence, this qualitative interviews research proposed with diverse patients and types of cancers – where we will compare those who improve and do not improve - is crucial."

1. **How will the researchers standardize the behaviour patterns in patients with various cancers, genders, and conditions?**

ACT+ is personalised and includes a range of interventions which target people's experience of symptoms, distress and improvement of Quality of Life. We do not, as part of ACT+ standardise behavioural goals. We are instead interested in understanding the full range of different experiences and behaviours of participants in relation to ACT+, so it is not useful to focus on standardising behaviour patterns. While quantitative research aims to standardise and limit variables under investigation, qualitative research on the other hand does not pre-specify in this way what should be attended to, as it is designed to explore complex phenomena (Peshkin, 1988). The protocol for the main quantitative trial looking at the effectiveness and cost-effectiveness of the ACT+ intervention will be available in the public domain shortly. We have added the following note:

"ACT+ is personalised to participants and includes a range of theoretically informed interventions which target people's experience of symptoms, distress and quality of life. As part of the intervention, behavioural goals are not standardized.Instead, we are interested in understanding

the full range of different experiences and behaviours of participants in relation to their health. We do not standardise behaviour patterns. While quantitative research aims to standardise and limit variables under investigation, qualitative research (separate from the therapy under investigation) as undertaken in this study does not pre-specify what should be attended to, as it is designed to explore complex phenomena (Peshkin, 1988).”

1. **Despite the qualitative nature of the protocol is essential to the capacity to distinguish the differential response patterns in the patients according to the anatomical site of cancer, the functional implications, the gender, and the role function affected or not by the tumor or patient age, and the influence of the aging or comorbidities.**

As above, qualitative research is able to explore this complexity. We will take on board the reviewer's comments here by ensuring we enquire about these topics in the interview where relevant, i.e. where they are raised by participants as important to understanding ACT+, including anatomical site of cancer, comorbidities, functional implications, gender role or patient age. We have added the following note:

“The interviewer will specifically enquire about issues highlighted by participants as relating to ACT+ and/or its effectiveness, including but not limited to, the anatomical site of cancer, comorbidities, functional implications, gender and patient age.”

1. **Even the therapeutic team will develop a differential behavior in front of different types of cancer, so it is imperative to delimitate the specific cancer and even the clinical stage or the treatment for the cancer.**

As above, we will specifically enquire about these topics where relevant.

1. **Authors must decide on anatomic site, histologic characteristics, clinical stage, and treatment modality and evaluate according to specific selection criteria, considering clinical and disease-specific characteristics.**

As above, as this is not quantitative research, we do not standardise our approach.

Competing Interests: I am an author.

Reviewer Report 18 August 2023

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This paper is the protocol of a preplanned secondary analysis of the trial SURECAN, on a qualitative study about the psychological intervention ACT+ among participants and the therapists who deliver the intervention. Should the intervention be proven successful by the main trial, with this secondary analysis the authors are aiming to assess ways to incorporate it into the NHS.

It's a well-designed study based on important practical and pragmatic questions to be answered.

There are, however, some questions I would like to be addressed before its publication:

1. The participants of the SURECAN trial are described as people living with and beyond cancer. However, I understood that the trial is directed to people who were treated for cancer and are disease-free, meaning the population of the SURECAN should be described as "people living beyond cancer" only. If I understood correctly, people living with cancer are excluded.

2. The authors justify the absence of registry of the protocol with the qualitative nature of the study. I suggest to rethink this decision or, in alternative, to expand on the justification, as there is bibliography in favor of registering qualitative studies [1].

3. Introduction section:

3.1. I feel that information on the importance of the topic is missing. Why do the authors believe that this qualitative study is important and useful? What is the background? What has been done in the past?

3.2. The five cancer groups are not consistent with what is advertised in the site of the trial - is it urological (as it is in the paper) or prostate (as it is stated in the site)?

3.3. The first and only time the acronym IAPT appears, it is not explained

4. The sample size of both parts A and B are not justified at all. I strongly advise to explain why is this the sample size, if there were any assumptions and which were they?

References

1. L. Haven T, Van Grootel D: Preregistering qualitative research. *Accountability in Research*. 2019; **26** (3): 229-244 Publisher Full Text

Is the rationale for, and objectives of, the study clearly described?

Yes

Is the study design appropriate for the research question?

Yes

Are sufficient details of the methods provided to allow replication by others?

Partly

Are the datasets clearly presented in a useable and accessible format?
Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Supportive care in Oncology, physical exercise and cancer, health-related quality of life

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Author Response 14 Dec 2023

Damien Ridge

Dear Professor Joaquim

Many thanks for noting our protocol represents "a well-designed study based on important practical and pragmatic questions to be answered."

We have addressed your questions in turn below, and believe that they have helped us to refine and clarify the manuscript:

1. **The participants of the SURECAN trial are described as people living with and beyond cancer. However, I understood that the trial is directed to people who were treated for cancer and are disease-free, meaning the population of the SURECAN should be described as "people living beyond cancer" only. If I understood correctly, people living with cancer are excluded.**

We have added the following clarification:

"The SURECAN trial is directed to people who have completed cancer treatment with curative intent. For example, some people with prostate cancer continue with long-term, ongoing maintenance treatment in the form of androgen suppression therapy. People receiving this type of maintenance treatment are eligible for recruitment into the SURECAN trial. In addition, people with certain haematological cancers are treated with the intention of long-term remission, which means they are never technically disease-free. This is why we have included within our eligibility definition, "treated with curative intent/long-term remission". For these reasons we prefer the term 'living with and beyond' cancer."

2. **The authors justify the absence of registry of the protocol with the qualitative nature of the study. I suggest to rethink this decision or, an alternative, to expand on the justification, as there is bibliography in favor of registering qualitative studies [1].**

We have added the following text to the protocol:

"Currently, templates for preregistering qualitative protocols are generally not yet well developed for qualitative research (e.g. quantitative assumptions, templates not fitting qualitative research paradigms), especially given qualitative research involves ongoing iterative changes to study designs to respond to emerging insights in the field (Branney et al., 2023). There is still some work needed to ensure templates are suitable for qualitative preregistration (Haven et al., 2020), and for this reason we have not preregistered our protocol."

3. **Introduction section:**

3.1. **I feel that information on the importance of the topic is missing. Why do the authors believe that this qualitative study is important and useful? What is the background? What has been done in the past?**

We have added the following text:

"This current qualitative study is particularly important because if the SURECAN trial is successful, and ACT+ is integrated into the NHS, it is critical to know more about why some patients benefit and others do not. This is so that ACT+ can be optimised to help the most patients in the NHS. When we have used a similar study approach in a previous trial of Graded Exercise Therapy, we discovered factors linked to participant improvement (e.g. patient motivation, being able to tolerate an initial phase of no improvement) (Cheshire et al., 2020). Thus, this allows practitioners tosubsequently refine their treatment approach to address factors that will improve the likelihood of success."

3.2. **The five cancer groups are not consistent with what is advertised in the site of the trial - is it urological (as it is in the paper) or prostate (as it is stated in the site)?**

Urological cancer, as stated in the paper, is correct. At the time that the SURECAN website went live, prostate cancer was one of the five cancer groups. During the pilot study, we broadened the eligibility criteria so as to include people who had been treated for either bladder cancer or renal cancer. Thus, the cancer group name was changed from 'prostate' to 'urological', and the SURECAN website has been updated to reflect this change, see: https://surecanstudy.qmul.ac.uk

3.3. **The first and only time the acronym IAPT appears, it is not explained**

IAPT stands for Improving Access to Psychological Therapies. Since January 2023, IAPT services have a new name: "NHS Talking Therapies" (https://www.england.nhs.uk/blog/whats-in-a-name-nhs-talking-therapies-for-anxiety-and-depression-the-new-name-for-iapt-services/). We have amended the protocol and replaced "IAPT services" with "NHS Talking Therapies services".

4. **The sample size of both parts A and B are not justified at all. I strongly advise to explain why is this the sample size, if there were any assumptions and which were they?**

We have added the following text to address part A:

"Our previous research has shown that we need to recruit at least 9 participants in each of the improvement and non-improvement groups to make useful comparisons between participants (Cheshire et al., 2020). As we will not know which group the participants fall into until after the trial is unblinded, we estimate that a sample of up to 30 will ensure we have sufficient numbers in each group to be able to compare patients with improved and not improved 'quality of life' scores."

As stated for part B:

"*We aim to recruit 10 therapists participating in the SURECAN trial, out of around 25-30 therapists who are participating in the SURECAN trial. This sample size allows us to purposefully sample (Campbell et al., 2020), to improve rigour by including a range of views according to differences in host organisations, core professions, levels of experience and genders*."

Competing Interests: I am an author.

Reviewer Report 20 July 2023

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Rebecca L. Gould
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This is a well-written protocol for an interesting qualitative interview study which constitutes part of a mixed methods process evaluation of the SURECAN trial. The SURECAN trial is a pragmatic, parallel, single blind, two-arm randomised controlled trial of Acceptance and Commitment Therapy plus support to return to work and/or physical activity and usual aftercare (ACT+) for improving quality of life in people who are living with and beyond cancer in comparison to usual aftercare alone. Up to 30 people who are living with and beyond cancer, who have been randomly allocated to the ACT+ arm, will be interviewed, as well as up to 10 therapists involved in intervention delivery. Data will be analysed using thematic analysis. The protocol would benefit from further clarification of the following issues:

1. How improvement vs. no improvement will be defined in relation to QoL following ACT+. This needs to be specified *a priori* in order to avoid potential bias in qualitative data analysis in relation to research question 1 for Part A.

2. The justification as to why research question 2 for Part A will only be explored in trial

participants and not therapists.

3. What the ACT+ intervention comprises as very little information is provided about it (e.g. brief information about the number of sessions, delivery format, how therapists are trained and supervised, etc).

4. The reason as to why one of the inclusion criteria for trial participants is having "received at least four sessions of ACT+" (e.g. because at least four sessions is considered a sufficient dose of ACT+).

5. It would be useful to highlight that it will not be possible to ensure equal numbers of trial participants who improved vs. those who did not, nor will it be possible to purposively sample trial participants who improved vs. those who did not as the researchers will be blinded to treatment outcome.

6. The justification for a sample size of 10 therapists.

7. Whether the interview guides will be pilot tested prior to recruitment (and if not, why not).

8. How Patient and Public Involvement members will be involved in the qualitative study.

9. Whether specific reporting guidelines will be used when reporting the qualitative study, such as the consolidated criteria for reporting qualitative research.

Is the rationale for, and objectives of, the study clearly described?
Yes

Is the study design appropriate for the research question?
Yes

Are sufficient details of the methods provided to allow replication by others?
Partly

Are the datasets clearly presented in a useable and accessible format?
Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Psychological therapies, clinical trials

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Author Response 14 Dec 2023

Damien Ridge

Dear Professor Gould,

Many thanks for noting our protocol "well-written" and "an interesting qualitative interview study", as well as for your helpful comments aimed at improving the manuscript. We have further clarified the manuscript by addressing each of your points in turn as below:

1. **How improvement vs. no improvement will be defined in relation to QoL following ACT+. This needs to be specified *a priori* in order to avoid potential bias in qualitative data analysis in relation to research question 1 for Part A.**

We have added the following clarification to the manuscript:

"Improvement will be identified as an increase of more than 6 points on the FACT-G scale. This will only be determined for individual participants at the end of the study after data lock. Participants are sampled and interviewed with the researchers blind to their change in FACT-G score. We anticipate our sample is large enough to meaningfully compare participants who appear to have improved and not improved on these criteria. The change or not in FACT-G will then be used to interpret the analysis."

1. **The justification as to why research question 2 for Part A will only be explored in trial participants and not therapists.**

The study was designed such that research questions 1 and 2 (Part A) would be addressed at the end of the trial when we will be unblinded to treatment outcomes and can conduct further analyses, comparing interview findings from participants who improved and those who did not improve following ACT+. Addressing research question 2 (Part A) in interviews by gathering the views of therapists is also worth doing, and we have added this to the protocol.

1. **What the ACT+ intervention comprises, as very little information is provided about it (e.g. brief information about the number of sessions, delivery format, how therapists are trained and supervised, etc).**

We have added the following information to the protocol:

"Trial participants receive eight one-hour sessions of ACT+ weekly or fortnightly delivered by telephone or online. Therapists attend an ACT+ training workshop delivered over two to three days and receive regular supervision during the trial from an experienced cognitive behavioural therapist with extensive training in ACT. We have reported in more depth on the development and evaluation of the training (Moschopoulou et al., 2022). Additional information about the intervention will be available in the protocol for the main quantitative trial looking at the effectiveness and cost-effectiveness of the ACT+ intervention, to be published in the public domain in due course."

1. **The reason as to why one of the inclusion criteria for trial participants is having "received at least four sessions of ACT+" (e.g. because at least four sessions is considered a sufficient dose of ACT+).**

As the reviewer suggests, we have included at least four sessions of ACT+, as this is considered the minimum 'optimal dose' of routine psychotherapies according to a recent systematic review (Robinson et al., 2020), which we have now explained in the protocol:

"Four sessions of ACT+ were considered the minimum 'optimal dose', since research shows

improvements generally take at least 4 sessions for those with common mental health problems who are likely to respond to short-term psychological treatments (Robinson et al., 2020).'

1. **It would be useful to highlight that it will not be possible to ensure equal numbers of trial participants who improved vs. those who did not, nor will it be possible to purposively sample trial participants who improved vs. those who did not as the researchers will be blinded to treatment outcome.**

We have added this note to the protocol:

"It will not be possible to ensure equal numbers of trial participants who improved versus those who did not. Nor will it be possible to purposively sample trial participants who improved versus those who did not, as the researchers will be blinded to treatment outcome during the sampling phase."

1. **The justification for a sample size of 10 therapists.**

To answer our research question for Part B, we judged that we would need to interview a small proportion of participating therapists, not all of them. We estimated that a sample size of ten out of an anticipated 25-30 therapists participating in SURECAN would suffice, provided we include a range of host organisations, core professions, experience and genders in our sampling. We have included this information:

"We aim to recruit 10 therapists participating in the SURECAN trial, out of around 25-30 therapists who are participating in the SURECAN trial. This sample size allows us to purposefully sample (Campbell et al., 2020), to improve rigour by including a range of views according to differences in host organisations, core professions, levels of experience and genders."

1. **Whether the interview guides will be pilot tested prior to recruitment (and if not, why not).**

The interview guides were not pilot-tested prior to recruitment, however, we have added the following clarifying information to the protocol:

"While the interview guides were not pilot tested, they were developed collaboratively by the study team, drawing on: members' wide expertise, and interview guides we had developed for the SURECAN pre-pilot study (a small test-run of ACT+, followed by individual interviews with participating patients and ACT+-trained therapists). We also drew from interview guides used in a similar study comparing trial participants' experiences of improvement and non-improvement for an intervention (Cheshire et al., 2020). Additionally, the interview guide for trial participants was reviewed by five of the SURECAN study PPI representatives. Finally, in qualitative research, it should be noted that interview guides are seen as 'a work in progress' (Adams, 2015). It is recommended that guides be further refined periodically as the researcher conducts interviews in the field, as emerging insights suggest how topics should be refined or added."

1. **How Patient and Public Involvement members will be involved in the qualitative study.**

The following information has been added to the protocol:

"Two Patient and Public Involvement (PPI) representatives were grant co-applicants for the SURECAN research programme. Along with other PPI representatives, they have been actively involved in SURECAN through regular programme management meetings as well as specific PPI meetings, and through participation in reviewing and commenting on patient-facing materials

used in the ACT+ therapy sessions. Five SURECAN PPI representatives reviewed the invitation letter/email, the study information sheet and the interview schedule for trial participants in this qualitative study. Interim findings from this qualitative study will be presented to the SURECAN PPI representatives for debate."

1. **Whether specific reporting guidelines will be used when reporting the qualitative study, such as the consolidated criteria for reporting qualitative research.**

While we will be cognisant of the items in the checklist of the consolidated criteria for reporting qualitative research in our reporting, we note recent research that questions the credibility of such checklists (Buus & Perron, 2020). Additionally, their apparently transparent criteria risk undermining the rigour and quality of qualitative research (King, 2021). Thus, we will use the checklist as an advisory only.

Competing Interests: I am an author.