

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents\*

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| Section/item | Item No | Description | Addressed on page number |
| **Administrative information** |  |
| Title | 1 | Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym | 1 |
| Trial registration | 2a | Trial identifier and registry name. If not yet registered, name of intended registry | 5 |
| 2b | All items from the World Health Organization Trial Registration Data Set | N/A |
| Protocol version | 3 | Date and version identifier | 5 |
| Funding | 4 | Sources and types of financial, material, and other support | 1 |
| Roles and responsibilities | 5a | Names, affiliations, and roles of protocol contributors | 13 |
| 5b | Name and contact information for the trial sponsor | 1 |
|  | 5c | Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities | 1 |
|  | 5d | Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) | N/A |
| Introduction |  |  |  |
| Background and rationale | 6a | Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention | 3-4 |
|  | 6b | Explanation for choice of comparators | 4 |
| Objectives | 7 | Specific objectives or hypotheses | 4 |
| Trial design | 8 | Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) | 4 |
| Methods: Participants, interventions, and outcomes |  |
| Study setting | 9 | Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained | 5 |
| Eligibility criteria | 10 | Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) | 5 |
| Interventions | 11a | Interventions for each group with sufficient detail to allow replication, including how and when they will be administered | 7 |
| 11b | Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) | 7 |
| 11c | Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) | 11 |
| 11d | Relevant concomitant care and interventions that are permitted or prohibited during the trial | 5 |
| Outcomes | 12 | Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended | 10 |
| Participant timeline | 13 | Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) | Fig 1 |
| Sample size | 14 | Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations | 5 |
| Recruitment | 15 | Strategies for achieving adequate participant enrolment to reach target sample size | 5-6 |
| **Methods: Assignment of interventions (for controlled trials)** |  |
| Allocation: |  |  |  |
| Sequence generation | 16a | Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions | 6 |
| Allocation concealment mechanism | 16b | Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned | 6 |
| Implementation | 16c | Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions | 6 |
| Blinding (masking) | 17a | Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how | 6 |
|  | 17b | If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant’s allocated intervention during the trial | N/A |
| **Methods: Data collection, management, and analysis** |  |
| Data collection methods | 18a | Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol | 8-10 |
|  | 18b | Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols | 7 |
| Data management | 19 | Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol | N/A |
| Statistical methods | 20a | Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol | 10-11 |
|  | 20b | Methods for any additional analyses (eg, subgroup and adjusted analyses) | 10-11 |
|  | 20c | Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation) | 10 |
| **Methods: Monitoring** |  |
| Data monitoring | 21a | Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed | N/A |
|  | 21b | Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial | N/A |
| Harms | 22 | Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct | 7 |
| Auditing | 23 | Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor | 5 |
| Ethics and dissemination |  |
| Research ethics approval | 24 | Plans for seeking research ethics committee/institutional review board (REC/IRB) approval | 5 |
| Protocol amendments | 25 | Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators) | N/A |
| Consent or assent | 26a | Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) | 6 |
|  | 26b | Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable | N/A |
| Confidentiality | 27 | How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial | 5 |
| Declaration of interests | 28 | Financial and other competing interests for principal investigators for the overall trial and each study site | 1 |
| Access to data | 29 | Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators | 1 |
| Ancillary and post-trial care | 30 | Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation | 7 |
| Dissemination policy | 31a | Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions | 5 |
|  | 31b | Authorship eligibility guidelines and any intended use of professional writers | N/A |
|  | 31c | Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code | 5 |
| Appendices |  |  |  |
| Informed consent materials | 32 | Model consent form and other related documentation given to participants and authorised surrogates | Supplementary materials |
| Biological specimens | 33 | Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable | N/A |

\*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons “[Attribution-NonCommercial-NoDerivs 3.0 Unported](http://www.creativecommons.org/licenses/by-nc-nd/3.0/)” license.

**Participant Information Statement**

***Research Study: Cognitive Behavioural Therapy***

 ***for Death Anxiety: A Randomised Controlled Trial***

Dr Rachel Menzies (Responsible Researcher)

School of Psychology
Email: rachel.menzies@sydney.edu.au

1. **What is this study about?**

We are conducting a research study on an online Cognitive Behavioural Therapy (CBT) treatment for fears of death. The study aims to assess how effective this new online psychological treatment is at reducing death anxiety, compared with a waitlist control condition.

This Participant Information Statement tells you about the research study. Please read this sheet carefully and ask questions about anything that you don’t understand or want to know more about. You can keep a copy of this page by printing it out or saving it to the Bookmarks tab of your Internet browser.

1. **Who is running the study?**

The study is being carried out by the following researchers:

* Dr. Rachel Menzies, Research Fellow, School of Psychology, The University of Sydney
* Dr. Fjola Helgadottir, Clinical Psychologist, Vancouver CBT Centre; Co-owner, AI Therapy
* Bethany Richmond, Research Assistant, The University of Sydney
* Daelin Coutts-Bain, Research Assistant, The University of Sydney
* Dennyson Veloso, Research Assistant, The University of Sydney
* Claudia Lyndon, Research Assistant, Menzies Anxiety Centre
* Georgina Brown, Research Assistant, Menzies Anxiety Centre

This study is being funded by an NHMRC (National Health and Medical Research Council) Investigator Grant.

1. **Who can take part in the study?**

To be eligible for inclusion in this study, you must be an adult (aged over 18) who is currently living in Australia. You must also have regular access to the internet, and have functional written and spoken English. In addition, you must meet criteria for an anxiety-related disorder, and have high levels of death anxiety.

If you are taking medication for depression or anxiety, you must have been on a stable dose for more than 8 weeks to take part in this study.

Unfortunately, you will not be eligible for this study if you have:

* Suicidal intent
* Substance abuse or dependence
* A psychotic illness
* Received consistent psychotherapy within the last 6 months
1. **What will the study involve for me?**

If you give your consent to participate in this study, you will first complete a short online pre-screening questionnaire to confirm your eligibility for the study. This questionnaire will ask for some basic demographic information, as well as asking about your mental health and death anxiety. We will also ask for a contact number and email.

Based on the results of this pre-screening survey, you may be contacted so that we may arrange an interview with you. This interview is to confirm your eligibility, and will involve asking about your mental health history. This interview will take approximately 2 hours, and can be conducted over the telephone or video (e.g., Zoom).

If you are deemed eligible, you will then be randomly assigned to either the treatment group *or* to a waitlist control condition.

If you have been assigned to the treatment group, you can immediately begin accessing the online treatment program. If you are allocated to the waitlist control condition, you will not receive access to the online treatment at this time. However, you will receive access to the online treatment at the completion of the study. The waitlist control condition is important, so that we can assess whether any benefits people report at the end of the study are actually due to the treatment itself.

The treatment is based on the principles of Cognitive Behavioural Therapy (CBT), which is an effective and evidence-based treatment for anxiety. The CBT treatment will involve starting to address and change unhelpful thoughts and behaviours that you may currently be experiencing, in order to reduce anxiety.

The treatment consists of seven modules, and can be completed at your own pace from any computer. You will be given a unique log-in to protect your own privacy. In total, we expect the online treatment will take an average of 10 hours to complete.

1. **Can I withdraw once I’ve started?**

Being in this study is completely voluntary and you do not have to take part. Your decision will not affect your current or future relationship with the researchers or anyone else at The University of Sydney.

If you would like to withdraw at any time, please contact Dr Rachel Menzies (rachel.menzies@sydney.edu.au). If you decide to withdraw, we will not collect any more information from you. Any information that we have already collected however will be kept in our study records and may be included in the study results. This is because it is important to know if people start the program and stop to determine whether it is a suitable program for others.

There may be circumstances where your participation is terminated by the trial sponsor or by the researchers. For instance, if an adverse event is assessed to be due to study participation, you may be instructed to immediately cease involvement in the study. Appropriate action will be taken to ensure you get the professional help you may require.

1. **Are there any risks or costs?**

It is possible that the treatment program may cause a short-term increase in feelings of psychological discomfort or distress, as is often the case with CBT treatments for anxiety. It is not uncommon for individuals to experience some anxiety when confronting their fears for the first time. However, with continued exposure to CBT treatments, distress has been shown to reduce in the long-term, making CBT the most effective treatment for anxiety. Therefore, the experience of more than transitory distress is unlikely. Please contact the responsible researcher at any time if you feel that the program is increasing your anxiety.

1. **What happens when the study ends?**

If you complete the online program, you will receive a free eBook to keep, summarising the content of the program for you. If you are in the waitlist group, you will receive access to the program following completion of the trial.

1. **Are there any benefits?**

CBT has been shown to be an effective treatment for death anxiety. In our previous study of this particular online treatment, most participants experienced some improvement in their death anxiety. However, we cannot guarantee that you will receive any direct benefits from being in the study. We hope that your participation might also be beneficial to others because we will be able to learn more about our online treatment, and whether it is more effective compared to a waitlist control condition.

1. **What will happen to information that is collected?**

By providing your consent, you are agreeing to us collecting information about you for the purposes of this study. During the study, your responses in the online treatment program will be hosted by a company specialising in secure, online psychological treatments. This company is co-owned by Fjola Helgadottir, one of the researchers involved in this study. Your data during the program will be encrypted and anonymous, and will be hosted on a secure server in Canada.

Any information you provide us will be stored securely and identifiable information will only be disclosed with your permission, unless we are required by law to disclose material.

Your questionnaire responses outside of the online treatment (e.g., in the initial pre-screening survey) will be stored electronically in a password-protected file on a secure computer. Only the researchers will be able to access this data. At the end of the storage period, data will be retained in perpetuity, and may be used in future research projects conducted by the researcher or other parties. However, your name will not be stored with the data, so nobody will know that you have been involved in this study. By providing your consent you are allowing us to use your information in future projects. We will seek ethical approval before using the information in these future projects.

The results from the study will be published in journal publications or presentations, but you will not be identified in any way.

1. **Will I be told the results of the study?**

You have a right to receive feedback about the overall results of this study. You can tell us that you wish to receive feedback by ticking the relevant box on the consent form. This feedback will be in the form of a brief lay summary. Further, you will receive personalised feedback at the completion of the treatment program. This will be in the form of graphs showing your scores on measures of anxiety, both before and after the treatment.

1. **What if I would like further information?**

When you have read this information, the following researcher will be available to discuss it with you further and answer any questions you may have:

* Dr Rachel Menzies, NHMRC Research Fellow in the School of Psychology at the University of Sydney (rachel.menzies@sydney.edu.au; 0481 350 925)
1. **What if I have a complaint or any concerns?**

The ethical aspects of this study have been approved by the Human Research Ethics Committee (HREC) of The University of Sydney [2023/351] according to the *National Statement on Ethical Conduct in Human Research (2007).*

If you are concerned about the way this study is being conducted or you wish to make a complaint to someone independent from the study, please contact the University:

Human Ethics Manager

human.ethics@sydney.edu.au

+61 2 8627 8176

***You can keep a copy of this information sheet by downloading the PDF here***

**Participant Consent Form**

***Research Study: Cognitive Behavioural Therapy***

 ***for Death Anxiety: A Randomised Controlled Trial***

Dr Rachel Menzies (Responsible Researcher)

School of Psychology
Email: rachel.menzies@sydney.edu.au

**Do you consent to take part in this study?**

* YES – I consent, and wish to take part in the study
* NO – I do NOT consent, and do NOT wish to take part in the study

**Would you like feedback on the overall results of this study?**

* YES
* NO

**Do you consent to being contacted for future studies?**

* YES
* NO

If you answered **yes** to either of these two questions, please provide your preferred contact details (email/telephone/postal address):

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| --- |
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