Trial protocol

Project name

Authors:

QA:

|  |  |  |
| --- | --- | --- |
| VERSION | DATE | REASON FOR REVISION/NOTES |
| *Any changes to the design to be agreed between the implementation partner(s) and the evaluators. Note any agreed changes in the table below.* | | |
| 1.1 |  |  |
| 1.0 [*original*] |  |  |
| Pre-registration |  | This design has been pre-registered on [insert registry].[[1]](#footnote-1) |

QA to be completed by an academic lead.

The QA rating system is based on Evaluation Security tool presented in the TASO Monitoring and Evaluation Framework.[[2]](#footnote-2)

|  |  |  |
| --- | --- | --- |
| **QA** | **Comments** | **Rating (out of 5)** |
| Design |  |  |
| Sample size |  |  |
| Outcome measure |  |  |
| Attrition |  |  |
| Validity |  |  |
| **Overall** |  |  |

# Summary

Note: for TASO funded projects these subheadings are to be adhered to and should not be replaced by a narrative executive summary.

[1 page summary broken down into headings below; normally easiest to complete at the end]

### Background

### Aims

### Intervention

### Design

### Outcome measures

### Analyses

# Background

* Names, affiliations, and roles of protocol contributors
* Roles and responsibilities of everyone involved in the research
* Sources and types of financial, material, and other support

|  |  |  |
| --- | --- | --- |
| Organisation | Name | Role and responsibilities |
|  |  |  |

# Aims

* Description of research question and justification for undertaking the research, including summary of relevant studies (published and unpublished)
* Specific objectives or hypotheses
* Explanation for choice of comparators (if relevant)

# Intervention

* Interventions with sufficient detail to allow replication, including how and when they will be administered
* Criteria for discontinuing or modifying allocated interventions
* Strategies to improve implementation, and any procedures for monitoring adherence
* TOC goes here (or in annex)

# Design

* Description of research design including
* For trials, include type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)
* Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants
* Diagram to go here (please use Lucidchart)

# Outcome measures

* Primary, secondary, and other outcomes, including the specific measurement variables, analysis metrics, methods of aggregation (e.g., median, proportion), and time point for each outcome.

|  |  |  |
| --- | --- | --- |
| **Outcome measure** | **Data to be collected** | **Point of collection** |
| **PRIMARY:** XXX |  |  |
| **SECONDARY:** XXX |  |  |

# Sample selection

* Description of study settings
* Inclusion and exclusion criteria for participants
* Expected sample size and rationale for this number
* Strategies for achieving adequate participant enrolment to reach target sample size

# Randomisation [can be dropped if not an RCT]

* Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification.
* 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.
* Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions?
* Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how?
* How will balance be checked?

1. **Identification strategy [can be dropped if not a quasi-experimental design]**

* Method for identifying a comparison group that is as similar as possible to the treatment group.
* Include details of the relevant observable characteristics that will be used in the identification strategy.
* If using a difference-in-differences design, detail how the parallel trends assumption will be met.

# Data collection

* 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
* Plans to promote participant retention and complete follow-up.
* 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

|  |  |  |
| --- | --- | --- |
| Data item | Timeframe | Collector |
|  |  |  |

# Procedure

* High-level project timeline in table below

|  |  |
| --- | --- |
| **Timeframe** | **Action** |
|  |  |

# Power calculations

Our assumptions are:

* Significance level: 0.05
* Power: 0.8
* Other assumptions to be included here
* Power graphs to go in annex

|  |  |  |  |
| --- | --- | --- | --- |
| **Sample size** | **Size of treatment group** | **Size of comparator group** | **MDES** |
| [A range of values can be given here in multiple rows to present optimistic/pessimistic estimates. Please include rows which incorporate estimates of sample attrition e.g. a 20% reduction in sample, size] |  |  | [Please present in terms of abstract effect size (Cohen’s d and Cohen’s h etc.) and also translate into a real-life impact effect (e.g. a 10pp increase)] |

# Analytical strategy

* 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.
* Include your model here and describe any variables you intend to use.
* Methods for any additional analyses (eg, subgroup and adjusted analyses).
* Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)
* Plans for any cost-benefit analysis

# Ethical considerations

# Risks

|  |  |  |  |
| --- | --- | --- | --- |
| **Part of evaluation** | **Risk** | **Mitigation strategy** | **Risk owner** |
|  |  |  |  |

# Annex

* Please include the standard code that will be used for randomisation (if applicable) and analysis

1. Insert link to pre-registration - TASO recommends registering all trials on the [Open Science Framework.](https://osf.io/) https://osf.io/ [↑](#footnote-ref-1)
2. https://taso.org.uk/evidence/evaluation/ [↑](#footnote-ref-2)