Analysis report

Project name

### Date

Authors:

QA:

QA to be completed by an Academic Lead, or another individual nominated by them before publication.

# 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*

*Results*

*Conclusions*

# Introduction

# Background

* Names, affiliations, and roles of contributors
* Roles and responsibilities of everyone involved in the project
* 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research question and justification for undertaking the research, including summary of relevant studies (published and unpublished)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 were administered
* TOC goes here (or in annex)

# Methods

# Design

* Description of research design
* For trials, include type of trial (e.g., parallel group, crossover, factorial, single group), allocation ratio, and framework (e.g., superiority, equivalence, noninferiority, exploratory)
* Important changes to methods after trial commencement
* Diagram to go here (please use Lucidchart)

# Randomisation [can be dropped if not an RCT]

* Method of generating the allocation sequence (e.g., computer-generated random numbers), and list of any factors for stratification.
* Mechanism of implementing the allocation sequence (e.g., central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned.
* Who generated the allocation sequence, who enrolled participants, and who assigned participants to interventions?
* Who was blinded after assignment to interventions (e.g., trial participants, care providers, outcome assessors, data analysts), and how?

# Identification strategy [can be dropped if not a quasi-experimental design]

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

# 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.
* Any changes to outcomes after project commenced

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

# Sample selection

* Description of study settings
* Inclusion and exclusion criteria for participants
* How sample size was determined [can link to TP]

# 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 used.
* Make sure any relevant plans from the TP are listed here.

# Results

# Participant flow

* Dates defining the periods of recruitment and follow-up
* Why the trial ended or was stopped
* For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome
* Discussion of attrition [include a table if appropriate]
* Please create something based on the CONSORT flow diagram found here: http://www.consort-statement.org/

# Description of data

* A table showing baseline demographic characteristics for each group
* Balance checks
* Descriptive stats for the outcomes

# Outcome of analysis

* For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)
* For binary outcomes, presentation of both absolute and relative effect sizes is recommended
* Results of any other analyses performed, including subgroup analyses and robustness checks, distinguishing pre-specified from exploratory

# Discussion

* Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses
* Generalisability (external validity, applicability) of the trial findings
* Interpretation