## 1. Participant flow

Provide an appropriate participant flow diagram.

In accordance with the CONSORT statement1, include for each group:

* the number of individuals assessed for eligibility (if collected)
* the number of participants allocated;
* the number of participants that received the intended treatment/intervention;
* the number of participants analysed for the primary outcome;
* the number of losses/exclusions after assignment, together with reasons

For randomised controlled trials, it is recommended to use the CONSORT Flow Diagram - provided below and also available at <http://www.consort-statement.org/consort-statement/flow-diagram>. The diagram can be amended for other trial designs.

Assessed for eligibility (n= )

Excluded (n= )

  Not meeting inclusion criteria (n= )

  Declined to participate (n= )

  Other reasons (n= )

Analysed (n= )  
 Excluded from analysis (give reasons) (n= )

Lost to follow-up (give reasons) (n= )

Discontinued intervention (give reasons) (n= )

Allocated to intervention (n= )

 Received allocated intervention (n= )

 Did not receive allocated intervention (give reasons) (n= )

Lost to follow-up (give reasons) (n= )

Discontinued intervention (give reasons) (n= )

Allocated to intervention (n= )

 Received allocated intervention (n= )

 Did not receive allocated intervention (give reasons) (n= )

Analysed (n= )  
 Excluded from analysis (give reasons) (n= )

## Allocation

## Analysis

## Follow-Up

Allocated (n= )

## Enrollment

## 2. Baseline characteristics

Provide a table of baseline demographic and clinical characteristics (including important pre-intervention prognostic factors) for each study group.

An example is provided below.

**Table 1. Example of reporting baseline demographic and clinical characteristics**

|  |  |  |
| --- | --- | --- |
|  | **Intervention (N=2954)** | **Placebo**  **(N=2972)** |
| Age (years; mean (SD)) | 65.9 (7.1) | 66.9 (7.5) |
| Sex (female; n (%)) | 1282 (43.3%) | 1265 (43.6%) |
| Smoking status: |  |  |
| Current (n (%)) | 290 (9.9%) | 285 (9.6%) |
| Past (n (%))  BMI (median; IQR)  Heart rate (beats per minute; mean; SE) | 1273 (43.1%)  23.6 (21.5-25.2)  67.5 (11.1) | 1283 (43.2%)  22.4 (21.1-23.9)  69.1 (11.9) |

## 3. Outcome measures

Provide results for the primary outcome (minimum requirement), and preferably all other outcomes listed in the registered trial record.

The below guidelines are adapted from the CONSORT statement1,2 and *Interpreting and reporting clinical trials: A guide to the CONSORT statement and the principles of randomised controlled trials3*.

For each outcome:

1. **Provide a summary of the outcome in each group.**

Examples include:

* 1. For binary outcomes: the number of participants with or without the event and the denominators
  2. For continuous outcomes: the mean, standard deviation, median, interquartile range

1. **Provide direction and size of effect, i.e. contrast between the groups.**

Examples include:

* 1. For binary outcomes: risk ratio/relative risk, odds ratio, risk difference
  2. For survival time data: hazard ratio, difference in median survival time
  3. For continuous outcomes: difference in means or medians

1. **Provide measure of variability for all outcomes to indicate the precision of the effect estimate.**

E.g. 95% Confidence intervals are commonly used

1. In addition, **P values** for determining statistical significance may also be provided.

Results of any other analyses performed (e.g. subgroup analyses, adjusted analyses) can also be reported in this section.

We recommend presenting outcome information in tables and/or figures.

Some example tables are provided on the following page.

**Table 2: Example of reporting summary of results for each study group (binary outcomes).**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Intervention**  **N=480** | | **Control**  **N=480** | | **Relative Risk (95% CI)** | **P-value** |
| **Endpoint** | **n(%)** | **N** | **n(%)** | **N** |  |  |
| **Primary endpoint** |  |  |  |  |  |  |
| Incidence of stroke  **Secondary endpoints**  Mortality  Hospital admission  HAM-D score <10 | 201 (42.7)  2 (0.004)  174 (36.6)  196 (40.8) | 471  467  466  463 | 194 (40.4)  1 (0.002)  154 (32.1)  160 (33.3) | 473  470  462  462 | 1.03 (0.89, 1.21)  2.00 (0.18, 21.9)  1.12 (0.95, 1.35)  1.23 (1.04, 1.45) | 0.65  0.57  0.17  0.02 |

**Table 3: Example of reporting of summary results for each study group (continuous outcomes).**

|  | **Intervention (n=64)** | |  | **Control (n=63)** | | **Difference (95% CI) at 6 months** |
| --- | --- | --- | --- | --- | --- | --- |
| **Baseline (mean (SD))** | **6 months (mean (SD))** | **Baseline (mean (SD))** | **6 months (mean (SD))** |
| SF-12 score | 63.3 (13.7) | 83.1 (15.1) |  | 64.9 (14.2) | 77.9 (17.6) | 4.52 (−0.74 to 9.66) |
| VAS pain score (0-100) | 4.24 (2.1) | 1.45 (2.1) |  | 4.14 (2.1) | 2.63 (2.7) | −1.27 (−2.18 to −0.38) |
| Serum cholesterol (mg) | 6.52 (2.2) | 2.52 (2.8) |  | 5.87 (2.1) | 3.65 (2.38) | −1.21 (−2.17 to −0.17) |

## 4. Adverse events/harms

Guidance for this section is based on the CONSORT Statement – Harms4.

Provide a summary of any adverse events/harms separately for each group which have not already been listed in trial outcomes.

For each adverse event/harm:

1. **Provide a measure of absolute risk per study arm.**

Example:

* 1. incidence

1. Provide separate information about the **severity/grade of the event**, if relevant.
2. Present appropriate metrics for **recurrent events**.

Example:

* 1. number of affected participants and number of events for each study group and rate (events per unit of person-time).

Any exploratory analyses for harms can also be provided in this section.

An example of adverse event reporting may be:

*3 of the 27 (11.1%) intervention group participants versus 1 of 26 (3.8%) control group participants experienced nausea grade >2 on 5-point Likert Scale within four hours of dosing. There were no recurrent nausea events in any participants.*

## Useful links

CONSORT website: <http://www.consort-statement.org/>

EQUATOR Network website: <http://www.equator-network.org/>

## References

(1) Moher D, Schulz KF, Altman DG, et al; for the CONSORT Group. The CONSORT statement revised recommendations for improving the quality of reports of parallel-group randomized trials. *Ann Intern Med* 2001; 134: 657-662.

(2) Moher D, Hopewell S, Schulz KF, Montori V, Gøtzsche PC, Devereaux PJ, Elbourne D, Egger M, Altman DG. CONSORT 2010 Explanation and Elaboration: updated guidelines for reporting parallel group randomised trials. *BMJ* 2010;340:c869.

(3) Keech A, Gebski V, Pike R. *Interpreting and reporting clinical trials: A guide to the CONSORT statement and the principles of randomised controlled trials*. Sydney, MJA books, Australasian Medical Publishing Company; 2007.

(4) Ioannidis JP, Evans SJ, Gøtzsche PC, O'Neill RT, Altman DG, Schulz K, et al. Better Reporting of Harms in Randomized Trials: An Extension of the CONSORT Statement. *Ann Intern Med*. 2004;141:781-788.