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**

Randomized (n= )

**Enrollment**

Number and causes of candidates not eligible for the study should be explained.

One research arm can be presented if the clinical trial does not have a control group. Multiple research arms can be presented if the clinical trial involves more than two groups.

Number and causes of participants lost during the follow-up period should be explained.

Number and causes of participants not included in the final analysis (protocol violation, etc.) should be explained.

In a non-randomized trial, the method of group assignment should be explained here.

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Figure 1. CONSORT 2010 flow diagram (adapted from <http://www.consort-statement.org/>).