

**Enrollment**

Assessed for eligibility (n = ...)

Excluded (n = ...)  
Not meeting inclusion criteria (n = ...)  
Declined to participate (n = ...)  
Other reasons (n = ...)

Randomised (n = ...)

**Allocation**

Allocated to intervention (n = ...)  
Received allocated intervention (n = ...)  
Did not receive allocated intervention (give reasons) (n = ...)

Allocated to intervention (n = ...)  
Received allocated intervention (n = ...)  
Did not receive allocated intervention (give reasons) (n = ...)

**Follow up**

Lost to follow up (n = ...) (give reasons)  
Discontinued intervention (n = ...) (give reasons)

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Discontinued intervention (n = ...) (give reasons)

**Analysis**

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

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