

Enrolment

Allocation

Follow-up

Analysis

Assessed for eligibility (n=...)

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

Randomised (n=...)

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=...)

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

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

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

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

Flow diagram of the progress through the phases of a parallel randomised trial of two groups (that is, enrolment, intervention allocation, follow-up, and data analysis)