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 = …)

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

Discontinued intervention (n = …) (give reasons)

Analysed (n = …)
- Excluded from analysis (give reasons) (n = …)

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

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

Discontinued intervention (n = …) (give reasons)

Analysed (n = …)
- Excluded from analysis (give reasons) (n = …)