

Assessed for eligibility
(n = 500)

Excluded (n = 100):

- Not meeting inclusion criteria: 60
- Declined to participate: 25
- Other reasons: 15

Randomized
(n = 400)

Allocated to intervention (n = 200)

- Received intervention (n = 195)
- Did not receive intervention (n = 5)

Allocated to control (n = 200)

- Received control (n = 198)
- Did not receive control (n = 2)

Lost to follow-up (n = 8)
Discontinued intervention (n = 4)

Lost to follow-up (n = 6)
Discontinued control (n = 3)

Analyzed (n = 200)
• Excluded from analysis (n = 0)

Analyzed (n = 200)
• Excluded from analysis (n = 0)