

Enrollment

Assessed for eligibility (n=250)

Excluded (n=20)

- ◆ Not meeting inclusion criteria
- ◆ Declined to participate
- ◆ Other reasons

Interventional Cohort (n=230)

Allocation

Allocated to intervention (n= 230)

- ◆ Received allocated intervention (n= 210)
- ◆ Did not receive allocated intervention (n= 20)

Historical Controls (n= 200)

- ◆ Did not receive allocated intervention

Follow-Up/Evaluation (at 2, 4 and 12 weeks)

Lost to follow-up (n=5)

Discontinued intervention (n= 5)

Lost to follow-up (n=0)

Analysis

Analysed (n=200)

Analysed (n=200)