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)

Analysis

- Analysed (n=200)

- 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

- Lost to follow-up (n=0)

Analysed (n=200)