Enrollment

- Assessed for eligibility (n= 124)
  
  Excluded (n= 49)
  - Not meeting inclusion criteria (n= 27)
  - Declined to participate (n= 18)
  - Other reasons (n= 4)

  Randomized (n= 75)

Allocation

Placebo group
- Allocated to intervention (n= 25)
- Received allocated intervention (n= 25)

PAS 200 group
- Allocated to intervention (n= 25)
- Received allocated intervention (n= 25)

PAS 400 group
- Allocated to intervention (n= 25)
- Received allocated intervention (n= 25)

Follow-Up

Placebo group
- Lost to follow-up (n= 0)
- Discontinued intervention (n= 2)
  - RID 025 did not keep appointment for V3, RID 055 did not keep appointment for V4

PAS 200 group
- Lost to follow-up (n= 0)
- Discontinued intervention (n= 0)

PAS 400 group
- Lost to follow-up (n= 0)
- Discontinued intervention (n= 0)

Analysis

Placebo group
- Analyzed (n= 24)
- Excluded from analysis (n= 1)
  - RID 041 dropped out because of physical condition

PAS 200 group
- Analyzed (n= 23)
- Excluded from analysis (n= 2)
  - RID 025 did not keep appointment for V3, RID 055 did not keep appointment for V4

PAS 400 group
- Analyzed (n= 25)
- Excluded from analysis (n= 0)