CONSORT 2010 Flow Diagram

**Enrollment**
- Assessed for eligibility (n=934)
  - Excluded (n=319)
    - Not meeting inclusion criteria (n=12)
    - Declined to participate (n=121)
    - Other reasons (n=186)

**Randomization** (n=615)
- Allocated to intervention (n=306)
  - Received allocated intervention (n=306)
  - Did not receive allocated intervention (give reasons) (n=0)
- Allocated to intervention (n=309)
  - Received allocated intervention (n=309)
  - Did not receive allocated intervention (give reasons) (n=0)

**Follow-Up**
- Lost to follow-up (n=56)
- Discontinued intervention (n=0)
- Lost to follow-up (n=71)
- Discontinued intervention (n=0)

**Analysis**
- Analysed (n=240)
  - Excluded from analysis (give reasons) (n=)
- Analysed (n=238)
  - Excluded from analysis (give reasons) (n=)