Assessed for eligibility (n= 55)

Excluded (n= 13)
   - Not meeting inclusion criteria (n= 4)
   - Refused to participate (n= 9)

Enrollment

Randomisation

Allocation

Allocated to intervention (n=21):
   - Received allocated intervention (n=20)
   - Did not receive allocated intervention: Disease progression (n=1)

Allocated to placebo (n=21):
   - Received allocated placebo (n=20)
   - Did not receive allocated placebo: Disease progression (n=1)

INTERVENTION GROUP (n=20)

Baseline

CONTROL GROUP (n=20)