

Enrolment

Assessed for eligibility (n=)

Excluded:
Not meeting inclusion criteria (n=)
Not assented (n=)
Declined to participate (n=)
Other reasons (n=)

Randomised: (n=)
Qualitative sub sample: (n=)

Allocation

Allocated to intervention (CCBC): (n=)
Received allocated intervention: (n=)
Did not receive allocated intervention (give reasons) (n=)

Allocated to control (FBC): (n=)
Received allocated intervention: (n=)
Did not receive allocated intervention (give reasons) (n=)

Follow-up

Lost to follow up (n=)
Discontinued intervention (give reasons) (n=)

Lost to follow up (n=)
Discontinued intervention (give reasons) (n=)

Analysis

Analysed for 6 and 12 month outcomes: (n=)
Excluded from analysis (give reasons) (n=0)

Analysed for 6 and 12 month outcomes: (n=)
Excluded from analysis (give reasons) (n=0)

