

Enrollment

Assessed for eligibility (n=140)

Excluded (n=)

- ◆ Not meeting inclusion criteria (n=)
- ◆ Declined to participate (n=)
- ◆ Other reasons (n=)

Randomized 1:1 (n=)

Allocation

Allocated to intervention (n=)

- ◆ Received allocated intervention (n=)
- ◆ Did not receive allocated intervention (give reasons) (n=)

Allocated to intervention (n=)

- ◆ Received allocated intervention (n=)
- ◆ Did not receive allocated intervention (give reasons) (n=)

Follow-Up 6 months

Lost to follow-up (give reasons) (n=)

Discontinued intervention (give reasons) (n=)

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Discontinued intervention (give reasons) (n=)

Analysis at 6, 12 months

Analyzed (n=)

- ◆ Excluded from analysis (give reasons) (n=)

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- ◆ Excluded from analysis (give reasons) (n=)