**SPIRIT-AI Extension**

**Modified CONSORT 2010 Flow Diagram**

Assessed for eligibility at participant level (n= )

Assessed for eligibility at input level (n= )

## Analysis

## Follow-Up

## Allocation

Randomized (n= )

Excluded (n= )

  Not meeting participant level inclusion criteria (n= )

  Declined to participate (n= )

  Other reasons (n= )

Excluded (n= )

  Not meeting participant level inclusion criteria (n= )

  Declined to participate (n= )

  Other reasons (n= )

Allocated to intervention (n= )

 Received allocated intervention (n= )

 Did not receive allocated intervention (give reasons) (n= )

 Missing or inadequate input data (n= )

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

 Discontinued intervention (give reasons) (n= )

 Missing or inadequate input data (n= )

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

 Discontinued intervention (give reasons) (n= )

 Missing or inadequate input data (n= )

Allocated to intervention (n= )

 Received allocated intervention (n= )

 Did not receive allocated intervention (give reasons) (n= )

 Missing or inadequate input data (n= )

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

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

## Enrollment

**CONSORT 2010 Flow Diagram**

## Enrollment

## Analysis

## Follow-Up

## Allocation

Analysed (n= )
 Excluded from analysis (give reasons) (n= )

Analysed (n= )
 Excluded from analysis (give reasons) (n= )

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

Discontinued intervention (give reasons) (n= )

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

Discontinued intervention (give reasons) (n= )

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= )

Randomized (n= )

Excluded (n= )

  Not meeting inclusion criteria (n= )

  Declined to participate (n= )

  Other reasons (n= )

Assessed for eligibility (n= )