

Assessed for eligibility (n=535)

Excluded (n=168)

- ◆ Not meeting inclusion criteria (n= 98)
- ◆ Declined to participate (n=13)
- ◆ Other reasons (incomplete data to assess inclusions or exclusions ) (n=57)

Randomized (n= 367)

Allocated to control (n=184)

- ◆ conventional therapy (n=180)
- ◆ 4 consents withdrawn

0 Lost to follow-up

Analyzed (n=180)

Allocated to intervention (n=183)

- ◆ Tα1 + conventional therapy (n=181)
- ◆ 1 consent withdrawn, 1 no longer met criteria

0 Lost to follow-up. 162 (89.5%) finished study and completed planned Tα1 therapy; 19 finished study but did not complete all the planned Tα1 therapy

Analyzed (n=181)