Figure 1. Consort flow chart

Patient approach

Approached (n = 225 patients)

No response (n = 121)
Excluded (n = 31)
Declined to participate (n = 31)

Provided with study information (n = 73 patients)

Pre-screened (n = 69 patients)

Excluded (n = 13)
Ineligible (n = 4)
Declined to participate (n = 9)

Attended baseline visit (n = 56 patients)

Excluded (n = 6)
Ineligible (n = 4)
Declined to participate (n = 2)

Randomisation

Intervention group
Allocated to intervention (n = 25 patients, n = 11 caregivers)
Received per protocol intervention (n = 23 patients)

Control group
(n = 25 patients, n = 10 caregivers)

Follow-up

Lost to follow-up (n = 3 patients, n = 3 caregivers)
Withdrawal immediately post randomisation (n = 1 caregiver)
Withdrawal prior to the 4-month timepoint (n = 3 patients, n = 2 caregivers)

Lost to follow-up (n = 2 patients, n = 1 caregiver)
Withdrawal prior to the 4-month timepoint (n = 2 patients, n = 0 caregivers)
Did not provide 6-month data (n = 1 caregiver)

Analysis

With complete primary outcome data (n = 22 patients)
With complete outcome data (n = 8 caregivers)

With complete primary outcome data (n = 23 patients)
With complete outcome data (n = 9 caregivers)