Figure 1. CONSORT flow chart

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Patient approach → Approached (n = 225 patients)

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

Study information → Provided with study information (n = 73 patients)

No response (n = 0)
Excluded (n = 4)
Ineligible (n = 1)
Declined to participate (n = 3)

Pre-screened (n = 69 patients)

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

Recruitment → 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 caregivers)

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)