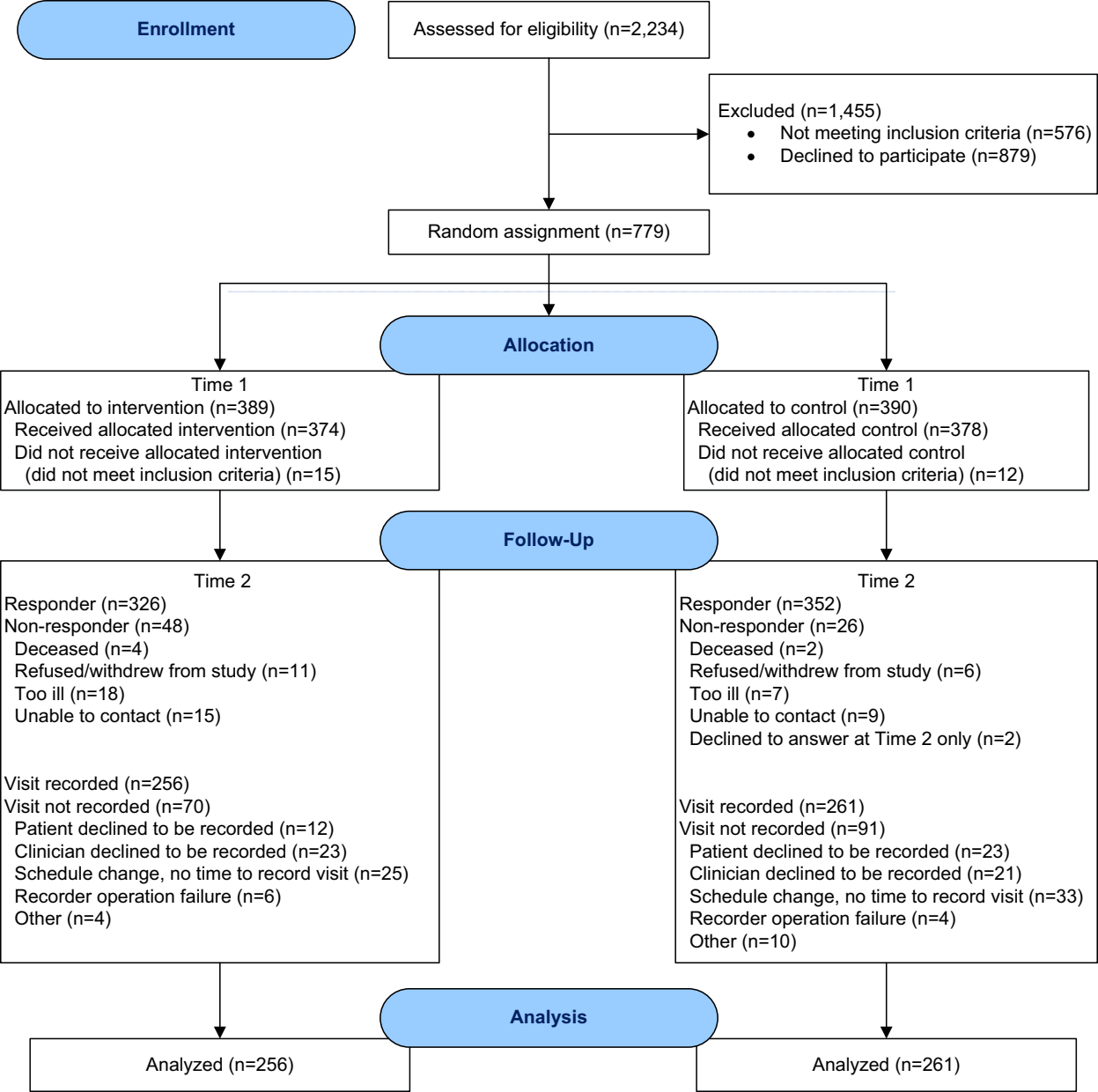
Enrollment
Assessed for eligibility (n=2,234)
Excluded (n=1,455)
• Not meeting inclusion criteria (n=576)
• Declined to participate (n=879)
Random assignment (n=779)
Allocation
Time 1
Allocated to intervention (n=389)
Received allocated intervention (n=374)
Did not receive allocated intervention
(did not meet inclusion criteria) (n=15)
Time 1
Allocated to control (n=390)
Received allocated control (n=378)
Did not receive allocated control
(did not meet inclusion criteria) (n=12)
Follow-Up
Time 2
Responder (n=326)
Non-responder (n=48)
Deceased (n=4)
Refused/withdrew from study (n=11)
Too ill (n=18)
Unable to contact (n=15)
Visit recorded (n=256)
Visit not recorded (n=70)
Patient declined to be recorded (n=12)
Clinician declined to be recorded (n=23)
Schedule change, no time to record visit (n=25)
Recorder operation failure (n=6)
Other (n=4)
Time 2
Responder (n=352)
Non-responder (n=26)
Deceased (n=2)
Refused/withdrew from study (n=6)
Too ill (n=7)
Unable to contact (n=9)
Declined to answer at Time 2 only (n=2)
Visit recorded (n=261)
Visit not recorded (n=91)
Patient declined to be recorded (n=23)
Clinician declined to be recorded (n=21)
Schedule change, no time to record visit (n=33)
Recorder operation failure (n=4)
Other (n=10)
Analysis
Analyzed (n=256)
Analyzed (n=261)