

Assessment for eligibility:  
n = 2200

Excluded: all patients not found eligible  
(25 %)

Eligibility for enrolment:  
n = 1650

Excluded: all patients who do not agree to  
participate in study  
(40 %)

Enrolment in study:  
n = 990

Excluded: all patients lost to follow-up or  
with incomplete data  
(20 %)

Data analysis after six-month follow-up:  
n = 792