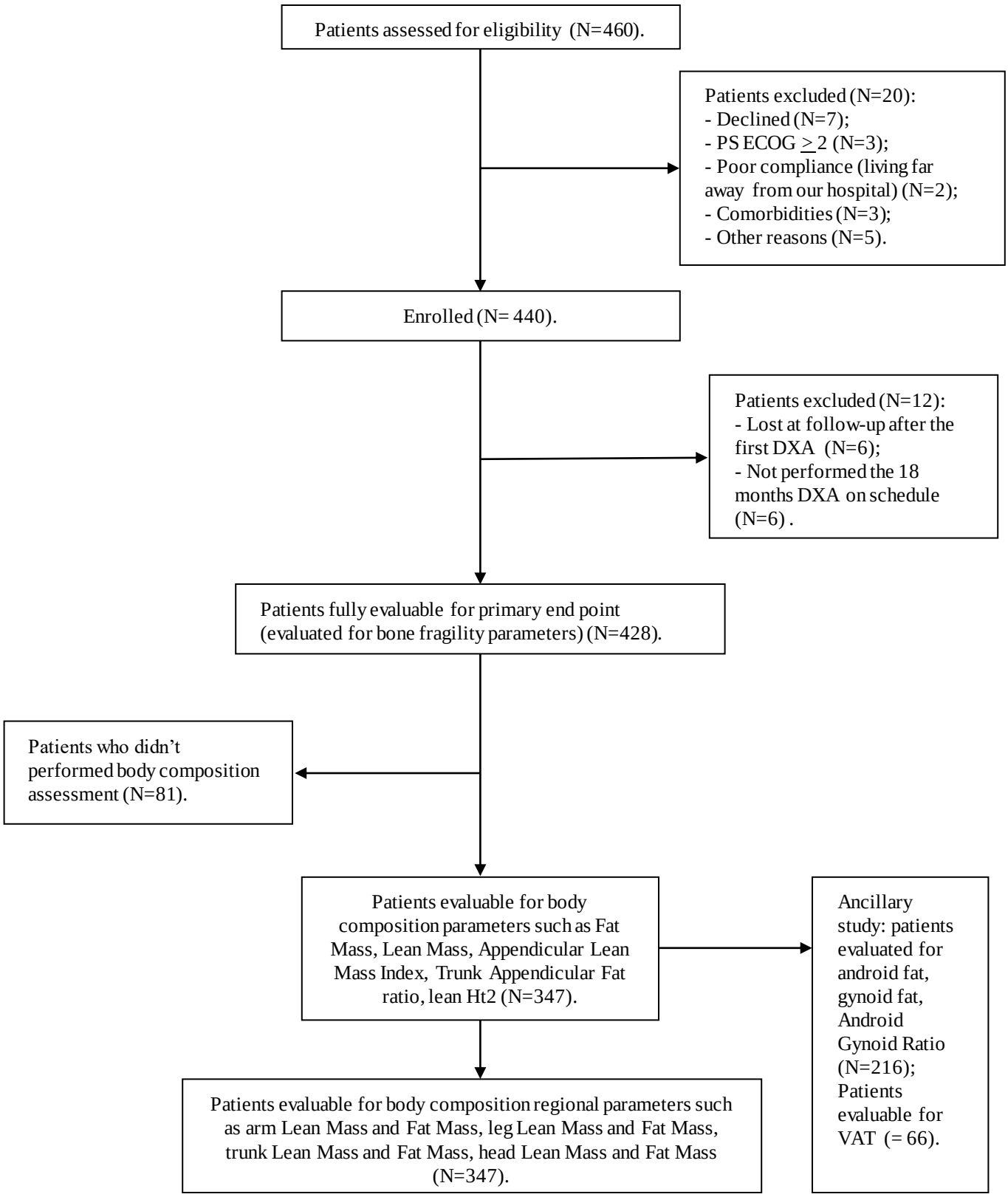Figure S1. Trial consort diagram.