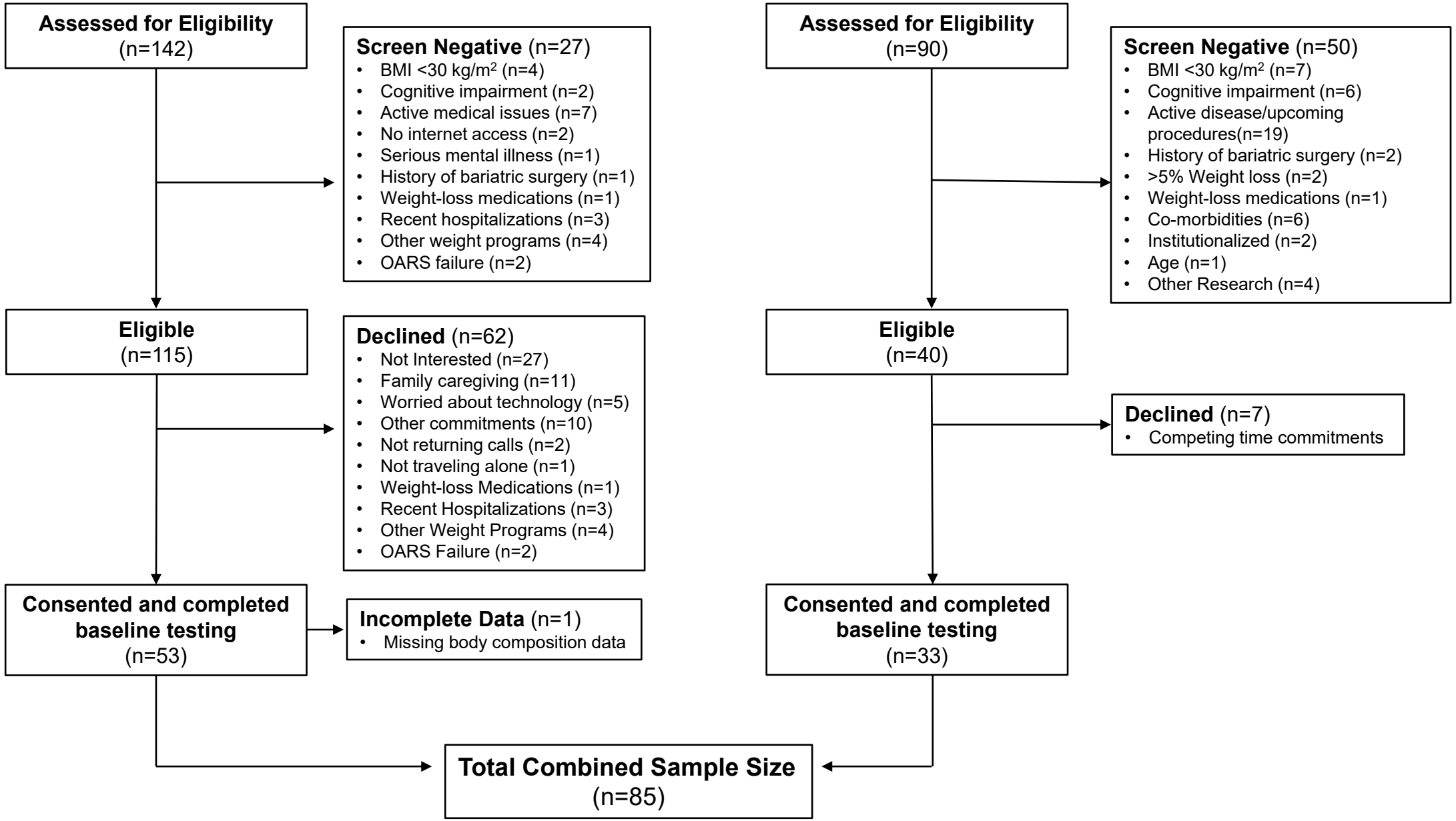SUPPORTING INFORMATION: CONSORT FLOW CHART