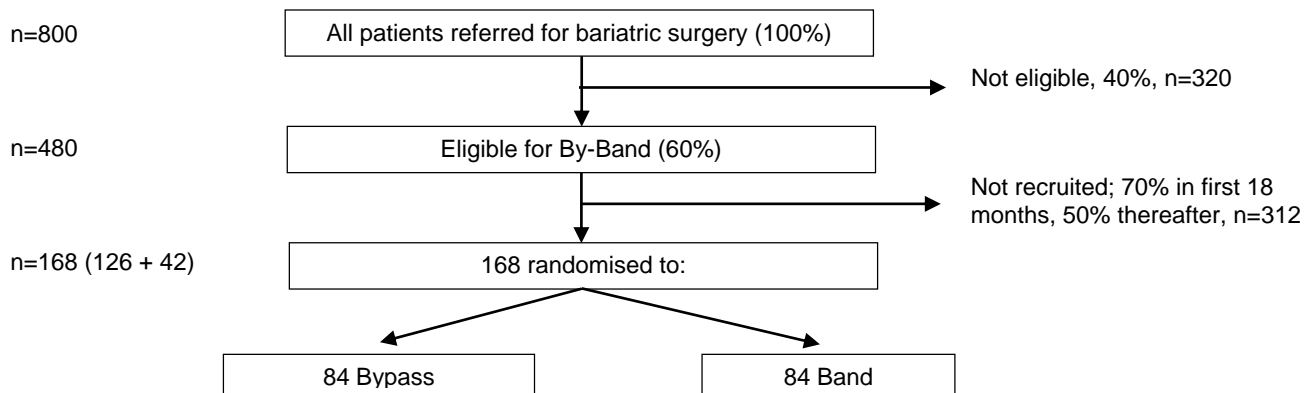
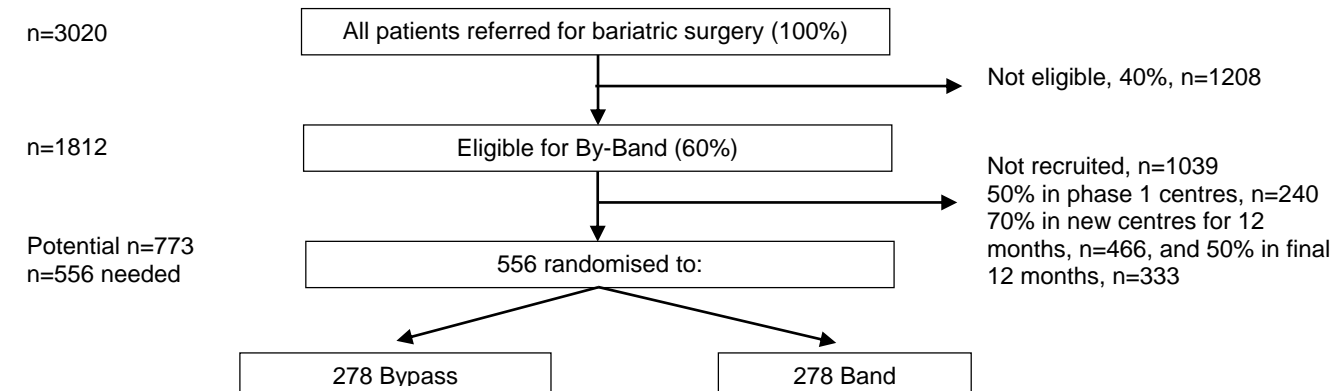


Phase 1. in 2 centres



Phase 2. in 8 centres



Phase 1 & 2 patients (168 + 556)
followed up after surgery, n=724

85% followed to primary outcome, n=614
in primary analyses at 3 years