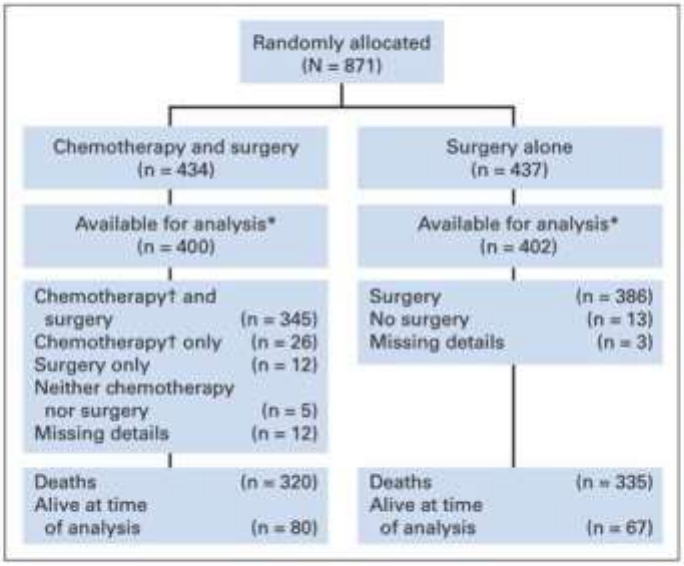CONSORT diagram of the OE02 trial