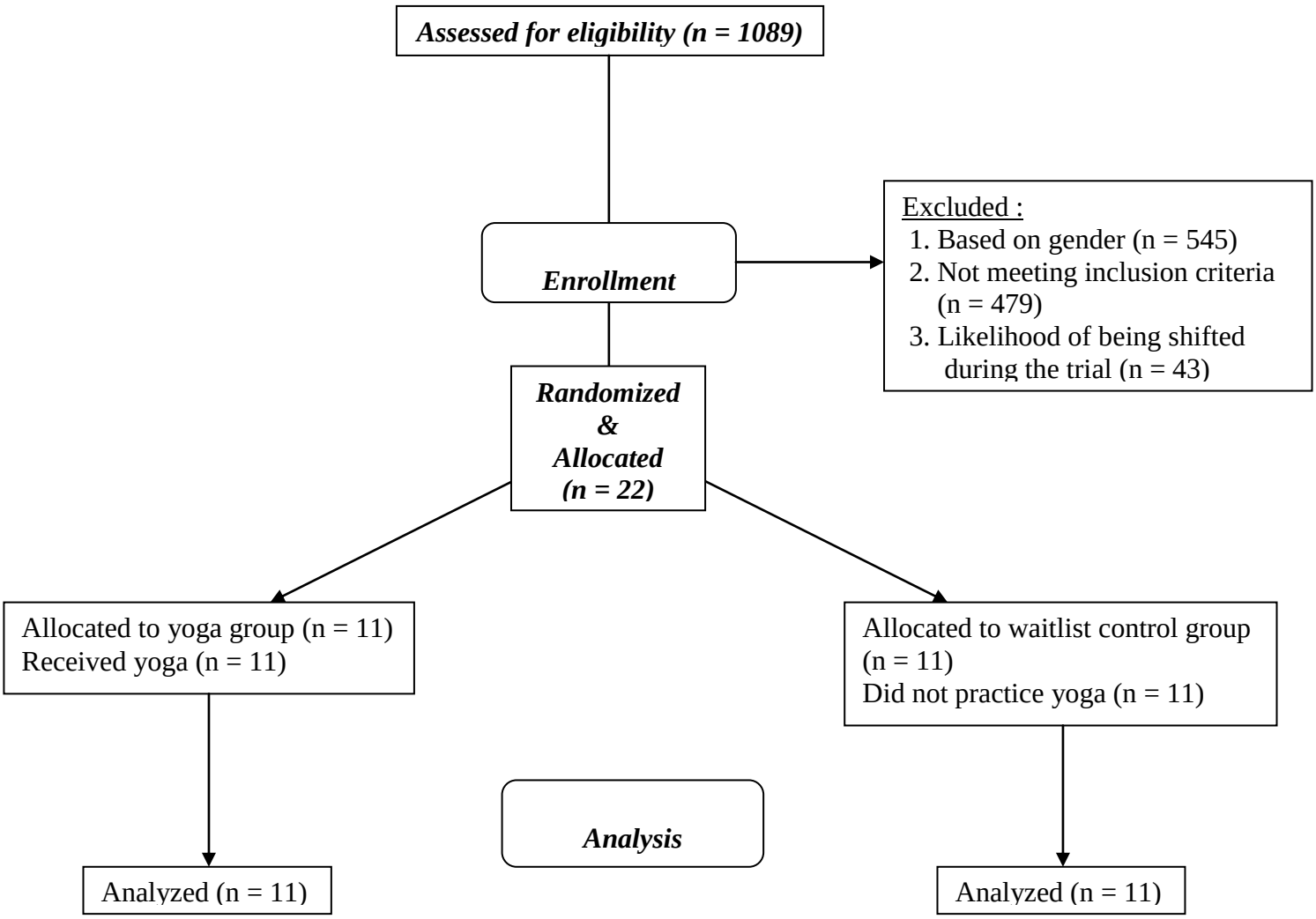The CONSORT diagram