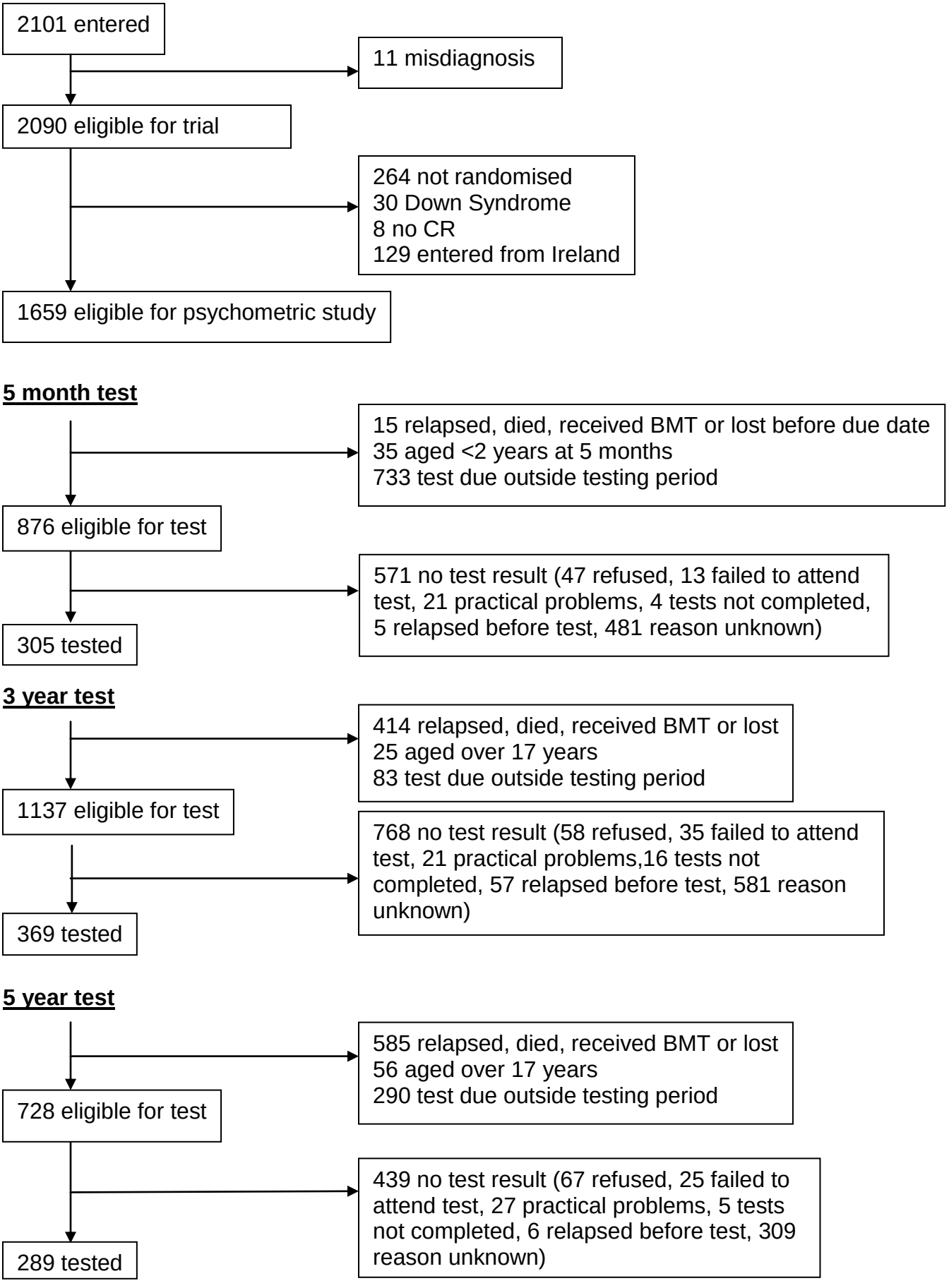CONSORT diagram