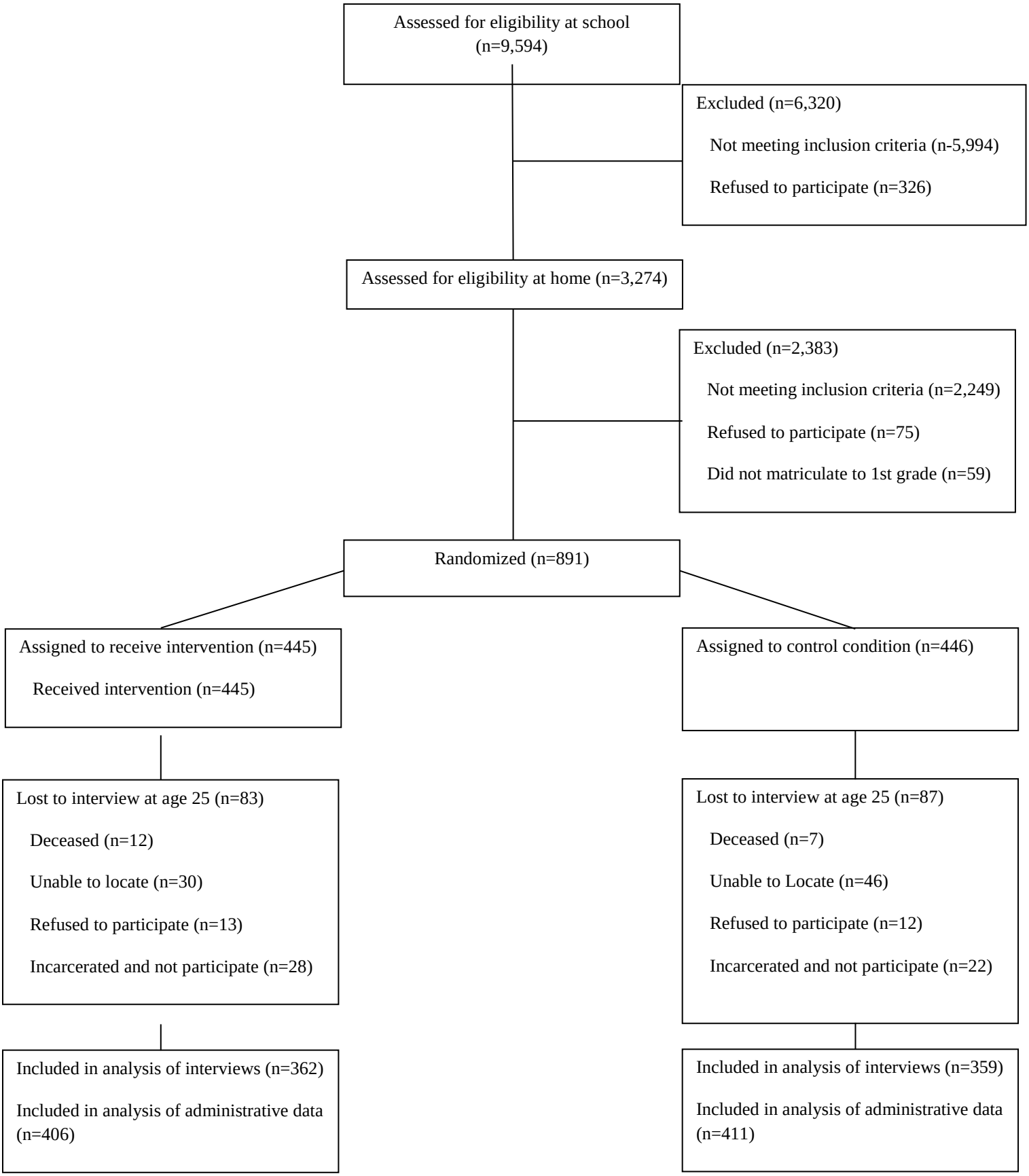CONSORT Flow Chart