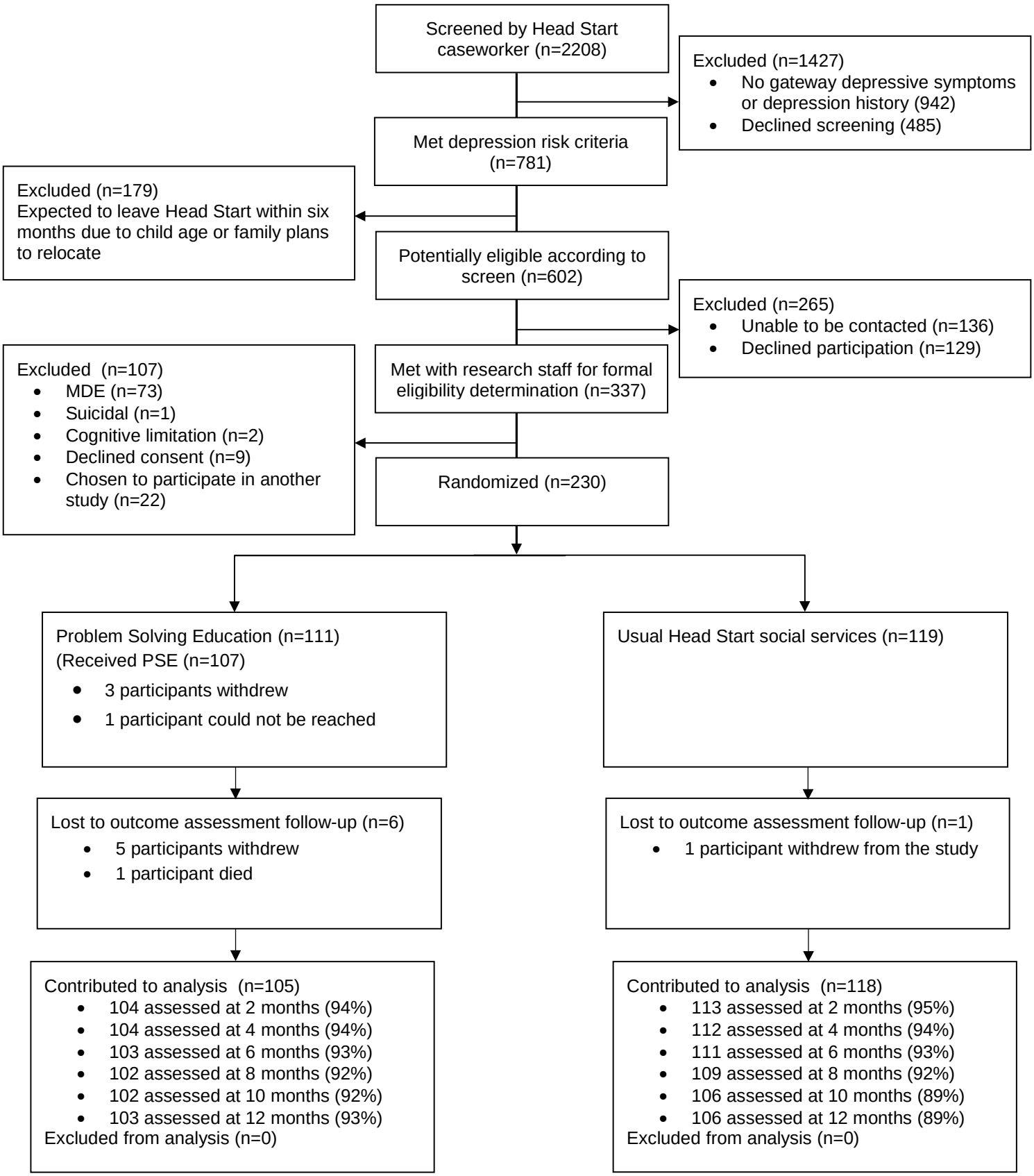CONSORT Diagram