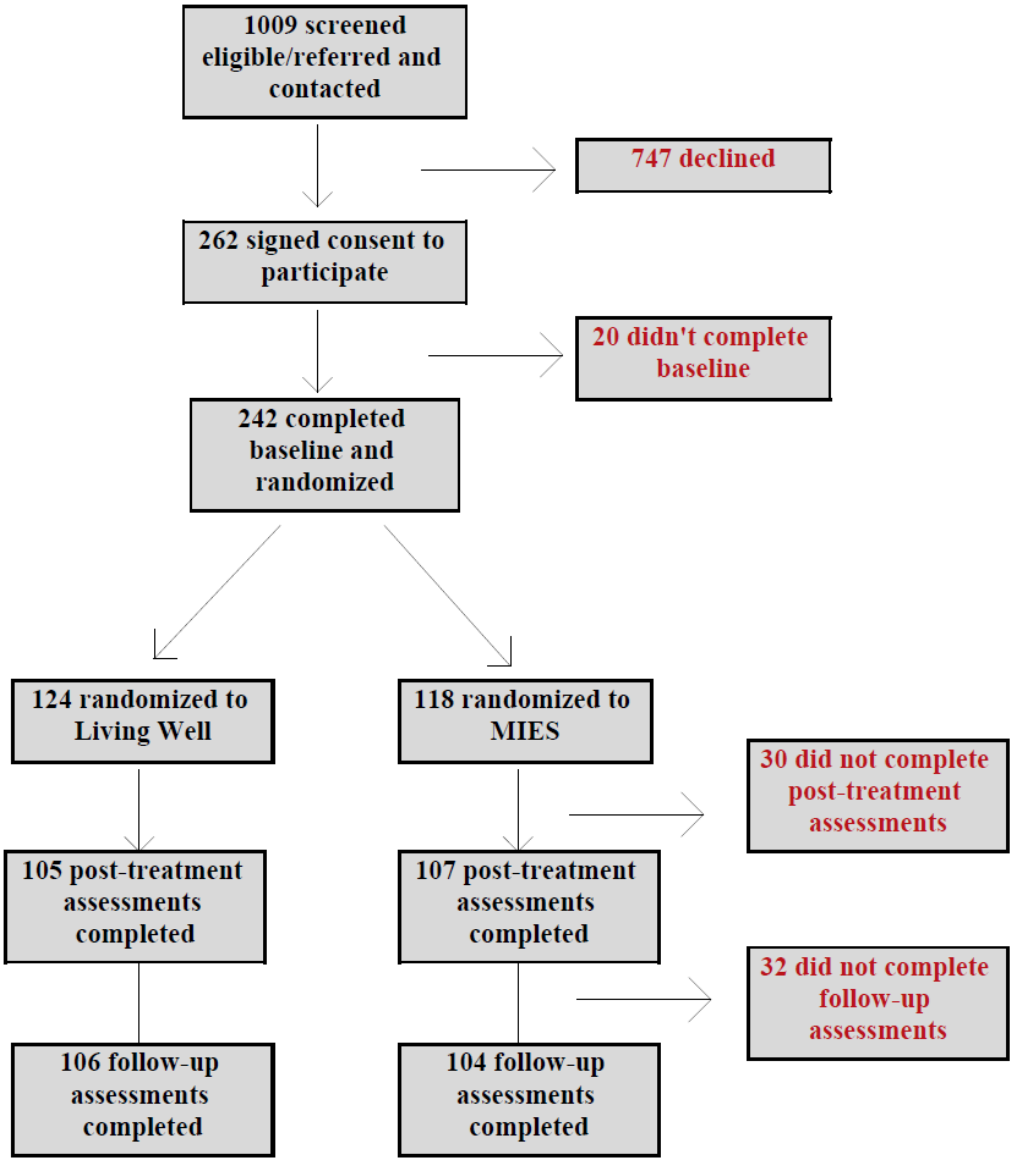Online supplement . CONSORT Diagram