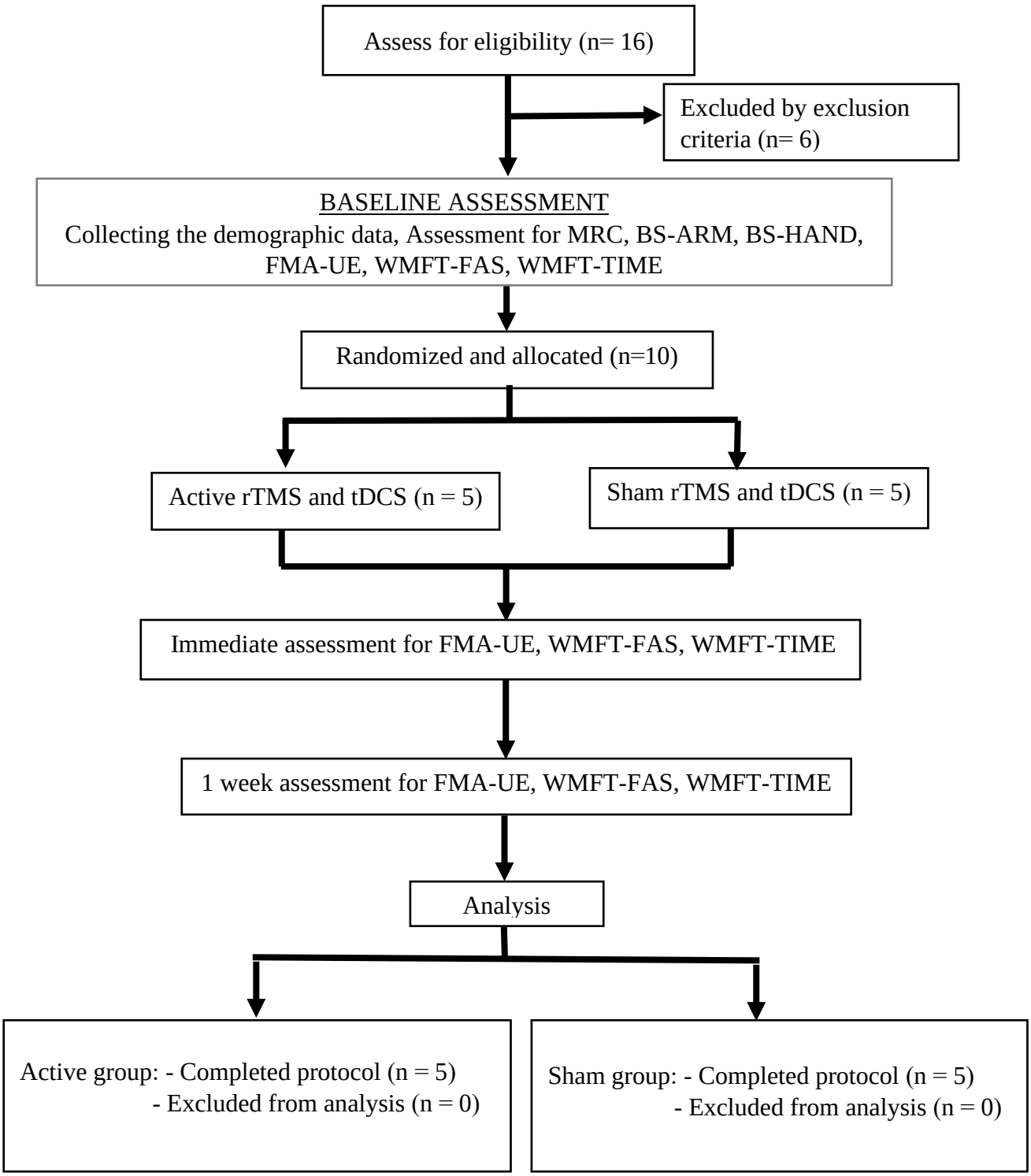Additional file 2: CONSORT Flow Diagram of Patients Through the Study