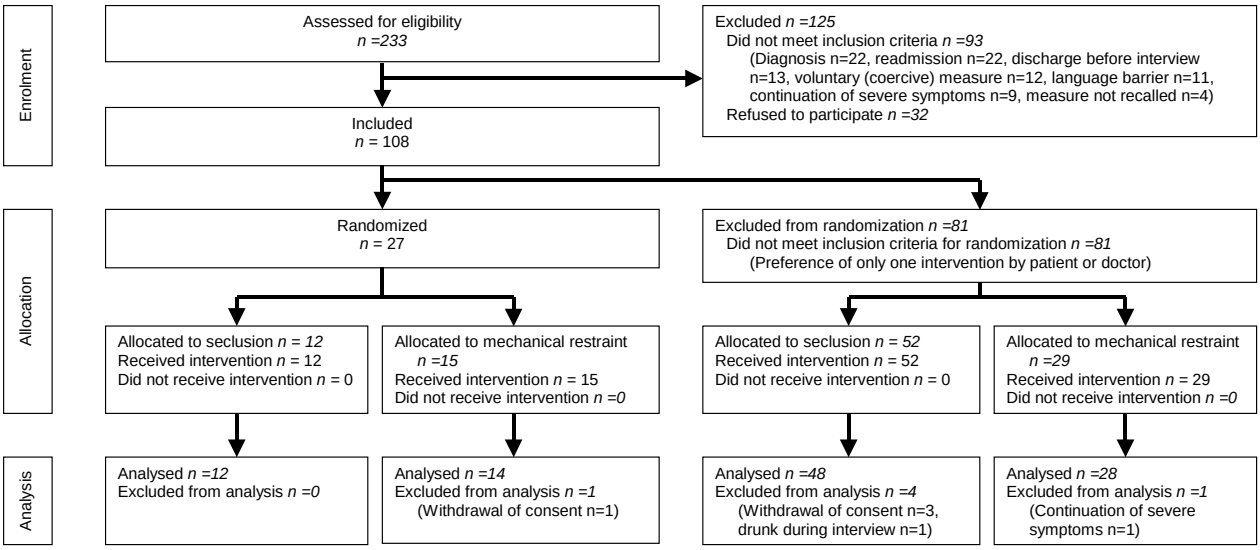CONSORT diagram showing enrollment, randomization, and analysis