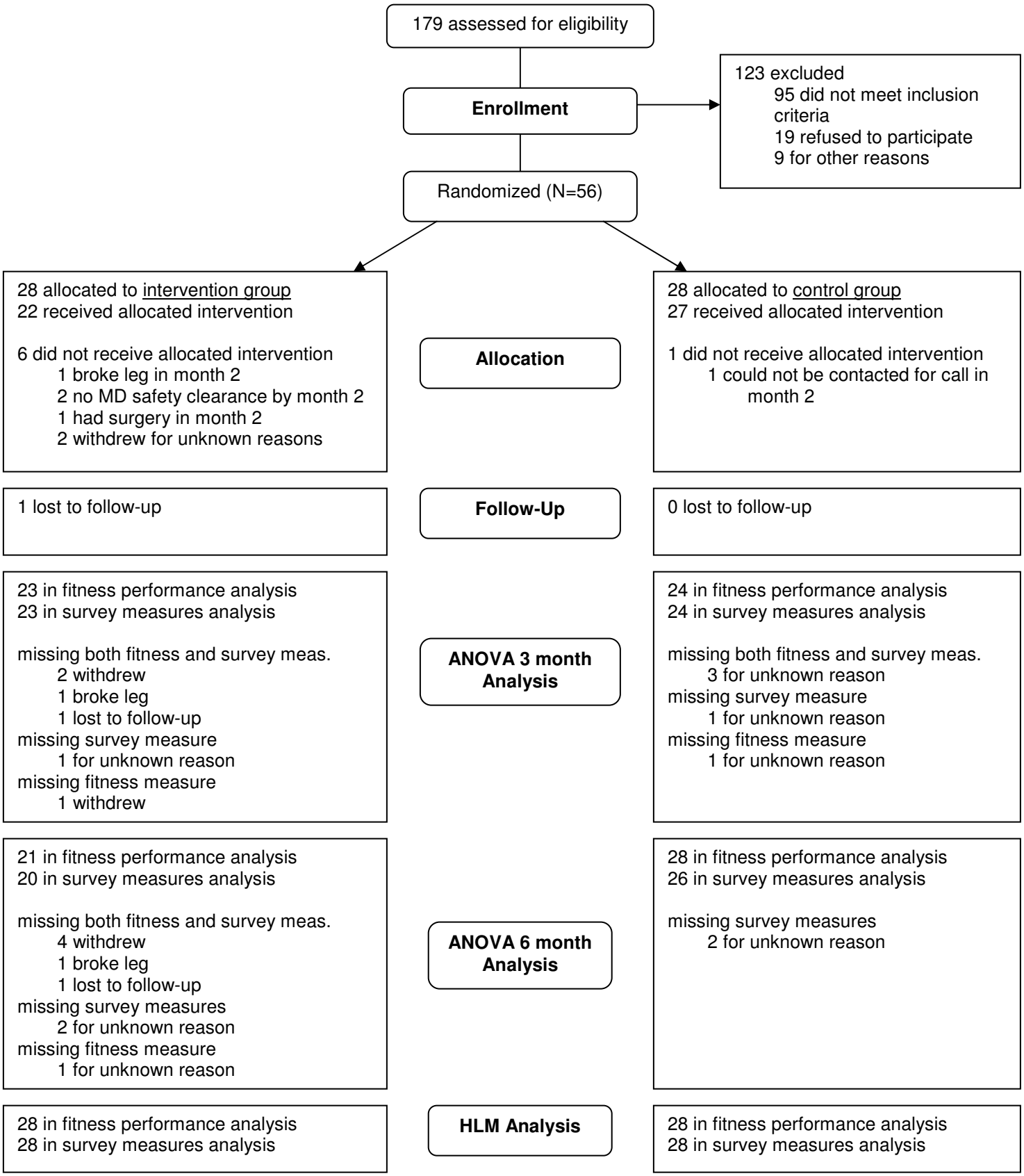Figure 1. Flow of Participants Through the Trial