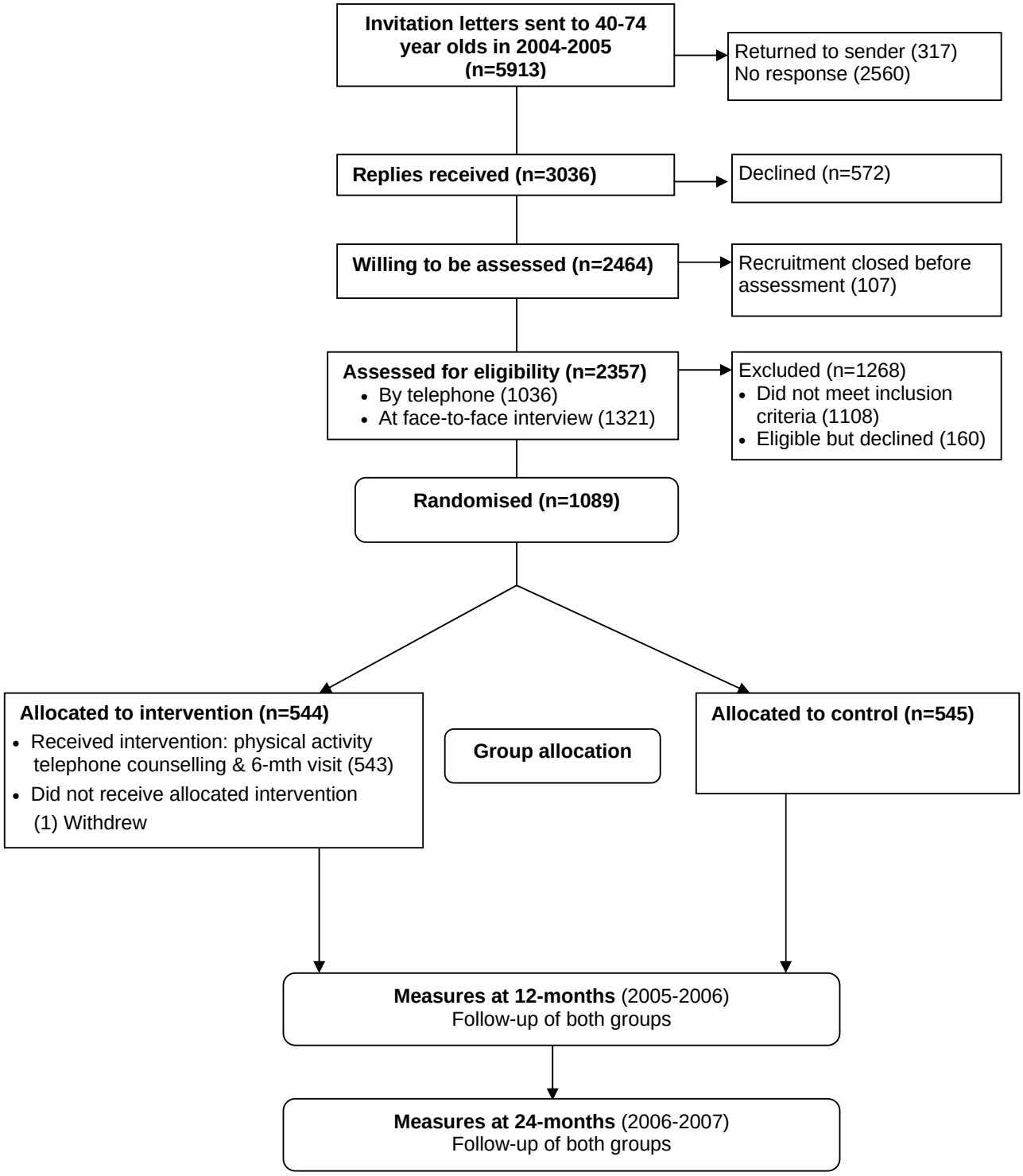Figure 1. Flowchart of participant recruitment and trial design