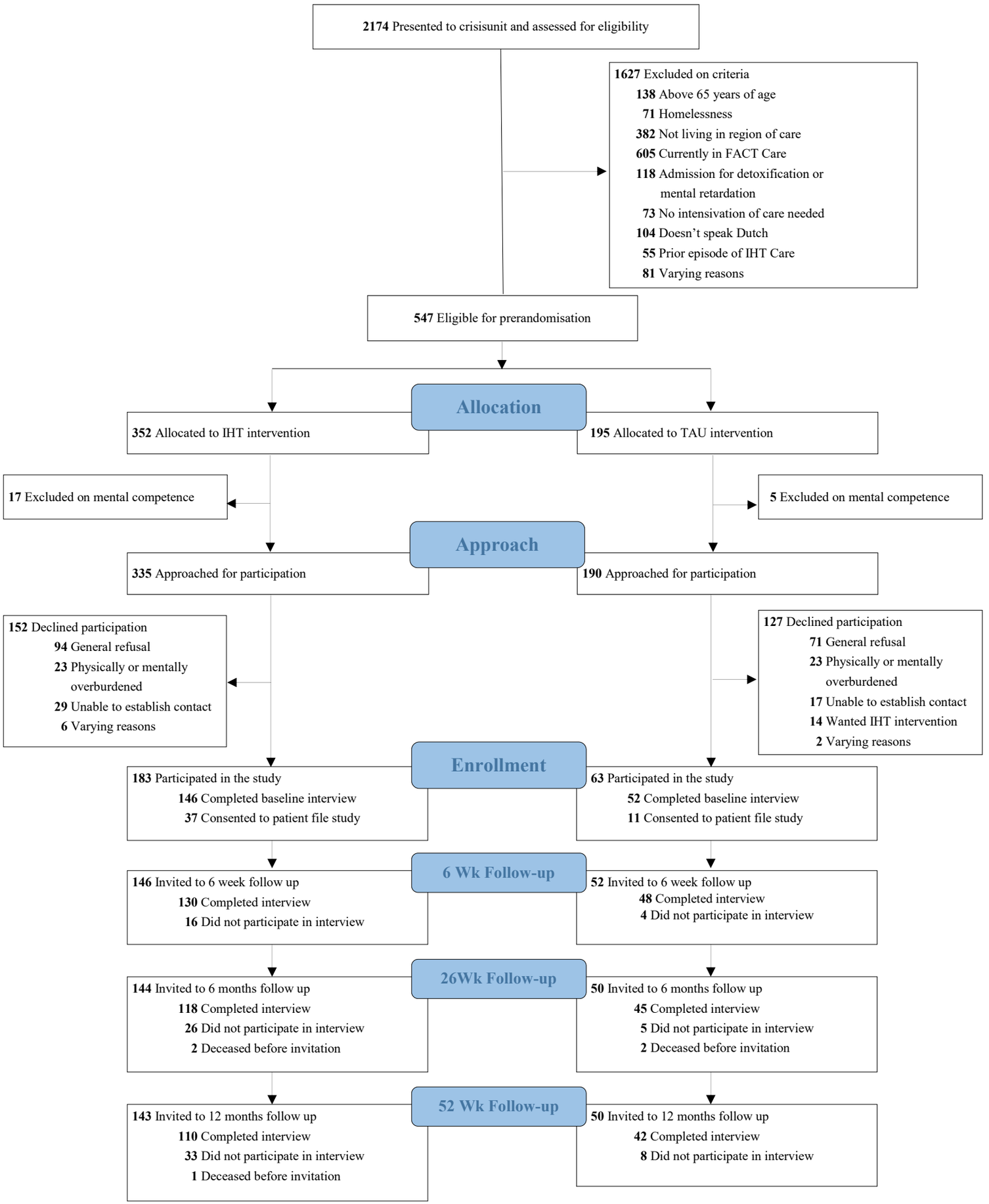Figure 1: Flowchart pre-randomisation and inclusion.