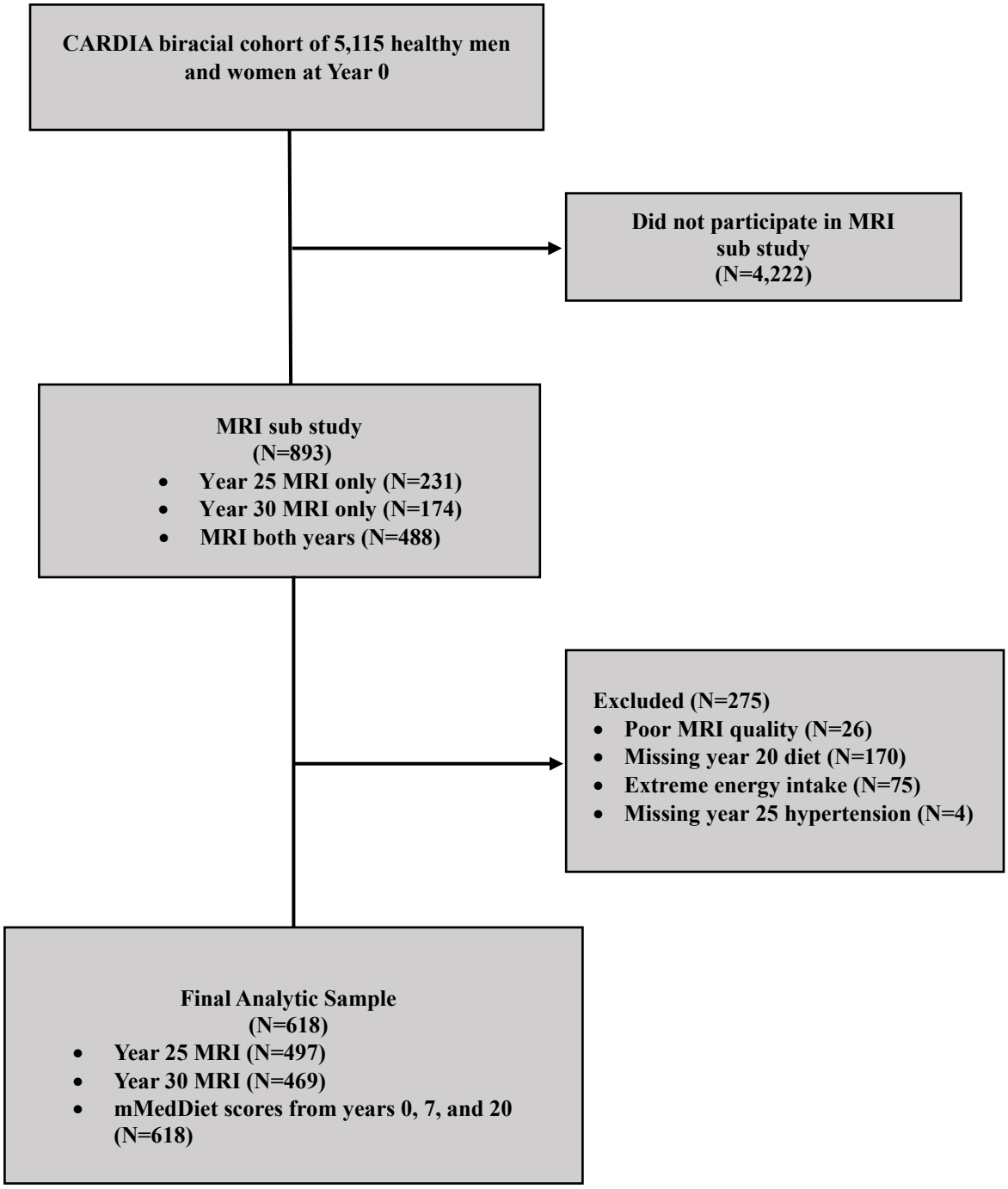Supplemental Figure 1: Exclusion Criteria