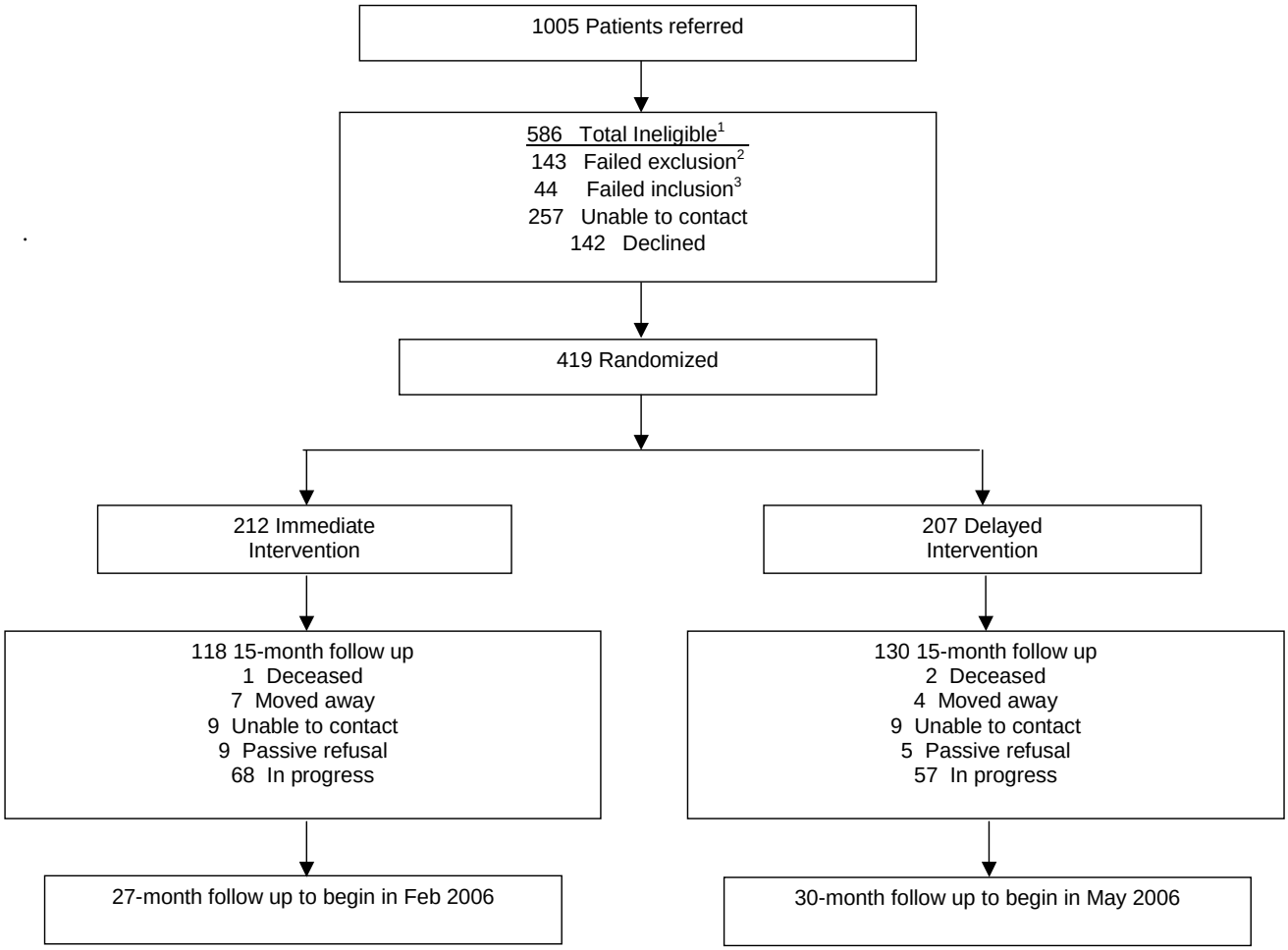

Figure 1
Enrollment and follow-up in the Stanford and San Mateo County Heart to Heart Trial. [1]A patient may be ineligible for more thanone reason. [2]Number of participants who failed to meet exclusion criteria: being resident in long-term facility (n = 1); moving away soon (26); age ≤ 35 or ≥ 85 (13); significant comorbidities (10); substance abuse (2); no telephone (1); family member already enrolled (7); anticipated absence >4 months (18); difficulty coming to appointments (35); participating in other research programs (21); pregnant or planning to become pregnant (2); no English or Spanish and no interpreter (7). [3]Number of participants who failed to meet inclusion criteria: Has CAD or CAD risk equivalent but did not have any of the CHD risk factors specified in Table 1 (n = 2); does not have CAD or CAD risk equivalent and did not have any of the CHD risk factors specified in Table 1 (n = 42).

sites and differences in physician practice patterns. A drawback of patient-level randomization is the possibility of contamination. We expect the extent and impact of contamination to be modest, however. By design, study-specific case managers who are independent of existing physician practices within the study clinic sites provide case-management to the intervention patients and the scheduling process is separate from that of the clinical sites. Much of the value of the intervention comes from activities that are not usually given high priority by primary care physicians. In addition, any potential for contamination produces a conservative bias, reducing the measured impact of the intervention and biasing the findings towards the null hypothesis. Furthermore, our statistical methods will specifically address the degree of intra-class correlation within physician's practices and thereby assess the likelihood and potential extent of contamination.

Study measurements

The primary outcome measure is the absolute CHD risk over 10 years. For participants without known CHD, the Framingham risk assessment algorithms published by Wilson et al. [33] will be used to estimate the 10-year risk