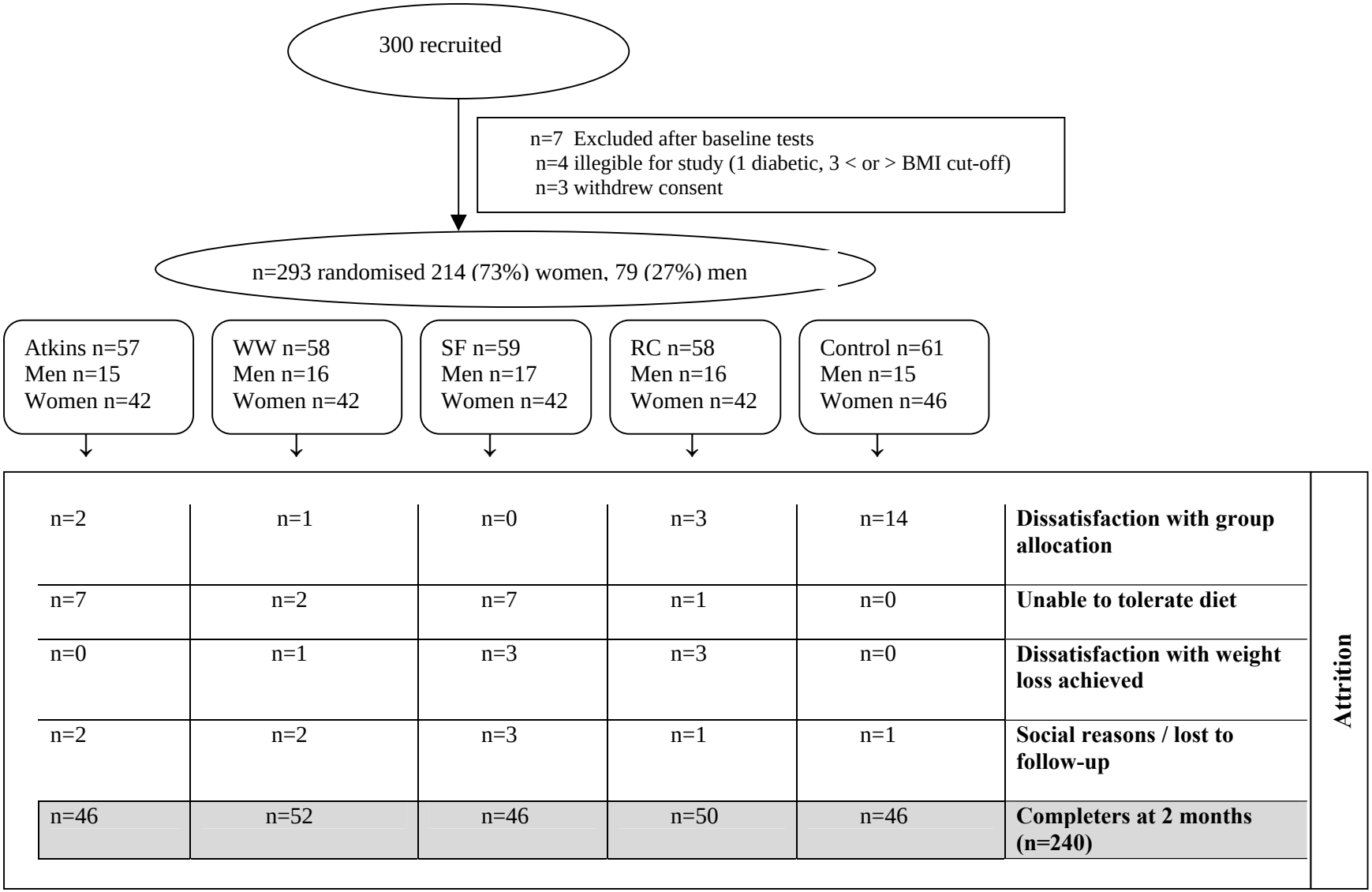Figure 1. Flow diagram showing details of recruitment and retention over the study period