Changes to the Original STRIDE Study Protocol

During the course of the study, modifications to the protocol were made. These were eight versions of the protocol, starting with 2.1 (version 1 was for the pilot study). The changes to the protocol in each version are described below.

Changes from Protocol Version 2.1 to 2.2

There were three changes to the protocol that were made in this revision of the protocol. The first two changes were made to improve the efficiency of ascertaining fall information. We eliminated the postal questionnaire to ascertain fall/fall injury data. Instead, obtained these data via telephone calls from the RAC to all participants. (Note: all STRIDE participants continued to use the fall calendars as a memory aid). We also changed the timing of follow-up calls to patients to inquire about falls/fall injuries from every 3 months to every 4 months. Finally, to comply with Pennsylvania state law, the list of people who were eligible to serve as proxy respondents for people who were unable to provide informed consent due to cognitive or hearing impairment was adjusted.

Changes from Protocol Version 2.2 to 2.3

In this revision, we changed the lower age limit for eligibility from 75 to 70. This change was made to increase our recruitment pool while continuing to include people at high risk of falls.

Changes from Protocol Version 2.3 to 2.4

This change to the protocol was made to provide more detail about data from CMS would be used in the adjudication process. When the trial was initially proposed it was not clear if we would be able to obtain CMS data and how data transfer and privacy issues would be managed. These procedures were described in this protocol update.

Changes from Protocol Version 2.4 to 2.5

This revision to the protocol changed the duration of the study from 36 months (18 months of recruitment and 18 months of follow-up) to 40 months (20 months of recruitment and minimum 20 months of follow-up). Target sample size adjusted to n = 5,322 for a 40-month study instead of n = 6000 for a 36-month study. This change was made to allow more time for the recruitment of participants. A modification in the approach to Interim monitoring was also made, as it changed from monitoring for efficacy and futility to efficacy or futility, if necessary.

Changes from Protocol Version 2.5 to 2.6

The definition of the primary outcome was modified to reflect the recommendations of the DSMB working group. This working group was established by the staff of the National Institute on Aging on the recommendation of the STRIDE DSMB to advise the DSMB about this issue. The definition was modified to reduce the risk of ascertainment bias which might have occurred with the previous definition.

Changes from Protocol Version 2.6 to 2.7

This revision extended the study from a minimum of 20 and maximum of 40 months follow-up to a minimum of 24 and maximum of 44 months of follow-up. This change was made at the recommendation of the DSMB to allow time for more events to be accrued.

Changes from Protocol Version 2.7 to 2.8

The final change to the protocol added new and updated information to the description of the statistical analysis plan in the protocol document.