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Official title: Shared Decision Making for Firearm Safety Among Older Adults With Early Changes Associated With Alzheimer's Disease/Alzheimer's Disease-Related Dementias (AD/ADRD)
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3.3 Data Analysis and Coordination

Aim 2: Our primary endpoint of interest for the pilot trial is the proportion of participants indicating the intervention is feasible. To assess feasibility, we will use the Feasibility of Intervention Measure (FIM) 3, which is comprised of 4 items, each of which is measured on a 5-point Likert scale.

We will average scores on the FIM across participants and will use the RED/ AMBER/ GREEN criteria for establishing success of our pilot trial.4 No established cut-points exist for the FIM; but higher scores indicate greater feasibility (i.e., 3.0 indicates "neither agree or disagree;" 5.0 indicates "completely agree"). The proportion of individuals with observed scores falling between 3.0 and 5.0 will be our measure of feasibility. The rationale for this range is that it indicates that the participant does not disagree (i.e., is either ambivalent or in agreement) that the intervention is feasible.

If we assume the upper limit of the RED zone is 75% and the lower limit of the GREEN zone is 90%, the sample size given 90% power is n=60, assuming an alpha of 0.05 for a one-sided test.

- The cut-points will be determined based on the number of participants scoring between 3.0 to 5.0 on the FIM and will be designated as follow: o If FIM scores are between 3.0 and 5.0 for 0 to 45 (0-75%) participants, this result will be statistically insignificant and will fall into the RED zone
    - If FIM scores are between 3.0 and 5.0 for 46 to 53 (76-89%) participants, this result will be potentially significant and will fall into the AMBER zone
    - If FIM scores are between 3.0 and 5.0 for 54 to 60 (90-100%) participants, this result will be significant and will fall into the GREEN zone

The expected cut-off for significance in the AMBER zone is 50.5 (84.2%) participants indicating FIM scores between 3.0 and 5.0. If the number of participants indicating FIM scores between 3.0 and 5.0 falls between 45 (upper limit Red zone) and 50 (significance cut-off in Amber zone), we will consider major amendments to our protocol. If the number of participants indicating FIM scores between 3.0 and 5.0 falls between 50 and 54 (lower limit Green zone), we will consider minor amendments to our protocol.

We will repeat this process for the AIM measure of intervention acceptability, our secondary endpoint. We will use these results to guide decisions about the suitability of progressing to a full trial.

We will collect and summarize data on ***safe storage of firearms*** measure - the eventual Randomized Control Trial (R33) primary clinical outcome – which is measured on an ordinal scale but will be dichotomized as "no improvement" or "any improvement". We will also collect data on our secondary measures - ***firearm storage knowledge*** and ***decisional conflict***. We will assess

differences pre and post intervention for the primary and secondary measures, using chi-square or one sample t-tests, as appropriate.