

**Project Title:** "Safety in Dementia": An Online Caregiver Intervention  
**NCT Number:** NCT05173922  
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## COMIRB Protocol

### COLORADO MULTIPLE INSTITUTIONAL REVIEW BOARD

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**Protocol #:** 21-4084

**Project Title:** "Safety in Dementia": An Online Caregiver Intervention

**Principal Investigator:** Marian Betz, MD, MPH

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### Study overview

*"It crossed my mind that maybe I should've taken the guns, and I didn't. It'll be a guilt that I'll never ever get away from"*<sup>1</sup> said a daughter after her dad had fatally shot her mom in a moment of Alzheimer's confusion. For many, firearms are a core component of the American ideal of "rugged individualism",<sup>2</sup> yet cognitive and behavioral changes that come with Alzheimer's Disease and related dementias (ADRD) can increase the injury risk. Suicide is the primary injury risk from firearms for people with ADRD, but ADRD-related confusion or paranoia can put others at risk. In the United States, an estimated 33-60% of people with ADRD have a firearm in the home,<sup>3,4</sup> and 38% of ADRD caregivers identify firearms as an issue to address.<sup>5</sup> Despite clinician counseling on other ADRD-related topics and public support for firearm safety discussions, firearm safety is rarely discussed with ADRD patients or caregivers.<sup>4</sup> For some caregivers, firearms are not a concern, because firearms either aren't present or are already inaccessible to the person with ADRD. But many other ADRD caregivers are left without guidance about when and how to address the sensitive topic of in-home firearms.

To address this gap, we previously developed "**Safety in Dementia**"<sup>6</sup> (SiD) for informal caregivers to address firearm safety (R34MH113539-NIA suppl). Based on the Ottawa Decision Support Framework<sup>7</sup> and the Health Belief Model,<sup>8</sup> SiD is an online decision aid that helps caregivers clarify values and preferences and then commit to implementing their preferred options. In an online pilot trial, 92% of participants said SiD was somewhat or very helpful for making a safety decision. Based on the NIH model of intervention development,<sup>9</sup> the next step is a Stage II efficacy trial to test how SiD affects decision-making and safety behaviors. Informal (unpaid) caregivers are diverse in their demographics and relationship to the person with ADRD, making innovative approaches key for research recruitment and for subsequent real-world engagement.

This 3-year R01 proposal responds to PAR-21-192. Based on theory and mechanistic considerations, we hypothesize SiD will increase informal caregivers' preparation and self-efficacy to make and implement decisions that effectively address firearm access, thereby reducing firearm injury risk. In an online randomized trial of SiD with national recruitment and longitudinal follow-up, we will recruit informal caregivers of community-dwelling adults with ADRD who have firearm access.

## **Background and Significance:**

**The population of community-dwelling people with dementia is growing in the United States:** About 5.8 million Americans – roughly 10% of all adults aged 65 years or older – are living with Alzheimer’s disease and related dementias (ADRD.)<sup>10</sup> Referred to as a “public health crisis” by the Centers for Disease Control and Prevention, ADRDs place a high level of burden on patients, care-partners, and the healthcare system.<sup>11</sup> An estimated 70% of people with ADRD live in the community,<sup>10</sup> with support by an estimated 16 million unpaid, informal caregivers (e.g., spouses or other family members).<sup>10</sup> Caregivers face myriad concerns and demands, from daily care to fundamental considerations of safety. A core question is how to ensure safety at home, given ADRD-related injury risks from unsupervised use of potentially dangerous items (e.g., stoves, power tools, firearms), access to motor vehicles, wandering out of an unlocked home, or other hazards within the home. The COVID-19 pandemic’s home quarantine recommendations and nursing home outbreaks further highlight the importance of ensuring safe environments to support aging in place and delay nursing home placement.

**Firearm access is common among older adults:** Approximately one third of older Americans (≥65 years) own a gun.<sup>12</sup> In our recent national survey of firearm owners aged ≥65 years, most were married white males and owned a median of three guns.<sup>13</sup> Frequency of use varied; while nearly half had handled a firearm once or less in the past year, 18% reported carrying a loaded handgun in the past month.<sup>13</sup> In this large sample of older firearm owners, only one fifth reported having a plan for securing, removing, or transferring firearms if they became unable to handle them safely, highlighting that such decisions often fall to caregivers.<sup>13</sup>

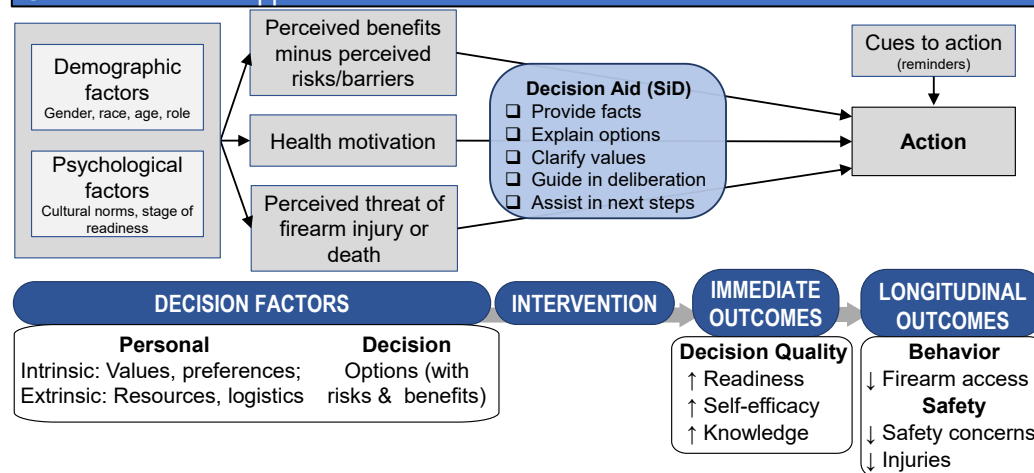
**Aging may increase firearm injury risk:** Safe firearm handling may be impacted by physical and cognitive changes that arise with normal physiologic aging, with diseases, or with use of medications. The primary firearm injury risk for older adults is death by suicide: 91% of older adult firearm deaths are due to suicide, and firearms are the most common method of suicide among persons with ADRD. Indeed, suicide risk is elevated among individuals with ADRD, especially in early ADRD.<sup>14,15</sup> In the US, 70% of older adult suicides are by firearm.<sup>16</sup> Firearm suicide rates are particularly high among older men,<sup>16</sup> and the suicide rate among the Baby Boomer cohort appears higher than previous generations.<sup>17,18</sup> The COVID-19 epidemic and associated isolation, social stressors, and surges in firearm purchases have raised concern about an impending suicide wave.<sup>19,20</sup> Given the advanced planning and high lethality of attempts among older adults, primary suicide prevention – including early attention to reducing firearm access in the presence of risk factors – is critical.<sup>21,22</sup>

**Dementia also raises other concerns about non-suicide firearm injury and death:** Behavioral symptoms that commonly co-occur with ADRD (e.g., delusions or paranoia) could heighten risk to others, as people with ADRD might mistake caregivers, health aides or others as intruders. Precise estimates of the frequency of such confrontations do not exist, but violence towards others occurs annually in approximately 1 to 3% of older adults with ADRD.<sup>23</sup> Rates of physical violence by adults with ADRD towards others (not necessarily with a firearm) are approximately 24% for the entire course of illness, ranging from 18-64% depending on the population and definition of violence.<sup>24,25</sup> Unintentional (“accidental”) firearm injuries can also occur, even among older adults with prior training and safe handling skills, due to impairments in judgment, dexterity, and memory. In a national survey, we found the majority of firearm-owning caregivers

thought unintentional firearm injuries are the most common in ADRD.<sup>4</sup> They may worry most intensely about accidental harm inflicted on others and neglect to consider suicide risk, highlighting a point for education and intervention.

**Caregivers face stress, including from decision making about firearm access:** The millions of informal caregivers of people with ADRD face myriad decisions, from daily needs to financial management and long-term goals of care. Caregivers are sometimes called “the invisible second patient”<sup>26</sup> due to the physical and emotional problems brought on by the stress and burden of caregiving.<sup>27</sup> Caregiving can also be rewarding, promoting positive feelings associated with family togetherness and helping others,<sup>28–30</sup> but these benefits do not eliminate caregiver stress. There is an urgent need for

**Figure 1. Theoretical framework of Safety in Dementia’s immediate and long-term impact.** Grey rectangles represent Health Belief Model. Blue ovals represent Ottawa Decision Support Framework and related measures.



effective, acceptable interventions to support informal caregivers in decision making and behavior change to act on those decisions. Ideally,

development and dissemination of such interventions – critically, to the broad, diverse community of informal caregivers – can reduce caregiving burden and delay nursing home placement, thereby supporting aging in place and reducing costs.<sup>27</sup> For firearm access specifically, caregivers worry about how to take action; questions relate to legal and logistic uncertainties and lack of guidance.<sup>31</sup> In a national survey, we found that although the majority supported ADRD-relevant firearm safety counseling by healthcare providers, only 5% had ever received it.<sup>4</sup>

### **Decision aids – based on evidence and theory – can help with difficult decisions:**

Caregivers must balance safety concerns (of both the person with ADRD and those around them) with considerations about the person with ADRD’s response (e.g., anger) and logistics (e.g., cost of various options). Decision aids are tools that facilitate and support decision-making and have been developed and used for a variety of medical decisions, but less commonly for decisions about injury prevention or “problems of living.” A common theoretical model is the Ottawa Decision Support Framework (**Figure 1**),<sup>7</sup> which draws upon concepts from psychology, decision conflict, social support, and self-efficacy. The framework posits that decisional needs (e.g., knowledge, conflict/uncertainty, and values) affect decision quality, with the highest quality decision being one that is both informed by and reflective of the individual’s values. Decision quality affects actions and, ultimately, impacts both health outcomes and the individual’s feelings about the decision, with higher quality decisions having better outcomes.

Decision aids enhance decision quality by addressing unmet decisional needs, by: identifying the decision to be made, providing a balanced description of the risks and benefits of various options, assisting in clarifying personal values, and activating the individual for decision making.<sup>32,33</sup> Decision aids improve communication and knowledge and decrease decisional conflict and regret.<sup>34</sup> Application of the Health Belief Model<sup>8</sup> further expands our theoretical framework for how decision aids encourage action.

**Internet tools can reach a broad range of caregivers:** The National Institute on Aging's (NIA) Informal Caregiving Panel and Alzheimer's Disease Research Summit prioritize and recommend the development of technologies to integrate evidence-based treatments and support caregivers in the context of ADRDs.<sup>35–37</sup> Internet tools offer the promise of reaching diverse groups across broad geographic regions and allow individualized timing and pace of use.<sup>38</sup> eHealth interventions for informal ADRD caregivers show promise,<sup>39–41</sup> are cost-efficient,<sup>42</sup> and offer a way to sustain caregiver engagement over time.<sup>40</sup> The privacy afforded by eHealth, already cited as important by ADRD caregivers,<sup>40</sup> may be particularly critical for the sensitive topic of firearms. ADRD caregivers may also prefer at-home internet resources or interventions because of limited ability or time to travel to an intervention site (e.g., due to being with a home-bound person).<sup>43</sup> In summary, eHealth offers the potential to support caregivers, including through reducing care burden and caregiver distress and, potentially, delaying nursing home placement and lowering overall dementia care costs.<sup>27</sup> However, theoretical grounding – and process measurement – are still needed. Framing of behavioral intervention development (e.g., NIH Stage Model for Behavioral Intervention Development<sup>9</sup>) is critical for appropriate tailoring and dissemination of effective interventions.<sup>44–46</sup>

**Safety in Dementia is a caregiver tool for firearm safety:** To address caregiver needs related to firearm access, and guided by theory, our team developed Safety in Dementia (SiD), described in more detail below.<sup>6</sup> The online tool was created following international decision aid standards<sup>32</sup> and recommendations for user-friendly web design for older adults.<sup>47–49</sup> SiD is based on behavior change and decision-making theories<sup>7,8</sup> (**Figure 1**) and includes content to help caregivers understand options (with a balanced presentation of benefits and drawbacks) and then be motivated to take the action that works best for their situation. SiD provides parallel sections on driving safety and general home hazards to broaden reach and contextualize firearm safety. We translated SiD into Spanish using a rigorous process and independent back-translation to English by certified translators. Our pilot trial of SiD, in a national sample of caregivers of community-dwelling people with ADRD, found 44% of caregivers had had safety concerns regarding firearm access and approximately 30% were currently considering options for what to do about firearm access. SiD was developed to help caregivers work through these considerations – and we now propose to test its efficacy.

## **Study Design, Research Methods, and Analysis**

**Overall study design:** Our study goals are to determine the efficacy of a web-based caregiver decision aid intervention (SiD), with or without reminders, and to compare methods of reaching caregivers. Our evaluation of SiD's efficacy corresponds to Stage II in the NIH Stage Model for Behavioral Intervention Development.<sup>9</sup> Our findings from Aims 1 & 2, combined with our proposed work with stakeholders (Aim 3), could identify necessary refinements (Stage I) and inform future efficacy, effectiveness or implementation trials.

**Aim 1: To test the efficacy of SiD on firearm safety decision quality and behaviors, among a national sample of informal caregivers of community-dwelling people with ADRD and firearm access (n=500).**

**Approach:** Prospective randomized trial of (a) SiD versus (b) web control, with 1-week text/email reminders. Primary outcome: immediate decision quality (preparation for decision making). Secondary outcomes: behavior (action to reduce firearm access) at 2 weeks, 2 months, and 6 months.

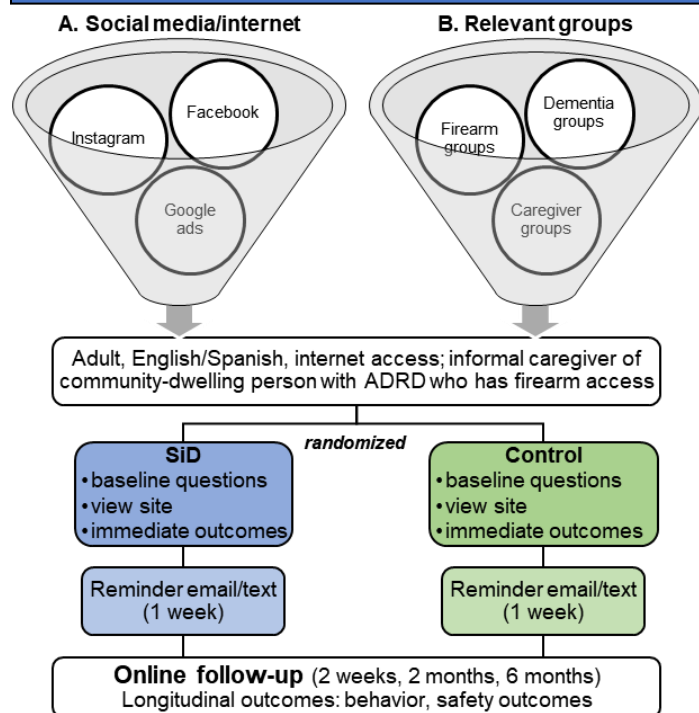
**H1a:** SiD is significantly associated with higher immediate decision quality, when compared to control.

**H1b:** SiD is significantly associated with taking action to reduce firearm access, when compared to control.

**Study design:** We will use an online randomized controlled trial of informal caregivers of community-dwelling individuals with ADRD and firearms at home (n=500), with longitudinal follow-up (**Figure 2**). Randomization will occur at the level of the individual participant. To reduce selection bias, we will use block randomization stratified by recruitment groups (social media/internet and via relevant organizations). We will assess outcome measures immediately after the intervention (Aim 1a) and longitudinally (Aim 1b).

**Study Population:** Eligible participants will be adults ( $\geq 18$  years) living in the United States who speak English or Spanish, are not in legal custody or institutionalized, and who are informal caregivers for a community dwelling person with ADRD and firearm access. Participants must have internet access but do not need to live in the same home (or state) as the person with ADRD, but the person with ADRD cannot live in any type of facility because facilities often have regulations prohibiting firearm possession. To support robust recruitment of Spanish-speaking caregivers,<sup>101</sup> we will follow a rigorous process for translating all written study materials, with translation into Spanish and then independent back-translation to English by certified translators. Discrepancies will be adjudicated by the translation team with attention to regional variations in idioms and expressions (e.g. Mexico versus Caribbean). We have already translated SiD itself into Spanish using these methods. This process ensures cultural relevance and linguistic accuracy. We will hire bilingual study staff and all study processes and materials will be provided in patient's preferred language (English or Spanish).

**Figure 2. Study flow.** Eligibility and SiD websites will have separate URLs with identical content to allow comparison (Aim 2). See also Table 3.



**Recruitment:** We will use an overall recruitment and enrollment strategy used with success in prior and other current work.<sup>61</sup> Participants will be recruited through two primary methods (social media/internet ads versus relevant organizations), as described below. All advertisements will contain similar messages and will direct individuals to a landing webpage with a description of the study. We will set up separate, identical landing webpages for each recruitment method and subgroup, to allow tracking of overall analytics (e.g., site views) and participation by recruitment modality. Those interested can answer a brief eligibility questionnaire online. Those interested and eligible based on their completion of the brief online eligibility questionnaire, will be contacted by a member of the study

team to confirm eligibility. The study team member will contact those that are interested and eligible up to 5 times via phone call, email, and/or text message. Those not interested in the study, or those not eligible, will be directed to an educational website.<sup>102</sup> Refinement of recruitment message and methods, described below, will be informed through discussions with our Expert Advisory Panel, consultants, and stakeholders.

**Recruitment message:** Initial study advertisements for the feasibility pilot were developed by the study team, with refinement of imagery and words during pilot testing. We are continuing to refine these messages through discussions with our Expert Advisory Panel, consultants, and stakeholders; questions include variations on wording (e.g., “caregiver” versus “concerned family member”), tone, graphics, and audience.

**Recruitment methods:** We will recruit through two general approaches, using the same messages.

A. **Social media/Internet:** Targeted advertisements will be disseminated via social media modalities most likely to be used by caregivers (e.g., Facebook and Instagram) as well as through Google Ads, as per our prior work. Social media advertisement campaign parameters will be set to “Reach,” and Google Ads will be parametrized to maximize click-throughs, per standard online advertising practice; both will be iteratively adjusted to ensure adequate gender and age diversity throughout the study. We will also use YouTube as a recruitment avenue for Social media/Internet. *We will be using the service of BUMP Digital Marketing to help with social media recruitment. BUMP will have absolutely no access to any participant information; they will simply be posting recruitment ads that link to a landing page*

*with information about the study that allows potential participants to visit our secure REDCap screening database if they are interested in participating.*

- B. **Relevant organizations:** Advertisements will be distributed through ‘trusted’ sources in dementia care, caregiver support, and firearms. These may include state or national organizations, support groups, ADRD research services (e.g., Trial Match), and other community-based organizations (e.g., religious groups, support groups). Distribution will include direct communication (e.g., emails or newsletters), posting on organizational sites, distributing flyers in-person at organizational sites, or inclusion in print newsletters, depending on organizational preference.

**Enrollment & randomization:** We will follow methods used successfully in past studies. All study procedures will occur via internet, telephone, or text-messaging, allowing for nationwide enrollment. All participants will receive incentives for participation (\$40 for enrollment, \$60 for 2-week and \$40 each for 2- and 6-month follow-ups). Eligible participants will be brought to an enrollment page which will validate identity (to reduce fraud or bot enrollment) and collect contact information. Enrolled participants will be randomly assigned in equal numbers to the SiD or control arm (**Figure 2**). Randomization will be stratified between recruitment group A (social media/internet) and B (relevant organizations). To reduce bias and aim for balance among arms, we will randomize in blocks of undisclosed size.<sup>103,104</sup> The PhD biostatistician (Dr. Peterson) will conceal allocation to study participants using a centralized, computer-generated list in REDCap.<sup>105</sup> Study staff will be unblinded to study arm since all Aim 1 study surveys will be self-administered.

**Intervention & control arms:** In the intervention arm, participants will be directed via hyperlink to SiD; control participants will be directed to the NIA Home Safety Checklist for Alzheimer’s Disease website.<sup>102</sup> In both intervention and control arms, participants may view the sites in whatever way, and for however long, they want. The control (NIA site) represents typical care, as it is an easily accessible website that provides basic education about home safety in the context of dementia. It provides limited guidance on firearms (*“Lock up or remove these potentially dangerous items from the home: ... Guns and other weapons, scissors, knives, power tools, and machinery”*)<sup>102</sup> without information about specific locking or disposal options or personalized guidance. Unlike SiD, the NIA website does not guide the individual through the decision or promote person-centric consideration of values and preferences, making it an appropriate control.<sup>106</sup>

**Baseline measurements:** Each participant will complete an introductory online questionnaire before viewing SiD or control (**Figure 2, Table 3**). Then, after reviewing SiD or control, participants in both arms will answer questions about preparation for decision making, self-efficacy, and knowledge (**Table 3**). At the end of the baseline session, all participants will receive a permanent hyperlink to the website to which they were randomized so they may visit it later if desired. Within each arm (SiD or control), all participants will receive a one-week reminder message. The reminder will include a hyperlink to their website and be delivered by email or text, depending on the participant’s preference. The reminder will also include a brief supportive message with encouragement to revisit the website and take steps to ensure safety.



<b>Table 3. Key study measures.</b> Shown in relation to timepoint (pre- or post-SiD or control) and analytic plan.						
Domain and Key Measures		Baseline		F/u	Analysis	
		Pre	Post		Outcome	Hyp. Scoring
<b>Immediate outcome</b>						
Readiness	Preparation for decision making		X	X	1° Outcome	1a Descriptive (contin.)
Self-efficacy	Decision self-efficacy	X		X	2° Outcome	1a Descriptive (contin.)
<b>Longitudinal outcome</b>						
Action to reduce access	Binary (any action versus none)	X		X	2° Outcome	1b Descriptive (cat.)
Firearm access	Binary (any access versus none)	X		X	2° Outcome	1b Descriptive (cat.)
<b>Other outcomes</b>						
Firearm injury/near-injury	Recent experiences	X		X	2° Outcome	1c Descriptive (contin.)
Caregiving experience	Zarit burden; Positive aspects of caregiving scale			X	2° Outcome	All Descriptive (cat.)
<b>Other covariates</b>						
Caregiver characteristics	Age, gender, race/ethnicity, language, SES, urban/rural	X			Covariate	All Descriptive (cat.)
Person with ADRD characteristics	Dementia severity, age, gender, race/ethnicity, urban/rural	X		X	Covariate	All Descriptive (cat.)
Caregiver relationship to person with ADRD	Relationship, living situation	X		X	Covariate	All Descriptive (cat.)

**Data management:** All data will be collected using self-reported measures on online questionnaires<sup>39</sup> through REDCap; data will be stored in a REDCap database hosted by UCD<sup>107</sup> or on password-protected servers. The trial is registered on clinicaltrials.gov (NCT05173922) and will follow CONSORT guidelines.<sup>45,108</sup>

**Measures:** Key measures in this trial (**Table 3**) are tied directly to our theoretical framework (**Figure 1**) and considerations of the most relevant outcomes to caregivers and people with ADRD.<sup>109</sup>

**Immediate outcomes:** Our primary outcome is SiD's effect on preparation for decision making, a core element of the Ottawa Decision Support Framework<sup>7</sup> as a precursor to behavior change (**Figure 1**). A high quality decision is defined as an informal caregiver making an informed decision consistent with their values.<sup>110,111</sup> The Preparation for Decision Making Scale assesses perception of how useful a decision aid is in preparing for subsequent decision-making. Scores range from 1-5, calculated from the average of 9 constructs (each ranging from 1, "strongly disagree" to 5, "strongly agree"). The scale has high test reliability (0.944).<sup>112</sup> In our pilot trial, participants had a mean score of 3.9 (SD 0.7) after viewing the SiD firearm section. We will measure decision self-efficacy (self-confidence or belief in one's capability to make decisions) using the Decision Self-Efficacy Scale,<sup>113</sup> as decision aids typically increase self-efficacy.<sup>34</sup> Transformed scores range from 0 (extremely low) to 100 (extremely high self-efficacy). In our pilot trial, participants had a mean score of 77.6 (SD 17.2) after viewing the SiD firearm section.

**Longitudinal outcomes:** Key secondary outcomes, also linked to our theoretical framework (**Figure 1**), are related to firearm access. Firearm access (and actions to

reduce access) for the person with ADRD will be assessed with multi-point scales we have used previously,<sup>67,114</sup> with binary categorization (any access to  $\geq 1$  firearm versus no access to any firearms) and progression towards reduced access (e.g., locking of additional firearm). This allows identification of smaller, albeit important, changes. We will assess firearm injury or near-injury in the person with ADRD or others in their home through questions about recent experiences (including incidents of threats with a firearm or “near-misses”) and perceived risks. We will measure caregiving experience, both burden and positive experiences. Caregiver burden will be measured by the short-form (3-item) Zarit Burden Interview.<sup>115–117</sup> Benefits of caregiving will be measured by the Positive Aspects of Caregiving Scale;<sup>118–120</sup> scores range from 0-36, calculated from the sum of 9 items (measured on a 5-point scale ranging from 0, “disagree a lot” to 4, “agree a lot”), with higher scores indicating positive experiences.

Other covariates: Additional measures are key covariates and for exploratory analyses. Caregiver characteristics will include basic demographic characteristics like age, gender, race/ethnicity, living situation (marital status, income, urban/rural), and education. Person with ADRD characteristics will include age, gender, race/ethnicity, and living situation (marital status, income, urban/rural). Caregiver-reported severity of dementia will be measured by the AD8 Dementia Screening. Characteristics of the caregiver relationship to person with ADRD will include type of relationship (e.g., spouse, non-related friend), living situation (together or apart; if apart, proximity). **Analysis:** We will follow recent published guidelines on statistical analyses in clinical trials.<sup>122</sup> Analyses will be performed according to the principle of intention-to-treat, including all randomized participants. Unless otherwise specified, hypothesis tests will be two-sided with  $\alpha=.05$ , with 95% confidence intervals or p values reported. All statistical analyses will be performed using R<sup>123</sup> or SAS version 9.4 software (SAS Institute Inc.). Descriptive statistics will be computed for baseline caregiver characteristics (including key covariates, **Table 3**), initially reporting on differences between: (a) two intervention arms and (b) complete follow-up vs. dropouts. Covariates will be screened in bivariate analyses and included in multivariate analysis if related to the outcome at  $p<.2$ , associated with dropout, or hypothesized *a priori* to be adjusted for. If there is evidence that normality assumptions were violated, we will use appropriate transformations, or the appropriate link function (e.g., logit link for dichotomized measures). We will employ general (or generalized) linear mixed models (GLMMs) to incorporate data structures that are longitudinal.<sup>124,125</sup> Analyses of SiD’s longitudinal effects may be vulnerable to bias, as control arm participants may be exposed to intervention arm messages through exposure to other publicly available materials. We will assess exposure to other sources of information through structured questions. To mitigate the impact of this potential bias, we will adjust for contamination as applicable. Goodness of fit statistics and model fitting diagnostics will be used to assess for influential points, outliers, and heteroscedasticity, and to evaluate alternative model specifications.

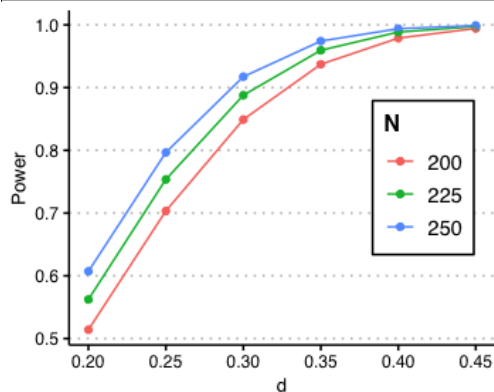
H1a: SiD is significantly associated with higher immediate decision quality, when compared to control. Our primary outcome measure will be mean Preparation for Decision Making score at baseline, after viewing SiD or control. We will utilize multiple linear regression to test SiD’s effect on decision quality. We will consider adjustment for baseline characteristics (e.g., age, gender, caregiver burden, severity of ADRD).

Secondary analyses will be conducted similarly; outcomes will be other components of decision quality (e.g., decision self-efficacy and knowledge). Linear mixed models (LMM) will be used to assess changes in self-efficacy and knowledge over time by treatment arm, allowing an interaction of treatment arm and time.

**H1b: SiD is significantly associated with taking action to reduce firearm access, when compared to control.** For access to firearms and actions to reduce access, we will use GLMM (e.g., with logit link) to account for correlations across measurements from the same individual, with adjustment for baseline characteristics as needed. We will test for an interaction between intervention and time to assess if SiD's effect varies over time. Secondary analyses will examine longitudinal change in experiences and reported safety concerns.

**Heterogeneity of treatment effect:** Differential effect of treatment will be assessed by caregiver age group, whether the caregiver lives with the person with ADRD (versus not), and recruitment group (see Aim 2). GLMM models will be used including an interaction between the intervention variable (SiD versus control) and the factor of interest (e.g., age of caregiver, dichotomized into younger and older adult). Exploratory heterogeneity of treatment effect will also be conducted by caregiver gender, urban versus rural residence, and language (English versus Spanish). Additional secondary analyses will examine longitudinal change in caregiver burden and reported safety concerns, including how these might affect treatment effect.

**Figure 3. Power vs effect size (d), by N1. Alpha=0.05; N2=N1; 2-sided T-test**



**Missing data:** Substantial efforts will be made to minimize missing data in data collection. We expect minimal missing in the primary outcome since this will be collected at enrollment. To minimize missing data for longitudinal outcomes we will, based on our prior successes, use multi-modal outreach for follow-ups, including email, text, and telephone outreach to non-responders. Prior to beginning analyses, we will examine the data carefully to determine whether patterns of missing seem ignorable (MCAR or MAR) or non-ignorable (MNAR).<sup>126–128</sup> For longitudinal analyses we will use likelihood-based methods that utilize all available data through GLMMs, adjusting for covariates that are associated with missingness. If missingness seems non-ignorable we will consider, as data permits, pattern mixture models.<sup>126,129</sup> We will also examine in sensitivity analyses change scores as outcomes, adjusting for baseline.

**Sample size:** We have powered this study conservatively for the primary outcome to allow comparisons by recruitment groups and other participant characteristics. The large sample size will also protect against uncertainty in the estimate of the effect size given the small sample size (n=15) in our pilot study. In our pilot trial of 15 caregivers, the mean Preparation for Decision Making scores was 3.9 (SD 0.7) after SiD versus 3.6 (SD=0.2) in the control group; this corresponds to a standardized effect size of 0.42 (3.9 versus 3.6 with a pooled SD of 0.7;  $d=0.3/0.7=0.42$ ).<sup>130</sup> Based on t-test, with the proposed sample size of N=500 participants, we will be able to detect a d=0.42 effect

size with very high power of >99% ( $\alpha=0.05$ ) between SiD and control for the primary outcome (preparation for decision making; **Figure 3**. Even if the effect is smaller (e.g.,  $d=0.30$ ) and the sample size is 80% (400 total) the power remains high at 84.9%. With a sample size of 500, we will have 125 in each of the final four analytic groups (stratified by recruitment group A versus B, SiD versus control). This sample will yield 80% power to detect any subgroup-specific standardized effect of  $d=0.36$  or greater between SiD and control, including by recruitment group and other participant characteristics (using t-test and assuming sample sizes of 125 in each subgroup). Power calculations were computed using R version 4.0.2.<sup>123</sup>

**Challenges & alternative strategies:** In terms of feasibility, the study team is uniquely positioned to test SiD, given the investigators' breadth and depth of complementary areas of expertise, as well as experience recruiting older adults for online trials and longitudinal studies. Online recruitment offers the potential for broad reach across geographic regions and has safety benefits in the era of COVID-19. However, it limits reach to individuals who cannot, or choose not to, regularly use social media, the internet, or email (estimated at 15-20% of ADRD caregivers). In Aim 3, we will explore how SiD might also be disseminated through clinical or other non-electronic settings, though the tool itself will remain primarily web-based. Recruitment of both English- and Spanish-speaking caregivers will enhance our understanding of the tool's effects, acceptability, and potential for dissemination and utilization in diverse communities. During development of study messages (Aim 1) and a SiD communication strategy (Aim 3), we will specifically explore variations within and across caregiver populations (e.g., by race, ethnicity, geography) and incorporate these findings to enhance reach and dissemination.<sup>101</sup> Some participants will complete longitudinal interviews (Aim 3); these interviews will occur after the 2-week and 6-month assessment points so as not to interfere with immediate or 2-week outcomes. Our sample size will allow for sensitivity analyses of 2- and 6-month outcomes excluding interview participants to identify treatment effect.

## **Aim 2: To compare varied methods in reaching informal caregivers.**

**Approach:** To inform future real-world testing and use, we will use data from Aim 1 trial's two recruitment strategies: (a) via social media/internet (Facebook, Instagram, Google ads); (b) via trusted relevant organizations (dementia, caregiving, firearms). Primary outcome: caregiver characteristics of each method. Secondary outcomes: participation and retention rates and relative cost of each method of outreach.

**H2a:** Caregivers reached via social media/internet will differ from those reached via relevant organizations.

**H2b:** Reach via social media/internet (versus relevant organizations) will be faster and lower cost.

**Study Design:** Data will come from the participants enrolled in the randomized controlled trial described above, including the longitudinal follow-up. As shown in **Figure 2**, trial enrollment will be stratified by two general methods: (A) social media/internet (Instagram, Facebook, Google ads) and (B) relevant organizations (dementia, caregiving, firearms). The use of duplicated, identical sites for eligibility screening and for SiD review, each with a unique URL, will allow us to know a participant's recruitment

group (A versus B), subgroup (e.g., Instagram versus Facebook), and language (English versus Spanish).

**Data management:** Data will include those collected from Aim 1 online questionnaires and stored in a REDCap database<sup>107</sup> or on password-protected servers. Additional data will come from Google Analytics for each of the unique eligibility and SiD websites; while these sites will be identical, they will separate the trial participants by their origin of enrollment (group and subgroup). Website analytics will be at the level of groups or subgroups, as we will not be able to identify individual participants from their website usage (i.e., they do not login to a site or have other markers of identity). For social media and internet advertisements, we also will track impressions, click-throughs, and enrollment, as per standard practice.

**Measures:** Key measures will include caregiver characteristics such as participation language (English versus Spanish) and self-reported age, gender, race/ethnicity, relationship to person with ADRD, and geographic location of residence among those enrolled (**Table 3**). For enrollment and retention of each group and subgroup, calculated measures will be the proportions of individuals who were eligible (among those who completed eligibility screening), who enrolled (among those eligible), and who remained in the trial until the 6-month point (among participants). We will calculate enrollment rates by calendar time. We will calculate the approximate cost per enrolled participant based on advertising costs, fees to organizations, and staff time. We will also examine website analytics; for each recruitment group and subgroup randomized to SiD, measures will include average time spent on SiD (mean and SD, and median and IQR) and pages viewed.

**Sample size:** As discussed above, a trial sample size of 500 will allow comparison of various subgroups. Trial enrollment and randomization will be stratified by group, with a goal of equal distribution by social media/internet (n=250 total) and via relevant organizations (n=250 total; **Figure 3**).

**Analysis:** We will report descriptive statistics with proportions (with 95% confidence intervals) and means (SD) or medians (with IQRs). We will use t-test, Wilcoxon, and Chi-square test, as appropriate for pairwise statistical comparisons between and across groups and subgroups. To compare more than two groups at a time, we will use appropriate statistical methods (e.g., ANOVA, Kruskal Wallis, Chi-square tests).

**H2a: Caregivers reached via social media/internet will differ from those reached via relevant organizations.** For initial analyses, we will compare participant characteristics between group A (social media/internet) and group B (relevant groups), with subgroup analysis by language (English versus Spanish). We will further divide analyses by the recruitment subgroup (e.g., Facebook versus Google Ads).

**H2b: Reach via social media/internet (versus relevant organizations) will be faster and lower cost.** Using website analytics from the eligibility screening websites, we will calculate (by recruitment group and subgroup, including separately by language) the proportion of individuals who were eligible, the proportion of eligible individuals who enrolled, and the rate of recruitment. We will calculate the cost of recruitment per participant based on advertising costs, fees paid to organizations, and estimates of study staff time.<sup>131,132</sup>

Secondary analyses: Among SiD participants, we will examine participants across recruitment groups and subgroups to compare website analytics (e.g., minutes on site) and trial retention at 6 months.

**Challenges & alternative strategies:** Our approach to recruitment via social media, internet ads, and through relevant organization brings the potential to reach diverse audiences, but we recognize that it may miss some populations. While most American adults use the internet, some populations do not have reliable access to or comfort using some platforms;<sup>53,57</sup> our analysis will examine whether certain populations are better reached via traditional recruitment methods. We will not use all social media or internet platforms, but we will focus on the more consistently- and widely-used options (e.g., Facebook) among our target population. Given the expected diversity in caregivers, our results may also shed light on the best methods for reaching younger caregivers. The sample of participants (n=60; Aim 3) with qualitative interviews may have higher trial retention because of increased contact; we will conduct retention analyses with and without the interview participants. We recognize that small numbers in some subgroups could limit analytic power, but findings about relative ease of reaching caregivers across methods will provide useful knowledge about real-world engagement.

**Aim 3: To explore stakeholder longitudinal experiences with SiD and firearm-related decisions.**

Approach: Data collection through: (a) embedded longitudinal qualitative research with a purposive sample of caregivers in Aim 1 trial; and (b) qualitative interviews with other stakeholders (service providers, experts). Primary areas of study: experiences in changing ADRD-related firearm access, views on SiD dissemination.

**Q3a:** What are caregiver experiences, over time, related to SiD use and firearm access in ADRD, and how are these experiences affected by caregiver characteristics (e.g., age, gender, geography)?

**Q3b:** What are the views of caregivers and other stakeholders concerning real-world SiD use, including optimal settings and factors affecting reach, receptivity, and perceived relevance?

**Study design:** This qualitative study is based on our theoretical framework (**Figure 1**). Use of longitudinal qualitative research methods<sup>133,134</sup> with a sample of trial participants will allow more in-depth exploration of our key considerations around outreach to caregivers, SiD use, and general decision-making about firearms. Longitudinal analysis allows for exploration of processes and changes by looking both backwards and forwards in time.<sup>135</sup> We will supplement this longitudinal exploration of caregiver experience with cross-sectional qualitative interviews with other key stakeholders. With caregivers and other stakeholders, interviews will be informed by the Consolidated Framework for Implementation Research (CFIR),<sup>136,137</sup> as use of dissemination & implementation (D&I) frameworks is critical when developing, testing and refining interventions in order to facilitate translation from research to practice.<sup>63</sup> The CFIR is a recommended, evidence-based framework whose constructs reflect the multi-dimensional factors most likely to affect “real world” intervention use.

**Study populations (Key stakeholders for engagement):** We will invite a sample of ADRD caregivers (n=60) in the Aim 1 trial to enroll in the embedded longitudinal

qualitative study. Invitation for qualitative interviews will occur after completion of 2-week follow-up (so as not to affect the key efficacy analyses described above). We will purposively sample caregivers based on key demographics to maximize diversity; demographic factors will include caregiver language, age group, gender, relationship to the person with ADRD, living situation (with or separate from the person with ADRD), geographic region (state and urban/rural location). We will also stratify sampling by recruitment method and trial arm; though we will prioritize conducting relatively more interviews with participants in the SiD arm (to allow discussion of SiD), interviews with control participants will allow us to explore acceptable recruitment approaches (to inform tailored messages and targeted dissemination strategies), as well as the “natural history” of decisions and experiences related to firearms, with a broader cross-section of caregivers. Interviews will be conducted in Spanish for those study participants whose primary, preferred language is Spanish. Key informant interviews with key stakeholders will focus on learning the perspectives of service providers (n=20) who may use the tool in real-world settings (e.g., providers from relevant healthcare settings, caregiver support organizations, and dementia care organizations) and additional experts from key stakeholder groups (n=20), drawing upon suggestions and connections from the study team, Expert Advisory Panel, and NIA officials (e.g., NIA, American Geriatrics Society, the Alzheimer’s Association, the NRA, and the National Shooting Sports Foundation). Snowball sampling will allow us to achieve the target of 20 interviews with key leaders of salient organizations and groups and ensure that we are including those deemed to be trusted experts from a variety of sectors and population perspectives. We will send up to 3 email invitations and describe the study in greater detail to interested respondents.

**Measures:** Semi-structured qualitative interview guides will explore key questions related to firearm access in ADRD, caregiver experiences and decision making about that access, and SiD itself, such as recommended modifications, preferred method for dissemination and use (e.g., clinical setting, community setting, at home), and the recommended target audience. When possible, we will build on existing interview guides<sup>137</sup> to ensure language is at an acceptable literacy level, is culturally sensitive and appropriate, and supports building rapport with key informants to enhance the quality (reliability and validity) of the data collected.

**Data collection and management:** We will conduct semi-structured interviews with a subsample of trial participants (n=60), as well as service providers (n=20) and experts (n=20). Interviews will follow a semi-structured interview guide, last 30-60 minutes, and be digitally recorded with permission and professionally transcribed. Interviews will be conducted by trained research study staff via telephone, video conference, or in person depending on participants’ preference and feasibility.

**Data analysis:** We will conduct a structured debrief following each key informant interview to process emerging insights and themes and support the identification of new, emergent questions that warrant further exploration in subsequent interviews. This structure for deliberately processing data as it is collected will also support development of an initial codebook (key, salient categories of information and their operational definitions) to guide systematic and consistent coding across multiple members of the study team. Qualitative data will be analyzed using Dedoose, an online

platform for team-based qualitative analysis with project-specific data encryption and tools to support establishing interrater reliability. Guided by our theoretical framework (**Figure 1**) and CFIR, we will use a team-based, mixed inductive-deductive approach to review and code transcripts, identify dominant themes, compare these themes across content areas and demographic groups. We will use recommended practices for longitudinal qualitative data to synthesize and concentrate data into meaningful findings.<sup>133,138,139</sup> “Member-checking” with key informants and the stakeholder advisory board will include discussion of final themes, thematic relationships, and insights emerging across sources.

Q3a: What are caregiver experiences, over time, related to SiD use and firearm access in ADRD, and how are these experiences affected by caregiver characteristics (e.g., age, gender, geography)?

Q3b: What are the views of caregivers and other stakeholders concerning real-world SiD use, including optimal settings and factors affecting reach, receptivity, and perceived relevance?

**Sample size:** We estimate needing 15-20 interviews per population subgroup to reach the “saturation point” (where additional interviews are unlikely to reveal new insights), while allowing for adequate group diversity.<sup>140</sup>

**Challenges & alternative strategies:** Although we have a general framework for this study aim and topical areas to explore, we plan to use an inductive analytic approach to allow themes and a final conceptual framework to arise from the interviews and facilitated processing discussions with the stakeholder advisory board and other stakeholders.<sup>141</sup> This approach requires iterative analyses to ensure subsequent interviews address emerging themes; we have used it successfully in the past. In longitudinal qualitative research, consideration of time and timing is important, as participant experiences or decisions may occur at different rates.<sup>135,142,143</sup> We plan to contact participants at fixed intervals (after 2-week and 6-month trial follow-up), rather than at the direction of participants based on when events occur. Interviews will include discussion of timing, however, including how recent events may have affected decision making or perspectives. Furthermore, we will share results with the Expert Advisory Group on an ongoing basis and engage them in facilitated discussions of the data emerging from each study aim. If we find any aspects of SiD are unacceptable, we will make the necessary edits, with re-review by stakeholders prior to future implementation.



## Study Milestones & Timeline

General milestones (**Table 4**) and timeline estimates are conservative and based on our team's experience in similar research. We obtained IRB approval for the feasibility pilot, which uses the same methods proposed in the full trial and was the basis for our recruitment estimates. Should we find that we are falling behind our anticipated timeline for any of the key study activities or milestones, our team will modify our study approaches or timeline.

Table 4. Study timeline with recruitment milestones														
		YEAR 1					YEAR 2				YEAR 3			
QUARTER		-1	1	2	3	4	1	2	3	4	1	2	3	4
Team meetings														
Prepare	Finalize study procedures													
	Obtain IRB approval													
	Hire and train research staff													
Trial (Aim 1/2)	Enrollment (baseline)				167		333		500					
	Follow-up: 2 weeks				139		306		472	500				
	Follow-up: 2 months				111		278		444	500				
	Follow-up: 6 months						167		333		500			
Qual. (Aim 3)	Caregivers: 2 weeks				12		27		42	50				
	Caregivers: 6 months						12		27		42	50		
	Providers & experts								10	10	10	10		
Data analysis														
Dissemination														

## **Eligibility**

### **Aim 1 (Trial; N=500):**

Adults ( $\geq 18$  years) living in the United States; caregiver for community dwelling person (i.e., not living in a facility) with dementia who has  $\geq 1$  firearm; fluent in English or Spanish. Caregiver participants must have internet access but do not need to live in the same home (or state) as the person with ADRD.

### **Aim 3 (Semi-structured qualitative interviews with members of relevant stakeholder groups; N=100):**

Adults ( $\geq 18$  years) living in the United States (all participants).

Caregiver interview participants must be enrolled in the Aim 1 trial (N=60; purposive sample of caregivers in Aim 1 trial)

Service provider interview participants must be healthcare or service providers who support caregivers or people with dementia (N=20)

Experts in relevant fields interview participants must be from fields or organizations who might disseminate Safety in Dementia tool (e.g., dementia, aging, caregiving, firearm organizations) (N=20)

## **Informed Consent**

We will seek a waiver of documentation of written informed consent for all study procedures. The informed consent processes for Aims 1 and 3 are consistent with prior work and IRB guidance.

For the trial (Aim 1), we will include robust consent language on the landing webpage that all participants will be directed to once they indicate interest in participating. This language will 1) provide detailed information about the study, what is involved in study participation, the study's purpose, along with the basic risks and benefits; 2) explain that if they meet certain eligibility criteria and elect to enroll in the study, they are agreeing for their de-identified data to be used for research purposes; 3) review critical rights of research participants (e.g., they may withdraw from the study at any time; they may elect not to answer one or more questions without any negative consequences; etc); and 4) provide contact information for study staff, in the event they have any questions. In the eligibility section, we will also include a series of Yes/No teach-back questions about what study participation entails and what the rights of research participants are (e.g., "You have the right to stop participating at any time."). If a potential participant answers one of these questions incorrectly, the correct information will be piped in as an interactive way to ensure those consenting to enter the study have a full understanding of what their participation entails.

For the qualitative interviews (Aim 3), we will conduct the informed consent process using a COMIRB-approved consent script to accommodate for the range of options we provide for the conduct of interviews (telephone, video conference, or in person). All qualitative interview participants will be sent a copy of the consent script for their records; this will include contact information for study staff and investigators. Caregiver participants in the trial who go on to participate in qualitative interviews (Aim 3) will complete the Aim 3 informed consent process in addition to the informed consent process at the beginning of Aim 1.

## **Description, Risks and Justification of Procedures**

### **Risks to Human Subjects**

This is a minimal risk study. One risk of this study is loss of privacy due to breach of confidentiality. We will make every attempt to keep information private. To ensure adequate protection of confidentiality, any age above 89 will be treated as an identifier and will be recorded as 89+ when collecting demographic data from participants. Data will be stored in a REDCap database hosted by UCD or on password-protected servers, with access limited to study personnel. The research team will diligently safeguard participant information in the collection, processing, and storage of data, and all of the data generated by the study will be kept strictly confidential. No reports will be released containing identifiers that would allow a study participant to be identified.

Some participants may be uncomfortable discussing firearms. They may choose not to answer certain questions. The research team will report any activities resulting in participant discomfort or injury to the IRB immediately.

### **Adequacy of Protection Against Risks**

All staff participating in the project will complete compliance and human subjects research training. All recruitment materials will be submitted for approval by the IRB. No one outside of the research team will know that a participant was involved in the study unless the participant discloses this him/herself. All research records and data will be kept in a locked file in the PI's offices and/or in a password-protected, secure network server; audio recordings will be destroyed after transcription to further protect confidentiality.

### **Potential Benefits to Human Subjects and Importance of the Knowledge to be Gained**

Caregiver study participants enrolled in the Aim 1 trial will be reimbursed in the amount of \$40 for their enrollment survey, \$60 for their two week follow-up survey, \$40 for their two month follow-up survey, and \$40 for their six month follow-up survey, for a maximum total of \$180 per participant enrolled only in the trial. Stakeholder study participants (Aim 3) who complete a qualitative interview will be reimbursed in the amount of \$50 per interview. Caregivers who participate in both the Aim 1 and Aim 3 studies may receive up to \$280 in total reimbursement.

Viewing information online (Aim 1) and/or engaging in a qualitative interview (Aim 3) may help some participants make more informed and values-concordant decisions about firearm safety, which could enhance participant and care recipient health over subsequent years. Findings from this proposed research will expand the knowledge on factors that affect decision making around firearm safety for people with dementia, which offers the potential to benefit the millions of caregivers and people with dementia in the US.

## **Future Directions**

We will synthesize the knowledge gained through our trial (Aims 1 and 2) with the findings from the qualitative research (Aim 3). The longitudinal qualitative research embedded in the trial will allow examination of experiences over time, including comparisons between those with SiD and those with control resources. These findings will influence future dissemination plans (Stages IV/V) or prompt return to Stage I for intervention refinement and subsequent Stage III community efficacy testing. In preparation for future dissemination, we will draft a communication strategy with a plan and framework to reach caregivers for use of SiD. This process will include identification of optimal messages for outreach and engagement. We expect to delineate the communication plan and messaging strategy through a toolkit intended to serve as an action-oriented guide for organizations interested in promoting use of SiD. For toolkit development, we will follow published recommendations, including using checklists<sup>144</sup> to ensure consistency with core components with which we want to maintain fidelity. The strategy will be reviewed by at least two national experts in the Dissemination and Implementation field recruited from our existing connections.<sup>144,145</sup> In addition to the dissemination of the toolkit and traditional academic deliverables (e.g., peer-reviewed publications), we will work with stakeholders to design and disseminate resources like press releases, sample organizational policies, community outreach or engagement templates, media op-eds, or toolkits. With guidance and engagement from our Expert Advisory Panel, we can leverage existing national networks to share our findings with service providers and caregivers. We will also strategically reach other outlets (e.g., trade publications popular among gun retailers and shooting range proprietors). This work has the potential for significant public health impact through effects on a growing segment of the US population – both those with ADRD and their informal caregivers – by shaping safety strategies at multiple levels. These include public health programming at the state or national level and direct medical and social service practice.

## BIBLIOGRAPHY

1. Bailey JA and M. Unlocked and loaded: Families confront dementia and guns [Internet]. USA TODAY. [cited 2020 Jun 19]. Available from: <https://www.usatoday.com/story/news/2018/07/01/guns-mental-health-elderly-dementia/738845002/>
2. Hirschman EC. Men, Dogs, Guns, and Cars: The Semiotics of Rugged Individualism. *J Advert.* Taylor & Francis, Ltd.; 2003;32(1):9–22.
3. Betz ME, McCourt AD, Vernick JS, Ranney ML, Maust DT, Wintemute GJ. Firearms and Dementia: Clinical Considerations. *Ann Intern Med.* 2018/05/26 ed. 2018 Jul 3;169(1):47–49.
4. Betz ME, Azrael D, Johnson RL, Knoepke CE, Ranney ML, Wintemute GJ, Matlock D, Suresh K, Miller M. Views on Firearm Safety Among Caregivers of People with Alzheimer’s Disease and Related Dementias. *JAMA Netw Open.* (in press);
5. Betz ME, Ranney ML, Knoepke CE, Johnson RL, Pallin R, Miller M, Wintemute GJ. Dementia and Firearms: an Exploratory Survey of Caregiver Needs. *J Gen Intern Med.* 2019 Oct;34(10):1984–1986.
6. Polzer E, Nearing K, Knoepke CE, Matlock D, Azrael D, Siry B, Meador L, Betz ME. Safety in Dementia’: Development of an online caregiver tool for firearm, driving and home safety.
7. O’Connor AM. Ottawa Decision Support Framework to Address Decisional Conflict [Internet]. 2006. Available from: <https://decisionaid.ohri.ca/docs/develop/ODSF.pdf>
8. Janz NK, Becker MH. The Health Belief Model: A Decade Later. *Health Educ Q.* 1984 Mar;11(1):1–47.
9. Onken LS, Carroll KM, Shoham V, Cuthbert BN, Riddle M. Reenvisioning Clinical Science. *Clin Psychol Sci.* 2014 Jan 1;2(1):22–34.
10. Alzheimer’s Association. 2020 Alzheimer’s Disease Facts and Figures [Internet]. 2020 [cited 2020 Jun 16]. Available from: <https://www.alz.org/media/Documents/alzheimers-facts-and-figures.pdf>
11. McGuire LC. A public health approach to Alzheimer’s disease: A testimony to the senate special committee on aging. [Internet]. 2018 [cited 2020 Jun 16]. Available from: <https://www.cdc.gov/washington/testimony/2018/t20180619.htm>
12. Parker K, Horowitz J, Igielnik R, Oliphant B, Brown A. America’s Complex Relationship With Guns [Internet]. Pew Research Center; 2017. Available from: <https://www.pewsocialtrends.org/2017/06/22/americas-complex-relationship-with-guns/>
13. Betz ME, Miller M, Matlock DD, Wintemute GJ, Johnson RL, Grogan C, Lum HD, Knoepke CE, Ranney ML, Suresh K, Azrael D. Older Firearm Owners and Advance Planning: Results of a National Survey. (under review);
14. Conejero I, Navucet S, Keller J, Olié E, Courtet P, Gabelle A. A Complex Relationship Between Suicide, Dementia, and Amyloid: A Narrative Review. *Front Neurosci* [Internet]. 2018 Jun 1 [cited

2020 Apr 21];12. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5992441/>  
PMCID: PMC5992441

15. Hartzell JW, Geary R, Gyure K, Chivukula VR, Haut MW. Completed suicide in an autopsy-confirmed case of early onset Alzheimer's disease. *Neurodegener Dis Manag. Future Medicine*; 2018 Jan 10;8(2):81–88.
16. CDC. Web-based Injury Statistics Query and Reporting System (WISQARS) [Internet]. Centers for Disease Control and Prevention, National Center for Injury Prevention and Control; 2021. Available from: <http://www.cdc.gov/injury/wisqars/index.html>
17. Conwell Y, Duberstein PR, Caine ED. Risk factors for suicide in later life. *Biol Psychiatry*. 2002 Aug 1;52(3):193–204.
18. Blazer DG, Bachar JR, Manton KG. Suicide in late life. Review and commentary. *J Am Geriatr Soc*. 1986 Jul;34(7):519–525. PMID: 3722669
19. Gunnell D, Appleby L, Arensman E, Hawton K, John A, Kapur N, Khan M, O'Connor RC, Pirkis J, COVID-19 Suicide Prevention Research Collaboration. Suicide risk and prevention during the COVID-19 pandemic. *Lancet Psychiatry*. 2020 Apr 21; PMID: 32330430
20. Botchway S, Fazel S. Remaining vigilant about COVID-19 and suicide. *Lancet Psychiatry* [Internet]. Elsevier; 2021 Apr 13 [cited 2021 Apr 23];0(0). Available from: [https://www.thelancet.com/journals/lanpsy/article/PIIS2215-0366\(21\)00117-6/abstract](https://www.thelancet.com/journals/lanpsy/article/PIIS2215-0366(21)00117-6/abstract) PMID: 33862017
21. Szanto K, Gildengers A, Mulsant BH, Brown G, Alexopoulos GS, Reynolds CF 3rd. Identification of suicidal ideation and prevention of suicidal behaviour in the elderly. *Drugs Aging*. 2002;19(1):11–24.
22. Conwell Y, Duberstein PR, Cox C, Herrmann J, Forbes N, Caine ED. Age differences in behaviors leading to completed suicide. *Am J Geriatr Psychiatry*. 1998 Spring;6(2):122–6.
23. Rosen T, Makaroun LK, Conwell Y, Betz M. Violence In Older Adults: Scope, Impact, Challenges, And Strategies For Prevention. *Health Aff Proj Hope*. 2019;38(10):1630–1637.
24. Lyketsos CG, Steinberg M, Tschanz JT, Norton MC, Steffens DC, Breitner JC. Mental and behavioral disturbances in dementia: findings from the Cache County Study on Memory in Aging. *Am J Psychiatry*. 2000;157(5):708–714.
25. Wharton TC, Ford BK. What is known about dementia care recipient violence and aggression against caregivers? *J Gerontol Soc Work*. 2014/06/24 ed. 2014;57(5):460–477.
26. Brodaty H, Donkin M. Family caregivers of people with dementia. *Dialogues Clin Neurosci*. 2009;11(2):217–228. PMCID: PMC3181916
27. Boots LMM, Vugt ME de, Knippenberg RJM van, Kempen GIJM, Verhey FRJ. A systematic review of Internet-based supportive interventions for caregivers of patients with dementia. *Int J Geriatr Psychiatry*. 2014;29(4):331–344.

28. Quinn C, Toms G. Influence of Positive Aspects of Dementia Caregiving on Caregivers' Well-Being: A Systematic Review. *The Gerontologist*. 2019 17;59(5):e584–e596. PMID: 30597058
29. Zarit SH. Positive aspects of caregiving: more than looking on the bright side. *Aging Ment Health*. 2012;16(6):673–674. PMID: 22746192
30. Lloyd J, Patterson T, Muers J. The positive aspects of caregiving in dementia: A critical review of the qualitative literature. *Dement Lond Engl*. 2016 Nov;15(6):1534–1561. PMID: 25547208
31. Polzer E, Nearing K, Knoepke CE, Matlock DD, McCourt A, Betz ME. Firearm access in dementia: legal and logistic challenges for caregivers. *Int Rev Psychiatry Abingdon Engl*. 2021 Apr 1;1–9. PMID: 33792478
32. Matlock DD, Spatz ES. Design and testing of tools for shared decision making. *Circ Cardiovasc Qual Outcomes*. 2014 May;7(3):487–92.
33. Bhandari G, Hassanein K, Deaves R. Debiasing investors with decision support systems: An experimental investigation. *Decis Support Syst*. 2008 Dec 1;46(1):399–410.
34. Stacey D, Legare F, Col NF, Bennett CL, Barry MJ, Eden KB, Holmes-Rovner M, Llewellyn-Thomas H, Lyddiatt A, Thomson R, Trevena L, Wu JH. Decision aids for people facing health treatment or screening decisions. *Cochrane Database Syst Rev*. 2014;1:CD001431.
35. Recommendations from the NIH AD Research Summit 2015 [Internet]. National Institute on Aging; Available from: <https://www.nia.nih.gov/research/recommendations-nih-ad-research-summit-2015>
36. Recommendations from the NIH AD Research Summit 2018 [Internet]. National Institute on Aging; 2018. Available from: <https://www.nia.nih.gov/research/administration/recommendations-nih-adresearch-summit-2018>
37. Next Steps for Research on Informal Caregiving [Internet]. National Institute on Aging; Available from: [https://www.nia.nih.gov/sites/default/files/2017-08/gerald-summary\\_11-21-14\\_0.pdf](https://www.nia.nih.gov/sites/default/files/2017-08/gerald-summary_11-21-14_0.pdf)
38. Schulz R, Beach SR, Czaja SJ, Martire LM, Monin JK. Family Caregiving for Older Adults. *Annu Rev Psychol*. 2020 04;71:635–659. PMCID: PMC7291827
39. Dam AEH, de Vugt ME, van Boxtel MPJ, Verhey FRJ. Effectiveness of an online social support intervention for caregivers of people with dementia: the study protocol of a randomised controlled trial. *Trials* [Internet]. 2017 Aug 29 [cited 2020 Jun 12];18. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5575867/> PMCID: PMC5575867
40. Glueckauf RL, Loomis JS. Alzheimer's Caregiver Support Online: lessons learned, initial findings and future directions. *NeuroRehabilitation*. 2003;18(2):135–146. PMID: 12867676
41. Martín-Carrasco M, Martín MF, Valero CP, Millán PR, García CI, Montalbán SR, Vázquez ALG, Piris SP, Vilanova MB. Effectiveness of a psychoeducational intervention program in the reduction of caregiver burden in Alzheimer's disease patients' caregivers. *Int J Geriatr Psychiatry*. 2009 May;24(5):489–499. PMID: 18949763



42. Lewis BA, Williams DM, Neighbors CJ, Jakicic JM, Marcus BH. Cost Analysis of Internet vs. Print Interventions for Physical Activity Promotion. *Psychol Sport Exerc.* 2010 May 1;11(3):246–249. PMID: PMC2853814
43. Serafini JD, Damianakis T, Marziali E. Clinical practice standards and ethical issues applied to a virtual group intervention for spousal caregivers of people with Alzheimer's. *Soc Work Health Care.* 2007;44(3):225–243. PMID: 17548277
44. Michie S, Abraham C, Eccles MP, Francis JJ, Hardeman W, Johnston M. Strengthening evaluation and implementation by specifying components of behaviour change interventions: a study protocol. *Implement Sci IS.* 2011 Feb 7;6:10. PMID: PMC3041694
45. Eysenbach G, Group C-E. CONSORT-EHEALTH: improving and standardizing evaluation reports of Web-based and mobile health interventions. *J Med Internet Res.* 2011;13(4):e126.
46. Simeon R, Dewidar O, Trawin J, Duench S, Manson H, Pardo Pardo J, Petkovic J, Hatcher Roberts J, Tugwell P, Yoganathan M, Presseau J, Welch V. Behavior Change Techniques Included in Reports of Social Media Interventions for Promoting Health Behaviors in Adults: Content Analysis Within a Systematic Review. *J Med Internet Res.* 2020 Jun 11;22(6):e16002. PMID: 32525482
47. Making Your Web Site Senior Friendly: A Checklist [Internet]. National Library of Medicine. Available from: <https://nnlm.gov/mar/guides/making-your-website-senior-friendly>
48. Charness N, Demiris G, Krupinski E. Designing telehealth for an aging population: A human factors perspective. Boca Raton, FL: CRC press, Taylor & Francis Group; 2011.
49. Czaja SJ, Boot WJ, Charness N, Rogers WA. Designing for older adults: Principles and creative human factors approaches. Boca Raton, FL: CRC press, Taylor & Francis Group; 2019.
50. Brassard B. NSSF-AFSP Suicide Prevention Partnership [Internet]. National Shooting Sports Foundation; 2016. Available from: <http://www.nssfblog.com/nssf-afsp-suicide-prevention-partnership/>
51. Polzer E, Brandspigel S, Kelly T, Betz M. "Gun shop projects" for suicide prevention in the USA: current state and future directions. *Inj Prev J Int Soc Child Adolesc Inj Prev.* 2020 Mar 25; PMID: 32213533
52. Kelly T, Brandspigel S, Polzer E, Betz ME. Firearm Storage Maps: A Pragmatic Approach to Reduce Firearm Suicide During Times of Risk. *Ann Intern Med* [Internet]. 2020 [cited 2020 Jan 21]; Available from: <https://doi.org/10.7326/M19-2944>
53. Leslie M, Khayatzaheh-Mahani A, MacKean G. Recruitment of caregivers into health services research: lessons from a user-centred design study. *Res Involv Engagem.*
54. Kalesan B, Villarreal MD, Keyes KM, Galea S. Gun ownership and social gun culture. *Inj Prev.* 2016 Jun;22(3):216–20.
55. Pierre JM. The psychology of guns: risk, fear, and motivated reasoning. *Palgrave Commun.* Palgrave; 2019 Dec 10;5(1):1–7.

56. Betz ME, Wintemute GJ. Physician counseling on firearm safety: A new kind of cultural competence. *JAMA*. 2015;314(5):449–450.
57. Demographics of Social Media Users and Adoption in the United States | Pew Research Center [Internet]. [cited 2020 Jun 16]. Available from: <https://www.pewresearch.org/internet/fact-sheet/social-media/>
58. Green BM, Van Horn KT, Gupte K, Evans M, Hayes S, Bhowmick A. Adaptive Engagement and Support Model for People with Chronic Health Conditions: Using Combined Content Analysis to Assess Online Health Communities. *J Med Internet Res*. 2020 Jun 3; PMID: 32492651
59. Use of the Internet for Health Information: United States, 2009 [Internet]. National Center for Health Statistics, Centers for Disease Control and Prevention; 2011. Available from: <https://www.cdc.gov/nchs/products/databriefs/db66.htm>
60. Chai PR, Chai P, Lewis DM, Group O, Ranney ML, Rosen RK, Boyer EW, Boyer E. Crowd-Sourced Focus Groups on Twitter: 140 Characters of Research Insight. *Proc 50th Hawaii Int Conf Syst Sci*. 2017. p. 8.
61. Ranney ML. Intervention Media to Prevent Adolescent Cyber-conflict Through Technology [Internet]. *ClinicalTrials.gov*. [cited 2020 Jun 16]. Available from: <https://clinicaltrials.gov/ct2/show/NCT04259216>
62. Brownson RC, Jacobs JA, Tabak RG, Hoehner CM, Stamatakis KA. Designing for Dissemination Among Public Health Researchers: Findings From a National Survey in the United States. *Am J Public Health*. 2013 Sep;103(9):1693–1699. PMCID: PMC3966680
63. Gitlin LN, Baier RR, Jutkowitz E, Baker ZG, Gustavson AM, Sefcik JS, Hodgson NA, Koeuth S, Gaugler JE. Dissemination and Implementation of Evidence-Based Dementia Care Using Embedded Pragmatic Trials. *J Am Geriatr Soc* [Internet]. 2020 Jul [cited 2020 Jul 3];68(S2). Available from: <https://onlinelibrary.wiley.com/doi/abs/10.1111/jgs.16622>
64. Cohen EL, Head KJ, McGladrey MJ, Hoover AG, Vanderpool RC, Bridger C, Carman A, Crosby RA, Darling E, Tucker-McLaughlin M, Winterbauer N. Designing for dissemination: lessons in message design from “1-2-3 pap.” *Health Commun*. 2015;30(2):196–207. PMCID: PMC4753793
65. Betz ME, Scott K, Jones J, Diguseppi C. “Are you still driving?” Metasynthesis of patient preferences for communication with health care providers. *Traffic Inj Prev*. 2016 May 18;17(4):367–73.
66. Betz ME, Haukoos JS, Schwartz R, DiGuseppi C, Kandasamy D, Beaty B, Juarez-Colunga E, Carr DB. Prospective Validation of a Screening Tool to Identify Older Adults in Need of a Driving Evaluation. *J Am Geriatr Soc*. 2018 Feb;66(2):357–363.
67. Betz ME, Knoepke CE, Simpson S, Siry BJ, Clement A, Saunders T, Johnson R, Azrael D, Boudreaux ED, Omeragic F, Adams LM, Almond S, Juarez-Colunga E, Matlock DD. An Interactive Web-Based Lethal Means Safety Decision Aid for Suicidal Adults (Lock to Live): Pilot Randomized Controlled Trial. *J Med Internet Res* [Internet]. 2020 Jan 29 [cited 2020 Mar 28];22(1). Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7016618/> PMCID: PMC7016618

68. Pallin R, Siry B, Azrael D, Knoepke CE, Matlock DD, Clement A, Ranney ML, Wintemute GJ, Betz ME. "Hey, let me hold your guns for a while": A qualitative study of messaging for firearm suicide prevention. *Behav Sci Law*. 2019;37(3):259–269.
69. Bulger EM, Kuhls DA, Campbell BT, Bonne S, Cunningham RM, Betz M, Dicker R, Ranney ML, Barsotti C, Hargarten S, Sakran JV, Rivara FP, James T, Lamis D, Timmerman G, Rogers SO, Choucair B, Stewart RM. Proceedings from the Medical Summit on Firearm Injury Prevention: A Public Health Approach to Reduce Death and Disability in the US. *J Am Coll Surg* [Internet]. 2019/05/21 ed. 2019 May 17; Available from: <https://www.ncbi.nlm.nih.gov/pubmed/31108194>
70. Ranney ML, Fletcher J, Alter H, Barsotti C, Bebartha VS, Betz ME, Carter PM, Cerda M, Cunningham RM, Crane P, Fahimi J, Miller MJ, Rowhani-Rahbar A, Vogel JA, Wintemute GJ, Waseem M, Shah MN, Acep Technical Advisory Group on Firearm Injury Research a S of the ARC. A Consensus-Driven Agenda for Emergency Medicine Firearm Injury Prevention Research. *Ann Emerg Med*. 2017 Feb;69(2):227–240.
71. Knoepke CE, Allen A, Ranney ML, Wintemute GJ, Matlock DD, Betz ME. Loaded Questions: Internet Commenters' Opinions on Physician-Patient Firearm Safety Conversations. *West J Emerg Med*. 2017/09/07 ed. 2017 Aug;18(5):903–912.
72. Portz JD, Fruhauf C, Bull S, Boxer RS, Bekelman DB, Casillas A, Gleason K, Bayliss EA. "Call a Teenager... That's What I Do!" - Grandchildren Help Older Adults Use New Technologies: Qualitative Study. *JMIR Aging*. 2019 Jun 6;2(1):e13713. PMID: PMC6715044
73. Knoepke CE, Ingle MP, Matlock DD, Brownson RC, Glasgow RE. Dissemination and stakeholder engagement practices among dissemination & implementation scientists: Results from an online survey. *PLoS ONE* [Internet]. 2019 Nov 13 [cited 2020 Apr 29];14(11). Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6853327/> PMID: PMC6853327
74. Drake C, Wald HL, Eber LB, Trojanowski JI, Nearing KA, Boxer RS. Research Priorities in Post-acute and Long-term Care: Results of a Stakeholder Needs Assessment. *J Am Med Dir Assoc*. 2019;20(7):911–915. PMID: 30982714
75. Wright LA, King DK, Retrum JH, Helander K, Wilkins S, Boggs JM, Portz JD, Nearing K, Gozansky WS. Lessons learned from community-based participatory research: establishing a partnership to support lesbian, gay, bisexual and transgender ageing in place. *Fam Pract*. 2017 01;34(3):330–335. PMID: PMC6279214
76. Pallin R, Spitzer SA, Ranney ML, Betz ME, Wintemute GJ. Preventing Firearm-Related Death and Injury. *Ann Intern Med*. 2019/06/04 ed. 2019 Jun 4;170(11):ITC81–ITC96.
77. Ranney ML, Betz ME, Dark C. #ThisIsOurLane - Firearm Safety as Health Care's Highway. *N Engl J Med*. 2018/12/06 ed. 2019 Jan 31;380(5):405–407.
78. Wintemute G, Betz ME, Ranney M. Yes, you can: Physicians, patients, and firearms. *Ann Intern Med*. May 17. 2016;165(3):205–13.
79. Betz ME, Knoepke CE, Siry B, Clement A, Azrael D, Ernestus S, Matlock DD. "Lock to Live": development of a firearm storage decision aid to enhance lethal means counselling and prevent

suicide. *Inj Prev* [Internet]. 2018/10/15 ed. 2018 Oct 13; Available from: <https://www.ncbi.nlm.nih.gov/pubmed/30317220>

80. McIlvennan CK, Thompson JS, Matlock DD, Cleveland JC Jr, Dunlay SM, LaRue SJ, Lewis EF, Patel CB, Walsh MN, Allen LA. A multicenter trial of a shared decision support intervention for patients and their caregivers offered destination therapy for advanced heart failure: DECIDE-LVAD: Rationale, design, and pilot data. *J Cardiovasc Nurs* [Internet]. 2016 May 19; Available from: <http://www.ncbi.nlm.nih.gov/pubmed/27203272>  
<http://ovidsp.tx.ovid.com/ovftpdfs/FPDDNCJCFOPPD00/fs047/ovft/live/gv024/00005082/00005082-201611000-00014.pdf>
81. Thompson JS, Matlock DD, McIlvennan CK, Jenkins AR, Allen LA. Development of a decision aid for patients with advanced heart failure considering a destination therapy left ventricular assist device. *JACC Heart Fail*. 2015 Dec;3(12):965–76.
82. Portz JD, Elsbernd K, Plys E, Ford KL, Zhang X, Gore MO, Moore SL, Zhou S, Bull S. Elements of Social Convoy Theory in Mobile Health for Palliative Care: Scoping Review. *JMIR MHealth UHealth*. 2020 Jan 6;8(1):e16060. PMID: PMC6971510
83. Casillas A, Cemballi AG, Abhat A, Lemberg M, Portz JD, Sadasivaiah S, Ratanawongsa N, Semere W, Brown A, Lyles C. An Untapped Potential in Primary Care? Making Patient Portals work for Caregivers in the Safety-net. *J Med Internet Res*. (in press);
84. Li G, Eby DW, Santos R, Mielenz TJ, Molnar LJ, Strogatz D, Betz ME, DiGuseppi C, Ryan LH, Jones V, Pitts SI, Hill LL, DiMaggio C, LeBlanc D, Andrews HF. Longitudinal Research on Aging Drivers (LongROAD): Study design and methods. *Inj Epidemiol*. 2017;4(1):22.
85. Betz ME, Jones J, Petroff E, Schwartz R. “I wish We could normalize driving health:” a qualitative study of clinician discussions with older drivers. *J Gen Intern Med* [Internet]. 2013;28. Available from: <http://dx.doi.org/10.1007/s11606-013-2498-x>
86. Betz ME, Jones J, Carr DB. System facilitators and barriers to discussing older driver safety in primary care settings. *Inj Prev* [Internet]. 2015 Jan 23; Available from: <http://injuryprevention.bmj.com/content/early/2015/01/23/injuryprev-2014-041450.abstract>  
<http://injuryprevention.bmj.com/content/21/4/231.full.pdf>
87. Betz ME, Dickerson A, Coolman T, Schold Davis E, Jones J, Schwartz R. Driving rehabilitation programs for older drivers in the United States. *Occup Ther Health Care*. 2014 Jul;28(3):306–17.
88. Betz ME, Jones J, Genco E, Carr DB, Diguseppi C, Haukoos JS, Lowenstein SR, Schwartz R. Perspectives on tiered older driver assessment in primary care settings. *Gerontologist* [Internet]. May 2. 2014; Available from: <http://www.ncbi.nlm.nih.gov/pubmed/24793645>  
<http://gerontologist.oxfordjournals.org/content/56/2/272.full.pdf>
89. Matlock DD, Jones J, Nowels CT, Jenkins A, Allen LA, Kutner JS. Evidence of Cognitive Bias in Decision Making Around Implantable-Cardioverter Defibrillators: A Qualitative Framework Analysis. *J Card Fail*. 2017/04/02 ed. 2017 Mar 28;

90. McIlvennan CK, Jones J, Allen LA, Lindenfeld J, Swetz KM, Nowels C, Matlock DD. Decision-making for destination therapy left ventricular assist devices: implications for caregivers. *Circ Cardiovasc Qual Outcomes*. 2015/03/12 ed. 2015 Mar;8(2):172–8.
91. Magid M, Jones J, Allen LA, McIlvennan CK, Magid K, Thompson JS, Matlock DD. The Perceptions of Important Elements of Caregiving for a Left Ventricular Assist Device Patient: A Qualitative Meta-Synthesis. *J Cardiovasc Nurs*. 2015/04/18 ed. 2016 May;31(3):215–25.
92. McIlvennan CK, Jones J, Allen LA, Swetz KM, Nowels C, Matlock DD. Bereaved Caregiver Perspectives on the End-of-Life Experience of Patients With a Left Ventricular Assist Device. *JAMA Intern Med*. 2016/03/22 ed. 2016 Apr;176(4):534–9.
93. Portz JD, Bayliss EA, Bull S, Boxer RS, Bekelman DB, Gleason K, Czaja S. Using the Technology Acceptance Model to Explore User Experience, Intent to Use, and Use Behavior of a Patient Portal Among Older Adults With Multiple Chronic Conditions: Descriptive Qualitative Study. *J Med Internet Res*. 2019 08;21(4):e11604. PMID: PMC6475817
94. Boggs JM, Portz JD, King DK, Wright LA, Helander K, Retrum JH, Gozansky WS. Perspectives of LGBTQ Older Adults on Aging in Place: A Qualitative Investigation. *J Homosex*. 2017;64(11):1539–1560. PMID: PMC6166662
95. Portz JD, Retrum JH, Wright LA, Boggs JM, Wilkins S, Grimm C, Gilchrist K, Gozansky WS. Assessing Capacity for Providing Culturally Competent Services to LGBT Older Adults. *J Gerontol Soc Work*. 2014;57(0):305–321. PMID: PMC4416410
96. Deutchman ME, Nearing K, Baumgarten B, Westfall JM. Interdisciplinary rural immersion week. *Rural Remote Health*. 2012;12:2045. PMID: 22803580
97. Thorsen MM, Patena JV, Guthrie KM, Spirito A, Ranney ML. Using High-Risk Adolescents’ Voices to Develop a Comprehensible Cognitive Behavioral Therapy–Based Text-Message Program. *Behav Med*. 2018 Apr 3;44(2):89–99.
98. Ranney ML, Pittman SK, Riese A, Koehler C, Ybarra ML, Cunningham RM, Spirito A, Rosen RK. What Counts?: A Qualitative Study of Adolescents’ Lived Experience With Online Victimization and Cyberbullying. *Acad Pediatr*. 2020 May;20(4):485–492.
99. Ranney ML, Choo EK, Cunningham RM, Spirito A, Thorsen M, Mello MJ, Morrow K. Acceptability, Language, and Structure of Text Message-Based Behavioral Interventions for High-Risk Adolescent Females: A Qualitative Study. *J Adolesc Health*. 2014 Jul;55(1):33–40.
100. Ranney ML, Meisel ZF, Choo EK, Garro AC, Sasson C, Morrow Guthrie K. Interview-based Qualitative Research in Emergency Care Part II: Data Collection, Analysis and Results Reporting. Newgard C, editor. *Acad Emerg Med*. 2015 Sep;22(9):1103–1112.
101. Quiñones AR, Mitchell SL, Jackson JD, Aranda MP, Dilworth-Anderson P, McCarthy EP, Hinton L. Achieving Health Equity in Embedded Pragmatic Trials for People Living with Dementia and Their Family Caregivers. *J Am Geriatr Soc [Internet]*. 2020 Jul [cited 2020 Jul 3];68(S2). Available from: <https://onlinelibrary.wiley.com/doi/abs/10.1111/jgs.16614>

102. National Institute on Aging: Home Safety Checklist for Alzheimer's Disease [Internet]. 2017 [cited 2020 Jun 11]. Available from: <https://www.nia.nih.gov/health/home-safety-checklist-alzheimers-disease>
103. Efird J. Blocked randomization with randomly selected block sizes. *Int J Env Res Public Health*. 2011 Jan;8(1):15–20.
104. Schulz KF, Grimes DA. Generation of allocation sequences in randomised trials: chance, not choice. *The Lancet*. 2002 Feb 9;359(9305):515–519.
105. Schulz KF, Grimes DA. Allocation concealment in randomised trials: defending against deciphering. *The Lancet*. 2002 Feb 16;359(9306):614–618.
106. Hopwood J, Walker N, McDonagh L, Rait G, Walters K, Iliffe S, Ross J, Davies N. Internet-Based Interventions Aimed at Supporting Family Caregivers of People With Dementia: Systematic Review. *J Med Internet Res*. 2018 Jun 12;20(6):e216.
107. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inf [Internet]*. 2009;42. Available from: <http://dx.doi.org/10.1016/j.jbi.2008.08.010>
108. Schulz KF, Altman DG, Moher D, Group C. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. *PLoS Med*. 2010 Mar;7(3):e1000251.
109. Hanson LC, Bennett AV, Jonsson M, Kelley A, Ritchie C, Saliba D, Teno J, Zimmerman S. Selecting Outcomes to Ensure Pragmatic Trials Are Relevant to People Living with Dementia. *J Am Geriatr Soc [Internet]*. 2020 Jul [cited 2020 Jul 3];68(S2). Available from: <https://onlinelibrary.wiley.com/doi/abs/10.1111/jgs.16619>
110. Sepucha K, Ozanne E, Silvia K, Partridge A, Mulley AG Jr. An approach to measuring the quality of breast cancer decisions. *Patient Educ Couns*. 2007 Feb;65(2):261–9.
111. Sepucha KR, Borkhoff CM, Lally J, Levin CA, Matlock DD, Ng CJ, Ropka ME, Stacey D, Joseph-Williams N, Wills CE, Thomson R. Establishing the effectiveness of patient decision aids: key constructs and measurement instruments. *BMC Med Inf Decis Mak*. 2013;13 Suppl 2:S12.
112. O'Connor AM. Preparation for Decision Making Scale [Internet]. [cited 2020 Jun 11]. Available from: [https://decisionaid.ohri.ca/docs/develop/User\\_Manuals/UM\\_PrepDM.pdf](https://decisionaid.ohri.ca/docs/develop/User_Manuals/UM_PrepDM.pdf)
113. O'Connor AM. Decision Self-Efficacy Scale [Internet]. 1995. Available from: [https://decisionaid.ohri.ca/docs/develop/Tools/Decision\\_SelfEfficacy.pdf](https://decisionaid.ohri.ca/docs/develop/Tools/Decision_SelfEfficacy.pdf)
114. Miller M, Salhi C, Barber C, Azrael D, Beatriz E, Berrigan J, Brandspigel S, Betz ME, Runyan C. Changes in Firearm and Medication Storage Practices in Homes of Youths at Risk for Suicide: Results of the SAFETY Study, a Clustered, Emergency Department–Based, Multisite, Stepped-Wedge Trial. *Ann Emerg Med [Internet]*. Elsevier; 2020 Apr 16 [cited 2020 Jun 19];0(0). Available from: [https://www.annemergmed.com/article/S0196-0644\(20\)30104-9/abstract](https://www.annemergmed.com/article/S0196-0644(20)30104-9/abstract) PMID: 32307124

115. Zarit SH, Zarit JM. The Memory and Behavior Problems Checklist and the Burden Interview. University Park, PA: Pennsylvania State University, Gerontology Center; 1990.
116. Bédard M, Molloy DW, Squire L, Dubois S, Lever JA, O'Donnell M. The Zarit Burden Interview: A New Short Version and Screening Version. *The Gerontologist*. Oxford Academic; 2001 Oct 1;41(5):652–657.
117. Martín-Carrasco M, Otermin P, Pérez-Camo V, Pujol J, Agüera L, Martín MJ, Gobartt AL, Pons S, Balañá M. EDUCA study: Psychometric properties of the Spanish version of the Zarit Caregiver Burden Scale. *Aging Ment Health*. Routledge; 2010 Aug 1;14(6):705–711. PMID: 20544413
118. Tarlow BJ, Wisniewski SR, Belle SH, Rubert M, Ory MG, Gallagher-Thompson D. Positive Aspects of Caregiving: Contributions of the REACH Project to the Development of New Measures for Alzheimer's Caregiving. *Res Aging* [Internet]. Sage Publications; 2016 Aug 17 [cited 2020 Jun 25]; Available from: <https://journals.sagepub.com/doi/10.1177/0164027504264493>
119. Siow JYM, Chan A, Østbye T, Cheng GH-L, Malhotra R. Validity and Reliability of the Positive Aspects of Caregiving (PAC) Scale and Development of Its Shorter Version (S-PAC) Among Family Caregivers of Older Adults. *The Gerontologist*. Oxford Academic; 2017 Aug 1;57(4):e75–e84.
120. Las Hayas C, López de Arroyabe E, Calvete E. Positive aspects of caregiving in Spanish caregivers of individuals with acquired brain injury. *Rehabil Psychol*. US: American Psychological Association; 2014;59(2):193–202.
121. Gitlin LN, Roth DL, Burgio LD, Loewenstein DA, Winter L, Nichols L, Argüelles S, Corcoran M, Burns R, Martindale J. Caregiver Appraisals of Functional Dependence in Individuals With Dementia and Associated Caregiver Upset: Psychometric Properties of a New Scale and Response Patterns by Caregiver and Care Recipient Characteristics. *J Aging Health* [Internet]. Sage Publications; 2016 Jun 30 [cited 2020 Jun 25]; Available from: <https://journals.sagepub.com/doi/10.1177/0898264304274184>
122. Gamble C, Krishan A, Stocken D, Lewis S, Juszcak E, Doré C, Williamson PR, Altman DG, Montgomery A, Lim P, Berlin J, Senn S, Day S, Barbachano Y, Loder E. Guidelines for the Content of Statistical Analysis Plans in Clinical Trials. *JAMA*. American Medical Association; 2017 Dec 19;318(23):2337–2343.
123. R: A language and environment for statistical computing [Internet]. R Core Team; [cited 2020 Jun 26]. Available from: <https://www.R-project.org/>
124. Diggle P, Heagerty P, Liang KY, Zeger S. *Analysis of Longitudinal Data*. Oxford University Press; 2002.
125. Fitzmaurice G, Davidian M, Verbeke G, Molenberghs G. *Handbooks of Modern Statistical Methods: Longitudinal Data Analysis*. Boca Raton, FL: Chapman & Hall/CRC; 2009.
126. Fairclough DL. *Design and Analysis of Quality of Life Studies in Clinical Trials*. New York, NY: Chapman and Hall/CRC; 2010.

127. Diggle P, Kenward MG. Informative Drop-Out in Longitudinal Data Analysis. *J R Stat Soc Ser C Appl Stat.* [Wiley, Royal Statistical Society]; 1994;43(1):49–93.
128. Hogan JW, Roy J, Korkontzelou C. Handling drop-out in longitudinal studies. *Stat Med.* 2004 May 15;23(9):1455–1497. PMID: 15116353
129. Hedeker D, Gibbons RD. Application of random-effects pattern-mixture models for missing data in longitudinal studies. *Psychol Methods.* US: American Psychological Association; 1997;2(1):64–78.
130. Cohen J. Statistical power analysis for the behavioral sciences. Lawrence Erlbaum Associates; 1988.
131. Leach MJ, Ziaian T, Francis A, Agnew T. Recruiting Dementia Caregivers Into Clinical Trials: Lessons Learnt From the Australian TRANSCENDENT Trial. *Alzheimer Dis Assoc Disord.* 2016;30(4):338–344.
132. Huynh L, Johns B, Liu S-H, Vedula SS, Li T, Puhan MA. Cost-effectiveness of health research study participant recruitment strategies: A systematic review. *Clin Trials J Soc Clin Trials.* 2014 Oct;11(5):576–583.
133. Calman L, Brunton L, Molassiotis A. Developing longitudinal qualitative designs: lessons learned and recommendations for health services research. *BMC Med Res Methodol.* 2013 Feb 6;13:14. PMCID: PMC3598728
134. Carduff E, Murray SA, Kendall M. Methodological developments in qualitative longitudinal research: the advantages and challenges of regular telephone contact with participants in a qualitative longitudinal interview study. *BMC Res Notes.* 2015 Apr 11;8:142. PMCID: PMC4406119
135. Neale B, Flowerdew J. Time, texture and childhood: The contours of longitudinal qualitative research. *Int J Soc Res Methodol.* Routledge; 2003 Jan 1;6(3):189–199.
136. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implement Sci.* 2009 Aug;4(1):50.
137. CFIR Guide: Interview Guide Tool [Internet]. CFIR Research Team, Center for Clinical Management Research; Available from: <http://www.cfirwiki.net/guide/app/index.html#/>
138. Sheard L, Marsh C. How to analyse longitudinal data from multiple sources in qualitative health research: the pen portrait analytic technique. *BMC Med Res Methodol.* 2019 Aug 2;19. PMCID: PMC6679485
139. Holland J. Qualitative Longitudinal Research: Exploring ways of researching lives through time. London South Bank University; 2007. Available from: <http://www.reallifemethods.ac.uk/training/workshops/qual-long/documents/ql-workshop-holland.pdf>
140. Creswell JW, Clark VL. Designing and conducting mixed methods research. Thousand Oaks, CA: Sage Publications; 2006.



141. Thomas DR. A general inductive approach for qualitative data analysis. [Internet]. School of Population Health, University of Auckland; 2003. Available from: [http://www.fmhs.auckland.ac.nz/soph/centres/hrmas/\\_docs/Inductive2003.pdf](http://www.fmhs.auckland.ac.nz/soph/centres/hrmas/_docs/Inductive2003.pdf)
142. Saldana J. Longitudinal Qualitative Research: Analyzing Change Through Time. Walnut Creek, CA: AltaMira Press; 2003.
143. Thomson R, Plumridge L, Holland J. Editorial: Longitudinal qualitative research - a developing methodology. *Int J Soc Res Methodol*. 2003 Jul;6(3):185–187.
144. Baumann AA, Morshed AB, Tabak RG, Proctor EK. Toolkits for dissemination and implementation research: Preliminary development. *J Clin Transl Sci*. 2018 Nov 27;2(4):239–244. PMID: PMC6382336
145. Morrato EH, Concannon TW, Meissner P, Shah ND, Turner BJ. Dissemination and implementation of comparative effectiveness evidence: key informant interviews with Clinical and Translational Science Award institutions. *J Comp Eff Res*. 2013 Mar;2(2):185–194. PMID: PMC3961460