



## Incorporating technology in research with older bereaved adults: Lessons learned from conducting an internet-based randomized controlled trial

### ARTICLE INFO

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### ABSTRACT

**Objective:** Digital health interventions (DHI) involve multiple interactions between the user, technology platform, and study team, posing challenges for implementation. This paper describes the lessons learned while implementing an internet-based randomized controlled trial (RCT) for reducing depression symptom burden in older acutely-bereaved adults.

**Methods:** The RCT was entitled “Widowed Elders’ Lifestyle after Loss” (or WELL), which compared the efficacy of a DHI to an enhanced usual care (EUC) for reducing depression symptoms in adults 60+ years who lost their spouse/life partner within the previous 12 months. Participants randomized to the DHI used their own tablet, smartphone, or pc to record the timing and regularity of sleep, meals, and physical activity twice daily, for 12 weeks. They also received weekly health coaching sessions from a clinician certified in motivational interviewing. Participants randomized to the EUC arm received weekly calls from research staff and were assessed on the same schedule as intervention participants. All study procedures were conducted virtually. Methodological and procedural challenges were discussed weekly with study staff and the primary investigator.

**Results:** Many challenges can be categorized as follows: recruiting virtually, obtaining informed consent, training older adults to use technology, and establishing rapport with older adults. Solutions required researcher and interventionist flexibility in adapting to new strategies. For instance, we redesigned the informed consent process to include a user-friendly brochure that enhanced participants’ understanding of the RCT and improved our enrollment rate. We also utilized user-engagement in refining an intervention protocol.

**Conclusion:** We resolved implementation challenges without compromising internal validity via interdisciplinary collaborations with mobile programmers to ensure our technology met the unique and varied needs of aging users. The solutions from this study may promote the recruitment and retention of older adults in research studies that use technology-based interventions.

## 1. Introduction

### 1.1. Aging widow(er)s

Approximately 1 million people are widowed each year in the United States; nearly 75 % are 65 years or older. The loss of a spouse or life partner (hereafter referred to as “spouse”) during late life is a normative experience, one to which most people manage to adapt to over time. Nevertheless, it is associated with an increased risk of developing debilitating mental and physical health problems. Loss of a spouse is associated with an intense period of suffering (Holmes and Rahe, 1967), loneliness (Stroebe et al., 2007), cognitive decline (Atalay and Staneva, 2020), and heightened risk of mortality (Stahl et al., 2016) including suicide (Erlangsen et al., 2004). In the first year following the death of their spouse, a substantial number of older widow(er)s (15–30 %) meet criteria for major depressive disorder (MDD) (Zisook and Shuchter, 1993) compared to community dwelling older adults (5–15 %) (Fiske et al., 2009; Fiest et al., 2011). Loss of a spouse is also associated with the exacerbation of pre-existing levels of depression and future episodes of

major depression even with no prior history of depression (Stroebe et al., 2007; Carr et al., 2001; Gilewski et al., 1991). Given that depression is the leading cause of disability and associated with early mortality (Hindi et al., 2011), it is critical to identify those individuals who are likely to suffer from depression after bereavement in order to target therapeutic support.

### 1.2. Interventions for aging widow(er)s

A variety of treatment modes have been tested for the emotional and psychological symptoms of spousal loss including include mutual support groups, psychotherapy, complicated grief therapy, and mindfulness techniques, among others (Davidow et al., 2022). A major limitation of existing interventions for aging widow(er)s is that they require in-person access to therapists and/or counselors who are trained in grief and bereavement support. Although using technology to deliver a behavioral intervention is not new, using technology to support acutely-bereaved older adults is novel. A recent review acknowledges the potential of technology to reach older bereaved adults and increase their access to

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treatment (Roberts et al., 2019).

Implementing and testing digital health interventions (DHI) involves multiple interactions between the user, technology platform, and study team, posing challenges for implementation. These challenges are amplified for older adults who have a range of technical abilities compared to younger users. Older users are also at high risk for exclusion in DHIs due to low technology literacy and age-related declines in cognitive processing (Martínez-Alcalá et al., 2018). We are unaware of existing interventions that leverage technology to deliver a behavioral health intervention to reduce depression among aging widow(er)s. Although DHIs provide opportunities for the delivery of broad evidence-based interventions with older adults, it is important to understand older adults' experiences and barriers to interacting with new technologies.

### 1.3. Purpose

The purpose of this report is to describe the challenges and solutions developed for implementing an internet-based intervention with older adults who recently experienced the death of their spouse ("Widowed Elders' Lifestyle after Loss" or WELL Study, NCT04016896). The intervention is part of a current randomized controlled trial (RCT) to test the efficacy of digital monitoring of sleep, meals, and physical activity plus motivational health coaching to reduce depression symptoms. We detail (a) application of the WELL intervention using specific technology; (b) challenges experienced delivering the DHI; and (c) solutions the research team developed to implement the DHI when challenges occurred. To date, the potential of DHIs to reduce depression has been scarcely realized, partly because of difficulties generating knowledge-base for development and delivery given the rapidly changing technology landscape (Murray et al., 2016). DHIs need to constantly evolve and be updated to be useful for future users. The lessons learned in this project may guide the development and delivery of future DHIs for late-life depression.

### 1.4. Pilot testing

In preparation for the WELL Study, a pilot RCT was conducted to adapt the digital health intervention (DHI) for older bereaved adults (Stahl et al., 2017). Fifty-seven participants were provided a study tablet (Asus ZenPad) with a diary-like app that was used for the recording of sleep, diet, and physical activity behaviors. Because participants were using a new piece of hardware, most of the technology problems related to basic tablet functions: swiping to log-in, accessing the app, and monitoring the battery life. Most technology problems could be addressed with a follow-up phone call with study staff. Study interventionists, or health coaches, engaged each participant in 12 sessions over a 3-month period. Each session lasted approximately 30 min. Data were collected at enrollment, after the intervention period (3 months later) and 3-, 6-, 9-months post-intervention. Our proposed methods were feasible: we retained 88 % of participants over follow-up and observed high levels of adherence in the use of the app for monitoring sleep, meals, and activity (90 %) and health coaching sessions (92 %) (Stahl et al., 2020). Acceptability of intervention components was also high: participants believed they became more mindful of their sleep-wake routine because of the monitoring app and perceived the health coaches to be "motivating" and "encouraging".

This pilot work demonstrated that older bereaved adults were interested in participating in our study and comfortable using technology to monitor their sleep-wake behaviors (Stahl et al., 2020). This pilot work also provided information that informed the design of the future definitive trial. First, we learned to offer technology "check-in" calls earlier in the intervention period to enhance self-efficacy with our digital tools. Second, we learned to permit participants to use their own device (smartphone, tablet, and/or pc) to engage in study components. We ultimately edited the delivery of the DHI to function as a web-based survey and personalized feedback website so that the entire protocol

(consent, intervention, assessments) was functional on participants' personal device. Third, we provided email and text reminders to optimize acceptance and to encourage compliance. Finally, we provided Wi-Fi enabled tablets to individuals who do not own their own device.

## 2. Description of the WELL study

### 2.1. Study enrollment

A total of 200 bereaved spouses will be enrolled in the current RCT (100 per group). As of 10/01/2022, 70 participants have enrolled in the trial. Recruitment started on 01/04/2021 and took approximately 21 months to enroll 70 participants. Recruitment was slower in the early stages of the RCT because we needed to learn different recruitment processes that worked for virtual participants. Because the study is virtual, there are no restrictions in where participants live within the United States. Most participants are recruited from the University of Pittsburgh and hospital systems located in Western Pennsylvania. After baseline data are collected, participants are randomized and stratified by variables known to influence the grieving process: participant gender, insomnia status, and death from COVID-19. The study coordinator notifies participants by phone of their group assignment (intervention or control). This study was reviewed and approved by the University of Pittsburgh Institutional Review Board (STUDY19080039).

### 2.2. Digital monitoring tools

Directly after baseline, the study coordinator calls each participant for a technology training call and provides instructions on how to access the digital diaries via Qualtrics, how to view their personalized feedback or "Lifestyle Log", and who to contact if problems arise with the digital diaries and/or personalized feedback web link. The study coordinator also provides the participant with a written step-by-step manual for recording their sleep, meals, and activity in the digital diaries and viewing their Lifestyle Log. The manual offers solutions to common technology problems.

User responses from the digital diaries are automatically fed into the Lifestyle Log which provides feedback in real-time regarding progress towards health goals and 24-hour sleep-wake routines. The Lifestyle Log is unique compared to currently available health apps because it graphically depicts the timing and regularity of health behaviors across a 24-hour period. Participants are instructed to fill out 2 Qualtrics surveys per day (a morning report and evening report) and to spend a minimum of 1 day/week using the personalized feedback via weblink to view their Lifestyle Log. All technology is managed by a programming team at the Center for Social and Urban Research at the University of Pittsburgh. This programming team manages the web-based survey and personalized feedback website and provides remote trouble-shooting/consultation with study staff.

### 2.3. Health coaching sessions

Behavior change can be challenging, requiring effort and motivation (Purath et al., 2014). Therefore, we propose that the effects of digital monitoring to optimize engagement in routine self-care may be enhanced by using motivational interviewing (MI) – a patient-centered approach to strengthen individuals' motivation and commitment to change (Britt et al., 2004). MI facilitates behavior change by helping patients resolve ambivalence about change in an empathetic and encouraging climate thereby empowering patients to achieve behavior change autonomously (Jelsma et al., 2015; Lord et al., 2015). Several clinical trials show that adherence to internet-based interventions is improved when human support from a therapist is included in the behavior change process (Zarski et al., 2016; Mohr et al., 2011).

Health coaches complete 12 intervention sessions over 3 months. Using the gold-standard MI treatment integrity manual, fidelity to four

components of MI are coded during each intervention session: open-ended questions, affirmations, reflective listening, and summarizing statements. Health coaches document the total number of completed sessions and takes notes on the topics discussed (e.g., behavioral routines or grief-related topics). Health coaches also record details about the participant's 24-hour sleep-wake routine and health goal(s). They also record each participants' confidence and motivation (on a scale of 1–10 with higher scores reflecting greater confidence and motivation) to attain their weekly health goals. Health coaching sessions are discussed in weekly patient review meetings. During these clinical review meetings, the health coaches discuss behavioral change strategies with a senior MI clinician who provides suggestions for encouraging a stable routine of sleep, meals, and activity. Health coaches also have access participants' Lifestyle Log and review with participants the behaviors recorded from the previous week.

### 3. Implementation of the digital health intervention

#### 3.1. Adherence to the DHI

Of the 35 participants who were randomized to receive the DHI, 30 (93 %) participants were retained during the 12-week intervention period. Reasons for drop-out included no longer being interested in the study and being overwhelmed with their personal life. One participant dropped out prior to starting the intervention period, whereas the other 4 participants dropped out during the intervention period. We observed an adherence average of 126 diaries out of a possible 168 sessions [2 times per day for 84 days]. This level of compliance (75 %) reflects average adherence to digital monitoring as well as a general interest in individualized health feedback. In terms of motivational health coaching, the average number of sessions received was 11.2 (range: 0–12 sessions), reflecting a very high level of compliance to the intervention (94 %) and reflects the value of including a human component to digital intervention work. Although health coaches were available for all sessions, participants reported missing sessions because of the everyday demands of the grieving process (e.g., financial and household maintenance) and priorities other than research. The average length of the coaching session was 33.6 min (range: 11–71 min).

#### 3.2. Lessons learned

Our research team met on a weekly basis during which methodological and procedural challenges from the WELL study were discussed. Solutions to challenges were discussed among the staff and the principal investigator. The study coordinator would then modify the IRB protocol based on the solutions developed. During these weekly meetings, we also addressed the feasibility of implementing the solutions and any burden concerns for staff or participants. We also consulted with our biostatistician to ensure that we resolved challenges without compromising internal validity. Examination of the first 30 randomly assigned intervention participants highlights some important lessons learned for others embarking on technology-driven geriatric mental health research. Four major areas to examine on a continuous basis include recruiting virtually, obtaining informed consent, training and supporting older adults to use technology, and establishing rapport with older participants virtually.

##### 3.2.1. Recruiting virtually

**3.2.1.1. Challenge.** We had trouble recruiting virtually because older adults were less likely to be online.

**3.2.1.2. Solutions.** We designed separate recruitment ads depending on the mode of delivery (see Fig. 1). For instance, print ads are more descriptive with a lot of text and written information whereas digital ads

are more visual with attention-grabbing images that can include motion. All recruitment ads included a QR code that directs interested persons to a “pre-screening” survey in REDCap where potential participants could immediately learn their eligibility status and contact the study team. We created Google ad words to increase the likelihood potential participants would find the WELL study when searching for bereavement and/or grief support in internet search engines.

We also advertised on three major social media platforms: Facebook, Twitter, and Instagram. All versions of advertisements included key words and hashtags that would make it easier for social media users to find information about our study (e.g., #grief, #bereavement, #loss, #UPMC, #research). Each post was tailored to meet each social media platform's image requirements and character limits (see Fig. 2a and b). For example, our Facebook posts, which have a 63,206-character limit, allowed us to write more information in a manner suitable for our target demographic. These same posts then were rewritten to meet Twitter's 280-character limit in a way where the same information could be communicated while still meeting the more restrictive requirement (e.g., integrating hashtags into sentences to save space).

A social media presence was created through the creation of unique content and frequent interactions on the platforms. Such interactions included responding to comments on our posts, as well as other accounts posting similar content regarding grief, bereavement, and mental health. Our content was created with a cohesive color scheme and attention-grabbing graphics to attract a broad audience on social media platforms. This included not only our target population (age 60+), but also younger users online who may know someone who was recently bereaved, such as a parent or grandparent. We used data from Facebook analytics to dictate post frequency and ultimately optimize social media reach on Facebook and Instagram. We also monitored similar data on our Facebook advertisements to ensure that the approach was cost-effective (see Supplemental Fig. 1). During the holidays, which are often difficult times for bereaved individuals, we increased our social media presence to reach people who may be looking for resources during this time by creating holiday-specific content and bolstering engagement with other users.

##### 3.2.2. Obtaining informed consent

**3.2.2.1. Challenge.** Participants felt overwhelmed and stunned with the length and style of the electronic consent (“eConsent”) in REDCap. Unfortunately, this confusion is consistent with the current state of eConsent process in clinical research (Soni et al., 2017). Participants did not fully comprehend the study aims, randomization, and right to withdraw from study activities. A small number of older adults declined to review the eConsent and requested to review a hard-copy of the informed consent (IC) form because they presumably lacked the technical skills, support, and/or access to digital tools to view the eConsent. Over half of these individuals ( $n = 7$  out of 12 [58 %]) declined participation. Several participants expressed embarrassment for asking for technical support to consent to the WELL study. This high rate of refusal made us aware that our eConsent may be introducing bias in our sample, excluding individuals with presumably fewer technical skills and confidence to use technology (i.e., preventing digital inclusion for older adults) (Martínez-Alcalá et al., 2018; Mannheim et al., 2019).

**3.2.2.2. Solutions.** To enhance participants' understanding of the RCT, we developed an IC brochure that summarized participants' misconceptions of the eConsent in a clear and coherent style (see Fig. 3). We followed guidelines from the Centers for Medicare & Medicaid Services for typeface (sans-serif), color contrast, and sharpness of detail to compensate for age-related declines in vision and cognitive processing to make our written material easier for older adults to use and understand. We now mail or email the IC brochure to potentially eligible participants prior to their eConsent meeting with research staff, and we encourage

Have you recently

**LOST A SPOUSE**

**OR PARTNER?**



**Join our study:**

- For ages 60+
- 100% virtual

**Contact us:**

📞 412-440-8418

📄 [bit.ly/wellstudy](https://bit.ly/wellstudy)



OR SCAN ME





## Print Ad

Did you lose your spouse  
or partner recently?

**Join the WELL Research Study:**

📄 [www.bit.ly/wellstudy](https://www.bit.ly/wellstudy)

📞 412-440-8418




## Digital Ad

Fig. 1. Print ads (left) are more descriptive whereas digital ads (right) are more visual and attention-grabbing.

them to write down questions they may have about study participation. After implementing this new process for IC, we lowered our decline rate for written IC from 58 % to 17 %.

### 3.2.3. Training older participants to use technology

**3.2.3.1. Challenge.** Participation in the DHI required basic internet skills, which frustrated some of our older participants. Low technology literacy increased the likelihood participants were nonadherent with study procedures.

**3.2.3.2. Solutions.** During the technology training call, the study coordinator trained participants to access (1) the digital diaries in Qualtrics; and (2) personalized “Lifestyle Log” via a web link. Participants complete/submit their first digital diary in tandem with the study coordinator. Technology training occurred in a separate, follow-up phone call after baseline to decrease participant burden. Dividing up the baseline assessment into smaller meetings and separating the technology training call from the baselines assessment allowed participants to feel confident in their ability to complete research activities. We sent daily reminders to complete the digital diaries via text and/or email. We also reminded participants that technology support is available to them daily during typical working hours.

Technology training took approximately 30 min for most participants. However, a small number (n) of participants required up to 2 h of technology training to learn how to use their tablet and/or smartphone. This low level of digital literacy highlights the need to actively train/support older adults in digital health interventions. For example, some participants needed assistance accessing their email so that they could receive daily email reminders while other participants needed assistance locating and opening a web browser to view their Lifestyle Log. These participants were thankful for the enhanced technology and internet skills that we taught them. Shortly after learning how to access and send emails, participants began communicating with study staff via email and elected to complete future assessments virtually via REDCap.

We also carefully built rapport (see below) with each participant to guide them through the technology training call. We learned that building a relationship and talking during the first phone call/encounter

helps the participant feel at ease which provides a sense of ease and encouragement for trying new technology.

### 3.2.4. Developing rapport with older participants

**3.2.4.1. Challenge.** We had trouble establishing and maintaining rapport with a high-risk sample of older participants with whom we never met in-person.

**3.2.4.2. Solutions.** To build a trusting and empathic relationship between participants and study staff we (a) encouraged participants to choose the mode of communication: Zoom or telephone; (b) provided several options for completing assessments: Zoom, telephone, paper-and-pencil, and/or REDCap; (c) included photos of study staff in email signature lines and the study website; (d) sent handwritten postcards to participants with appointment reminders; and (e) sent water bottles embossed with the study logo to participants as a thank-you gift.

During our first interaction we learned to engage in conversations driven by the participant. This conversation helped the participant to relax and built trust with research staff. We also functioned as a source of support for grieving older adults by recommending referrals to mental health services and/or complicated grief therapy. Additionally, we created and frequently update a resource guide ([www.pittwellstudy.com/resources](https://www.pittwellstudy.com/resources)) that details local and national grief and bereavement support services for older adults, as well as other virtual activities/events of interest to older adults.

## 4. Discussion

Two lessons learned from this digital geriatric mental health project deserve highlighting. First, when recruiting virtually, it is important to close the digital gap and ensure digital inclusion for older adults. Despite the fact that older adults use the Internet and mobile devices, the pace of digital innovation increases their risk for exclusion in DHIs (Seifert et al., 2019). Improving digital inclusion for older adults is important because exclusion may result in larger healthcare inequalities. In this study, older adults who were potentially eligible but declined to participate were individuals who requested a paper-copy of the informed consent

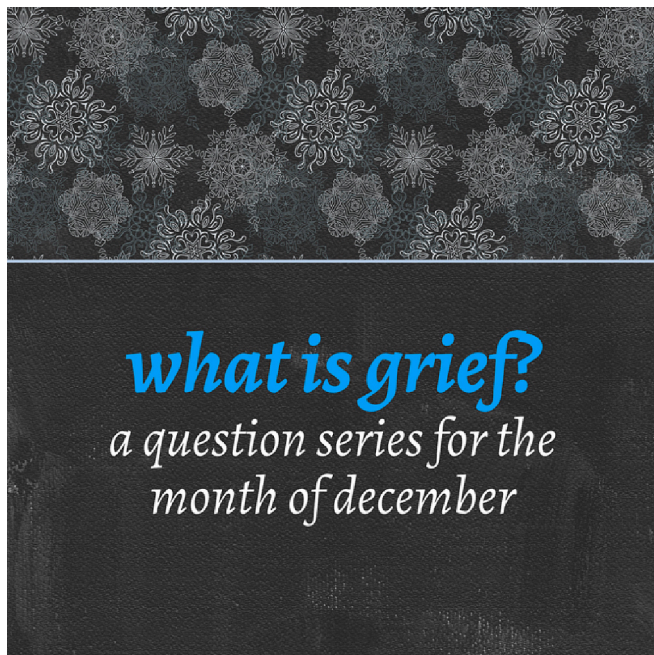


Fig. 2. a. Instagram caption.

As the holidays and transition into the new year begins, we understand that thinking about your late loved one might be difficult. We hope that this series of questions helps shed some light on how you're feeling.

If you or someone you know recently lost a spouse or partner, please visit the link in our bio or [pittwellstudy.com](http://pittwellstudy.com) #grief #GriefJourney #Bereavement #Loss #Research #UPMC #aging #pittsburgh #GriefandLossSupport #BereavementSupport #GriefIsLove #GriefAwareness #GriefAndHealing #GrievingProcess #StagesofGrief #GriefRecovery #DealingWithGrief #CopingwithGrief #LoveAndLoss #NormalizeGrief #GriefRevolution #GriefHurts #GriefSucks #GriefSupport #Emotions #MentalHealth #MentalHealthAwareness #Family.

b. Twitter caption.

As the #holidays and transition into the new year begins, we understand that thinking about your late loved one might be difficult. We hope that this series of questions helps shed some light on how you're feeling.

#grief #GriefJourney #Bereavement #Loss #Research #UPMC #Family.

form. It is plausible that these individuals lacked the technical skills to engage with computers or mobile devices that were necessary for eConsent (via REDCap) and consequently felt uncomfortable participating in our DHl.

Older age is a key determinant of digital exclusion, partly because older adults opt not to use new technologies (Heponiemi et al., 2022;

van Deursen and Helsper, 2015). Informed consent comprehension can also be affected by the format in which the information is delivered to participants (Gesualdo et al., 2021). It is possible that participants had the technical skills to view the e-Consent, but the information was presented in an unfriendly and overwhelming format. We overcame this challenge by redesigning the informed consent process to include an acceptable and easy-to-read study brochure. Providing potentially eligible participants with our study brochure reduced our consent decline rate from 58 % to 17 %.

Another lesson learned from this project is that engaging older participants in a virtual intervention study requires listening to their opinions about the use of our digital tools to learn about acceptance and to identify areas for improvement. Participants' acceptance of technology was influenced by explanation of privacy and security and access of digital platforms from their own personal device. Technology training was an ongoing process throughout the entire protocol. We also offered alternative and hybrid strategies for participation (e.g., telephone services and/or hard-copy assessments) for participants who were not able to use our digital platforms, even when supported by research staff. These solutions for technology acceptance are not only applicable in the clinical research setting, but in routine home settings where older adults are interacting with other digital technologies (e.g., health apps, activity watches, and digital pill boxes, among others) that may improve their quality of life.

In sum, DHIs offer innovative opportunities for individuals seeking mental health support, yet this approach brings challenges for aging populations who may not be able to benefit from DHIs because of age-related declines in cognitive processing, lack of internet service, and/or low digital literacy. By reporting our issues with digital implementation, we hope that other researchers will benefit from our experiences recruiting, engaging, and retaining older adults in an internet-delivered RCT.

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**Declaration of competing interest**

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

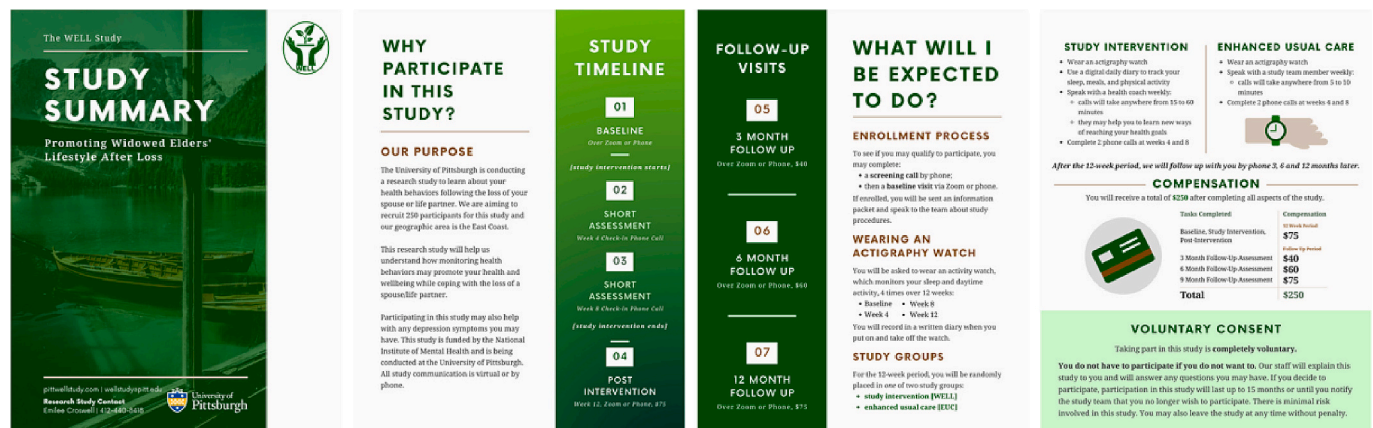


Fig. 3. The Informed Consent Summary brochure was designed with reader usability and comprehension in mind.

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Thandi Lyew<sup>a</sup>, Joseph Kazan<sup>b</sup>, Khusbu Patel<sup>b</sup>, Emilee Croswell<sup>b</sup>,  
Sejuty Minhaj<sup>b</sup>, Adrianna Lopaczynski<sup>b</sup>, Ioana Neagoe<sup>b</sup>, Sarah  
T. Stahl<sup>b,\*</sup>

<sup>a</sup> Annenberg School for Communication, University of Pennsylvania,  
Philadelphia, PA, USA

<sup>b</sup> Department of Psychiatry, University of Pittsburgh, Pittsburgh, PA, USA

\* Correspondence author at: Department of Psychiatry, University of  
Pittsburgh, 3811 O'Hara Street, Pittsburgh, PA 15213, USA.  
E-mail address: sarah.stahl@pitt.edu (S.T. Stahl).