

Protocol

Single-Group Trial of an Internet-Delivered Insomnia Intervention Among Higher-Intensity Family Caregivers: Rationale and Protocol for a Mixed Methods Study

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Abstract

Background: Family caregivers are more likely to experience insomnia relative to noncaregivers but have significant barriers to accessing gold standard cognitive behavioral therapy for insomnia treatment. Delivering interventions to caregivers through the internet may help increase access to care, particularly among higher-intensity caregivers who provide assistance with multiple care tasks over many hours per week. Although there are existing internet interventions that have been thoroughly studied and demonstrated as effective in the general population, the extent to which these interventions may be effective for caregivers without tailoring to address this population's unique psychosocial needs has not been studied.

Objective: The goal of this trial is to determine what tailoring may be necessary for which caregivers to ensure they receive optimal benefit from an existing evidence-based, internet-delivered cognitive behavioral therapy for insomnia program named Sleep Healthy Using the Internet (SHUTi). Specifically, we will test the association between caregivers' engagement with SHUTi and their caregiving context characteristics (ie, caregiving strain, self-efficacy, and guilt) and environment (ie, proximity to care recipient; functional status, cognitive status, and problem behavior of care recipient; and type of care provided). Among caregivers using the program, we will also test the associations between change in known treatment mechanisms (sleep beliefs and sleep locus of control) and caregiving context factors.

Methods: A total of 100 higher-intensity caregivers with significant insomnia symptoms will be recruited from across the United States to receive access to SHUTi in an open-label trial with mixed methods preassessments and postassessments. At postassessment (9 weeks following preassessment completion), participants will be categorized according to their engagement with the program (nonusers, incomplete users, or complete users). Study analyses will address 3 specific aims: to examine the association between caregivers' engagement with SHUTi and their caregiving context (aim 1a); to describe caregivers' barriers to and motivations for SHUTi engagement from open-ended survey responses (aim 1b); and among caregivers using SHUTi, to determine whether cognitive mechanisms of change targeted by SHUTi are associated with differences in caregiving context (aim 2).

Results: Institutional review board approvals have been received. Data collection is anticipated to begin in December 2021 and is expected to be completed in 2023.

Conclusions: Findings will inform the next research steps for tailoring and testing SHUTi for optimal impact and reach among caregivers. Beyond implication to the SHUTi program, the findings will be translatable across intervention programs and will

hold significant promise to reduce inefficiencies in developing digital health interventions for caregivers while also increasing their impact and reach for this underserved population.

Trial Registration: ClinicalTrials.gov; NCT04986904; <https://clinicaltrials.gov/ct2/show/NCT04986904?term=NCT04986904>
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KEYWORDS

family caregiver; cognitive behavioral therapy; insomnia; sleep initiation and maintenance disorders; eHealth; protocol; mobile phone

Introduction

Background

An estimated 47.9 million Americans provide unpaid care to ≥ 1 family members or close individuals with serious health conditions [1]. Support from family members to individuals who are seriously ill is critical to the sustainability of the US health care system [2]; however, it places a significant strain on these caregivers. Insomnia is among the most common, distressing, and impairing psychophysiological issues for caregivers [3,4]. As the responsibilities and stressors of the caregiving role can both precipitate and perpetuate insomnia [5], caregivers are up to 3 times more likely to report sleep disturbances than the general population (up to 90% vs approximately 33%-50%, respectively) [6,7]. Cognitive behavioral therapy for insomnia (CBT-I), the gold standard treatment for insomnia [6], has shown promise among caregivers; however, their uptake and completion of this therapy has been limited [8-10]. As such, directly assessing how the caregiving context affects CBT-I engagement and efficacy could help to ensure that caregivers have equitable access to and benefit from this evidence-based intervention.

Among caregivers, those who spend many hours per week supporting multiple care tasks for a loved one—or *higher-intensity caregivers*—have more difficulty in accessing affordable support services, although they are also more interested in receiving support to manage their own emotional and physical well-being [1,11]. Existing psychosocial services for caregivers are primarily delivered in person. Although these interventions have generally been effective, they have low enrollment, high dropout, and limited reach to caregivers who already have inadequate health care access [12-15].

Digital health interventions can lower the barriers to entry to supportive care for higher-intensity caregivers, as they are conveniently accessible anywhere and anytime through an internet-enabled device. These interventions are also more scalable and sustainable than standard in-person practices [16]. For these reasons, caregivers themselves express strong interest in digital health interventions [17-19], and leaders in caregiving research have deemed the development and distribution of technology-based solutions to support caregivers as a high priority [20-23].

Most digital health interventions tested among caregivers have been developed de novo for specific caregiving contexts [24-29] in recognition of the unique deficits, risk factors, and needs that caregivers experience. Compared with noncaregivers, caregivers

report unique barriers to broadly accessing psychosocial support, including guilt [30-32] and chaotic schedules [31,32]. More specifically, with regards to behavioral treatment for sleep, caregivers report unique worry about the impact of sleep loss on their ability to provide care [33-35] and challenges with nighttime symptom management [34,35]. Tailoring interventions to specific user groups such as caregivers increases information salience, which increases users' attention to information and, therefore, the likelihood that the information will motivate behavior change [36]. When tested empirically, tailoring typically adds only small gains in outcomes relative to generic materials, although gains are typically maintained over time [37,38]. Although potentially appealing, tailoring reduces intervention reach as it narrows the user base and also increases the time for dissemination and costs for intervention development. Ultimately, the decision to tailor, and how to tailor, must balance any expected gains in treatment outcomes against the drawbacks of reduced reach and increased costs to maximize intervention impact.

Sleep Healthy Using the Internet (SHUTi [39,40]) is a fully automated, internet-delivered CBT-I program developed for the general population that holds significant promise for addressing insomnia among caregivers. In a recent trial of SHUTi among older adults, participants who self-identified as family caregivers ($n=18$) reported less improvement in their insomnia after using SHUTi (insomnia severity index [ISI] score difference= -2.37 , 95% CI $0.17-4.57$; $P=.03$) and were less likely to rate their sleep quality as improved ($\chi^2_1 [N=190]=4.8$; $P=.03$) compared with noncaregivers ($n=189$) [41]. However, significant differences ($P>.10$) between caregivers and noncaregivers were not observed for changes in cognitive mechanisms—more adaptive sleep beliefs and internalized sleep locus of control—or for ratings of program satisfaction, fit, or usability. Building on these preliminary observations, the goal of this trial is to determine what tailoring may be necessary for caregivers to receive optimal benefit from SHUTi.

To address this question, higher-intensity caregivers with significant insomnia symptoms will be recruited to receive access to SHUTi in a single-group, open-label trial with mixed methods preassessments and postassessments. This study design is recommended for establishing the plausibility of supporting subsequent fully powered efficacy testing [42]. At the end of the intervention period, caregivers will be categorized according to their level of engagement with the 6 SHUTi intervention lessons (or weekly *Cores*): nonusers (ie, completed 0 Cores),

incomplete users (ie, completed ≤ 3 Cores), and complete users (ie, completed ≥ 4 Cores).

Primary Trial Aims

Test the Association of SHUTi Engagement With Caregiving Context

Specifically, we will test how caregivers' engagement with SHUTi is associated with their user characteristics and environmental characteristics (aim 1a). We will also describe caregivers' barriers to and motivations for SHUTi engagement from open-ended survey responses (aim 1b).

Test the Association Between SHUTi Efficacy on Known Cognitive Mechanisms With Caregiving Context

Among caregivers using SHUTi, we will test whether cognitive mechanisms of change targeted by SHUTi are associated with differences in caregiving-related user or environmental characteristics.

Methods

Participants

This protocol manuscript has been developed in accordance with reporting recommended by the 2013 SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) statement [43,44]; see [Textbox 1](#) for key study information. The protocol was revised following peer review through the National Institutes of Health; see [Multimedia Appendix 1](#) for reviews and [Multimedia Appendix 2](#) [1,6,40,45-54] for our team's response to reviews during the *just in time* period for our responsive protocol changes. Participants will be higher-intensity family caregivers reporting significant insomnia symptoms. Family caregiving is defined according to the National Alliance for Caregiving 2020 Caregiving in the United States survey methods [1]. Specifically, a family caregiver will be someone who is currently providing unpaid care to a relative or friend, aged ≥ 18 years, to help them take care of themselves and/or providing more than the normal amount of unpaid care for a child aged < 18 years because of a medical, behavioral, or other condition or disability.

Higher-intensity caregiving will be defined by scoring ≥ 5 points on a scale modified from the National Alliance for Caregiving

Level of Care Index. Scoring is the function of the given number of hours of care and types of care tasks provided for activities of daily living (ADL; including medical and nursing tasks), instrumental ADL, and for child care recipients, selected caregiver support activities. If a caregiver provides care to > 1 care recipient, the total amount of time and all care tasks across all care recipients are considered together to compute the care intensity score. See [Table 1](#) for point assignments, which are summed to a total index score.

Although we considered reducing sample heterogeneity in the caregiving context, we chose to keep the caregiving inclusion criteria broad as it increases the generalizability of our findings. A broad sample will also facilitate our aim of understanding how broad or specific a caregiving audience can be addressed by a particular digital health intervention. Higher-intensity caregivers, regardless of disease context, share significant psychological (eg, guilt) and practical (eg, limited time) barriers that make them less likely than lower-intensity caregivers to be able to access care while also at risk for worse health outcomes. Therefore, our sample of higher-intensity caregivers will provide actionable insights into how to increase digital health intervention access to caregivers with the most barriers to care.

Potentially eligible caregivers must also have regular access to the internet (whether by computer, tablet, or smartphone) and be willing to receive study-related emails. Internet access is required to complete the SHUTi intervention. Although this requirement may introduce some bias to the sample, there is a strong rationale for it. Using 2017 nationally representative survey data [55], we found that 88% of caregivers reported accessing the internet (vs 89% of the general population [56]), and there was no difference in internet access by caregivers' level of distress, burden, or rurality [57]. Limitations in reach imposed by requiring internet access for this study will be offset by the increased convenience of a fully automated internet intervention (relative to the care delivered in person or scheduled with a provider).

Eligible caregivers will also be required to score ≥ 10 on the 7-item ISI [58]. This score corresponds to the cutoff suggestive of clinically significant insomnia symptoms among community samples [58]. All inclusion and exclusion criteria are listed in [Textbox 1](#).

Textbox 1. World Health Organization trial registration data set.

Primary registry and trial identifying number

- ClinicalTrials.gov NCT04986904

Date of registration in primary registry

- August 3, 2021

Secondary identifying numbers

- R21TR003522
- University of Virginia Health Sciences Research Institutional Review Board protocol HSR210255
- University of Pittsburgh Office of Research Protections Institutional Review Board protocol STUDY21080076

Source of monetary or material support

- National Institutes of Health—National Center for Advancing Translational Sciences (*this funding source has no significant role in the design of this study and will not have any role during its execution, analyses, interpretation of the data, or decision to submit the results*)

Primary sponsor

- University of Virginia

Secondary sponsor

- University of Pittsburgh

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Public title

- SHUTi CARE (Sleep Healthy Using the Internet—caregiver acceptability research)

Scientific title

- Optimizing efficiency and impact of digital health interventions for caregivers: A mixed methods approach

Country of recruitment

- United States

Health conditions or problems studied

- Family caregivers
- Insomnia
- Sleep initiation and maintenance disorders

Intervention

- SHUTi—internet-delivered cognitive behavioral therapy for insomnia program

Ages eligible for study

- ≥18 years

Sexes eligible for study

- All

Accepts healthy volunteers

- No

Inclusion criteria

- Caregiving

- Current higher-intensity caregiving (ie, level ≥ 3 on National Alliance for Caregiving Level of Care index)
- Expect to provide high-intensity caregiving for at least another 3 months (study duration)
- Sleep
 - Insomnia severity index score ≥ 10
- Internet access
 - Have access to any internet-enabled device (computer, tablet, or smartphone)
 - Willing to be emailed about the study
- Miscellaneous
 - Able to speak and read English
 - Residing in the United States or US territory

Exclusion criteria

- Sleep
 - Irregular schedule that would prevent adoption of intervention strategies (ie, shift work and typical bedtime earlier than 8 PM or later than 2 AM or arising time earlier than 4 AM or later than 10 AM)
 - Current behavioral or psychological treatment for insomnia
- Medical and psychiatric contraindications
 - Presence of another unmanaged sleep disorder (restless leg syndrome or periodic limb movement disorder, obstructive sleep apnea, narcolepsy, or parasomnia)
 - Diagnosis of dementia, Alzheimer disease, Parkinson disease, Huntington disease, schizophrenia, or psychosis
 - History of the following without recovery: stroke, traumatic brain injury, brain infection, or brain tumor
 - Current pregnancy or breastfeeding, chemotherapy for cancer, alcohol dependence or abuse, or substance dependence or abuse
 - Current unmanaged hyperthyroidism, severe respiratory disease, or epilepsy
 - Change in medication regimen for steroids, amphetamines stimulants, or prescribed sleep medications within the past 3 months
 - History of manic or hypomanic episode
- Miscellaneous
 - Severe computer literacy challenges

Study type

- Interventional

Allocation

- Not applicable

Intervention model

- Single-group assignment

Masking

- None (open label)

Primary purpose

- Treatment

Date of first enrollment

- December 2021 (anticipated)

Target sample size

<ul style="list-style-type: none"> 100 <p>Recruitment status</p> <ul style="list-style-type: none"> Recruiting <p>Primary outcome</p> <ul style="list-style-type: none"> SHUTi engagement (time frame: 9-week postassessment) <p>Key secondary outcomes</p> <ul style="list-style-type: none"> Open-ended feedback about SHUTi (time frame: 9-week postassessment) SHUTi evaluation (time frame: 9-week postassessment) Change in sleep-related cognitions (time frame: preassessment and 9-week postassessment) Change in sleep locus of control (time frame: preassessment and 9-week postassessment)

Table 1. Level of care index for higher-intensity caregiving^a.

Points	Hours of care (average week)	Type of care provided	
		Adult care recipient	Child care recipient ^b
1	0-8	0 ADL ^{c,d} , 1 IADL ^e	0 ADL, 1 IADL or CSA ^f
2	9-20	0 ADL, ≥2 IADLs	0 ADL, ≥2 IADL or CSAs (eg, 1 IADL plus 1 CSA)
3	21-40	1 ADL, any number IADLs	1 ADL, any number IADL or CSAs
4	≥41	≥2 ADLs, any number IADLs	≥2 ADLs, any number IADL or CSAs

^aOn the basis of the National Association for Caregiving (2020) Level of Care Index.

^bCaregivers for child care recipients are only asked about developmentally appropriate ADLs and 3 IADLs: assisting with medical or nursing tasks, managing finances, and arranging outside services.

^cADL: activity of daily living.

^dIncludes medical and nursing tasks.

^eIADL: instrumental activity of daily living.

^fCSA: caregiver support activities—advocating with health care providers, community services, schools, or government agencies; monitoring the severity of their condition; communicating with health care professionals.

Procedures

Potential participants will learn about our trial from any of the three primary recruitment pathways (Figure 1 step 1): (1) University of Pittsburgh research registries, either receiving a letter through the Center for Social and Urban Research Caregiver Research Registry or matching with the study through the Clinical and Translational Science Institute Pitt+Me Research Registry; (2) web-based advertisement, including national social media advertisement campaigns by the University of Virginia Health System, social media postings, and website and newsletter postings through pertinent community organizations; or (3) in-clinic advertisements and informational flyers and handouts provided through partnering clinics at the University of Virginia and University of Pittsburgh.

Potentially interested individuals will contact the research staff and visit the study website for more information about the study. Interested individuals will complete a brief web-based interest and prescreening form (step 2). Where indicated, individuals' identities will be verified using TLOxp (TransUnion), a web-based people search tool [59]. Potentially eligible individuals will be contacted by research staff by phone to

complete eligibility screening, answer any remaining questions about the trial, and obtain informed consent to participate (step 3). Informed consent to participate will be collected electronically via DocuSign, and participants will have the opportunity to download a digitally signed copy of the form.

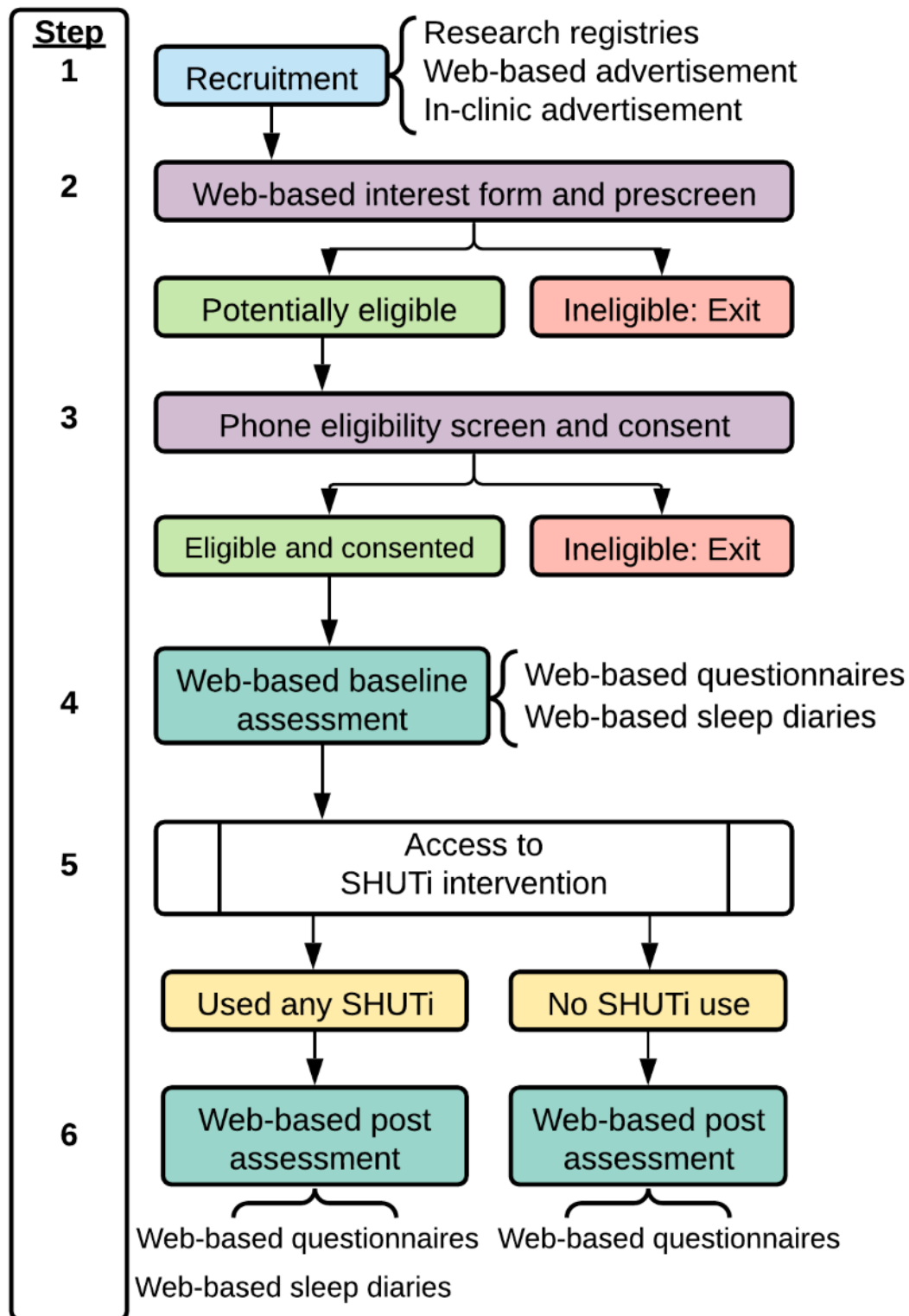
Enrolled participants will then be emailed log-in information for the SHUTi intervention website to complete preassessment (step 4). They will first complete a web-based questionnaire battery; then, participants will complete daily web-based sleep diaries through the SHUTi system. Participants must enter 10 daily sleep diaries in 14 days to advance through this stage. Upon completing these preassessment sleep diaries, participants will be compensated US \$40.

Following completion of the preassessment, all participants will be advanced to the SHUTi intervention in this single-group, open-label trial (step 5; see *Intervention* section for more details). At the end of the 9-week intervention period, regardless of intervention progress, participants will complete postassessment (step 6). If a participant completes ≥1 Core, they will complete the full battery of questionnaires and 10 web-based sleep diaries. If a participant completes no Cores,

they will complete a brief postassessment questionnaire battery. These nonusers will not be asked to complete the full battery of questionnaires or sleep diaries to encourage retention.

Participants will be compensated US \$40 upon completion of the postassessment.

Figure 1. Trial procedures. SHUTi: Sleep Healthy Using the Internet.



Intervention

Our team has established SHUTi as an effective treatment for insomnia over the past 15 years [39,40,45,60-65]. A complete description of the intervention has been published previously [40]; key intervention details are included here. SHUTi is a

fully automated internet-delivered insomnia intervention that is tailored from user-inputted data. The intervention is based on CBT-I, covering the primary tenets of sleep restriction, stimulus control, cognitive restructuring, sleep hygiene, and relapse prevention [40,66]. Study staff will be available to provide technical support; however, no clinical support will be

provided to users. In this trial, participants will receive access to the standard SHUTi program—meaning that the program has no tailoring to any specific user population. There is no content in the program that specifically addresses caregiving or caregiving-related impacts on sleep or treatment.

SHUTi content will be metered out over time through 6 *Cores*, or lessons, each of which will take approximately 45 minutes to 1 hour to complete. Core content ([Textbox 2](#)) will be delivered in a way that is designed to be engaging based on learning theory and instructional design [67], with interactive features such as graphical feedback of entered data, animations, quizzes, and videos. Cores will be delivered to users on a time-

and activity-based schedule. Specifically, the next Core will be made available to the user 1 week following their completion of the prior Core, which will allow participants time to practice skills. Users can track their sleep using daily web-based sleep diaries, each of which will take approximately ≤ 3 minutes to complete. The intervention will provide tailored content to users based on these diaries (eg, tailored *sleep prescriptions* as part of the sleep restriction technique) and other user-entered data. Participants will receive regular automated emails from the SHUTi program to support user engagement (eg, reminders to complete sleep diaries and notifications that a new Core is available).

Textbox 2. Sleep Healthy Using the Internet intervention content by Core.

Core 1: Overview

Insomnia defined, types, prevalence, risk factors, and impact (ie, daytime fatigue, psychological well-being, physical health, and economic cost); setting treatment goals; and treatment overview, appropriateness, and effectiveness

Core 2: Sleep Behavior 1

Explanation of poor sleep habits; situational or chronic sleep difficulties; cycle of chronic insomnia; introduction of sleep restriction; explanation of sleep efficiency; and instruction on adjustments of sleep window based on sleep efficiency

Core 3: Sleep Behavior 2

Introduction of stimulus control (ie, going to bed when sleepy, leaving bed if unable to sleep, regular sleep schedule, using bed for sleep only, and no napping)

Core 4: Sleep Thoughts

Relationship between thinking patterns and emotions; contributions of thought patterns to sleeplessness; cognitive restructuring; keeping realistic expectations; revising misconceptions about insomnia; eliminating catastrophizing; reducing sleep emphasis; developing tolerance for sleep loss effects; and dealing with setbacks

Core 5: Sleep Education

Sleep hygiene guidelines; avoiding stimulants; and effects of diet, environment, and exercise

Core 6: Problem Prevention

Relapse prevention techniques; considering therapeutic gains; review of sleep behavior techniques; sleep medication information; and maintaining program techniques

Measures

Overview

Study measures are summarized in [Table 2](#). Web-based questionnaires will be completed through a Health Insurance

Portability and Accountability Act–compliant web-based survey manager (Qualtrics Highly Sensitive Data). All items will include validation to notify participants if they skip an item to reduce accidentally missing data; however, responses will not be required, as participants may skip any question they would like.

Table 2. Measures.

Variable and measure	Outcome measured	Time	
		Pre	Post
Sample characteristics			
Sociodemographics	Age, gender, race or ethnicity, household income, health literacy, and relationship to care recipient	✓	
Predictors: caregiving-related user characteristics			
Caregiving strain	Pearlin Stress Scale–caregiving overload subscale	✓	✓
Caregiving self-efficacy	Pearlin Stress Scale–caregiving competence subscale	✓	
Caregiving guilt	Caregiver Guilt Questionnaire–guilt about doing wrong by the CR ^a , not rising to the occasion as a caregiver, and self-care subscales	✓	
Predictors: caregiving-related environmental characteristics			
Proximity to CR ^a	Whether bedpartner, live together but not bedpartner, or other situations	✓	
CR functional status	Modified Barthel Activities of Daily Living Index	✓	
CR cognitive status	Pearlin Stress Scale–cognitive status subscale	✓	
CR problem behavior	Pearlin Stress Scale–problematic behavior subscale (includes nighttime problems)	✓	
Caregiving tasks	Involvement in supporting activities of daily living, instrumental activities of daily living, and caregiver support activities	✓	
Changes in caregiving	Single item question (with follow-up open-ended response) to assess if caregiving situation has significantly changed during study		✓
Aim 1 outcomes: SHUTi^b engagement			
Core completion	Nonuser (no Cores completed); incompleter (1-3 Cores); completer (4-6 Cores)		Throughout SHUTi
Open-ended feedback	Free-response survey items—separate surveys for nonusers and users		✓
SHUTi utility and barriers	Internet Intervention Utility, Evaluation, and Adherence Questionnaires—selected items		✓ ^c
Aim 2 outcomes: SHUTi efficacy on known cognitive mechanisms			
Sleep beliefs	Dysfunctional Beliefs and Attitudes About Sleep	✓	✓ ^c
Sleep control	Sleep Locus of Control Scale	✓	✓ ^c
Exploratory: preliminary efficacy			
Insomnia severity	Insomnia severity index-2 item	✓	✓
Sleep diary metrics	10 days of sleep diaries in 14-day period	✓	✓ ^c
Health-related quality of life	PROMIS ^d : 2-item Global Physical Health	✓	✓
General distress	Patient Health Questionnaire-4	✓	✓

^aCR: care recipient.

^bSHUTi: Sleep Healthy Using the Internet.

^cAssessed among SHUTi users (ie, incompleters and completers) only.

^dPROMIS: Patient-Reported Outcomes Measurement Information System.

Outcomes: Aim 1

The primary trial outcome will be the level of participants' engagement with SHUTi, operationalized by intervention Core completion. Participants will be categorized according to their Core completion: (1) nonusers, who complete no Cores; (2) incompleters, who complete 1 to 3 Cores; and (3) completers, who complete 4 to 6 Cores. Those completing ≥ 4 Cores are considered to have completed the program as they have completed content related to primary treatment change

mechanisms; also, approximately all (>90%) participants continue on to complete all 6 Cores based on multiple past SHUTi trials. Participants' Core completion will be automatically tracked by the SHUTi intervention platform.

Following the intervention period, we will also assess caregivers' barriers to the uptake and use of SHUTi (nonusers); their perceived satisfaction, utility, and efficacy of SHUTi (users—both incompleters and completers); and ways in which we may tailor the SHUTi program to better fit family caregivers' needs related to sleep. Depending on whether the participant is

a nonuser or user, they will complete open-ended free-response items, 4 items from the Client Satisfaction Questionnaire [68], and selected items from the Internet Intervention Utility, Evaluation, and Adherence Questionnaires [40].

Outcomes: Aim 2

We will assess SHUTi users' change in key cognitive mechanisms of sleep beliefs (Dysfunctional Beliefs and Attitudes about Sleep [69]) and sleep locus of control (Sleep Locus of Control Scale [70]). These variables have been previously demonstrated to mediate SHUTi benefits on insomnia symptom severity [45].

Predictors: Caregiving Context

We will test the association of SHUTi engagement and change in cognitive mechanisms with caregiving-related user characteristics and environmental characteristics.

Caregiving-Related User Characteristics

We will assess 3 potentially modifiable, subjective aspects of caregiving: (1) caregiving strain (Pearlin Stress Scale [PSS]–caregiving overload subscale [71]), (2) caregiving self-efficacy (PSS–caregiving competence subscale [71]), and (3) caregiving guilt (Caregiver Guilt Questionnaire—guilt about doing wrong by the care recipient, not rising to the occasion as a caregiver, and self-care subscales [72]).

Caregiving-Related Environmental Characteristics

We will also assess 5 structural factors in the caregiving situation. In the event that the caregiver provides care to >1 care recipient, they will respond to the following about their main care recipient (ie, care recipient to whom they provide the most care), as has been done previously [1]: (1) proximity to the care recipient—whether bedpartner, living together but not bedpartner, or other living situation—(2) care recipient's functional status (Modified Barthel ADL Index [73]), (3) care recipient's cognitive status (PSS–cognitive status subscale [71]), (4) care recipient's problem behavior (PSS–problematic behavior subscale [71]), and (5) care provided—involvement in supporting ADL, instrumental ADL, and caregiver support activities.

Preliminary Efficacy Outcomes

As an exploratory analysis of SHUTi efficacy, we will also examine changes in caregivers' self-reported insomnia severity (ISI-2 item [74]), metrics from sleep diaries (eg, sleep onset latency, wake after sleep onset, and sleep quality; SHUTi users only), health-related quality of life (Patient-Reported Outcomes Measurement Information System Global Physical Health-2 item [75]), general distress (Patient Health Questionnaire-4 [76]), and caregiving strain (PSS–caregiving overload subscale [71]).

Sample Size and Power Analysis

A total of 100 caregivers will be enrolled in this trial. This sample size was identified based on a power analysis to detect moderate effects of the caregiving context variables on the primary outcome of engagement with SHUTi. We estimated the expected caregiver engagement with SHUTi based on our team's prior research. On the basis of engagement rates from a recently completed trial of an untailed internet depression management program among family caregivers [77] (nonusers=35%; incompleters=40%; completers=25%) and average completion rates across multiple SHUTi trials [61-63] (nonusers=10%; incompleters=25%; completers=65%), we estimate that the sample in the proposed trial will be categorized as follows: 22% (22/100) nonusers, 33% (33/100) incompleters, and 45% (45/100) completers. Assuming these engagement rates, the minimally detectable proportional odds for aim 1a analyses at power=80% with $\alpha=.05$ would be a moderate effect size [78] (minimally detectable proportional odds=2.9) for a sample size of N=100 based on the rate of dichotomized predictor exposures (computed using the Whitehead formula [79] in R Hmisc [80]). An example of a detectable scenario (user status associated with caregiving strain) under these conditions is presented in Table 3. In this hypothetical situation, caregivers who did not complete any SHUTi Cores (nonusers) were more likely to report high caregiving strain relative to caregivers who completed any SHUTi Cores (users). As this primary analysis uses preassessment questionnaire data, and engagement is automatically assessed in the SHUTi intervention platform, the final sample size determination does not need to account for attrition.

Table 3. Example of a detectable scenario for aim 1a (odds ratio 3.4; N=100).

Engagement status	Caregiving strain		Sample (%)
	Above median	Below median	
Nonuser, n (%)	16 (72.7)	6 (27.3)	22
User, n (%)	34 (43.6)	44 (56.4)	78
Sample (%)	50	50	100

Data Analysis Plan

Aim 1a: Test the Association of SHUTi Engagement With Caregiver User and Environmental Characteristics

To test the effect of caregiver context on SHUTi engagement, ordered logistic regressions assuming proportional odds will be fit for each caregiving-related user and environmental characteristics on SHUTi Core completion, which is a 3-level

ordinal-dependent variable (ie, nonusers vs incompleters vs completers). Where the proportional odds assumption is violated ($P<.05$), follow-up sensitivity analyses will be conducted: 2 logistic regressions will compare proportional odds between nonusers and users (incompleters and completers) and between noncompleters (nonusers and incompleters) and completers. For users, we will also examine the associations between user and environmental characteristics with SHUTi evaluations on

the Internet Intervention Utility, Evaluation, and Adherence Questionnaires.

Aim 1b: Describe Caregivers' Barriers to and Motivations for SHUTi Engagement

Users' open-ended survey responses from the postassessment will be qualitatively coded using 2 methods. First, an a priori codebook will be used to tag data according to whether it is (1) specific to SHUTi, (2) specific to CBT-I but not exclusively SHUTi, or (3) specific to digital health interventions but not exclusively SHUTi. This will facilitate the examination of the extent to which caregiver-specific tailoring recommendations are specific to SHUTi versus generalizable to other evidence-based psychosocial digital health interventions. Next, responses will be coded inductively using thematic text analysis [81] to identify themes related to caregivers' barriers to and motivations for SHUTi uptake and use as well as how caregiver-specific tailoring may affect each of those constructs. The coding team will iteratively determine a set of codes; identify, review, and name themes; and synthesize data into final actionable recommendations for tailoring SHUTi and other digital health interventions for caregivers.

Findings and resulting recommendations will be returned to caregivers who indicate that they are willing to be recontacted for synthesized member checking [82]. A concise report of the results will be sent to the caregivers. Then, the caregivers will review the report and comment on how the results compare and contrast with their experiences and needs, and their returned responses will be coded to ascertain the level of resonance with the researchers' results. The findings and recommendations will be revised according to the synthesized member checking results.

Aim 2: Test the Association of SHUTi Efficacy on Known Cognitive Mechanisms With Caregiving Context

Among SHUTi users, continuous regression modeling will test the association of each caregiving context predictor with cognitive mechanisms assessed at postassessment, controlling for preassessment [83]. Models will control for the level of SHUTi engagement, with significance set at $\alpha=.05$.

Preliminary Efficacy

The preliminary efficacy of SHUTi for caregivers will be explored by computing within-group effect size on the change from preassessment to postassessment on insomnia symptoms (ie, self-reported severity), sleep outcomes (ie, sleep diary metrics), and related constructs of general distress and caregiving strain.

Results

This study is funded by the National Institutes of Health–National Center for Advancing Translational Sciences (R21TR003522; project duration: July 2021–June 2023). The study protocol has been reviewed and approved by the University of Virginia (UVA) institutional review board (IRB) for health sciences research (protocol HSR210255; initial approval date: September 2021), which serves as the IRB of record. The protocol has also been initiated through the

University of Pittsburgh Office of Research Protections (STUDY21080076). Study modifications will be reviewed and approved by the UVA IRB, and the University of Pittsburgh IRB will be notified of these modifications as necessary. The UVA IRB will review the protocol and progress reports for this trial annually. This trial is registered with ClinicalTrials.gov (NCT04986904). Data collection is anticipated to begin in December 2021 and is expected to be completed in 2023.

Discussion

Principal Findings

This study will provide the data necessary to ensure the highest impact and efficiency from existing evidence-based digital health interventions to meet pressing psychosocial needs among caregivers. Specifically, this study will inform the next research steps for tailoring and testing SHUTi for optimal impact and reach among caregivers. More broadly, our results will address a key translational science research question for the caregiving field, namely, how existing evidence-based digital health interventions can be most effectively translated to meet psychosocial needs among caregivers

This is the first study to address this broad translational question by systematically studying what tailoring may be necessary to increase the impact of an existing evidence-based digital health intervention program among higher-intensity caregivers. Much of the available psychosocial care for caregivers is delivered face to face, a modality that has significant practical and financial barriers limiting accessibility for caregivers [31,32]. The findings will help address how to serve caregivers more quickly and effectively by addressing prevalent and high-burden psychosocial concerns with existing evidence-based digital health interventions. As the effects of SHUTi have been robustly established across multiple clinical trials, the present trial among family caregivers will be able to isolate the effects of caregiving context on the use and impact of SHUTi for this specific population.

Relatedly, this trial takes a fundamentally different approach to caregiving intervention development by directly studying the ways in which key intervention targets should differ—or not—according to the caregiving context. Caregiver interventions have primarily been developed for specific caregivers defined by the care recipient's disease [22,26,29]. This is appropriate for certain psychoeducational or caregiver training interventions. However, for interventions targeting specific problems such as insomnia, which is caused and exacerbated by multiple behavioral and psychological factors, it is not clear whether needs differ across caregiving contexts to justify increased specificity in the intervention. This trial will specifically assess how the caregiving context may relate to intervention engagement and efficacy among higher-intensity caregivers who are known to be at the highest risk for poor outcomes but have the most difficulty accessing interventions [1,11]. By examining what tailoring may be necessary for which caregivers, we can better balance intervention efficacy against reach by ensuring that interventions are applicable to the broadest possible population of family caregivers.

We expect that findings from this mixed methods proposal will direct the next research steps toward 1 of 2 primary paths. If the findings suggest that caregiving-related user and environmental characteristics are not related to SHUTi engagement or efficacy, with no significant intervention tailoring requirements identified by caregivers, then a trial designed to understand the efficacy of and dissemination strategies for the existing SHUTi program (without tailoring) among caregivers will be warranted. On the other hand, if findings suggest meaningful differences in SHUTi engagement or efficacy by caregiving context or if key themes arise regarding intervention tailoring that may better engage and support caregivers, then tailoring and testing SHUTi for caregivers will be warranted. Potential changes may include modifying content to be more caregiver salient, addressing specific caregiving-related barriers

to sleep recommendations, or wrapping the intervention in an implementation intervention to promote engagement.

Findings from the proposed work will not only be necessary to direct the next research on SHUTi specifically but will also deliver key insights on tailoring other evidence-based digital health interventions for caregivers. By doing so, findings will advance the science toward our long-term goal of improving the quality and impact of digital health interventions for caregivers while reducing intervention development inefficiency—a goal identified as a high priority for current caregiving research. As such, findings will be translatable across intervention programs and hold significant promise for reducing inefficiencies in developing digital health interventions for caregivers while also increasing their impact and reach for this underserved population.

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Authors' Contributions

KMS conceived the study. KMS, LMR, DB, MM, FC, and HD designed the study and obtained grant funding. JVG and JK will help with study implementation. WY will provide statistical expertise in clinical trial design and conduct primary statistical analyses. All authors contributed to the refinement of the study protocol and have approved the final manuscript.

Conflicts of Interest

Over the past 3 years, DJB has served as a paid consultant to the National Cancer Institute, Pear Therapeutics, Sleep Number, Idorsia, and Weight Watchers International. DJB is an author of the Pittsburgh Sleep Quality Index, Pittsburgh Sleep Quality Index Addendum for posttraumatic stress disorder, Brief Pittsburgh Sleep Quality Index, Daytime Insomnia Symptoms Scale, Pittsburgh Sleep Diary, Insomnia Symptom Questionnaire, and RU_SATED (copyrights held by the University of Pittsburgh). These instruments have been licensed to commercial entities for fees. He is also a coauthor of the Consensus Sleep Diary (copyright held by Ryerson University), which is licensed to commercial entities for a fee. LMR reports relationships with BeHealth Solutions (equity ownership and member of the board of directors) and Pear Therapeutics (consultant), which are 2 companies that develop and disseminate digital therapeutics, including licensing the therapeutic developed, based, in part, on early versions of the software used in the research reported in this paper. These companies had no role in the preparation of this manuscript. LMR is also a consultant to Mahana Therapeutics, a separate digital therapeutic company not affiliated with this research. The terms of these arrangements have been reviewed and approved by the University of Virginia in accordance with its policies.

Multimedia Appendix 1

Peer-review report by the National Center for Advancing Translational Sciences (NCATS), National Institutes of Health (NIH, USA).

[\[PDF File \(Adobe PDF File\), 115 KB-Multimedia Appendix 1\]](#)

Multimedia Appendix 2

Response to National Institute of Health reviewer feedback submitted at just-in-time phase.

[\[PDF File \(Adobe PDF File\), 141 KB-Multimedia Appendix 2\]](#)

References

1. National Alliance for Caregiving. Caregiving in the United States 2020. AARP Public Policy Institute. 2020. URL: <https://www.aarp.org/ppi/info-2020/caregiving-in-the-united-states.html> [accessed 2021-12-30]
2. Reinhard S, Feinberg L, Choula R, Houser A. Valuing the invaluable: 2015 update. AARP Public Policy Institute. 2015. URL: https://www.thelundreport.org/sites/default/files/u19224/ValuingtheInvaluable_EMBARGOED%20UNTIL%20JULY%202016%202015.pdf [accessed 2021-12-30]

3. Trivedi R, Beaver K, Bouldin E, Eugenio E, Zeliadt S, Nelson K, et al. Characteristics and well-being of informal caregivers: results from a nationally-representative US survey. *Chronic Illn* 2014 Sep;10(3):167-179. [doi: [10.1177/1742395313506947](https://doi.org/10.1177/1742395313506947)] [Medline: [24154869](https://pubmed.ncbi.nlm.nih.gov/24154869/)]
4. Ho SC, Chan A, Woo J, Chong P, Sham A. Impact of caregiving on health and quality of life: a comparative population-based study of caregivers for elderly persons and noncaregivers. *J Gerontol A Biol Sci Med Sci* 2009 Aug;64(8):873-879. [doi: [10.1093/gerona/glp034](https://doi.org/10.1093/gerona/glp034)] [Medline: [19351695](https://pubmed.ncbi.nlm.nih.gov/19351695/)]
5. Shaffer KM, Garland SN, Mao JJ, Applebaum AJ. Insomnia among cancer caregivers: a proposal for tailored cognitive behavioral therapy. *J Psychother Integr* 2018 Sep;28(3):275-291 [FREE Full text] [doi: [10.1037/int0000105](https://doi.org/10.1037/int0000105)] [Medline: [30245560](https://pubmed.ncbi.nlm.nih.gov/30245560/)]
6. Schutte-Rodin S, Broch L, Buysse D, Dorsey C, Sateia M. Clinical guideline for the evaluation and management of chronic insomnia in adults. *J Clin Sleep Med* 2008 Oct 15;4(5):487-504 [FREE Full text] [Medline: [18853708](https://pubmed.ncbi.nlm.nih.gov/18853708/)]
7. Wilcox S, King AC. Sleep complaints in older women who are family caregivers. *J Gerontol B Psychol Sci Soc Sci* 1999 May 01;54(3):189-198. [doi: [10.1093/geronb/54b.3.p189](https://doi.org/10.1093/geronb/54b.3.p189)] [Medline: [10363041](https://pubmed.ncbi.nlm.nih.gov/10363041/)]
8. Carter PA. A brief behavioral sleep intervention for family caregivers of persons with cancer. *Cancer Nurs* 2006;29(2):95-103. [doi: [10.1097/00002820-200603000-00003](https://doi.org/10.1097/00002820-200603000-00003)] [Medline: [16565618](https://pubmed.ncbi.nlm.nih.gov/16565618/)]
9. McCurry SM, Logsdon RG, Vitiello MV, Teri L. Successful behavioral treatment for reported sleep problems in elderly caregivers of dementia patients: a controlled study. *J Gerontol B Psychol Sci Soc Sci* 1998 Mar 01;53(2):122-129. [doi: [10.1093/geronb/53b.2.p122](https://doi.org/10.1093/geronb/53b.2.p122)] [Medline: [9520929](https://pubmed.ncbi.nlm.nih.gov/9520929/)]
10. McCrae CS, Tierney CG, McNamara JPH. Behavioral intervention for insomnia: future directions for nontraditional caregivers at various stages of care. *Clin Gerontol* 2006 Mar;29(2):95-114. [doi: [10.1300/j018v29n02_10](https://doi.org/10.1300/j018v29n02_10)]
11. Caregiving in the US fact sheet: the “Typical” high intensity caregiver. National Alliance for Caregiving and AARP. 2020. URL: <https://www.aarp.org/content/dam/aarp/ppi/2020/05/high-intensity-caregiver.doi.10.26419-2Fppi.00103.010.pdf> [accessed 2021-12-30]
12. Romito F, Goldzweig G, Cormio C, Hagedoorn M, Andersen BL. Informal caregiving for cancer patients. *Cancer* 2013 Jun 01;119 Suppl 11:2160-2169 [FREE Full text] [doi: [10.1002/cncr.28057](https://doi.org/10.1002/cncr.28057)] [Medline: [23695928](https://pubmed.ncbi.nlm.nih.gov/23695928/)]
13. Applebaum AJ, Breitbart W. Care for the cancer caregiver: a systematic review. *Palliat Support Care* 2013 Jun;11(3):231-252 [FREE Full text] [doi: [10.1017/S1478951512000594](https://doi.org/10.1017/S1478951512000594)] [Medline: [23046977](https://pubmed.ncbi.nlm.nih.gov/23046977/)]
14. Northouse LL, Katapodi MC, Song L, Zhang L, Mood DW. Interventions with family caregivers of cancer patients: meta-analysis of randomized trials. *CA Cancer J Clin* 2010 Aug 16;60(5):317-339 [FREE Full text] [doi: [10.3322/caac.20081](https://doi.org/10.3322/caac.20081)] [Medline: [20709946](https://pubmed.ncbi.nlm.nih.gov/20709946/)]
15. Thompson CA, Spilsbury K, Hall J, Birks Y, Barnes C, Adamson J. Systematic review of information and support interventions for caregivers of people with dementia. *BMC Geriatr* 2007 Jul 27;7(1):18 [FREE Full text] [doi: [10.1186/1471-2318-7-18](https://doi.org/10.1186/1471-2318-7-18)] [Medline: [17662119](https://pubmed.ncbi.nlm.nih.gov/17662119/)]
16. Tate DF, Finkelstein EA, Khavjou O, Gustafson A. Cost effectiveness of internet interventions: review and recommendations. *Ann Behav Med* 2009 Aug 17;38(1):40-45 [FREE Full text] [doi: [10.1007/s12160-009-9131-6](https://doi.org/10.1007/s12160-009-9131-6)] [Medline: [19834778](https://pubmed.ncbi.nlm.nih.gov/19834778/)]
17. Galvin JE, Duda JE, Kaufer DI, Lippa CF, Taylor A, Zarit SH. Lewy body dementia: caregiver burden and unmet needs. *Alzheimer Dis Assoc Disord* 2010;24(2):177-181 [FREE Full text] [doi: [10.1097/WAD.0b013e3181c72b5d](https://doi.org/10.1097/WAD.0b013e3181c72b5d)] [Medline: [20505434](https://pubmed.ncbi.nlm.nih.gov/20505434/)]
18. Caregivers and technology: what they want and need. AARP - Project Catalyst. 2016. URL: https://www.aarp.org/content/dam/aarp/research/surveys_statistics/lrc/2018/caregivers-technology-needs.doi.10.26419-2Fres.00191.002.pdf [accessed 2021-12-30]
19. Fox S, Duggan M, Purcell K. Family caregivers are wired for health. Pew Research Center. 2013. URL: <http://www.pewinternet.org/2013/06/20/family-caregivers-are-wired-for-health/> [accessed 2021-12-30]
20. Kent EE, Rowland JH, Northouse L, Litzelman K, Chou WS, Shelburne N, et al. Caring for caregivers and patients: research and clinical priorities for informal cancer caregiving. *Cancer* 2016 Jul 01;122(13):1987-1995 [FREE Full text] [doi: [10.1002/cncr.29939](https://doi.org/10.1002/cncr.29939)] [Medline: [26991807](https://pubmed.ncbi.nlm.nih.gov/26991807/)]
21. Schulz R, Wahl H, Matthews JT, De Vito Dabbs A, Beach SR, Czaja SJ. Advancing the aging and technology agenda in gerontology. *Gerontologist* 2015 Oct 27;55(5):724-734 [FREE Full text] [doi: [10.1093/geront/gnu071](https://doi.org/10.1093/geront/gnu071)] [Medline: [25165042](https://pubmed.ncbi.nlm.nih.gov/25165042/)]
22. National Academies of Sciences, Engineering, and Medicine. Families caring for an aging America. Washington, DC: The National Academies Press; 2016.
23. Adler R, Mehta R. Catalyzing technology to support family caregiving. National Alliance for Caregiving. 2014. URL: https://www.caregiving.org/wp-content/uploads/2010/01/Catalyzing-Technology-to-Support-Family-Caregiving_FINAL.pdf [accessed 2021-12-30]
24. Egan KJ, Pinto-Bruno AC, Bighelli I, Berg-Weger M, van Straten A, Albanese E, et al. Online training and support programs designed to improve mental health and reduce burden among caregivers of people with dementia: a systematic review. *J Am Med Dir Assoc* 2018 Mar;19(3):200-206. [doi: [10.1016/j.jamda.2017.10.023](https://doi.org/10.1016/j.jamda.2017.10.023)] [Medline: [29306605](https://pubmed.ncbi.nlm.nih.gov/29306605/)]
25. Kaltenbaugh D, Klem ML, Hu L, Turi E, Haines A, Hagerty Lingler J. Using Web-based interventions to support caregivers of patients with cancer: a systematic review. *Oncol Nurs Forum* 2015 Mar;42(2):156-164. [doi: [10.1188/15.ONF.156-164](https://doi.org/10.1188/15.ONF.156-164)] [Medline: [25806882](https://pubmed.ncbi.nlm.nih.gov/25806882/)]

26. Dyer E, Kansagara D, McInnes D, Freeman M, Woods S. Mobile Applications and Internet-based Approaches for Supporting Non-professional Caregivers: A Systematic Review. Washington (DC): Department of Veterans Affairs (US); 2012.
27. Wasilewski MB, Stinson JN, Cameron JI. Web-based health interventions for family caregivers of elderly individuals: a scoping review. *Int J Med Inform* 2017 Jul;103:109-138. [doi: [10.1016/j.ijmedinf.2017.04.009](https://doi.org/10.1016/j.ijmedinf.2017.04.009)] [Medline: [28550996](https://pubmed.ncbi.nlm.nih.gov/28550996/)]
28. Boots LM, de Vugt ME, van Knippenberg RJ, Kempen GI, Verhey FR. A systematic review of Internet-based supportive interventions for caregivers of patients with dementia. *Int J Geriatr Psychiatry* 2014 Apr 20;29(4):331-344. [doi: [10.1002/gps.4016](https://doi.org/10.1002/gps.4016)] [Medline: [23963684](https://pubmed.ncbi.nlm.nih.gov/23963684/)]
29. Hu C, Kung S, Rummans T, Clark M, Lapid M. Reducing caregiver stress with internet-based interventions: a systematic review of open-label and randomized controlled trials. *J Am Med Inform Assoc* 2015 Apr;22(e1):194-209. [doi: [10.1136/amiajnl-2014-002817](https://doi.org/10.1136/amiajnl-2014-002817)] [Medline: [25125686](https://pubmed.ncbi.nlm.nih.gov/25125686/)]
30. Waligora K, Bahouth M, Han HR. The self-care needs and behaviors of dementia informal caregivers: a systematic review. *Gerontologist* 2019 Sep 17;59(5):565-583. [doi: [10.1093/geront/gny076](https://doi.org/10.1093/geront/gny076)] [Medline: [29931147](https://pubmed.ncbi.nlm.nih.gov/29931147/)]
31. Applebaum AJ, Farran CJ, Marziliano AM, Pasternak AR, Breitbart W. Preliminary study of themes of meaning and psychosocial service use among informal cancer caregivers. *Palliat Support Care* 2014 Apr;12(2):139-148 [FREE Full text] [doi: [10.1017/S1478951513000084](https://doi.org/10.1017/S1478951513000084)] [Medline: [23919966](https://pubmed.ncbi.nlm.nih.gov/23919966/)]
32. Shaw J, Harrison J, Young J, Butow P, Sandroussi C, Martin D, et al. Coping with newly diagnosed upper gastrointestinal cancer: a longitudinal qualitative study of family caregivers' role perception and supportive care needs. *Support Care Cancer* 2013 Mar 30;21(3):749-756. [doi: [10.1007/s00520-012-1575-8](https://doi.org/10.1007/s00520-012-1575-8)] [Medline: [22933130](https://pubmed.ncbi.nlm.nih.gov/22933130/)]
33. Lancee J, Eisma M, van Zanten KB, Topper M. When thinking impairs sleep: trait, daytime and nighttime repetitive thinking in insomnia. *Behav Sleep Med* 2017;15(1):53-69. [doi: [10.1080/15402002.2015.1083022](https://doi.org/10.1080/15402002.2015.1083022)] [Medline: [26651373](https://pubmed.ncbi.nlm.nih.gov/26651373/)]
34. McCurry SM, Logsdon RG, Teri L, Vitiello MV. Sleep disturbances in caregivers of persons with dementia: contributing factors and treatment implications. *Sleep Med Rev* 2007 Apr;11(2):143-153 [FREE Full text] [doi: [10.1016/j.smrv.2006.09.002](https://doi.org/10.1016/j.smrv.2006.09.002)] [Medline: [17287134](https://pubmed.ncbi.nlm.nih.gov/17287134/)]
35. Lee K, Yiin J, Lu S, Chao Y. The burden of caregiving and sleep disturbance among family caregivers of advanced cancer patients. *Cancer Nurs* 2015;38(4):10-18. [doi: [10.1097/NCC.000000000000166](https://doi.org/10.1097/NCC.000000000000166)] [Medline: [24978619](https://pubmed.ncbi.nlm.nih.gov/24978619/)]
36. Kreuter MW, Strecher VJ, Glassman B. One size does not fit all: the case for tailoring print materials. *Ann Behav Med* 1999;21(4):276-283. [doi: [10.1007/BF02895958](https://doi.org/10.1007/BF02895958)] [Medline: [10721433](https://pubmed.ncbi.nlm.nih.gov/10721433/)]
37. Noar SM, Benac CN, Harris MS. Does tailoring matter? Meta-analytic review of tailored print health behavior change interventions. *Psychol Bull* 2007 Jul;133(4):673-693. [doi: [10.1037/0033-2909.133.4.673](https://doi.org/10.1037/0033-2909.133.4.673)] [Medline: [17592961](https://pubmed.ncbi.nlm.nih.gov/17592961/)]
38. Lustria ML, Noar SM, Cortese J, Van Stee SK, Glueckauf RL, Lee J. A meta-analysis of web-delivered tailored health behavior change interventions. *J Health Commun* 2013 Sep;18(9):1039-1069. [doi: [10.1080/10810730.2013.768727](https://doi.org/10.1080/10810730.2013.768727)] [Medline: [23750972](https://pubmed.ncbi.nlm.nih.gov/23750972/)]
39. Research-Tested Intervention Programs (RTIPs): Sleep Healthy Using the Internet (SHUTi). National Cancer Institute. 2019. URL: <https://rtips.cancer.gov/rtips/programDetails.do?programId=2678268> [accessed 2021-12-30]
40. Thorndike FP, Saylor DK, Bailey ET, Gonder-Frederick L, Morin CM, Ritterband LM. Development and perceived utility and impact of an internet intervention for insomnia. *E J Appl Psychol* 2008;4(2):32-42 [FREE Full text] [doi: [10.7790/ejap.v4i2.133](https://doi.org/10.7790/ejap.v4i2.133)] [Medline: [20953264](https://pubmed.ncbi.nlm.nih.gov/20953264/)]
41. Shaffer K, Camacho F, Mattos M, Buysse D, Donovan H, Ingersoll K, et al. Comparing efficacy, evaluation, and use of an internet-based insomnia intervention between caregivers and non-caregivers. *Ann Behav Med* 2021:S112 [FREE Full text]
42. Freedland KE. Pilot trials in health-related behavioral intervention research: problems, solutions, and recommendations. *Health Psychol* 2020 Oct;39(10):851-862. [doi: [10.1037/hea0000946](https://doi.org/10.1037/hea0000946)] [Medline: [32614197](https://pubmed.ncbi.nlm.nih.gov/32614197/)]
43. Chan A, Tetzlaff JM, Gøtzsche PC, Altman DG, Mann H, Berlin JA, et al. SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials. *Br Med J* 2013 Jan 08;346:e7586 [FREE Full text] [doi: [10.1136/bmj.e7586](https://doi.org/10.1136/bmj.e7586)] [Medline: [23303884](https://pubmed.ncbi.nlm.nih.gov/23303884/)]
44. Chan A, Tetzlaff J, Altman D, Laupacis A, Gøtzsche PC, Krleža-Jerić K, et al. SPIRIT 2013 statement: defining standard protocol items for clinical trials. *Ann Intern Med* 2013 Mar 05;158(3):200-207 [FREE Full text] [doi: [10.7326/0003-4819-158-3-201302050-00583](https://doi.org/10.7326/0003-4819-158-3-201302050-00583)] [Medline: [23295957](https://pubmed.ncbi.nlm.nih.gov/23295957/)]
45. Chow PI, Ingersoll KS, Thorndike FP, Lord HR, Gonder-Frederick L, Morin CM, et al. Cognitive mechanisms of sleep outcomes in a randomized clinical trial of internet-based cognitive behavioral therapy for insomnia. *Sleep Med* 2018 Jul;47:77-85 [FREE Full text] [doi: [10.1016/j.sleep.2017.11.1140](https://doi.org/10.1016/j.sleep.2017.11.1140)] [Medline: [29778918](https://pubmed.ncbi.nlm.nih.gov/29778918/)]
46. Bandura A. *Social Foundations of Thought and Action: A Social Cognitive Theory*. Hoboken, New Jersey: Prentice-Hall; 1986.
47. Webb TL, Joseph J, Yardley L, Michie S. Using the internet to promote health behavior change: a systematic review and meta-analysis of the impact of theoretical basis, use of behavior change techniques, and mode of delivery on efficacy. *J Med Internet Res* 2010 Feb 17;12(1):e4 [FREE Full text] [doi: [10.2196/jmir.1376](https://doi.org/10.2196/jmir.1376)] [Medline: [20164043](https://pubmed.ncbi.nlm.nih.gov/20164043/)]
48. Ritterband LM, Borowitz S, Cox DJ, Kovatchev B, Walker LS, Lucas V, et al. Using the internet to provide information prescriptions. *Pediatrics* 2005 Nov;116(5):e643-e647. [doi: [10.1542/peds.2005-0404](https://doi.org/10.1542/peds.2005-0404)] [Medline: [16263978](https://pubmed.ncbi.nlm.nih.gov/16263978/)]

49. Ritterband LM, Cox DJ, Gordon TL, Borowitz SM, Kovatchev BP, Walker LS, et al. Examining the added value of audio, graphics, and interactivity in an internet intervention for pediatric encopresis. *Children's Health Care* 2006 Mar;35(1):47-59. [doi: [10.1207/s15326888chc3501_5](https://doi.org/10.1207/s15326888chc3501_5)]
50. Magee JC, Ritterband LM, Thorndike FP, Cox DJ, Borowitz SM. Exploring the relationship between parental worry about their children's health and usage of an internet intervention for pediatric encopresis. *J Pediatr Psychol* 2009 Jun;34(5):530-538 [FREE Full text] [doi: [10.1093/jpepsy/jsn091](https://doi.org/10.1093/jpepsy/jsn091)] [Medline: [18772228](https://pubmed.ncbi.nlm.nih.gov/18772228/)]
51. Shaffer K, Ingersoll K, Chow P, Thorndike F, Bailey E, Shepard J, et al. Timing and tailoring of internet-based cognitive-behavioral treatment for insomnia for cancer survivors: A qualitative study. *Psychooncology* 2019 Sep;28(9):1934-1937 [FREE Full text] [doi: [10.1002/pon.5180](https://doi.org/10.1002/pon.5180)] [Medline: [31319444](https://pubmed.ncbi.nlm.nih.gov/31319444/)]
52. Shaffer KM, Benvenuto S, Zaleta AK, Levine M, Bellantoni C, Dannaoui A, et al. Feasibility and acceptability of distress screening for family caregivers at a cancer surgery center. *Oncol Nurs Forum* 2019 Mar 01;46(2):159-169 [FREE Full text] [doi: [10.1188/19.ONF.159-169](https://doi.org/10.1188/19.ONF.159-169)] [Medline: [30767970](https://pubmed.ncbi.nlm.nih.gov/30767970/)]
53. Shaffer K, Kennedy E, Glazer J, Clayton A, Cohn W, Millard T, et al. Including partners in discussions of sexual side effects from breast cancer: a qualitative study of survivors, partners, and providers. *OSF Preprints* 2021:1-24 [FREE Full text] [doi: [10.31219/osf.io/q4enf](https://doi.org/10.31219/osf.io/q4enf)]
54. Shaffer KM, Kennedy E, Glazer JV, Clayton AH, Cohn W, Millard TA, et al. Addressing sexual concerns of female breast cancer survivors and partners: a qualitative study of survivors, partners, and oncology providers about Internet intervention preferences. *Support Care Cancer* 2021 Dec;29(12):7451-7460. [doi: [10.1007/s00520-021-06302-w](https://doi.org/10.1007/s00520-021-06302-w)] [Medline: [34080054](https://pubmed.ncbi.nlm.nih.gov/34080054/)]
55. Nelson D, Kreps G, Hesse B, Croyle R, Willis G, Arora N, et al. The Health Information National Trends Survey (HINTS): development, design, and dissemination. *J Health Commun* 2004 Sep;9(5):443-481. [doi: [10.1080/10810730490504233](https://doi.org/10.1080/10810730490504233)] [Medline: [15513791](https://pubmed.ncbi.nlm.nih.gov/15513791/)]
56. Internet/broadband fact sheet. Pew Research Center. 2018 Feb. URL: <http://www.pewinternet.org/fact-sheet/internet-broadband/> [accessed 2021-12-30]
57. Shaffer KM, Chow PI, Cohn WF, Ingersoll KS, Ritterband LM. Informal caregivers' use of internet-based health resources: an analysis of the health information national trends survey. *JMIR Aging* 2018 Dec 18;1(2):e11051 [FREE Full text] [doi: [10.2196/11051](https://doi.org/10.2196/11051)] [Medline: [31518244](https://pubmed.ncbi.nlm.nih.gov/31518244/)]
58. Morin C, Belleville G, Bélanger L, Ivers H. The Insomnia Severity Index: psychometric indicators to detect insomnia cases and evaluate treatment response. *Sleep* 2011 May 01;34(5):601-608 [FREE Full text] [doi: [10.1093/sleep/34.5.601](https://doi.org/10.1093/sleep/34.5.601)] [Medline: [21532953](https://pubmed.ncbi.nlm.nih.gov/21532953/)]
59. Glazer JV, MacDonnell K, Frederick C, Ingersoll K, Ritterband LM. Liar! Liar! Identifying eligibility fraud by applicants in digital health research. *Internet Interv* 2021 Sep;25:100401 [FREE Full text] [doi: [10.1016/j.invent.2021.100401](https://doi.org/10.1016/j.invent.2021.100401)] [Medline: [34094883](https://pubmed.ncbi.nlm.nih.gov/34094883/)]
60. Christensen H, Batterham PJ, Gosling JA, Ritterband LM, Griffiths KM, Thorndike FP, et al. Effectiveness of an online insomnia program (SHUTi) for prevention of depressive episodes (the GoodNight Study): a randomised controlled trial. *Lancet Psychiatry* 2016 Jan 27;333-341. [doi: [10.1016/S2215-0366\(15\)00536-2](https://doi.org/10.1016/S2215-0366(15)00536-2)] [Medline: [26827250](https://pubmed.ncbi.nlm.nih.gov/26827250/)]
61. Luyster FS, Ritterband LM, Sereika SM, Buysse DJ, Wenzel SE, Strollo PJ. Internet-based cognitive-behavioral therapy for insomnia in adults with asthma: a pilot study. *Behav Sleep Med* 2020;18(1):10-22 [FREE Full text] [doi: [10.1080/15402002.2018.1518229](https://doi.org/10.1080/15402002.2018.1518229)] [Medline: [30252506](https://pubmed.ncbi.nlm.nih.gov/30252506/)]
62. Zachariae R, Amidi A, Damholdt M, Clausen C, Dahlggaard J, Lord H, et al. Internet-delivered cognitive-behavioral therapy for insomnia in breast cancer survivors: a randomized controlled trial. *J Natl Cancer Inst* 2018 Aug 01;110(8):880-887 [FREE Full text] [doi: [10.1093/jnci/djx293](https://doi.org/10.1093/jnci/djx293)] [Medline: [29471478](https://pubmed.ncbi.nlm.nih.gov/29471478/)]
63. Ritterband LM, Thorndike FP, Ingersoll KS, Lord HR, Gonder-Frederick L, Frederick C, et al. Effect of a web-based cognitive behavior therapy for insomnia intervention with 1-year follow-up: a randomized clinical trial. *JAMA Psychiatry* 2017 Jan 01;74(1):68-75. [doi: [10.1001/jamapsychiatry.2016.3249](https://doi.org/10.1001/jamapsychiatry.2016.3249)] [Medline: [27902836](https://pubmed.ncbi.nlm.nih.gov/27902836/)]
64. Ritterband LM, Thorndike FP, Gonder-Frederick LA, Magee JC, Bailey ET, Saylor DK, et al. Efficacy of an internet-based behavioral intervention for adults with insomnia. *Arch Gen Psychiatry* 2009 Jul;66(7):692-698 [FREE Full text] [doi: [10.1001/archgenpsychiatry.2009.66](https://doi.org/10.1001/archgenpsychiatry.2009.66)] [Medline: [19581560](https://pubmed.ncbi.nlm.nih.gov/19581560/)]
65. Thorndike FP, Ritterband LM, Gonder-Frederick LA, Lord HR, Ingersoll KS, Morin CM. A randomized controlled trial of an internet intervention for adults with insomnia: effects on comorbid psychological and fatigue symptoms. *J Clin Psychol* 2013 Oct;69(10):1078-1093 [FREE Full text] [doi: [10.1002/jclp.22032](https://doi.org/10.1002/jclp.22032)] [Medline: [24014057](https://pubmed.ncbi.nlm.nih.gov/24014057/)]
66. Morin C. *Insomnia: Psychological Assessment and Management*. New York: The Guilford Press; 1993.
67. Hilgart MM, Ritterband LM, Thorndike FP, Kinzie MB. Using instructional design process to improve design and development of internet interventions. *J Med Internet Res* 2012 Jun 28;14(3):e89 [FREE Full text] [doi: [10.2196/jmir.1890](https://doi.org/10.2196/jmir.1890)] [Medline: [22743534](https://pubmed.ncbi.nlm.nih.gov/22743534/)]
68. Attkisson C, Zwick R. The client satisfaction questionnaire. Psychometric properties and correlations with service utilization and psychotherapy outcome. *Eval Program Plann* 1982;5(3):233-237. [doi: [10.1016/0149-7189\(82\)90074-x](https://doi.org/10.1016/0149-7189(82)90074-x)] [Medline: [10259963](https://pubmed.ncbi.nlm.nih.gov/10259963/)]
69. Morin C, Vallières A, Ivers H. Dysfunctional beliefs and attitudes about sleep (DBAS): validation of a brief version (DBAS-16). *Sleep* 2007 Nov;30(11):1547-1554 [FREE Full text] [doi: [10.1093/sleep/30.11.1547](https://doi.org/10.1093/sleep/30.11.1547)] [Medline: [18041487](https://pubmed.ncbi.nlm.nih.gov/18041487/)]

70. Vincent N, Sande G, Read C, Giannuzzi T. Sleep locus of control: report on a new scale. *Behav Sleep Med* 2004 May;2(2):79-93. [doi: [10.1207/s15402010bsm0202_1](https://doi.org/10.1207/s15402010bsm0202_1)] [Medline: [15600226](https://pubmed.ncbi.nlm.nih.gov/15600226/)]
71. Pearlin LI, Mullan JT, Semple SJ, Skaff MM. Caregiving and the stress process: an overview of concepts and their measures. *Gerontologist* 1990 Oct;30(5):583-594. [doi: [10.1093/geront/30.5.583](https://doi.org/10.1093/geront/30.5.583)] [Medline: [2276631](https://pubmed.ncbi.nlm.nih.gov/2276631/)]
72. Losada A, Márquez-González M, Peñacoba C, Romero-Moreno R. Development and validation of the Caregiver Guilt Questionnaire. *Int Psychogeriatr* 2010 Jun;22(4):650-660. [doi: [10.1017/S1041610210000074](https://doi.org/10.1017/S1041610210000074)] [Medline: [20170587](https://pubmed.ncbi.nlm.nih.gov/20170587/)]
73. Collin C, Wade DT, Davies S, Horne V. The Barthel ADL Index: a reliability study. *Int Disabil Stud* 1988;10(2):61-63. [doi: [10.3109/09638288809164103](https://doi.org/10.3109/09638288809164103)] [Medline: [3403500](https://pubmed.ncbi.nlm.nih.gov/3403500/)]
74. Kraepelien M, Blom K, Forsell E, Isacsson NH, Bjurner P, Morin CM, et al. A very brief self-report scale for measuring insomnia severity using two items from the Insomnia Severity Index - development and validation in a clinical population. *Sleep Med* 2021 May;81:365-374 [FREE Full text] [doi: [10.1016/j.sleep.2021.03.003](https://doi.org/10.1016/j.sleep.2021.03.003)] [Medline: [33813233](https://pubmed.ncbi.nlm.nih.gov/33813233/)]
75. Hays RD, Schalet BD, Spritzer KL, Cella D. Two-item PROMIS® global physical and mental health scales. *J Patient Rep Outcomes* 2017 Sep 12;1(1):2 [FREE Full text] [doi: [10.1186/s41687-017-0003-8](https://doi.org/10.1186/s41687-017-0003-8)] [Medline: [29757325](https://pubmed.ncbi.nlm.nih.gov/29757325/)]
76. Kroenke K, Spitzer RL, Williams JB, Löwe B. An ultra-brief screening scale for anxiety and depression: the PHQ-4. *Psychosomatics* 2009;50(6):613-621. [doi: [10.1176/appi.psy.50.6.613](https://doi.org/10.1176/appi.psy.50.6.613)] [Medline: [19996233](https://pubmed.ncbi.nlm.nih.gov/19996233/)]
77. Boele FW, Weimer JM, Proudfoot J, Marsland AL, Armstrong TS, Given CW, et al. The effects of SmartCare on neuro-oncology family caregivers' distress: a randomized controlled trial. *Support Care Cancer* 2021 Oct 16. [doi: [10.1007/s00520-021-06555-5](https://doi.org/10.1007/s00520-021-06555-5)] [Medline: [34655326](https://pubmed.ncbi.nlm.nih.gov/34655326/)]
78. Chen H, Cohen P, Chen S. How big is a big odds ratio? Interpreting the magnitudes of odds ratios in epidemiological studies. *Commun Stat Simul Comput* 2010 Mar 31;39(4):860-864. [doi: [10.1080/03610911003650383](https://doi.org/10.1080/03610911003650383)]
79. Whitehead J. Sample size calculations for ordered categorical data. *Stat Med* 1993 Dec 30;12(24):2257-2271. [doi: [10.1002/sim.4780122404](https://doi.org/10.1002/sim.4780122404)] [Medline: [8134732](https://pubmed.ncbi.nlm.nih.gov/8134732/)]
80. Harrell Jr FE. Hmisc: Harrell Miscellaneous. Cran.R-Project. URL: <https://CRAN.R-project.org/package=Hmisc> [accessed 2020-09-30]
81. Green J, Thorogood N. *Qualitative Methods for Health Research*. Thousand Oaks, CA: SAGE Publications; 2013.
82. Birt L, Scott S, Cavers D, Campbell C, Walter F. Member checking: a tool to enhance trustworthiness or merely a nod to validation? *Qual Health Res* 2016 Nov;26(13):1802-1811. [doi: [10.1177/1049732316654870](https://doi.org/10.1177/1049732316654870)] [Medline: [27340178](https://pubmed.ncbi.nlm.nih.gov/27340178/)]
83. Valeri L, Vanderweele TJ. Mediation analysis allowing for exposure-mediator interactions and causal interpretation: theoretical assumptions and implementation with SAS and SPSS macros. *Psychol Methods* 2013 Jun;18(2):137-150 [FREE Full text] [doi: [10.1037/a0031034](https://doi.org/10.1037/a0031034)] [Medline: [23379553](https://pubmed.ncbi.nlm.nih.gov/23379553/)]

Abbreviations

ADL: activities of daily living

CBT-I: cognitive behavioral therapy for insomnia

IRB: institutional review board

ISI: insomnia severity index

NIH: National Institutes of Health

PSS: Pearlin Stress Scale

SHUTi: Sleep Healthy Using the Internet

SPIRIT: Standard Protocol Items: Recommendations for Interventional Trials

UVA: University of Virginia

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