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SPRING 2022

# Featured Study: WeCareAdvisor

## *Testing a Tool to Reduce Behavioral Symptoms and Caregiver Distress*

Behavioral and psychological symptoms can be experienced by people diagnosed with any type of frontotemporal degeneration (FTD). Treating their disruptive changes in behavior can be difficult and stressful. To assist caregivers of persons with dementia to manage these symptoms, researchers have developed a tool that is an online platform called WeCareAdvisor.

A nationwide remote clinical trial to evaluate this tool hopes to show it will reduce caregiver stress, improve their confidence when managing behaviors, and reduce the frequency and severity of symptoms.

"WeCareAdvisor is for any family caregiver who is challenged by a wide range of behavioral and psychological symptoms," explained Laura N. Gitlin, Ph.D., Distinguished University Professor and Dean of the College of Nursing and Health Professions at Drexel University in Philadelphia, PA. Dr. Gitlin along with Helen C. Kales, MD, of the University of California, Davis, are principal investigators for the National Institute on Aging (NIA) funded study.

"Caregivers receive strategies for behavioral symptoms that are tailored to their particular situation. We are evaluating whether these tailored strategies help the family caregiver prevent and/or manage behavioral symptoms and reduces their distress," Dr. Gitlin said.

WeCareAdvisor was built with a tailoring function that guides caregivers through a step-by-step process involving a series of questions to understand why a dementia-related symptom is occurring. Based on the caregiver's answers to specific questions, it provides strategies that are customized to the situation to help the caregiver manage the behavior.

"The strategies caregivers receive depend upon how they answer the questions" she noted. "Some strategies, such as those related to communications, may be similar for any type of behavioral symptom being addressed."

In addition to being a tool to help address dementia-related behavioral symptoms, the WeCareAdvisor also offers disease education and daily tips for managing caregiver stress.

While the platform offers a positive approach to managing behaviors, Dr. Gitlin noted that using it doesn't rule out the possible need for medications. She encouraged caregivers to work with the diagnosed person's doctor to manage their disease.

### DEVELOPMENT

The researchers developed WeCareAdvisor while Dr. Gitlin was at Johns Hopkins University in Baltimore and Dr. Kales was at the University of Michigan in Ann Arbor.

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The two worked very closely with a firm to develop the elements of the platform, often meeting for two hours a couple of times a week for more than 18 months. Then they conducted a small, randomized trial with 57 caregivers, 30 from the Baltimore area and 27 in the Ann Arbor area.

"In that small trial, funded by the National Institute of Nursing Research, we showed that families loved the tool and didn't want to give it up," Dr. Gitlin said. "The user data was very compelling, showing high utilization of each of the components of the tool. They also benefitted. They reported less distress, and targeted behaviors seemed to decrease."

As a beta test, the study lasted one month in order to understand the immediate benefits of using the tool and patterns of utilization. Based on the promising findings from this beta test, a grant was submitted and funded for a Phase 3 randomized trial to evaluate its efficacy on a larger scale. (They both also moved to new positions at different institutions.)

This new clinical trial for WeCareAdvisor is funded by a five-year grant from the NIA, and it will recruit 326 family caregivers who will test the tool over a six-month period.

"In preparing for this trial, we refined many aspects of the tool," Dr. Gitlin said. "We added materials to the Caregiver Survival Guide (the tool's education component); and we modified the tool so that it can function on a smartphone, computer, or tablet."

## SEEKING FTD CAREGIVERS

To be eligible for the WeCareAdvisor Study, volunteers must be the *primary* caregiver to a person with any type of dementia for at least six months and manage at least one behavioral symptom. Certain medical


issues affecting the caregiver or person diagnosed with dementia could prevent participation.

Participants must be 21 years old or older, speak English, and live in the United States or a U.S. territory. They must have an email account and own a smartphone, tablet, laptop, or desktop computer that connects to the internet so they can access the tool and interact with the study team.

Caregivers who enrolled will use the tool for either three months or six months, depending upon the group they are assigned. Telephone interviews are conducted at the point of enrolling in the study, then at one month, three months, and six months. After each interview, caregivers are compensated for their time with an Amazon gift card.

"The beauty of our approach, regardless of group assignment, is that everyone has the opportunity to try the tool and see if it works for them," she said.

The study seeks to enroll 326 caregivers of persons living with any kind of dementia. The tool is not disease-specific, however, Dr. Gitlin said that she hopes the various types of frontotemporal degeneration (FTD) will be represented.

"If we enroll a substantial number of people with a known etiology, whether that be mixed dementia, Alzheimer's, frontotemporal disorders, Lewy Body,

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etc., then we will be able to examine for a subgroup the kinds of behavioral symptoms that are identified and whether the strategies offered through the WeCareAdvisor are helpful," explained Dr. Gitlin. "If we have sufficient numbers of caregivers who report caring for a person with a specific type of dementia such as an FTD disorder, then we may be able to determine if the tool is helpful for that group in particular."

A statement of diagnosis from a physician is required. The study will track the type of dementia as reported by the participant.

Results will reflect short-term and long-term changes in caregiver distress and their confidence in managing behavioral and psychological symptoms. Caregivers will also be asked to report on the frequency and severity of the behaviors displayed by the diagnosed person, and the study will evaluate both short- and long-term changes in behavioral occurrences.

## DICE APPROACH

WeCareAdvisor offers recommendations to caregivers based on a four-step approach that Dr. Kales, Dr. Lyketsos from Johns Hopkins, and Dr. Gitlin led the development of in 2011 called DICE:

- DESCRIBE the behavior from the caregiver's perspective to obtain an accurate characterization and the context in which it is occurring.
- INVESTIGATE by having the health care provider examine, exclude, and identify possible underlying causes of the behavior.
- CREATE and implement a treatment plan for the behavior as a partnership between the caregiver and the provider.
- EVALUATE which parts of the treatment plan were attempted and effective.

"The WeCareAdvisor operationalizes the DICE approach by having a caregiver initially ***describe*** a behavior based on a set of questions; then ***investigate*** or evaluate underlying causes by responding to a set of questions; followed by ***create*** the DICE 'prescription' which provides strategies based on responses to these questions," Dr. Gitlin explained.

After caregivers try the recommended strategies, they are asked to ***evaluate*** the use of each one to determine what worked, what didn't work, and whether more strategies are needed.

She said they were surprised that caregivers participate in all four steps, including evaluating strategies.

## CHALLENGES

Time and reach are the two greatest challenges for this study.

"We know it takes a lot for a family caregiver to join a study, and they don't always have time," she said. "They could be working outside the home in addition to their caregiving."

The WeCareAdvisor Study is reaching out across the United States to enroll a diverse population based on location, race, and ethnic background. Dr. Gitlin hopes that this will enable people who live in urban and rural areas to participate as well as caregivers who may not have access to services or who previously have been excluded from such trials.

"We are very concerned about reach," she said. "We want our reach to be broad and involve families that may not have participated or considered participating in a clinical trial."

The COVID-19 pandemic forced the researchers to modify the study design which has positively

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facilitated the ability to be more inclusive in the recruitment approach. Changes made were:

- Replacing in-home, in-person interviews with telephone calls
- Adjusting platform operation from grant-funded iPad to caregivers' personal internet-connected device
- Expanding recruitment from a single metropolitan area (Philadelphia) to be nationwide.

The researchers also anticipate that the revised approach due to the pandemic may shorten the time to produce, market, and distribute the tool for commercial use. Since it is an online platform and not a treatment device, she said that WeCareAdvisor would not need to be approved by the U.S. Food and Drug Administration (FDA).

If this larger trial has the success of the first one, the next steps would be to figure out how to commercialize the platform.

"In the end, hopefully, there will be positive outcomes," she said. "Our intent, if all goes well, is to scale it and get it out the door to help as many people as possible."

For more details and enrollment information, read the listing on ClinicalTrials.gov, visit the study's website at WeCareAdvisorStudy.com, or contact study coordinators with Drexel University by phone at 267-359-1111 or by email at WeCare@drexel.edu.

**LEARN MORE ABOUT WeCareAdvisor**

**LEARN MORE ABOUT DR. GITLIN**

## WeCareAdvisor Study for Caregivers of People Living with Dementia

**Information provided by (Responsible Party):**
Drexel University

**Official Title:** Efficacy of the WeCareAdvisor: An Online Tool to Help Caregivers Manage Behavioral and Psychological Symptoms in Persons Living With Dementia

**Brief Summary:**
The WeCareAdvisor is an online tool to help caregivers manage behavioral and psychological symptoms of people living with dementia. The trial will evaluate its efficacy to reduce caregiver distress, improve confidence in managing behaviors, as well as reduce occurrences and severity of behavioral and psychological symptoms.

**Recruitment Status:** Recruiting
**Study Type:** Interventional
**Estimated Enrollment:** 326 participants
**Allocation:** Randomized
**Intervention Model:** Factorial Assignment
**Intervention Model Description:** Prospective randomized trial involving an immediate treatment group (Group A) and a 3-month waitlist control group (Group B). Also, groups will be randomized to different prompting conditions (email only, telephone, and email) to remind participants to use the tool.
**Masking Description:** Single-blind allocation. Study interviewers will be masked for group allocation. Other research personnel (investigator, project manager, interventionist) may become aware of group allocation. Caregivers will be asked not to disclose to interviewers the group to which they are assigned.

**Primary Purpose:** Treatment
**Actual Study State Date:** December 7, 2021
**Estimated Primary Completion Date:** March 2025
**Estimated Study Completion Date:** October 2025

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**Arms and Interventions/Treatments:**

1. Experimental: Immediate treatment group with High-Intensity Prompts — Behavioral: Caregivers will use the WeCareAdvisor tool for six months and receive telephone and email prompts.
2. Experimental: Immediate treatment group with Low-Intensity Prompts — Behavioral: Caregivers will use the WeCareAdvisor tool for six months and receive email prompts only.
3. Experimental: Waitlist Control after three months with High-Intensity prompts — Behavioral: After three months, caregivers will receive WeCareAdvisor and telephone and email prompts.
4. Experimental: Waitlist Control after three months with Low-Intensity Prompts — Behavioral: After three months, caregivers will receive WeCareAdvisor and email prompts only.

**Primary Outcome Measures:**

1. Short-term Change in Caregiver Distress with Behaviors *[Time Frame: 1 Month]*
   For each of 13 domains of behavioral symptoms endorsed on the Neuropsychiatric Inventory-Clinician version (NPI-C), caregivers rate level of distress with behavior (0=not distressing to 5=extremely upset)
2. Long-term Change in Caregiver Distress with Behaviors (3-Months) *[Time Frame: 3 months]*
   For each of 13 domains of behavioral symptoms endorsed on the Neuropsychiatric Inventory-Clinician version (NPI-C), caregivers rate level of distress with behavior (0=not distressing to 5=extremely upset)
3. Short-Term Change in Caregiver Confidence Managing Behavioral and Psychological Symptoms of Dementia *[Time Frame: 1 month]*
   Caregivers will rate their level of confidence in dementia signs and symptom management using the 25-item Caregiver Confidence in Medical Sign/Symptom Management scale. For each of 13 domains of behavioral symptoms endorsed on the Neuropsychiatric Inventory-Clinician version, caregivers rate confidence in managing behaviors (0=low confidence to 10=high confidence)
4. Long-Term Change in Caregiver Confidence Managing Behavioral and Psychological Symptoms of Dementia *[Time Frame: 3 months]*
   Caregivers will rate their level of confidence in dementia signs and symptom management using the 25-item Caregiver Confidence in Medical Sign/Symptom Management scale. For each of 13 domains of behavioral symptoms endorsed on the Neuropsychiatric Inventory-Clinician version, caregivers rate confidence managing behaviors (0=low-confidence to 10=high-confidence)
5. Short-Term Change in Person Living with Dementia — Frequency and Severity of Behaviors *[Time Frame: 1 Month]*
   Neuropsychiatric Inventory-Clinician version (NPI-C) is a well-validated questionnaire measuring frequency (0=none to 4=very frequently) and severity (0=none to 3=marked)
6. Long-Term Change in Person Living with Dementia- Frequency and Severity of Behaviors *[Time Frame: 3 Months]*
   Neuropsychiatric Inventory- Clinician version (NPI-C) is a well-validated questionnaire measuring frequency (0=none to 4=very frequently) and severity (0=none to 3=marked)

**Secondary Outcome Measures:**

1. Short-Term Change in Person with Dementia — Level of Physical Dependence *[Time Frame: 1 month]*
   Caregivers will identify the staging of functionality that the person living with dementia has, using the Functional Assessment Staging (FAST) scale.

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2. Long-Term Term Change in Person with Dementia — Level of Physical Dependence *[Time Frame: 3 months]*
   Caregivers will identify the staging of functionality that the person of living with dementia has, using the Functional Assessment Staging (FAST) scale from 0=normal aging to 7=severe dementia
3. Short-Term Change in Person with Dementia — Level of Functioning *[Time Frame: 1 month]*
   Caregiver Assessment of Function (CAFU), a psychometrically sound scale measuring # of ADLs/ IADLs needing assistance, and dependence level (1=total dependence to 7=total independence)
4. Long-Term Change in Person with Dementia — Level of Functioning *[Time Frame: 3 months]*
   Caregiver Assessment of Function (CAFU), a psychometrically sound scale measuring # of ADLs/ IADLs needing assistance, and dependence level (1=total dependence to 7=total independence)
5. Change in Person with Dementia's Medications *[Time Frame: 6 months]*
   Caregivers are asked to retrieve (e.g., Brown bag review) prescription and non-prescription medications of the person living with dementia and relay the name, frequency, and dosage for each medication to the interviewer.
   The investigators will track information on changes in psychotropic medication use for persons living with dementia (intensifications, reductions, additions/deletions, or 'prn' or as needed use)
6. Short-term Change in Caregiver's Depressive Symptoms *[Time Frame: 1 month]*
   Caregiver depression will be measured using the Patient Health Questionnaire (PHQ-8), scoring from 0-27, with higher scores indicating higher levels of depression.
7. Long-term Change in Caregiver's Depressive Symptoms *[Time Frame: 3 months]*
   Caregiver depression will be measured using the Patient Health Questionnaire (PHQ-8), scoring from 0-27, with higher scores indicating higher levels of depression
8. Short Term Change in Caregiver Wellbeing *[Time Frame: 1 Month]*
   The investigators will use the 13-item Perceived Change for Better Index which assesses caregiver perceived change (1=gotten worse to 5=improved a lot) in affective wellbeing, somatic, ability to manage daily care. It is sensitive to change and has strong psychometric properties.
9. Long Term Change in Caregiver Wellbeing *[Time Frame: 3 Months]*
   The investigators will use the 13-item Perceived Change for Better Index which assesses caregiver perceived change (0=gotten worse to 5=improved a lot) in affective wellbeing, somatic, ability to manage daily care. It is sensitive to change and has strong psychometric properties.
10. Short Term Change in Caregiver- Negative Communications *[Time Frame: 1 Month]*
    The investigators will use six items from various scales that assess frequency of use (1=Never to 5=Always) of negative communications by caregivers with persons with dementia (yelling, threatening, criticizing, withdrawing from patient, using harsh tone, and screaming).
11. Long Term Change in Caregiver- Negative Communications *[Time Frame: 3 Months]*
    The investigators will use six items from various scales that assess frequency of use (1=Never to 5=Always) of negative communications by caregivers with persons with dementia (yelling, threatening, criticizing, withdrawing from patient, using harsh tone, and screaming).
12. Utilization of tool use *[Time Frame: Through study completion, up to 6 months.]*

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Dashboard data indicating number of times using the tool, number of times using each section of the tool, amount of time spent and for each section of the tool, number of DICE sessions started and completed.

**Eligibility:**

- **Ages:** 21 years and older
- **Sexes:** All

**Inclusion Criteria:**

- self-identify as the primary caregiver to the person diagnosed with dementia;
- has been a primary caregiver for at least 6 months;
- report managing >1 behavioral symptom(s) in the past month;
- has an email account or smartphone (to receive daily tips and reminder messages);
- English speaking;
- has own smartphone, tablet, laptop, or desktop computer and access to the Internet;
- If person living with dementia is on an anti-dementia or psychotropic medication, they must be on a stable dose for at least 60 days prior to enrollment.
- If the caregiver is on an anti-depression or other psychotropic medication, they must be on a stable dose for at least 60 days prior to enrollment
- Lives in the United States or a U.S. territory

**Exclusion Criteria:**

- Caregiver is currently involved in another clinical trial of psychosocial or educational interventions for dementia
- Caregiver has a visual impairment that prohibits interaction with the tool, and/or has a hearing impairment sufficient to prohibit telephone communication
- Caregiver reports person living with dementia is not responsive to his/her environment (e.g., unable to understand short commands or recognize a person coming in/out of the room)
- Caregiver reports person living with dementia is an active suicide risk
- Caregiver reports person living with dementia is likely to have an imminent placement in a long-term care facility (within 6 months)
- Either caregiver or person living with dementia has a terminal disease with a life expectancy < 6 months, is in active treatment for cancer, or has had 3 or more acute medical hospitalizations over the past year

**Location:** Online

**Contact:** WeCareAdvisor Study Team

- 267-359-1111
- wecare@drexel.edu

**Sponsor and Collaborators:**

- Drexel University
- University of California, Davis
- National Institute on Aging (NIA)
- Johns Hopkins University

**Principal Investigators:**

- Laura N. Gitlin, PhD, Drexel University
- Helen C. Kales, MD, University of California, Davis

**ClinicalTrials.gov Identifier:** NCT05012410

**Other Study ID Numbers:**

- 2007007999
- 1R01AG061116-01 (U.S. NIH Grant/Contract)

**Individual Participant Data (IPD) Sharing Statement:**

- Plan to Share IPD: No
- Plan Description: Data will be stored after 7 years following completion of the study and reporting of the main outcome.

**Studies a U.S. FDA-regulated Drug:** No

**Studies a U.S. FDA-regulated Device:** No

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