Digital Health Application for Training and Support of Elder Caregivers
CLARE Mobile App

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Purpose of the Study

Our proposed pilot will investigate the feasibility of using a digital health application, Communication, Learning, Advocacy, Resources and Expertise (CLARE), in training and support of family and friends (i.e., caregivers) of older adults, many of whom are elders themselves. Our training and support will focus on discharge care of patients including early mobility, and self-care among caregivers through walking activities. We have three study aims: (1) to test the feasibility of CLARE in caregiving training and support during the early days of hospital discharge; (2) to use the Unified Theory of Acceptance and Use of Technology behavioral framework (UTAUT) to determine factors that will promote intent and use of CLARE among elder caregivers; and (3) (exploratory) - to explore preliminary efficacy of CLARE in improving caregiving preparedness to inform effect size and variability in outcome for our future work.

Background & Significance

In 2020, of the 53 million reported caregivers in the U.S., more than 10 million (19%) were aged 65 and above. Approximately two-thirds of individuals who required home caregiving (care-recipients) were older adults. Caregivers are considered the bedrock of homecare. Caregiving responsibilities are particularly heightened after hospital discharge when disease symptoms linger, and new care plans are initiated. Caregiving is critically important for older adults whose functional capacity is easily compromised due to hospitalization. Of approximately 33 million admitted to hospitals in 2020, 36% were older adults. The surge in technology has allowed healthcare to treat many chronic conditions in ambulatory settings. This means hospital admissions are reserved only for the sickest of sick. As the health acuity of admitted patients increases, upon discharge, their home caregivers will inevitably face more complex caregiving responsibilities. Yet, discharge practices have not changed much in more than three decades. Many hospitals still rely on patient/caregiver bedside teaching conducted mostly by nurses whose time and attention are understandably focused on caring for those still acutely ill. As a result, bedside discharge teaching has often been described as limited or rushed and many caregivers are left unprepared for their home caregiving responsibilities. Inadequately prepared caregivers often experience high levels of caregiving stress and often neglect their self-care. When caregivers are ill-prepared for their caregiving role, it places their loved ones at high risk to receive inappropriate care. The increasing complexity in home caregiving and the rising number of caregivers create an impetus to discover new approaches to support and train caregivers. Our prior studies show that caregivers benefited from enhanced support and training for discharge care through increased levels in caregiving preparedness. However, our face-to-face approach in our studies hindered our ability to reach many caregivers, especially those with disproportionate numbers of negative social determinants of health such as living in rural areas, lack of access to transportation, and lack of leave opportunities at work. One viable solution to maximize reach and access to programs is the use of technology. In 2021, we piloted a virtual program for Covid caregivers using an embedded video training link sent by email. However, only 54% of caregivers viewed our video. Most admitted that they were too preoccupied with patient care and household tasks to check emails. Rather, we noted caregivers responded quickly to text messages. Based on this experience and the extant literature on use of phone applications in patient care management, our team built CLARE, a digital health application that offers training and support to Covid caregivers.

Design & Procedures

Each caregiver will receive a unique invitation code to use the CLARE app. Our team will guide the caregiver through features of the application including how to complete demographics questionnaire and surveys for caregiving preparedness, and how to reply to reminders. CLARE will feature materials on hospital discharge preparation, Covid care, and caregiver self-care, all vetted by the DUHS Patient and Family Education department. Existing teaching on Covid covers isolation; quarantine; home sanitization; and monitoring for Covid symptoms such as cough, fever, fatigue, and shortness of breath. Content will be reviewed and amended to reflect the latest CDC guidelines for Covid care at the time of pilot implementation. CLARE will also include reminders on examining the After-Visit-Summary to determine home medications and information on follow-up appointments with patient's primary care providers. For caregiver support, we have included self-care strategies to manage anxiety and stress. For this pilot, we will add two modules. The first additional module will pertain to the importance of early mobility of patients with instructions on how to assist based on functional capacity: independent, partial assistance, dependent. For example, for physically independent patients, we will provide progressive distance walking activities from Day 1 to Day 7 (e.g., walking to sitting at the dining table to eat meals on Day 1 to walking around neighborhood as tolerated on Day 7). For patients needing partial assistance, we will include body mechanics for caregivers as they assist patients during walking or from sitting to standing. And, for physically dependent patients, CLARE will provide teaching on passive range of motion for early day of discharge to progress to active range of motion. The second additional module will be for caregiver self-care. We will include the importance of walking and provide daily reminders for activities that will involve walking. CLARE will provide caregiver training and support up to 7 days after hospital discharge. Seven days is intentional as post-hospital clinic visit frequently happens within this period where formal handoff of care from hospital to primary care occurs. We will push daily task reminders in the morning followed by words of encouragement in the afternoon to hopefully sustain caregivers' motivation to continue using CLARE. We will encourage caregivers to use CLARE's chat functionality to communicate with our team ad lib. We will promptly document and forward all medical questions to our hospital collaborators that include physicians, nurses, case managers, and physical/occupational therapists.

Selection of Subjects

To be eligible, caregivers must be the primary person who will aid patients at home after hospital discharge. Caregivers must be at least 35 years of age and provide care to a loved one who is also 55 years and above. Caregivers must possess a smart phone or a tablet.

In identifying subjects, we will implement the same process that we had used in our recent Covid caregiver training project. Our team will review patient roster at DUH at least twice weekly to identify patients, 55 years and above, admitted for Covid-related issues. Using the hospital text-messaging system, we will send text to corresponding admitting providers that we will call the emergency contact of patient as indicated in the patient's chart to determine if this person is the patient's caregiver. In the text to providers, we will provide a call back number and inform the provider that if we do not hear back

from them within 24 hours, that we will proceed with making the telephone call. During our engagement call, we will verify if the emergency contact person is the patient's caregiver. In our previous caregiving trial on Covid, an overwhelming majority of emergency contact people were found to be patients' caregivers themselves. If the emergency contact person is the patient's caregiver, our team will ascertain that the caregiver is 35 years and above, and able to speak and read in English, and possess a smart phone. If yes to all, we will describe the study and allow caregiver to ask questions. If interested in participating but still undecided, we will plan for a follow-up call within 24 hours. If interested and ready to participate, we will obtain verbal consent.

If the emergency contact person is not the patient's caregiver, we will ask the person if she/he knows of patient's caregiver. If yes, we will leave our contact telephone number with the emergency contact person to share with this caregiver. When the caregiver calls us, we will follow the same engagement/recruitment process described above.

Subject Recruitment and Compensation

Subject recruitment will follow the same workflow used in our recent Covid caregiver trial. Hospital providers will use the caregiver consult template we developed in Epic once they have ascertained the presence of a caregiver on an elder patient admitted with a Covid diagnosis and planned discharge home. The consult template includes data points to collect caregiver names and contact information. Once our team receives the consult via Epic's System List, our team will contact the caregiver by phone to assess eligibility and interest in participation. If interested, we will obtain verbal consent by phone. To begin caregiver training, the caregiver will receive an SMS link and/or e-mail to download the digital health application on their own smartphone or tablet.

Consent Process

Primary caregivers are individuals who have the capacity to provide assistance and care to patients (their loved ones) after hospital discharge. These are the caregivers that we will recruit to this pilot study. Thus, we do not anticipate any individuals with diminished capacity to be enrolled to our study.

Risk/Benefit Assessment

All recruitment procedures will comply with HIPAA and will receive approval from the Institutional Review Board at Duke University Medical Center. The consent process informs participants about the study, indicates the participation is voluntary and that he or she has the right to stop at any time. Risks are enumerated in the informed consent form and described orally during the consent process. Agreed wording for key messages during participant interactions, role plays, and explanatory materials will be developed. Recruitment and retention will be monitored; recruitment strategies will be adjusted in response to problems identified. Patients of all caregiver participants will continue to receive standard care provided by their health care providers at Duke University Hospital. Potential participants who

meet eligibility criteria will be provided with written materials describing the study, its purposes, and its requirements. A member of the research team will conduct informed consent and explain all study procedures.

Efforts will be made to reduce inconvenience to participants by scheduling assessments at times that are most convenient to them. Participants will be informed that they can withdraw from the study at any time for any reason. Protection of confidentiality will be accomplished by assigning each participant a distinct research code number and using this code number rather than the person's name on all documents and electronic data acquired from the individual. Should there be hard copies containing data acquired from participants, they will be kept in locked files at the study site, and only this project's staff will have access to these files. No name or other unique identifiers will be included in any of the datasets used in the planned analyses of this project. The names, addresses, telephone numbers and other identifying information that correspond to study codes will be stored in a separate secured file. Access to this master file will be limited to study personnel on a "need to know" basis. All research staff will sign a statement of confidentiality indicating that all participant information is not to be discussed outside of the research setting. Importantly, all aspects of the trial that involve confidential patient information will be managed in accordance with HIPAA requirements.

Study's participants will be caregivers (family and friends), 35 years and above, who will be the primary sources of assistance and care of elder patients with Covid at home after hospital discharge. Therefore, we will not be recruiting children, pregnant women, prisoners, or cognitively impaired individuals.

There are several potential benefits to study participants. First, as the US population continues to age and survivorship from chronic diseases increases, the number of individuals living at home who require assistance will rise as well. Many of these caregiving responsibilities are assumed by the family and friends of these individuals. Without appropriate training and support provided to their caregivers, patients are at risk of receiving suboptimal care. Additionally, lack of preparedness in caregiving has been associated with a high degree of stress among caregivers. If successful, this pilot may provide another approach to support and training caregivers. Second, if deemed feasible, this caregiver app may augment discharge practices offered by hospitals in the country. With the average hospital days of care trending down in the past years, the care that patients need to promote recovery will be passed on to their caregivers. Thus, better trained and supported caregivers may lead to less adverse events happening after hospital discharge that may result in a decrease in avoidable healthcare utilization. Third, without support, many caregivers are at much higher risks to experience anxiety, depression, and burden. Providing training and support to caregivers during periods when caregiving is particularly challenging, such as during the hospital to home discharge, may mitigate some of the risks associated with psychological distress.

If found feasible, the use of technology in caregiver support and training (i.e., CLARE app) has the potential to enhance access to valuable information and resources in home care. Better prepared caregivers in caregiving may lead to decrease in avoidable adverse events among patients after hospital discharge and may also promote caregiver well-being.

Data Analysis & Statistical Considerations

The proposed sample size of 50 is not based on formal power analysis, but a reasonable sample size to assess the feasibility of the intervention, the primary goal of the trial. This sample size should also be adequate to estimate the effect size and variation in outcomes that we need for future clinical trial planning. For this pilot, our quantitative variable for analysis is caregiving preparedness.

Below describes our statistical plan and design related to the project aims.

Aim 1: Feasibility of CLARE. Among eligible caregivers we have a goal of at least 60% enrollment rate. Among participants, we will examine engagement in CLARE by assessing the percentage of daily completed tasks. We expect a minimum 60% completion rate per daily task for each caregiver.

Aim 2: Intent and use of CLARE. Using Nvivo, we will look for themes of modifiable factors that can be enhanced to facilitate use of CLARE and barriers that can be eliminated. We will explore differences in themes of responses by caregiver gender and levels of experience and comfort in technology. To ensure credibility and dependability of analyses, two team members will perform thematic analysis. For validation, another team member will read 20% of transcripts.

Aim 3 (exploratory): Impact of CLARE: We will calculate Cohen's d in change in efficacy outcome between baseline and end of study participation in preparedness score in caregiving. We will also estimate the variability in change in this outcome, which can be used for power analysis for future efficacy testing in a randomized clinical trial. We will also assess the percentage of daily completed tasks in caregiver self-care and expect a minimum 60% completion rate per daily task for each caregiver.